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Occupational Exposure to Hexavalent Chromium; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. H054A]

RIN 1218–AB45

Occupational Exposure to Hexavalent Chromium

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is amending the existing standard which limits occupational exposure to hexavalent chromium (Cr(VI)). OSHA has determined based upon the best evidence currently available that at the current permissible exposure limit (PEL) for Cr(VI), workers face a significant risk to material impairment of their health. The evidence in the record for this rulemaking indicates that workers exposed to Cr(VI) are at an increased risk of developing lung cancer. The record also indicates that occupational exposure to Cr(VI) may result in asthma, and damage to the nasal epithelia and skin.

The final rule establishes an 8-hour time-weighted average (TWA) exposure limit of 5 micrograms of Cr(VI) per cubic meter of air (5 $\mu g/m^3$). This is a considerable reduction from the previous PEL of 1 milligram per 10 cubic meters of air (1 mg/10 m^3, or 100 $\mu g/m^3$) reported as CrO_3, which is equivalent to a limit of 52 $\mu g/m^3$ as Cr(VI). The final rule also contains ancillary provisions for worker protection such as requirements for exposure determination, preferred exposure control methods, including a compliance alternative for a small sector for which the new PEL is infeasible, respiratory protection, protective clothing and equipment, hygiene areas and practices, medical surveillance, recordkeeping, and start-up dates that include four years for the implementation of engineering controls to meet the PEL.

The final standard separately regulates general industry, construction, and shipyards in order to tailor requirements to the unique circumstances found in each of these sectors.

The PEL established by this rule reduces the significant risk posed to workers by occupational exposure to Cr(VI) to the maximum extent that is technologically and economically feasible.

DATES: This final rule becomes effective on May 30, 2006. Start-up dates for specific provisions are set in § 1910.1026(n) for general industry; § 1915.1026(l) for shipyards; and § 1926.1126(l) for construction. However, affected parties do not have to comply with the information collection requirements in the final rule until the Department of Labor publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of these standards.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Ropp, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1999.

SUPPLEMENTARY INFORMATION: The following table of contents lays out the structure of the preamble to the final standards. This preamble contains a detailed description of OSHA's legal obligations, the analyses and rationale supporting the Agency's determination, including a summary of and response to comments and data submitted during the rulemaking.

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I. General

This final rule establishes a permissible exposure limit (PEL) of 5 micrograms of Cr(VI) per cubic meter of air (5 μg/m^3) as an 8-hour time-weighted average for all Cr(VI) compounds. After consideration of all comments and evidence submitted during this rulemaking, OSHA has made a final determination that a PEL of 5 μg/m^3 is necessary to reduce the significant health risks posed by occupational exposures to Cr(VI); it is the lowest level that is technologically and economically feasible for industries impacted by this rule. A full explanation of OSHA's rationale for establishing this PEL is presented in the following preamble sections: V (Health Effects), VI (Quantitative Risk Assessment), VII (Significance of Risk), VIII (Summary of the Final Economic Analysis and Regulatory Flexibility Analysis), and XV (Summary and Explanation of the Standard, paragraph (c), Permissible Exposure Limit).

OSHA is establishing three separate standards covering occupational exposures to Cr(VI) for: general industry (29 CFR 1910.1026); shipyards (29 CFR 1915.1026), and construction (29 CFR 1926.1126). In addition to the PEL, these three standards include ancillary provisions for exposure determination, methods of compliance, respiratory protection, protective work clothing and equipment, hygiene areas and practices, medical surveillance, communication of Cr(VI) hazards to employees, recordkeeping, and compliance dates. The general industry standard has additional provisions for regulated areas and housekeeping. The Summary and Explanation section of this preamble (Section XV, paragraphs (d) through (n)) includes a full discussion of the basis for including these provisions in the final standards.

Several major changes were made to the October 4, 2004 proposed rule as a result of OSHA's analysis of comments and data received during the comment periods and public hearings. The major changes are summarized below and are fully discussed in the Summary and Explanation section of this preamble (Section XV)

Scope. As proposed, the standards apply to occupational exposures to Cr(VI) in all forms and compounds with limited exceptions. OSHA has made a final determination to exclude from coverage of these final standards exposures that occur in the application of pesticides containing Cr(VI) (e.g., the treatment of wood with preservatives). These exposures are already covered by the Environmental Protection Agency. OSHA is also excluding exposures to portland cement and exposures in work settings where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of Cr(VI) in concentrations at or above 0.5 μg/m^3 under any expected conditions of use. OSHA believes that the weight of evidence in this rulemaking demonstrates that the primary risk in these two exposure scenarios can be effectively addressed through existing OSHA standards for personal protective equipment, hygiene, hazard communication and the PELs for portland cement or particulates not otherwise regulated (PNOR).

Permissible Exposure Limit. OSHA proposed a PEL of 1 μg/m^3 but has now determined that a PEL 5 μg/m^3 is the lowest level that is technologically and economically feasible.

Exposure Determination. OSHA did not include a provision for exposure determination in the proposed shipyard and construction standards, reasoning that the obligation to meet the proposed PEL would implicitly necessitate performance-based monitoring by the employer to ensure compliance with the PEL. However, OSHA was convinced by arguments presented during the rulemaking that an explicit requirement for exposure determination is necessary to ensure that employee exposures are adequately characterized. Therefore OSHA has included a provision for exposure determination for general industry, shipyards and construction in the final rule. In order to provide additional flexibility in characterizing employee exposures, OSHA is allowing employers to choose between a scheduled monitoring option and a performance-based option for making exposure determinations.

Methods of Compliance. Under the proposed rule employers were to use engineering and work practice controls to achieve the proposed PEL unless the employer could demonstrate such controls are not feasible. In the final rule, OSHA has retained this exception but has added a provision that only requires employers to use engineering and work practice controls to reduce or maintain employee exposures to 25 μg/m^3 when painting aircraft or large aircraft parts in the aerospace industry to the extent such controls are feasible. The employer must then supplement those engineering controls with respiratory protection to achieve the PEL. As discussed more fully in the Summary of the Final Economic Analysis and Regulatory Flexibility Analysis (Section VIII) and the Summary and Explanation (Section XV) OSHA has determined that this is the lowest level achievable through the use of engineering and work practice controls alone for these limited operations.

Housekeeping. In the proposed rule, cleaning methods such as shoveling, sweeping, and brushing were prohibited unless they were the only effective means available to clean surfaces contaminated with Cr(VI). The final standard has modified this prohibition to make clear only *dry* shoveling, sweeping and brushing are prohibited so that effective wet shoveling, sweeping, and brushing would be allowed. OSHA is also adding a provision that allows the use of compressed air to remove Cr(VI) when no alternative method is feasible.

Medical Surveillance. As proposed and continued in these final standards, medical surveillance is required to be provided to employees experiencing signs or symptoms of the adverse health effects associated with Cr(VI) exposure or exposed in an emergency. In addition, for general industry, employees exposed above the PEL for 30 or more days a year were to be provided medical surveillance. In the final standard, OSHA has changed the trigger for medical surveillance to exposure above the action level (instead of the PEL) for 30 days a year to take into account the existing risks at the new PEL. This provision has also been extended to the standards for shipyards and construction since those employers now will be required to perform an exposure determination and thus will be able to determine which employees are exposed above the action level 30 or more days a year.

Communication of Hazards. In the proposed standard, OSHA specified the sign for the demarcation of regulated areas in general industry and the label for contaminated work clothing or equipment and Cr(VI) contaminated waste and debris. The proposed standard also listed the various elements to be covered for employee training. In order to simplify requirements under this section of the final standard and reduce confusion between this standard and the Hazard Communication Standard, OSHA has removed the requirement for special signs and labels and the specification of employee training elements. Instead, the final standard requires that signs, labels and training be in accordance with the Hazard Communication Standard (29 CFR 1910.1200). The only additional training elements required in the final rule are those related specifically to the contents of the final Cr(VI) standards. While the final standards have removed language in the communication of hazards provisions to make them more consistent with OSHA's existing Hazard Communication Standard, the employers obligation to mark regulated areas (where regulated areas are required), to label Cr(VI) contaminated clothing and wastes, and to train on the hazards of Cr(VI) have not changed.

Recordkeeping. In the proposed standards for shipyards and construction there were no recordkeeping requirements for exposure records since there was not a requirement for exposure determination. The final standard now requires exposure determination for shipyards and construction and therefore, OSHA has also added provisions for exposure records to be maintained in these final standards. In keeping with its intent to be consistent with the Hazard Communication Standard, OSHA has removed the requirement for training records in the final standards.

Dates. In the proposed standard, the effective date of the standard was 60 days after the publication date; the start-up date for all provisions except engineering controls was 90 days after the effective date; and the start-up date for engineering controls was two years after the effective date. OSHA believes that it is appropriate to allow additional time for employers, particularly small employers, to meet the requirements of the final rule. The effective and start-up dates have been extended as follows: the effective date for the final rule is changed to 90 days after the publication date; the start-up date for all provisions except engineering controls is changed to 180 days after the effective date for employers with 20 or more employees; the start-up date for all provisions except engineering controls is changed to one year after the effective date for employers with 19 or fewer employees; and the start-up date for engineering controls is changed to four years after the effective date for all employers.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (''the Act'') is to,

> * * * assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources. 29 U.S.C. 651(b).

To achieve this goal Congress authorized the Secretary of Labor (the Secretary) to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b) (requiring employers to comply with OSHA standards), 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment).

The Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as this standard regulating occupational exposure to Cr(VI), the Secretary,

> * * * shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. 29 U.S.C. § 655(b)(5).

The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, she must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 641–42 (1980) (plurality opinion) (''The Benzene case''). The Court further observed that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' and must be ''based largely on policy considerations.'' The Benzene case, 448 U.S. at 655. The Court gave the example that if,

> * * * the odds are one in a billion that a person will die from cancer * * * the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. * * * *Id.*

OSHA standards must be both technologically and economically feasible. *United Steelworkers* v. *Marshall*, 647 F.2d 1189, 1264 (D.C. Cir. 1980) (''The Lead I case''). The Supreme Court has defined feasibility as ''capable of being done.'' *American Textile Mfrs. Inst.* v. *Donovan*, 425 U.S. 490, 509 (1981) (''The Cotton dust case''). The courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> * * * within the limits of the best available evidence * * * that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. *See* The Lead I case, 647 F.2d at 1272.

With respect to economic feasibility, the courts have held that a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry. *See* The Lead case, 647 F.2d at 1265. A court must examine the cost of compliance with an OSHA standard ''in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices.'' *Id.*

> [The] practical question is whether the standard threatens the competitive stability of an industry, * * * or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration. *Id.* (*citing Industrial Union Dept., AFL–CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974)).

The courts have further observed that granting companies reasonable time to comply with new PEL's may enhance economic feasibility. *Id.* While a standard must be economically feasible, the Supreme Court has held that a cost-benefit analysis of health standards is not required by the Act because a feasibility analysis is. The Cotton dust case, 453 U.S. at 509. Finally, unlike safety standards, health standards must eliminate risk or reduce it to the maximum extent that is technologically and economically feasible. See *International Union, United Automobile, Aerospace & Agricultural Implement Workers of America, UAW* v. *OSHA*, 938 F.2d 1310, 1313 (D.C. Cir. 1991); Control of Hazardous Energy Sources (Lockout/Tagout), Final rule; supplemental statement of reasons, (58 FR 16612, March 30, 1993).

III. Events Leading to the Final Standard

OSHA's previous standards for workplace exposure to Cr(VI) were adopted in 1971, pursuant to section 6(a) of the Act, from a 1943 American National Standards Institute (ANSI) recommendation originally established to control irritation and damage to nasal tissues (36 FR at 10466, 5/29/71; Ex. 20–3). OSHA's general industry standard set a permissible exposure limit (PEL) of 1 mg chromium trioxide per 10 m^3 air in the workplace (1 mg/10 m^3 CrO_3) as a ceiling concentration, which corresponds to a concentration of 52 μg/m^3 Cr(VI). A separate rule promulgated for the construction industry set an eight-hour time-weighted-average PEL of 1 mg/10 m^3 CrO_3, also equivalent to 52 μg/m^3 Cr(VI), adopted from the American Conference of Governmental Industrial Hygienists (ACGIH) 1970 Threshold Limit Value (TLV) (36 FR at 7340, 4/17/71).

Following the ANSI standard of 1943, other occupational and public health organizations evaluated Cr(VI) as a workplace and environmental hazard and formulated recommendations to control exposure. The ACGIH first recommended control of workplace exposures to chromium in 1946, recommending a time-weighted average Maximum Allowable Concentration (later called a Threshold Limit Value) of 100 μg/m^3 for chromic acid and chromates as Cr_2O_3 (Ex. 5–37), and later classified certain Cr(VI) compounds as class A1 (confirmed human) carcinogens in 1974. In 1975, the NIOSH Criteria for a Recommended Standard recommended that occupational exposure to Cr(VI) compounds should be limited to a 10-hour TWA of 1 μg/m^3, except for some forms of Cr(VI) then believed to be noncarcinogenic (Ex. 3–92). The National Toxicology Program's First Annual Report on Carcinogens identified calcium chromate, chromium chromate, strontium chromate, and zinc chromate as carcinogens in 1980 (Ex. 35–157).

During the 1980s, regulatory and standards organizations came to recognize Cr(VI) compounds in general as carcinogens. The Environmental Protection Agency (EPA) Health Assessment Document of 1984 stated that,

> * * * using the IARC [International Agency for Research on Cancer] classification scheme, the level of evidence available for the combined animal and human data would place hexavalent chromium (Cr VI) compounds into Group 1, meaning that there is decisive evidence for the carcinogenicity of those compounds in humans (Ex. 19–1, p. 7–107).

In 1988 IARC evaluated the available evidence regarding Cr(VI) carcinogenicity, concluding in 1990 that

> * * * [t]here is sufficient evidence in humans for the carcinogenicity of chromium[VI] compounds as encountered in the chromate production, chromate pigment production and chromium plating industries, [and] sufficient evidence in experimental animals for the carcinogenicity of calcium chromate, zinc chromates, strontium chromate and lead chromates (Ex. 18–3, p. 213).

In September 1988, NIOSH advised OSHA to consider all Cr(VI) compounds as potential occupational carcinogens (Ex. 31–22–22). ACGIH now classifies water-insoluble and water-soluble Cr(IV) compounds as class A1 carcinogens (Ex. 35–207). Current ACGIH standards include specific 8-hour time-weighted average TLVs for calcium chromate (1 μg/m^3), lead chromate (12 μg/m^3), strontium chromate (0.5 μg/m^3), and zinc chromates (10 μg/m^3), and generic TLVs for water soluble (50 μg/m^3) and insoluble (10 μg/m^3) forms of hexavalent chromium not otherwise classified, all measured as chromium (Ex. 35–207).

In July 1993, OSHA was petitioned for an emergency temporary standard to reduce occupational exposures to Cr(VI) compounds (Ex. 1). The Oil, Chemical, and Atomic Workers International Union (OCAW) and Public Citizen's Health Research Group (Public Citizen), citing evidence that occupational exposure to Cr(VI) increases workers' risk of lung cancer, petitioned OSHA to promulgate an emergency temporary standard to lower the PEL for Cr(VI) compounds to 0.5 μg/m^3 as an eight-hour time-weighted average (TWA). Upon review of the petition, OSHA agreed that there was evidence of increased cancer risk from exposure to Cr(VI) at the existing PEL, but found that the available data did not show the ''grave danger'' required to support an emergency temporary standard (Ex. 1–C). The Agency therefore denied the request for an emergency temporary standard, but initiated Section 6(b)(5) rulemaking and began performing preliminary analyses relevant to the rule.

In 1997, Public Citizen petitioned the United States Court of Appeals for the Third Circuit to compel OSHA to complete rulemaking lowering the standard for occupational exposure to Cr(VI). The Court denied Public Citizen's request, concluding that there was no unreasonable delay and dismissed the suit. *Oil, Chemical and Atomic Workers Union and Public Citizen Health Research Group* v. *OSHA*, 145 F.3d 120 (3rd Cir. 1998). Afterwards, the Agency continued its data collection and analytic efforts on Cr(VI) (Ex. 35–208, p. 3). In 2002, Public Citizen again petitioned the Court to compel OSHA to commence rulemaking to lower the Cr(VI) standard (Ex. 31–24–1). Meanwhile on August 22, 2002, OSHA published a Request for Information on Cr(VI) to solicit additional information on key issues related to controlling exposures to Cr(VI) (FR 67 at 54389), and on December 4, 2002 announced its intent to proceed with developing a proposed standard (Ex. 35–306). On December 24, 2002, the Court granted Public Citizen's petition, and ordered the Agency to proceed expeditiously with a Cr(VI) standard. *See Public Citizen Health Research Group* v. *Chao*, 314 F.3d 143 (3rd Cir. 2002)). In a subsequent order, the Court established a compressed schedule for completion of the rulemaking, with deadlines of October 4, 2004 for publication of a proposed standard and January 18, 2006 for publication of a final standard (Ex. 35–304).

In 2003, as required by the Small Business Regulatory Enforcement Act (SBREFA), OSHA initiated SBREFA proceedings, seeking the advice of small business representatives on the proposed rule. The SBREFA panel, including representatives from OSHA, the Small Business Administration (SBA), and the Office of Management and Budget (OMB), was convened on December 23, 2003. The panel conferred with representatives from small entities in chemical, alloy, and pigment manufacturing, electroplating, welding, aerospace, concrete, shipbuilding, masonry, and construction on March 16–17, 2004, and delivered its final report to OSHA on April 20, 2004. The Panel's report, including comments from the small entity representatives (SERS) and recommendations to OSHA for the proposed rule, is available in the Cr(VI) rulemaking docket (Ex. 34). The SBREFA Panel made recommendations on a variety of subjects. The most important recommendations with respect to alternatives that OSHA should consider included: A higher PEL than the PEL of 1; excluding cement from the scope of the standard; the use of SECALs for some industries; different PELS for different Hexavalent chromium compounds; a multi-year phase-in to the standards; and further consideration to approaches suited to the special conditions of the maritime and construction industries. OSHA has adapted many of these recommendations: The PEL is now 5; cement has been excluded from the scope of the standard; a compliance alternative, similar to a SECAL, has been used in aerospace industry; the standard allows four years to phase in engineering controls; and a new performance based monitoring approach for all industries, among other changes, all of which should make it easier for all industries with changing work place conditions to meet the standard in a cost effective way. A full discussion of all of the recommendations, and OSHA's responses to them, is provided in Section VIII of this Preamble.

In addition to undertaking SBREFA proceedings, in early 2004, OSHA provided the Advisory Committee on Construction Safety and Health (ACCSH) and the Maritime Advisory Committee on Occupational Safety and Health (MACOSH) with copies of the draft proposed rule for review. OSHA representatives met with ACCSH in February 2004 and May 2004 to discuss the rulemaking and receive their comments and recommendations. On February 13, 2004, ACCSH recommended that portland cement should be included within the scope of the proposed standard (Ex. 35–307, pp. 288–293) and that identical PELs should be set for construction, maritime, and general industry (Ex. 35–307, pp. 293–297). On May 18, 2004, ACCSH recommended that the construction industry should be included in the current rulemaking, and affirmed its earlier recommendation regarding portland cement. OSHA representatives met with MACOSH in March 2004. On March 3, 2004, MACOSH collected and forwarded additional exposure monitoring data to OSHA to help the Agency better evaluate exposures to Cr(VI) in shipyards (Ex. 35–309, p. 208). MACOSH also recommended a separate Cr(VI) standard for the maritime industry, arguing that maritime involves different exposures and requires different means of exposure control than general industry and construction (Ex. 35–309, p. 227).

In accordance with the Court's rulemaking schedule, OSHA published the proposed standard for hexavalent chromium on October 4, 2004 (69 FR at 59306). The proposal included a notice of public hearing in Washington, DC (69 FR at 59306, 59445–59446). The notice also invited interested persons to submit comments on the proposal until January 3, 2005. In the proposal, OSHA solicited public input on 65 issues regarding the human health risks of Cr(VI) exposure, the impact of the proposed rule on Cr(VI) users, and other issues of particular interest to the Agency (69 FR at 59306–59312).

OSHA convened the public hearing on February 1, 2005, with Administrative Law Judges John M. Vittone and Thomas M. Burke presiding. At the conclusion of the hearing on February 15, 2005, Judge Burke set a deadline of March 21, 2005, for the submission of post hearing comments, additional information and data relevant to the rulemaking, and a deadline of April 20, 2005, for the submission of additional written comments, arguments, summations, and briefs. A wide range of employees, employers, union representatives, trade associations, government agencies and other interested parties participated in the public hearing or contributed written comments. Issues raised in their comments and testimony are addressed in the relevant sections of this preamble (*e.g.*, comments on the risk assessment are discussed in section VI; comments on the benefits analysis in section VIII). On December 22, 2005, OSHA filed a motion with the U.S. Court of Appeals for the Third Circuit requesting an extension of the court-mandated deadline for the publication of the final rule by six weeks, to February 28, 2006 (Ex. 48–13). The Court granted the request on January 17, 2006 (Ex. 48–15).

As mandated by the Act, the final standard on occupational exposure to hexavalent chromium is based on careful consideration of the entire record of this proceeding, including materials discussed or relied upon in the proposal, the record of the hearing, and all written comments and exhibits received.

OSHA has developed separate final standards for general industry, shipyards, and the construction industry. The Agency has concluded that excess exposure to Cr(VI) in any form poses a significant risk of material impairment to the health of workers, by causing or contributing to adverse health effects including lung cancer, non-cancer respiratory effects, and dermal effects. OSHA determined that the TWA PEL should not be set above 5 $\mu g/m^3$ based on the evidence in the record and its own quantitative risk assessment. The TWA PEL of 5 $\mu g/m^3$ reduces the significant risk posed to workers by occupational exposure to Cr(VI) to the maximum extent that is technologically and economically feasible. (See discussion of the PEL in Section XV below.)

IV. Chemical Properties and Industrial Uses

Chromium is a metal that exists in several oxidation or valence states, ranging from chromium (−II) to chromium (+VI). The elemental valence state, chromium (0), does not occur in nature. Chromium compounds are very stable in the trivalent state and occur naturally in this state in ores such as ferrochromite, or chromite ore ($FeCr_2O_4$). The hexavalent, Cr(VI) or chromate, is the second most stable state. It rarely occurs naturally; most Cr(VI) compounds are man made.

Chromium compounds in higher valence states are able to undergo ''reduction'' to lower valence states; chromium compounds in lower valence states are able to undergo ''oxidation'' to higher valence states. Thus, Cr(VI) compounds can be reduced to Cr(III) in the presence of oxidizable organic matter. Chromium can also be reduced in the presence of inorganic chemicals such as iron.

Chromium does exist in less stable oxidation (valence) states such as Cr(II), Cr(IV), and Cr(V). Anhydrous Cr(II) salts are relatively stable, but the divalent state (II, or chromous) is generally relatively unstable and is readily oxidized to the trivalent (III or chromic) state. Compounds in valence states such as (IV) and (V) usually require special handling procedures as a result of their instability. Cr(IV) oxide (CrO_2) is used in magnetic recording and storage devices, but very few other Cr(IV) compounds have industrial use. Evidence exists that both Cr(IV) and Cr(V) are formed as transient intermediates in the reduction of Cr(VI) to Cr(III) in the body.

Chromium (III) is also an essential nutrient that plays a role in glucose, fat, and protein metabolism by causing the action of insulin to be more effective. Chromium picolinate, a trivalent form of chromium combined with picolinic acid, is used as a dietary supplement, because it is claimed to speed metabolism.

Elemental chromium and the chromium compounds in their different valence states have various physical and chemical properties, including differing solubilities. Most chromium species are solid. Elemental chromium is a steel gray solid, with high melting and boiling points (1857 °C and 2672 °C, respectively), and is insoluble in water and common organic solvents. Chromium (III) chloride is a violet or purple solid, with high melting and sublimation points (1150 °C and 1300 °C, respectively), and is slightly soluble in hot water and insoluble in common organic solvents. Ferrochromite is a brown-black solid; chromium (III) oxide is a green solid; and chromium (III) sulfate is a violet or red solid, insoluble in water and slightly soluble in ethanol. Chromium (III) picolinate is a ruby red crystal soluble in water (1 part per million at 25 °C). Chromium (IV) oxide is a brown-black solid that decomposes at 300 °C and is insoluble in water.

Cr(VI) compounds have mostly lemon yellow to orange to dark red hues. They are typically crystalline, granular, or powdery although one compound (chromyl chloride) exists in liquid form. For example, chromyl chloride is a dark red liquid that decomposes into chromate ion and hydrochloric acid in water. Chromic acids are dark red crystals that are very soluble in water. Other examples of soluble chromates are sodium chromate (yellow crystals) and sodium dichromate (reddish to bright orange crystals). Lead chromate oxide is typically a red crystalline powder. Zinc chromate is typically seen as lemon yellow crystals which decompose in hot water and are soluble in acids and liquid ammonia. Other chromates such as barium, calcium, lead, strontium, and zinc chromates vary in color from light yellow to greenish yellow to orange-yellow and exist in solid form as crystals or powder.

The Color Pigments Manufacturers Association (CPMA) provided additional information on lead chromate and some other chromates used in their pigments (Ex. 38–205, pp. 12–13). CPMA describes two main lead chromate color groups: the chrome yellow pigments and the orange to red varieties known as molybdate orange pigments. The chrome yellow pigments are solid solution crystal compositions of lead chromate and lead sulfate. Molybdate orange pigments are solid solution crystal compositions of lead chromate, lead sulfate, and lead molybdate (Ex. 38–205, p. 12). CPMA also describes a basic lead chromate called ''chrome orange,'' and a lead chromate precipitated ''onto a core'' of silica (Ex. 38–205, p. 13).

OSHA re-examined available information on solubility values in light of comments from the CPMA and Dominion Color Corporation (DCC) on qualitative solubility designations and CPMA's claim of low bioavailability of lead chromate due to its extremely low solubility (Exs. 38–201–1, p. 4; 38–205, p. 95). There was not always agreement or consistency with the qualitative assignments of solubilities. Quantitative values for the same compound also differ depending on the source of information.

The Table IV–1 is the result of OSHA's re-examination of quantitative water solubility values and qualitative designations. Qualitative designations as well as quantitative values are listed as they were provided by the source. As can be seen by the Table IV–1, qualitative descriptions vary by the descriptive terminology chosen by the source.

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Table IV-1: SOLUBILITIES FOR SELECTED CHROMATE COMPOUNDS AS REPORTED BY VARIOUS REFERENCES

Compound	**Handbook of Chemistry and Physics 53rd ed. (1)** **Solubility[a] g/l**	**IARC 1990 (2)** **Solubility[a] g/l**	**ACGIH 2001 (3)** **Solubility[a] g/l**	**Handbook of Chemistry and Physics 83rd & 85th Eds. (4)** **Solubility[a] g/l**
Lead chromate	0.000058 - Insoluble	0.00058 - Very Slightly Soluble	0.000058 - Insoluble	0.00017
Basic lead chromate	Insoluble	Insoluble		
Lead oxide				Insoluble
Barium chromate	0.0034	0.0044 - Very Slightly Soluble		0.0026
Strontium chromate	1.2	1.2 - Slightly Soluble	1.2 Slightly Soluble	1.06
Zinc chromate	Insoluble	Insoluble	Sparingly Soluble	30.8
Zinc chromate hydroxide		Slightly Soluble	Sparingly Soluble	
Zinc Potassium chromate (commercial pigment)	2.5-5.0		Sparingly Soluble	

Compound	**Handbook of Chemistry and Physics 53rd ed. (1)** **Solubility[a] g/l**	**IARC 1990 (2)** **Solubility[a] g/l**	**ACGIH 2001 (3)** **Solubility[a] g/l**	**Handbook of Chemistry and Physics 83rd & 85th Eds.(4)** **Solubility[a] g/l**
Potassium dichromate	49.0	49.0 Soluble		151
Calcium chromate	163.0	163.0 Soluble (hydrated form) Slightly Soluble (not hydrated)	163 Soluble (hydrated form) Slightly Soluble (not hydrated)	132 (dihydrate form)
Potassium chromate	629.0	629.0-Soluble		650
Sodium chromate	873.0	873.0 - Soluble		876
Sodium dichromate	1800.0 anhydride	1800.0 - Soluble		1870

[a] Solubility in water. Values and qualitative descriptions of solubility are listed as reported by the reference.

(1) *Handbook of Chemistry and Physics*, 53rd Edition, 1972-1973.

(2) International Agency for Research on Cancer, *IARC Monographs*, Vol. 49, 1990.

(3) American Conference of Governmental Industrial Hygienists (ACGIH), *Threshold Limit Values Documentation*, 2001

(4) *Handbook of Chemistry and Physics*, 83rd Edition, 2002-2003; and 85th Edition, 2004-2005.

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OSHA has made some generalizations to describe the water solubilities of chromates in subsequent sections of this **Federal Register** notice. OSHA has divided Cr(VI) compounds and mixtures into three categories based on solubility values. Compounds and mixtures with water solubilities less than 0.01 g/l are referred to as water insoluble. Compounds and mixtures between 0.01 g/l and 500 g/l are referred to as slightly soluble. Compounds and mixtures with water solubility values of 500 g/l or greater are referred to as highly water soluble. It should be noted that these boundaries for insoluble, slightly soluble, and highly soluble are arbitrary designations for the sake of further description elsewhere in this document. Quantitative values take precedence over qualitative designations. For example, zinc chromates would be slightly soluble where their solubility values exceed 0.01 g/l.

Some major users of chromium are the metallurgical, refractory, and chemical industries. Chromium is used by the metallurgical industry to produce stainless steel, alloy steel, and nonferrous alloys. Chromium is alloyed with other metals and plated on metal and plastic substrates to improve corrosion resistance and provide protective coatings for automotive and equipment accessories. Welders use stainless steel welding rods when joining metal parts.

Cr(VI) compounds are widely used in the chemical industry in pigments, metal plating, and chemical synthesis as ingredients and catalysts. Chromates are used as high quality pigments for textile dyes, paints, inks, glass, and plastics. Cr(VI) can be produced during welding operations even if the chromium was originally present in another valence state. While Cr(VI) is not intentionally added to portland cement, it is often present as an impurity.

Occupational exposures to Cr(VI) can occur from inhalation of mists (e.g., chrome plating, painting), dusts (e.g., inorganic pigments), or fumes (e.g., stainless steel welding), and from dermal contact (e.g., cement workers).

There are about thirty major industries and processes where Cr(VI) is used. These include producers of chromates and related chemicals from chromite ore, electroplating, welding, painting, chromate pigment production and use, steel mills, and iron and steel foundries. A detailed discussion of the uses of Cr(VI) in industry is found in Section VIII of this preamble.

V. Health Effects

This section summarizes key studies of adverse health effects resulting from exposure to hexavalent chromium (Cr(VI)) in humans and experimental animals, as well as information on the fate of Cr(VI) in the body and laboratory research that relates to its toxic mode of action. The primary health impairments from workplace exposure to Cr(VI) are lung cancer, asthma, and damage to the nasal epithelia and skin. While this chapter on health effects does not describe all of the many studies that have been conducted on Cr(VI) toxicity, it includes a selection of those that are relevant to the rulemaking and representative of the scientific literature on Cr(VI) health effects.

A. Absorption, Distribution, Metabolic Reduction and Elimination

Although chromium can exist in a number of different valence states, Cr(VI) is the form considered to be the greatest health risk. Cr(VI) enters the body by inhalation, ingestion, or absorption through the skin. For occupational exposure, the airways and skin are the primary routes of uptake. The following discussion summarizes key aspects of Cr(VI) uptake, distribution, metabolism, and elimination.

1. Deposition and Clearance of Inhaled Cr(VI) From the Respiratory Tract

Various anatomical, physical and physiological factors determine both the fractional and regional deposition of inhaled particulate matter. Due to the airflow patterns in the lung, more particles tend to deposit at certain preferred regions in the lung. It is therefore possible to have a buildup of chromium at certain sites in the bronchial tree that could create areas of very high chromium concentration. A high degree of correspondence between the efficiency of particle deposition and the frequency of bronchial tumors at sites in the upper bronchial tree was reported in research by Schlesinger and Lippman that compared the distribution of cancer sites in published reports of primary bronchogenic tumors with experimentally determined particle deposition patterns (Ex. 35–102).

Large inhaled particles (>5 µm) are efficiently removed from the air-stream in the extrathoracic region (Ex. 35–175). Particles greater than 2.5 µm are generally deposited in the tracheobronchial regions, whereas particles less than 2.5 µm are generally deposited in the pulmonary region. Some larger particles (>2.5 µm) can reach the pulmonary region. The mucociliary escalator predominantly clears particles that deposit in the extrathoracic and the tracheobronchial region of the lung. Individuals exposed to high particulate levels of Cr(VI) may also have altered respiratory mucociliary clearance. Particulates that reach the alveoli can be absorbed into the bloodstream or cleared by phagocytosis.

2. Absorption of Inhaled Cr(VI) Into the Bloodstream

The absorption of inhaled chromium compounds depends on a number of factors, including physical and chemical properties of the particles (oxidation state, size, solubility) and the activity of alveolar macrophages (Ex. 35–41). The hexavalent chromate anions $(CrO_4)^{2-}$ enter cells via facilitated diffusion through non-specific anion channels (similar to phosphate and sulfate anions). As demonstrated in research by Suzuki *et al.*, a portion of water soluble Cr(VI) is rapidly transported to the bloodstream in rats (Ex. 35–97). Rats were exposed to 7.3–15.9 mg Cr(VI)/m^3 as potassium dichromate for 2–6 hours. Following exposure to Cr(VI), the ratio of blood chromium/lung chromium was 1.44±0.30 at 0.5 hours, 0.81±0.10 at 18 hours, 0.85±0.20 at 48 hours, and 0.96±0.22 at 168 hours after exposure.

Once the Cr(VI) particles reach the alveoli, absorption into the bloodstream is greatly dependent on solubility. More soluble chromates are absorbed faster than water insoluble chromates, while insoluble chromates are poorly absorbed and therefore have longer resident time in the lungs. This effect has been demonstrated in research by Bragt and van Dura on the kinetics of three Cr(VI) compounds: highly soluble sodium chromate, slightly soluble zinc chromate and water insoluble lead chromate (Ex. 35–56). They instilled ^{51}chromium-labeled compounds (0.38 mg Cr(VI)/kg as sodium chromate, 0.36 mg Cr(VI)/kg as zinc chromate, or 0.21 mg Cr(VI)/kg as lead chromate) intratracheally in rats. Peak blood levels of ^{51}chromium were reached after 30 minutes for sodium chromate (0.35 µg chromium/ml), and after 24 hours for zinc chromate (0.60 µg chromium/ml) and lead chromate (0.007 µg chromium/ml). At 30 minutes after administration, the lungs contained 36, 25, and 81% of the respective dose of the sodium, zinc, and lead chromate. On day six, >80% of the dose of all three compounds had been cleared from the lungs, during which time the disappearance from lungs followed linear first-order kinetics. The residual amount left in the lungs on day 50 or 51 was 3.0, 3.9, and 13.9%, respectively. From these results authors concluded that zinc chromate, which is less soluble than sodium chromate, is more slowly absorbed from the lungs. Lead chromate was more poorly and slowly absorbed, as indicated by very low levels in blood and greater retention in the lungs. The authors also noted that the kinetics of sodium and zinc chromates were very similar. Zinc chromate, which is less soluble than sodium chromate, was slowly absorbed from the lung, but the maximal blood levels were higher than those resulting from an equivalent dose of sodium chromate. The authors believe that this was probably the result of hemorrhages macroscopically visible in the lungs of zinc chromate-treated rats 24 hours following intratracheal administration. Boeing Corporation commented that this study does not show that the highly water soluble sodium chromate is cleared more rapidly or retained in the lung for shorter periods than the less soluble zinc chromate (Ex. 38–106–2, p. 18–19). This comment is addressed in the Carcinogenic Effects Conclusion Section V.B.9 dealing with the carcinogenicity of slightly soluble Cr(VI) compounds.

Studies by Langard *et al.* and Adachi *et al.* provide further evidence of absorption of chromates from the lungs (Exs. 35–93; 189). In Langard *et al.*, rats exposed to 2.1 mg Cr(VI)/m^3 as zinc chromate for 6 hours/day achieved steady state concentrations in the blood after 4 days of exposure (Ex. 35–93). Adachi *et al.* studied rats that were subject to a single inhalation exposure to chromic acid mist generated from electroplating at a concentration of 3.18 mg Cr(VI)/m^3 for 30 minutes which was then rapidly absorbed from the lungs (Ex. 189). The amount of chromium in the lungs of these rats declined from 13.0 mg immediately after exposure to 1.1 mg after 4 weeks, with an overall half-life of five days.

Several other studies have reported absorption of chromium from the lungs after intratracheal instillation (Exs. 7–9; 9–81; Visek *et al.* 1953 as cited in Ex. 35–41). These studies indicated that 53–85% of Cr(VI) compounds (particle size <5 μm) were cleared from the lungs by absorption into the bloodstream or by mucociliary clearance in the pharynx; the rest remained in the lungs. Absorption of Cr(VI) from the respiratory tract of workers has been shown in several studies that identified chromium in the urine, serum and red blood cells following occupational exposure (Exs. 5–12; 35–294; 35–84).

Evidence indicates that even chromates encapsulated in a paint matrix may be released in the lungs (Ex. 31–15, p. 2). In a study of chromates in aircraft spray paint, LaPuma *et al.* measured the mass of Cr(VI) released from particles into water originating from three types of paint particles: solvent-borne epoxy (25% strontium chromate ($SrCrO_4$)), water-borne epoxy (30% $SrCrO_4$) and polyurethane (20% $SrCrO_4$) (Ex. 31–2–1). The mean fraction of Cr(VI) released into the water after one and 24 hours for each primer averaged: 70% and 85% (solvent epoxy), 74% and 84% (water epoxy), and 94% and 95% (polyurethane). Correlations between particle size and the fraction of Cr(VI) released indicated that smaller particles (<5 μm) release a larger fraction of Cr(VI) versus larger particles (>5 μm). This study demonstrates that the paint matrix only modestly hinders Cr(VI) release into a fluid, especially with smaller particles. Larger particles, which contain the majority of Cr(VI) due to their size, appear to release proportionally less Cr(VI) (as a percent of total Cr(VI)) than smaller particles. Some commenters suggested that the above research shows that the slightly soluble Cr(VI) from aircraft spray paint is less likely to reach and be absorbed in the bronchoalveolar region of the lung than a highly soluble Cr(VI) form, such as chromic acid aerosol (Exs. 38–106–2; 39–43, 44–33). This issue is further discussed in the Carcinogenic Effects Conclusion Section V.B.9.a and in the Quantitative Risk Assessment Section VI.G.4.a.

A number of questions remain unanswered regarding encapsulated Cr(VI) and bioavailability from the lung. There is a lack of detailed information on the efficiency of encapsulation and whether all of the chromate molecules are encapsulated. The stability of the encapsulated product in physiological and environmental conditions over time has not been demonstrated. Finally, the fate of inhaled encapsulated Cr(VI) in the respiratory tract and the extent of distribution in systemic tissues has not been thoroughly studied.

3. Dermal Absorption of Cr(VI)

Both human and animal studies demonstrate that Cr(VI) compounds are absorbed after dermal exposure. Dermal absorption depends on the oxidation state of chromium, the vehicle and the integrity of the skin. Cr(VI) readily traverses the epidermis to the dermis (Exs. 9–49; 309). The histological distribution of Cr(VI) within intact human skin was studied by Liden and Lundberg (Ex. 35–80). They applied test solutions of potassium dichromate in petrolatum or in water as occluded circular patches of filter paper to the skin. Results with potassium dichromate in water revealed that Cr(VI) penetrated beyond the dermis and penetration reached steady state with resorption by the lymph and blood vessels by 5 hours. About 10 times more chromium penetrated when potassium dichromate was applied in petrolatum than when applied in water, indicating that organic solvents facilitate the absorption of Cr(VI) from the skin. Research by Baranowska-Dutkiewicz also demonstrated that the absorption rates of sodium chromate solutions from the occluded forearm skin of volunteers increase with increasing concentration (Ex. 35–75). The rates were 1.1 μg Cr(VI)/cm^2/hour for a 0.01 molar solution, 6.4 μg Cr(VI)/cm^2/hour for a 0.1 molar solution, and 10 μg Cr(VI)/cm^2/hour for a 0.2 molar solution.

Additional studies have demonstrated that the absorption of Cr(VI) compounds can take place through the dermal route. Using volunteers, Mali found that potassium dichromate penetrates the intact epidermis (Exs. 9–49; 35–41). Wahlberg and Skog demonstrated the presence of chromium in the blood, spleen, bone marrow, lymph glands, urine and kidneys of guinea pigs dermally exposed to ^{51}chromium labeled Cr(VI) compounds (Ex. 35–81).

4. Absorption of Cr(VI) by the Oral Route

Inhaled Cr(VI) can enter the digestive tract as a result of mucocilliary clearance and swallowing. Studies indicate Cr(VI) is absorbed from the gastrointestinal tract. For example, in a study by Donaldson and Barreras, the six-day fecal and 24-hour urinary excretion patterns of radioactivity in groups of six volunteers given Cr(VI) as sodium chromate labeled with ^{51}chromium indicated that at least 2.1% of the Cr(VI) was absorbed. After intraduodenal administration at least 10% of the Cr(VI) compound was absorbed. These studies also demonstrated that Cr(VI) compounds are reduced to Cr(III) compounds in the stomach, thereby accounting for the relatively poor gastrointestinal absorption of orally administered Cr(VI) compounds (Exs. 35–96; 35–41). In the gastrointestinal tract, Cr(VI) can be reduced to Cr(III) by gastric juices, which is then poorly absorbed (Underwood, 1971 as cited in Ex. 19–1; Ex. 35–85).

In a study conducted by Clapp *et al.*, treatment of rats by gavage with an unencapsulated lead chromate pigment or with a silica-encapsulated lead chromate pigment resulted in no measurable blood levels of chromium (measured as Cr(III), detection limit = 10 μg/L) after two or four weeks of treatment or after a two-week recovery period. However, kidney levels of chromium (measured as Cr(III)) were significantly higher in the rats that received the unencapsulated pigment when compared to the rats that received the encapsulated pigment, indicating that silica encapsulation may reduce the gastrointestinal bioavailability of chromium from lead chromate pigments (Ex. 11–5). This study does not address the bioavailability of encapsulated chromate pigments from the lung where residence time could be different.

5. Distribution of Cr(VI) in the Body

Once in the bloodstream, Cr(VI) is taken up into erythrocytes, where it is reduced to lower oxidation states and forms chromium protein complexes during reduction (Ex. 35–41). Once complexed with protein, chromium cannot leave the cell and chromium ions are unable to repenetrate the membrane and move back into the plasma (Exs. 7–6; 7–7; 19–1; 35–41; 35–52). Once inside the blood cell, the intracellular Cr(VI) reduction to Cr(III) depletes Cr(VI) concentration in the red blood cell (Ex. 35–89). This serves to enhance diffusion of Cr(VI) from the plasma into the erythrocyte resulting in very low plasma levels of Cr(VI). It is also believed that the rate of uptake of Cr(VI) by red blood cells may not exceed the rate at which they reduce Cr(VI) to Cr(III) (Ex. 35–99). The higher tissue levels of chromium after administration of Cr(VI) than after administration of Cr(III) reflect the greater tendency of Cr(VI) to traverse plasma membranes and bind to intracellular proteins in the various tissues, which may explain the greater degree of toxicity associated with Cr(VI) (MacKenzie *et al.* 1958 as cited in 35–52; Maruyama 1982 as cited in 35–41; Ex. 35–71).

Examination of autopsy tissues from chromate workers who were occupationally exposed to Cr(VI) showed that the highest chromium levels were in the lungs. The liver, bladder, and bone also had chromium levels above background. Mancuso examined tissues from three individuals with lung cancer who were exposed to chromium in the workplace (Ex. 124). One was employed for 15 years as a welder, the second and third worked for 10.2 years and 31.8 years, respectively, in ore milling and preparations and boiler operations. The cumulative chromium exposures for the three workers were estimated to be 3.45, 4.59, and 11.38 mg/m^3-years, respectively. Tissues from the first worker were analyzed 3.5 years after last exposure, the second worker 18 years after last exposure, and the third worker 0.6 years after last exposure. All tissues from the three workers had elevated levels of chromium, with the possible exception of neural tissues. Levels were orders of magnitude higher in the lungs when compared to other tissues. Similar results were also reported in autopsy studies of people who may have been exposed to chromium in the workplace as well as chrome platers and chromate refining workers (Exs. 35–92; 21–1; 35–74; 35–88).

Animal studies have shown similar distribution patterns after inhalation exposure. For example, a study by Baetjer *et al.* investigated the distribution of Cr(VI) in guinea pigs after intratracheal instillation of slightly soluble potassium dichromate (Ex. 7–8). At 24 hours after instillation, 11% of the original dose of chromium from potassium dichromate remained in the lungs, 8% in the erythrocytes, 1% in plasma, 3% in the kidney, and 4% in the liver. The muscle, skin, and adrenal glands contained only a trace. All tissue concentrations of chromium declined to low or nondetectable levels in 140 days, with the exception of the lungs and spleen.

6. Metabolic Reduction of Cr(VI)

Cr(VI) is reduced to Cr(III) in the lungs by a variety of reducing agents. This serves to limit uptake into lung cells and absorption into the bloodstream. Cr(V) and Cr(IV) are transient intermediates in this process. The genotoxic effects produced by the Cr(VI) are related to the reduction process and are further discussed in the section V.B.8 on Mechanistic Considerations.

In vivo and *in vitro* experiments in rats indicated that, in the lungs, Cr(VI) can be reduced to Cr(III) by ascorbate and glutathione. A study by Suzuki and Fukuda showed that the reduction of Cr(VI) by glutathione is slower than the reduction by ascorbate (Ex. 35–65). Other studies have reported the reduction of Cr(VI) to Cr(III) by epithelial lining fluid (ELF) obtained from the lungs of 15 individuals by bronchial lavage. The average overall reduction capacity was 0.6 µg Cr(VI)/mg of ELF protein. In addition, cell extracts made from pulmonary alveolar macrophages derived from five healthy male volunteers were able to reduce an average of 4.8 µg Cr(VI)/10^6 cells or 14.4 µg Cr(VI)/mg protein (Ex. 35–83). Postmitochondrial (S12) preparations of human lung cells (peripheral lung parenchyma and bronchial preparations) were also able to reduce Cr(VI) to Cr(III) (De Flora *et al.* 1984 as cited in Ex. 35–41).

7. Elimination of Cr(VI) From the Body

Excretion of chromium from Cr(VI) compounds is predominantly in the urine, although there is some biliary excretion into the feces. In both urine and feces, the chromium is present as low molecular weight Cr(III) complexes. Absorbed chromium is excreted from the body in a rapid phase representing clearance from the blood and at least two slower phases representing clearance from tissues. Urinary excretion accounts for over 50% of eliminated chromium (Ex. 35–41). Although chromium is excreted in urine and feces, the intestine plays only a minor part in chromium elimination, representing only about 5% of elimination from the blood (Ex. 19–1). Normal urinary levels of chromium in humans have been reported to range from 0.24–1.8 µg/L with a median level of 0.4 µg/L (Ex. 35–79). Humans exposed to 0.01–0.1 mg Cr(VI)/m^3 as potassium dichromate (8-hour time-weighted average) had urinary excretion levels from 0.0247 to 0.037 mg Cr(III)/L. Workers exposed mainly to Cr(VI) compounds had higher urinary chromium levels than workers exposed primarily to Cr(III) compounds. An analysis of the urine did not detect Cr(VI), indicating that Cr(VI) was rapidly reduced before excretion (Exs. 35–294; 5–48).

A half-life of 15–41 hours has been estimated for chromium in urine for four welders using a linear one-compartment kinetic model (Exs. 35–73; 5–52; 5–53). Limited work on modeling the absorption and deposition of chromium indicates that adipose and muscle tissue retain chromium at a moderate level for about two weeks, while the liver and spleen store chromium for up to 12 months. The estimated half-life for whole body chromium retention is 22 days for Cr(VI) (Ex. 19–1). The half-life of chromium in the human lung is 616 days, which is similar to the half-life in rats (Ex. 7–5).

Elimination of chromium was shown to be very slow in rats exposed to 2.1 mg Cr(VI)/m^3 as zinc chromate six hours/day for four days. Urinary levels of chromium remained almost constant for four days after exposure and then decreased (Ex. 35–93). After intratracheal administration of sodium dichromate to rats, peak urinary chromium concentrations were observed at six hours, after which the urinary concentrations declined rapidly (Ex. 35–94). The more prolonged elimination of the moderately soluble zinc chromate as compared to the more soluble sodium dichromate is consistent with the influence of Cr(VI) solubility on absorption from the respiratory tract discussed earlier.

Information regarding the excretion of chromium in humans after dermal exposure to chromium or its compounds is limited. Fourteen days after application of a salve containing water soluble potassium chromate, which resulted in skin necrosis and sloughing at the application site, chromium was found at 8 mg/L in the urine and 0.61 mg/100 g in the feces of one individual (Brieger 1920 as cited in Ex. 19–1). A slight increase over background levels of urinary chromium was observed in four subjects submersed in a tub of chlorinated water containing 22 mg Cr(VI)/L as potassium dichromate for three hours (Ex. 31–22–6). For three of the four subjects, the increase in urinary chromium excretion was less than 1 μg/day over the five-day collection period. Chromium was detected in the urine of guinea pigs after radiolabeled sodium chromate solution was applied to the skin (Ex. 35–81).

8. Physiologically-Based Pharmacokinetic Modeling

Physiologically-based pharmacokinetic (PBPK) models have been developed that simulate absorption, distribution, metabolism, and excretion of Cr(VI) and Cr(III) compounds in humans (Ex. 35–95) and rats (Exs. 35–86; 35–70). The original model (Ex. 35–86) evolved from a similar model for lead, and contained compartments for the lung, GI tract, skin, blood, liver, kidney, bone, well-perfused tissues, and slowly perfused tissues. The model was refined to include two lung subcompartments for chromium, one of which allowed inhaled chromium to enter the blood and GI tract and the other only allowed chromium to enter the GI tract (Ex. 35–70). Reduction of Cr(VI) to Cr(III) was considered to occur in every tissue compartment except bone.

The model was developed from several data sets in which rats were dosed with Cr(VI) or Cr(III) intravenously, orally or by intratracheal instillation, because different distribution and excretion patterns occur depending on the route of administration. In most cases, the model parameters (*e.g.*, tissue partitioning, absorption, reduction rates) were estimated by fitting model simulations to experimental data. The optimized rat model was validated against the 1978 Langard inhalation study (Ex. 35–93). Chromium blood levels were overpredicted during the four-day inhalation exposure period, but blood levels during the post-exposure period were well predicted by the model. The model-predicted levels of liver chromium were high, but other tissue levels were closely estimated.

A human PBPK model recently developed by O'Flaherty *et al.* is able to predict tissue levels from ingestion of Cr(VI) (Ex. 35–95). The model incorporates differential oral absorption of Cr(VI) and Cr(III), rapid reduction of Cr(VI) to Cr(III) in major body fluids and tissues, and concentration-dependent urinary clearance. The model does not include a physiologic lung compartment, but can be used to estimate an upper limit on pulmonary absorption of inhaled chromium. The model was calibrated against blood and urine chromium concentration data from a group of controlled studies in which adult human volunteers drank solutions of soluble Cr(III) or Cr(VI).

PBPK models are increasingly used in risk assessments, primarily to predict the concentration of a potentially toxic chemical that will be delivered to any given target tissue following various combinations of route, dose level, and test species. Further development of the respiratory tract portion of the model, specific Cr(VI) rate data on extracellular reduction and uptake into lung cells, and more precise understanding of critical pathways inside target cells would improve the model value for risk assessment purposes.

9. Summary

Based on the studies presented above, evidence exists in the literature that shows Cr(VI) can be systemically absorbed by the respiratory tract. The absorption of inhaled chromium compounds depends on a number of factors, including physical and chemical properties of the particles (oxidation state, size, and solubility), the reduction capacity of the ELF and alveolar macrophages and clearance by the mucocliary escalator and phagocytosis. Highly water soluble Cr(VI) compounds (*e.g.* sodium chromate) enter the bloodstream more readily than highly insoluble Cr(VI) compounds (*e.g.* lead chromate). However, insoluble compounds may have longer residence time in lung. Absorption of Cr(VI) can also take place after oral and dermal exposure, particularly if the exposures are high.

The chromate $(CrO_4)^{2-}$ enters cells via facilitated diffusion through non-specific anion channels (similar to phosphate and sulfate anions). Following absorption of Cr(VI) compounds from various exposure routes, chromium is taken up by the blood cells and is widely distributed in tissues as Cr(VI). Inside blood cells and tissues, Cr(VI) is rapidly reduced to lower oxidation states and bound to macromolecules which may result in genotoxic or cytotoxic effects. However, in the blood a substantial proportion of Cr(VI) is taken up into erythrocytes, where it is reduced to Cr(III) and becomes bound to hemoglobin and other proteins.

Inhaled Cr(VI) is reduced to Cr(III) *in vivo* by a variety of reducing agents. Ascorbate and glutathione in the ELF and macrophages have been shown to reduce Cr(VI) to Cr(III) in the lungs. After oral exposure, gastric juices are also responsible for reducing Cr(VI) to Cr(III). This serves to limit the amount of Cr(VI) systemically absorbed.

Absorbed chromium is excreted from the body in a rapid phase representing clearance from the blood and at least two slower phases representing clearance from tissues. Urinary excretion is the primary route of elimination, accounting for over 50% of eliminated chromium. Although chromium is excreted in urine and feces, the intestine plays only a minor part in chromium elimination representing only about 5% of elimination from the blood.

B. Carcinogenic Effects

There has been extensive study on the potential for Cr(VI) to cause carcinogenic effects, particularly cancer of the lung. OSHA reviewed epidemiologic data from several industry sectors including chromate production, chromate pigment production, chromium plating, stainless steel welding, and ferrochromium production. Supporting evidence from animal studies and mechanistic considerations are also evaluated in this section.

1. Evidence from Chromate Production Workers

The epidemiologic literature of workers in the chromate production industry represents the earliest and best-documented relationship between exposure to chromium and lung cancer. The earliest study of chromate production workers in the United States was reported by Machle and Gregorius in 1948 (Ex. 7–2). In the United States, two chromate production plants, one in Baltimore, MD, and one in Painesville, OH, have been the subject of multiple studies. Both plants were included in the 1948 Machle and Gregorius study and again in the study conducted by the Public Health Service and published in 1953 (Ex. 7–3). Both of these studies reported the results in aggregate. The Baltimore chromate production plant was studied by Hayes *et al.* (Ex. 7–14) and more recently by Gibb *et al.* (Ex. 31–22–11). The chromate production plant in Painesville, OH, has been followed since the 1950s by Mancuso with his most recent follow-up published in 1997. The most recent study of the Painesville plant was published by Luippold *et al.* (Ex. 31–18–4). The studies by Gibb and Luippold present historical exposure data for the time periods covered by their respective studies. The Gibb exposure data are especially interesting since the industrial hygiene data were collected on a routine basis and not for compliance purposes. These routine air measurements may be more representative of those typically encountered by the exposed workers. In Great Britain, three plants have been studied repeatedly, with reports published between 1952 and 1991. Other studies of cohorts in the United States, Germany, Italy and Japan are also reported. The elevated lung cancer mortality reported in the great majority of these cohorts and the significant upward trends with duration of employment and cumulative exposure provide some of the strongest evidence that Cr(VI) is carcinogenic to workers. A summary of selected human epidemiologic studies in chromate production workers is presented in Table V–1.

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TABLE V-1: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Chromate Production

Reference/Exhibit Number	**Study Population**	**Reference Population**	**Chromium (VI) Exposure**	**Lung Cancer Risk**
Hayes et al. (1979, Ex. 7-14) Braver et al. (1985, Ex. 7-17)	1803 male workers initially employed 3 or more months 1945-1974 at old and new Baltimore MD production facility; follow-up through 1977	Baltimore City mortality	Primarily sodium chromate and dichromate production. Avg Cr(VI) of 21 to 413 $\mu g/m^3$ and avg duration 1.6 yr to 13 yr depending on subcohort, plant, and year employed	-O/E of 2.0 ($p<0.01$) based on 59 lung cancer deaths -Increased risk with duration of employment
Gibb et al. (2000, Ex. 31-22-11)	2357 male workers initially employed 1950-1974 only at new Baltimore MD production facility; follow-up through 1992	U.S. mortality	Primarily sodium chromate and dichromate. Mean cumulative Cr(VI) of 0.070 mg/ m^3 - yr and work duration of 3.1 yr	-O/E of 1.86 ($p<0.01$) based on 71 lung cancer deaths -Significant upward mortality trend with cumulative Cr(VI) exposure
Mancuso (1997, Ex. 23) Mancuso (1975, Ex. 7-11) Mancuso and Heuper (1951, Ex. 7-13) Bourne and Yee (1950, Ex. 7-98)	332 male workers employed at Painesville OH facility 1931-1937; follow-up through 1993	Mortality rate directly calculated using the distribution of person years by age group for the entire exposed population as the standard	Primarily sodium chromate and dichromate production with some calcium chromate as a result of using high lime process. Most cumulative soluble Cr(VI) between 0.25 and 4.0 mg/ m^3 – yr based on 1949 survey	O/E not calculated but significant increase in age-adjusted lung cancer death rate with cumulative chromium exposure based on 66 deaths
Luippold et al. (2003, Ex. 31-18-4)	492 male workers employed one year between 1940 and 1972 at Painesville OH facility; follow-up through 1997	U.S. and Ohio Mortality Rates	Primarily sodium chromate and dichromate production with minor calcium chromate Mean cumulative soluble Cr(VI) of 1.58 mg/ m^3 - yr	-O/E of 2.41($p<0.01$) based on Ohio rates and 51 deaths -Significant upward mortality trend with cumulative Cr(VI) exposure
Davies et al. (1991, Ex. 7-99) Alderson et al. (1981, Ex. 7-22) Bistrup and Case (1956, Ex. 7-20)	2298 male chromate production workers employed for one year between 1950 and 1976 at three different UK plants; follow-up through 1989	Cancer mortality of England, Wales and Scotland and unexposed local workers	Principally sodium chromate and dichromate production with some calcium chromate before switch from high lime to no lime process. Avg soluble Cr(VI) in early 1950s from 2 to 880 $\mu g/m^3$ depending on job.	-O/E of 1.97 ($p<0.01$) pre-process change based on 175 deaths -SMR of 1.02 (NS) post-process change based on 14 deaths - Increased risk for high exposed compared with less exposed
Korallus et al. (1993, Ex. 7-91) Korallus et al. (1982, Ex. 7-26) Birk et al. (2005, Ex. 48-4)	1417 chromate production workers employed for one year between 1948 and 1987 at two different German plants; follow-up through 1988. 901 'post-process change' [to no lime process] workers followed	Mortality rates for North Rhine-Westphalia region of Germany where plants located as well as German national rates	Principally sodium chromate and dichromate production with some calcium chromate before switch from high lime to no lime process. Annual mean Cr(VI) between 6.2 and 38 $\mu g/m^3$ after 1977. Cr(VI) exposure not	-O/E of 2.27($p<0.01$) pre-process change based on 66 deaths -O/E of 1.22 (NS) post-process change based on 22 deaths -O/E of 2.09 ($p<0.05$) post-process change with $\geq 200\ \mu g$ urinary Cr/dl – yr based on 12 deaths

	through 1998.		reported before 1977.	
Pastides <u>et al.</u> (1994, Ex. 7-93)	398 chromate production workers employed for one year between September 4, 1971 and December 31, 1989 at a North Carolina plant; follow-up through 1989	Mortality rates for eight North Carolina counties, state rates (not reported), and U.S. mortality rates	Principally sodium bichromate and chromic acid production with as a result of low lime process. About 50% of personal air monitoring samples < 1 μg/m^3 Cr(VI), 75% < 3 μg/m^3, and 96% < 25 μg/m^3.	-O/E of 127 based on U.S. rates and 2 deaths -O/E of 97 based on North Carolina county rates
Luippold <u>et al.</u> (2005, Ex. 47-24-2)	430 chromate production workers employed for one year at low lime North Carolina plant studied by Pastides <u>et al.</u> (1994); 187 chromate production workers employed for one year at a second plant after switch to low lime process in 1980; follow-up through 1998	State-specific mortality rates and U.S. mortality rates (not reported)	Principally sodium dichromate and chromic acid production as a result of low lime process. Airborne Cr(VI) levels typically < 1.5 μg/m^3; highest recorded levels < 10 μg/m^3.	-O/E of 84 based on state-specific rates and 3 deaths

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

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The basic hexavalent chromate production process involves milling and mixing trivalent chromite ore with soda ash, sometimes in the presence of lime (Exs. 7–103; 35–61). The mixture is 'roasted' at a high temperature, which oxidizes much of the chromite to hexavalent sodium chromate. Depending on the lime content used in the process, the roast also contains other chromate species, especially calcium chromate under high lime conditions. The highly water-soluble sodium chromate is water-extracted from the water-insoluble trivalent chromite and the less water-soluble chromates (*e.g.*, calcium chromate) in the 'leaching' process. The sodium chromate leachate is reacted with sulfuric acid and sodium bisulfate to form sodium dichromate. The sodium dichromate is prepared and packaged as a crystalline powder to be sold as final product or sometimes used as the starting material to make other chromates such as chromic acid and potassium dichromate.

a. Cohort Studies of the Baltimore Facility. The Hayes *et al.* study of the Baltimore, Maryland chromate production plant was designed to determine whether changes in the industrial process at one chromium chemical production facility were associated with a decreased risk of cancer, particularly cancer of the respiratory system (Ex. 7–14). Four thousand two hundred and seventeen (4,217) employees were identified as newly employed between January 1, 1945 and December 31, 1974. Excluded from this initial enumeration were employees who: (1) were working as of 1945, but had been hired prior to 1945 and (2) had been hired since 1945 but who had previously been employed at the plant. Excluded from the final cohort were those employed less than 90 days; women; those with unknown length of employment; those with no work history; and those of unknown age. The final cohort included 2,101 employees (1,803 hourly and 298 salaried).

Hayes divided the production process into three departments: (1) The mill and roast or ''dry end'' department which consists of grinding, roasting and leaching processes; (2) the bichromate department which consists of the acidification and crystallization processes; and (3) the special products department which produces secondary products including chromic acid. The bichromate and special products departments are referred to as the ''wet end''.

The construction of a new mill and roast and bichromate plant that opened during 1950 and 1951 and a new chromic acid and special products plant that opened in 1960 were cited by Hayes as ''notable production changes'' (Ex. 7–14). The new facilities were designed to ''obtain improvements in process technique and in environmental control of exposure to chromium bearing dusts * * *'' (Ex. 7–14).

Plant-related work and health histories were abstracted for each employee from plant records. Each job on the employee's work history was characterized according to whether the job exposure occurred in (1) a newly constructed facility, (2) an old facility, or (3) could not be classified as having occurred in the new or the old facility. Those who ever worked in an old facility or whose work location(s) could not be distinguished based upon job title were considered as having a high or questionable exposure. Only those who worked exclusively in the new facility were defined for study purposes as ''low exposure''. Data on cigarette smoking were abstracted from plant records, but were not utilized in any analyses since the investigators thought them ''not to be of sufficient quality to allow analysis.''

One thousand one hundred and sixty nine (1,169) cohort members were identified as alive, 494 not individually identified as alive and 438 as deceased. Death certificates could not be located for 35 reported decedents. Deaths were coded to the 8th revision of the International Classification of Diseases.

Mortality analysis was limited to the 1,803 hourly employees calculating the standardized mortality ratios (SMRs) for specific causes of death. The SMR is a ratio of the number of deaths observed in the study population to the number that would be expected if that study population had the same specific mortality rate as a standard reference population (*e.g.*, age-, gender-, calendar year adjusted U.S. population). The SMR is typically multiplied by 100, so a SMR greater than 100 represents an elevated mortality in the study cohort relative to the reference group. In the Hayes study, the expected number of deaths was based upon Baltimore, Maryland male mortality rates standardized for age, race and time period. For those where race was unknown, the expected numbers were derived from mortality rates for whites. Cancer of the trachea, bronchus and lung accounted for 69% of the 86 cancer deaths identified and was statistically significantly elevated (O=59; E=29.16; SMR=202; 95% CI: 155–263).

Analysis of lung cancer deaths among hourly workers by year of initial employment (1945–1949; 1950–1959 and 1960–1974), exposure category (low exposure or questionable/high exposure) and duration of employment (short term defined as 90 days–2 years; long term defined as 3 years +) was also conducted. For those workers characterized as having questionable/high exposure, the SMRs were significantly elevated for the 1945–1949 and the 1950–1959 hire periods and for both short- and long-term workers (not statistically significant for the short-term workers initially hired 1945–1949). For those characterized as low exposure, there was an elevated SMR for the long-term workers hired between 1950 and 1959, but based only on three deaths (not statistically significant). No lung cancer cases were observed for workers hired 1960–1974.

Case-control analyses of (1) a history of ever having been employed in selected jobs or combinations of jobs or (2) a history of specified morbid conditions and combinations of conditions reported on plant medical records were conducted. Cases were defined as decedents (both hourly and salaried were included in the analyses) whose underlying or contributing cause of death was lung cancer. Controls were defined as deaths from causes other than malignant or benign tumors. Cases and controls were matched on race (white/non-white), year of initial employment (+/−3 years), age at time of initial employment (+/−5 years) and total duration of employment (90 days–2 years; 3–4 years and 5 years +). An odds ratio (OR) was determined where the ratio is the odds of employment in a job involving Cr(VI) exposure for the cases relative to the controls.

Based upon matched pairs, analysis by job position showed significantly elevated odds ratios for special products (OR=2.6) and bichromate and special products (OR=3.3). The relative risk for bichromate alone was also elevated (OR=2.1, not statistically significant).

The possible association of lung cancer and three health conditions (skin ulcers, nasal perforation and dermatitis) as recorded in the plant medical records was also assessed. Of the three medical conditions, only the odds ratio for dermatitis was statistically significant (OR=3.0). When various combinations of the three conditions were examined, the odds ratio for having all three conditions was statistically significantly elevated (OR=6.0).

Braver *et al.* used data from the Hayes study discussed above and the results of 555 air samples taken during the period 1945–1950 by the Baltimore City Health Department, the U.S. Public Health Service, and the companies that owned the plant, in an attempt to examine the relationship between exposure to Cr(VI) and the occurrence of lung cancer (Ex. 7–17). According to the authors, methods for determining the air concentrations of Cr(VI) have changed since the industrial hygiene data were collected at the Baltimore plant between 1945 and 1959. The authors asked the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health

Administration (OSHA) to review the available documents on the methods of collecting air samples, stability of Cr(VI) in the sampling media after collection and the methods of analyzing Cr(VI) that were used to collect the samples during that period.

Air samples were collected by both midget impingers and high volume samplers. According to the NIOSH/OSHA review, high volume samplers could have led to a ''significant'' loss of Cr(VI) due to the reduction of Cr(VI) to Cr(III) by glass or cellulose ester filters, acid extraction of the chromate from the filter, or improper storage of samples. The midget impinger was ''less subject'' to loss of Cr(VI) according to the panel since neither filters nor acid extraction from filters was employed. However, if iron was present or if the samples were stored for too long, conversion from Cr(VI) to Cr(III) may have occurred. The midget impinger can only detect water soluble Cr(VI). The authors noted that, according to a 1949 industrial hygiene survey by the U.S. Public Health Service, very little water insoluble Cr(VI) was found at the Baltimore plant. One NIOSH/OSHA panel member characterized midget impinger results as ''reproducible'' and ''accuracy * * * fairly solid unless substantial reducing agents (*e.g.*, iron) are present'' (Ex. 7–17, p. 370). Based upon the panel's recommendations, the authors used the midget impinger results to develop their exposure estimates even though the panel concluded that the midget impinger methods ''tend toward underestimation'' of Cr(VI).

The authors also cite other factors related to the industrial hygiene data that could have potentially influenced the accuracy of their exposure estimates (either overestimating or underestimating the exposure). These include: Measurements may have been taken primarily in ''problem'' areas of the plant; the plants may have been cleaned or certain processes shut down prior to industrial hygiene monitoring by outside groups; respirator use; and periodic high exposures (due to infrequent maintenance operations or failure of exposure control equipment) which were not measured and therefore not reflected in the available data.

The authors estimated exposure indices for cohorts rather than for specific individuals using hire period (1945–1949 or 1950–1959) and duration of exposure, defined as short (at least 90 days but less than three years) and long (three years or more). The usual exposure to Cr(VI) for both the short- and long-term workers hired 1945–1949 was calculated as the average of the mean annual air concentration for 1945–1947 and 1949 (data were missing for 1948). This was estimated to be 413 μg/m^3. The usual exposure to Cr(VI) was estimated to be 218 μg/m^3 for the short and long employees hired between 1950 and 1959 based on air measurements in the older facility in the early 1950s.

Cumulative exposure was calculated as the usual exposure level times average duration. Short-term workers, regardless of length of employment, were assumed to have received 1.6 years of exposure regardless of hire period. For long-term workers, the average length of exposure was 12.3 years. Those hired 1945–1949 were assigned five years at an exposure of 413 μg/m^3 and 7.3 years at an exposure of 218 μg/m^3. For the long-term workers hired between 1950 and 1959, the average length of exposure was estimated to be 13.4 years. The authors estimated that the cumulative exposures at which ''significant increases in lung cancer mortality'' were observed in the Hayes study were 0.35, 0.67, 2.93 and 3.65 mg/m^3—years. The association seen by the authors appears more likely to be the result of duration of employment rather than the magnitude of exposure since the variation in the latter was small.

Gibb *et al.* relied upon the Hayes study to investigate mortality in a second cohort of the Baltimore plant (Ex. 31–22–11). The Hayes cohort was composed of 1,803 hourly and 298 salaried workers newly employed between January 1, 1945 and December 31, 1974. Gibb excluded 734 workers who began work prior to August 1, 1950 and included 990 workers employed after August 1, 1950 who worked less than 90 days, resulting in a cohort of 2,357 males followed for the period August 1, 1950 through December 31, 1992. Fifty-one percent (1,205) of the cohort was white; 36% (848) nonwhite. Race was unknown for 13% (304) of the cohort. The plant closed in 1985.

Deaths were coded according to the 8th revision of the International Classification of Diseases. Person years of observation were calculated from the beginning of employment until death or December 31, 1992, whichever came earlier. Smoking data (yes/no) were available for 2,137 (93.3%) of the cohort from company records.

Between 1950 and 1985, approximately 70,000 measurements of airborne Cr(VI) were collected utilizing several different sampling methods. The program of routine air sampling for Cr(VI) was initiated to ''characterize 'typical/usual exposures' of workers'' (Ex. 31–22–11, p. 117). Area samples were collected during the earlier time periods, while both area and personal samples were collected starting in 1977. Exposure estimates were derived from the area sampling systems and were adjusted to ''an equivalent personal exposure estimate using job-specific ratios of the mean area and personal sampling exposure estimates for the period 1978–1985 * * *'' (Ex. 31–22–11, p. 117). According to the author, comparison of the area and personal samples showed ''no significant differences'' for about two-thirds of the job titles. For several job titles with a ''significant point source of contamination'' the area sampling methods ''significantly underestimated'' personal exposure estimates and were adjusted ''by the ratio of the two'' (Ex. 31–22–11, p. 118).

A job exposure matrix (JEM) was constructed, where air sampling data were available, containing annual average exposure for each job title. Data could not be located for the periods 1950–1956 and 1960–1961. Exposures were modeled for the missing data using the ratio of the measured exposure for a job title to the average of all measured job titles in the same department. For the time periods where ''extensive'' data were missing, a simple straight line interpolation between years with known exposures was employed.

To estimate airborne Cr(III) concentrations, 72 composite dust samples were collected at or near the fixed site air monitoring stations about three years after the facility closed. The dust samples were analyzed for Cr(VI) content using ion chromatography. Cr(III) content was determined through inductively coupled plasma spectroscopic analysis of the residue. The Cr(III):Cr(VI) ratio was calculated for each area corresponding to the air sampling zones and the measured Cr(VI) air concentration adjusted based on this ratio. Worker exposures were calculated for each job title and weighted by the fraction of time spent in each air-monitoring zone. The Cr(III):Cr(VI) ratio was derived in this manner for each job title based on the distribution of time spent in exposure zones in 1978. Cr(VI) exposures in the JEM were multiplied by this ratio to estimate Cr(III) exposures.

Information on smoking was collected at the time of hire for approximately 90% of the cohort. Of the 122 lung cancer cases, 116 were smokers and four were non smokers at the time of hire. Smoking status was unknown for two lung cancer cases. As discussed below, these data were used by the study authors to adjust for smoking in their proportional hazards regression models used to determine whether lung cancer mortality in the worker cohort increased with increasing cumulative Cr(VI) exposure.

A total of 855 observed deaths (472 white; 323 nonwhite and 60 race unknown) were reported. SMRs were calculated using U.S. rates for overall mortality. Maryland rates (the state in which the plant was located) were used to analyze lung cancer mortality in order to better account for regional differences in disease fatality. SMRs were not adjusted for smoking. In the public hearing, Dr. Gibb explained that it was more appropriate to adjust for smoking in the proportional hazards models than in the SMRs, because the analyst must make more assumptions to adjust the SMRs for smoking than to adjust the regression model (Tr. 124).

A statistically significant lung cancer SMR, based on the national rate, was found for whites (O=71; SMR=186; 95% CI: 145–234); nonwhites (O=47; SMR=188; 95% CI: 138–251) and the total cohort (O=122; SMR=180; 95% CI: 149–214). The ratio of observed to expected lung cancer deaths (O/E) for the entire cohort stratified by race and cumulative exposure quartile were computed. Cumulative exposure was lagged five years (only exposure occurring five years before a given age was counted). The cut point for the quartiles divided the cohort into four equal groups based upon their cumulative exposure at the end of their working history (0–0.00149 mgCrO^3/m3–yr; 0.0015–0.0089 mgCrO$_3$/m^3–yr; 0.009–0.0769 mgCrO$_3$/m^3–yr; and 0.077–5.25 mgCrO$_3$/m^3–yr). For whites, the relative risk of lung cancer was significantly elevated for the second through fourth exposure quartiles with O/E values of 0.8, 2.1, 2.1 and 1.7 for the four quartiles, respectively. For nonwhites, the O/E values by exposure quartiles were 1.1, 0.9, 1.2 and 2.9, respectively. Only the highest exposure quartile was significantly elevated. For the total cohort, a significant exposure-response trend was observed such that lung cancer mortality increased with increasing cumulative Cr(VI) exposure.

Proportional hazards models were used to assess the relationship between chromium exposure and the risk of lung cancer. The lowest exposure quartile was used as the reference group. The median exposure in each quartile was used as the measure of cumulative Cr(VI) exposure. When smoking status was included in the model, relative lung cancer risks of 1.83, 2.48 and 3.32 for the second, third and fourth exposure quartiles respectively were estimated. Smoking, Cr(III) exposure, and work duration were also significant predictors of lung cancer risk in the model.

The analysis attempted to separate the effects into two multivariate proportionate hazards models (one model incorporated the log of cumulative Cr(VI) exposure, the log of cumulative Cr(III) exposure and smoking; the second incorporated the log of cumulative Cr(VI), work duration and smoking). In either regression model, lung cancer mortality remained significantly associated ($p < .05$) with cumulative Cr(VI) exposure even after controlling for the combination of smoking and Cr(III) exposure or the combination of smoking and work duration. On the other hand, lung cancer mortality was not significantly associated with cumulative Cr(III) or work duration in the multivariate analysis indicating lung cancer risk was more strongly correlated with cumulative Cr(VI) exposure than the other variables.

Exponent, as part of a larger submission from the Chrome Coalition, submitted comments on the Gibb paper prior to the publication of the proposed rule. These comments asked that OSHA review methodological issues believed by Exponent to impact upon the usefulness of the Gibb data in a risk assessment analysis. While Exponent states that the Gibb study offers data that ''are substantially better for cancer risk than the Mancuso study * * * they believe that further scrutiny of some of the methods and analytical procedures is necessary (Ex. 31–18–15–1, p. 5).

The issues raised by Exponent and the Chrome Coalition (Ex. 31–18–14) concerning the Gibb paper are: selection of the appropriate reference population for compilation of expected numbers for use in the SMR analysis; inclusion of short term workers (< 1 year); expansion of the number of exposure groupings to evaluate dose response trends; analyzing dose response by peak JEM exposure levels; analyzing dose-response at exposures above and below the current PEL and calculating smoking-adjusted SMRs for use in dose-response assessments. Exponent obtained the original data from the Gibb study. The data were reanalyzed to address the issues cited above. Exponent's findings are presented in Exhibit 31–18–15–1 and are discussed below.

Exponent suggested that Gibb's use of U.S. and Maryland mortality rates for developing expectations for the SMR analysis was inappropriate. It suggested that Baltimore city mortality rates would have been the appropriate standard to select since those mortality rates would more accurately reflect the mortality experience of those who worked at the plant. Exponent reran the SMR analysis to compare the SMR values reported by Gibb (U.S. mortality rates for SMR analysis) with the results of an SMR analysis using Maryland mortality rates and Baltimore mortality rates. Gibb reported a lung cancer SMR of 1.86 (95% CI: 1.45–2.34) for white males based upon 71 lung cancer deaths using U.S. mortality rates. Reanalysis of the data produced a lung cancer SMR of 1.85 (95% CI: 1.44–2.33) for white males based on U.S. mortality rates, roughly the same value obtained by Gibb. When Maryland and Baltimore rates are used, the SMR drops to 1.70 and 1.25 respectively.

Exponent suggested conducting sensitivity analysis that excludes short-term workers (defined as those with one year of employment) since the epidemiologic literature suggests that the mortality of short-term workers is different than long-term workers. Short-term workers in the Gibb study comprise 65% of the cohort and 54% of the lung cancers. The Coalition also suggested that data pertaining to short-term employees' information are of ''questionable usefulness for assessing the increased cancer risk from chronic occupational exposure to Cr(VI)'' (Ex. 31–18–15–1, p. 5).

Lung cancer SMRs were calculated for those who worked for less than one year and for those who worked one year or more. Exponent defined short-term workers as those who worked less than one year ''because it is consistent with the inclusion criteria used by others studying chromate chemical production worker cohorts'' (Ex. 31–18–15–1, p. 12). Exponent also suggested that Gibb's breakdown of exposure by quartile was not the most ''appropriate'' way of assessing dose-response since cumulative Cr(VI) exposures remained near zero until the 50th to 60th percentile, ''so there was no real distinction between the first two quartiles * * * (Ex. 31–18–15–1, p. 24). They also suggested that combining ''all workers together at the 75th quartile * * * does not properly account for the heterogeneity of exposure in this group'' (Ex. 31–18–15–1, p. 24). The Exponent reanalysis used six cumulative exposure levels of Cr(VI) compared with the four cumulative exposure levels of Cr(VI) in the Gibb analysis. The lower levels of exposure were combined and ''more homogeneous'' categories were developed for the higher exposure levels.

Using these re-groupings and excluding workers with less than one year of employment, Exponent reported that the highest SMRs are seen in the highest exposure group (1.5–<5.25 mg

CrO_3/m³–years) for both white and nonwhite, based on either the Maryland or the Baltimore mortality rates. The authors did not find ''that the inclusion of short-term workers had a significant impact on the results, especially if Baltimore rates are used in the SMR calculations' (Ex. 31–18–15–1, p. 28).

Analysis of length of employment and ''peak'' (*i.e.*, highest recorded mean annual) exposure level to Cr(VI) was conducted. Exponent reported that approximately 50% of the cohort had ''only very low'' peak exposure levels (<7.2 µg CrO_3/m³ or approximately 3.6 µg/m³ of Cr(VI)). The majority of the short-term workers had peak exposures of <100 µg CrO_3/m³. There were five peak Cr(VI) exposure levels (<7.2 µg CrO_3/m³; 7.2–<19.3 µg CrO_3/m³; 19.3–<48.0 µg CrO_3/m³; 48.0–<105 µg CrO_3/m³; 105–<182 µg CrO_3/m³; and 182–<806 µg CrO_3/m³) included in the analyses. Overall, the lung cancer SMRs for the entire cohort grouped according to the six peak exposure categories were slightly higher using Maryland reference rates compared to Baltimore reference rates.

The Exponent analysis of workers who were ever exposed above the current PEL versus those never exposed above the current PEL produced slightly higher SMRs for those ever exposed, with the SMRs higher using the Maryland standard rather than the Baltimore standard. The only statistically significant result was for all lung cancer deaths combined.

Assessment was made of the potential impact of smoking on the lung cancer SMRs since Gibb did not adjust the SMRs for smoking. Exponent stated that the smoking-adjusted SMRs are more appropriate for use in the risk assessment than the unadjusted SMRs. It should be noted that smoking adjusted SMRs could not be calculated using Baltimore reference rates. As noted by the authors, the smoking adjusted SMRs produced using Maryland reference rates are, by exposure, ''reasonably consistent with the Baltimore-referenced SMRs'' (Ex. 31–18–15–1, p. 41).

Gibb *et al.* included workers regardless of duration of employment, and the cohort was heavily weighted by those individuals who worked less than 90 days. In an attempt to clarify this issue, Exponent produced analyses of short-term workers, particularly with respect to exposures. Exponent redefined short-term workers as those who worked less than one year, to be consistent with the definition used in other studies of chromate producers. OSHA finds this reanalysis excluding short-term workers to be useful. It suggests that including cohort workers employed less than one year did not substantively alter the conclusions of Gibb *et al.* with regard to the association between Cr(VI) exposure and lung cancer mortality. It should be noted that in the Hayes study of the Baltimore plant, the cohort is defined as anyone who worked 90 days or more.

Hayes *et al.* used Baltimore mortality rates while Gibb *et al.* used U.S. mortality rates to calculate expectations for overall SMRs. To calculate expectations for the analysis of lung cancer mortality and exposure, Gibb *et al.* used Maryland state mortality rates. The SMR analyses provided by Exponent using both Maryland and Baltimore rates are useful. The data showed that using Baltimore rates raised the expected number of lung cancer deaths and, thus, lowered the SMRs. However, there remained a statistically significant increase in lung cancer risk among the exposed workers and a significant upward trend with cumulative Cr(VI) exposure. The comparison group should be as similar as possible with respect to all other factors that may be related to the disease except the determinant under study. Since the largest portion of the cohort (45%) died in the city of Baltimore, and even those whose deaths occurred outside of Baltimore (16%) most likely lived in proximity to the city, the use of Baltimore mortality rates as an external reference population is preferable.

Gibb's selection of the cut points for the exposure quartiles was accomplished by dividing the workers in the cohort into four equal groups based on their cumulative exposure at the end of their working history. Using the same method but excluding the short-term workers would have resulted in slightly different cumulative exposure quartiles. Exponent expressed a preference for a six-tiered exposure grouping. The impact of using different exposure groupings is further discussed in section VI.C of the quantitative risk assessment.

The exposure matrix of Gibb *et al.* utilizes an unusually high-quality set of industrial hygiene data. Over 70,000 samples taken to characterize the ''typical/usual'' working environment is more extensive industrial hygiene data then is commonly available for most exposure assessments. However, there are several unresolved issues regarding the exposure assessment, including the impact of the different industrial hygiene sampling techniques used over the sampling time frame, how the use of different sampling techniques was taken into account in developing the exposure assessment and the use of area vs. personal samples.

Exponent and the Chrome Coalition also suggested that the SMRs should have been adjusted for smoking. According to Exponent, smoking adjusted SMRs based upon the Maryland mortality rates produced SMRs similar to the SMRs obtained using Baltimore mortality rates (Ex. 31–18–15–1). The accuracy of the smoking data is questionable since it represents information obtained at the time of hire. Hayes abstracted the smoking data from the plant medical records, but ''found it not to be of sufficient quality to allow analysis.'' One advantage to using the Baltimore mortality data may be to better control for the potential confounding of smoking.

The Gibb study is one of the better cohort mortality studies of workers in the chromium production industry. The quality of the available industrial hygiene data and its characterization as ''typical/usual'' makes the Gibb study particularly useful for risk assessment.

b. Cohort Studies of the Painesville Facility. The Ohio Department of Health conducted epidemiological and environmental studies at a plant in Painesville that manufactured sodium bichromate from chromite ore. Mancuso and Hueper (Ex. 7–12) reported an excess of respiratory cancer among chromate workers when compared to the county in which the plant was located. Among the 33 deaths in males who had worked at the plant for a minimum of one year, 18.2% were from respiratory cancer. In contrast, the expected frequency of respiratory cancer among males in the county in which the plant was located was 1.2%. Although the authors did not include a formal statistical comparison, the lung cancer mortality rate among the exposed workers would be significantly greater than the county rate.

Mancuso (Ex. 7–11) updated his 1951 study of 332 chromate production workers employed during the period 1931–1937. Age adjusted mortality rates were calculated by the direct method using the distribution of person years by age group for the total chromate population as the standard. Vital status follow-up through 1974 found 173 deaths. Of the 66 cancer deaths, 41 (62.1%) were lung cancers. A cluster of lung cancer deaths was observed in workers with 27–36 years since first employment.

Mancuso used industrial hygiene data collected in 1949 to calculate weighted average exposures to water-soluble (presumed to be Cr(VI)), insoluble (presumed to be principally Cr(III)) and total chromium (Ex. 7–98). The age-adjusted lung cancer death rate increased from 144.6 (based upon two deaths) to 649.6 (based upon 14 deaths) per 100,000 in five exposure categories ranging from a low of 0.25–0.49 to a high of 4.0+ mg/m^3–years for the insoluble Cr(III) exposures. For exposure to soluble Cr(VI), the age adjusted lung cancer rates ranged from 80.2 (based upon three deaths) to 998.7 (based upon 12 deaths) in five exposure categories ranging from <0.25 to 2.0+ mg/m^3–years. For total chromium, the age-adjusted death rates ranged from 225.7 (based upon three deaths) to 741.5 (based upon 16 deaths) for exposures ranging from 0.50–0.99 mg/m^3–years to 6.0+ mg/m^3–years.

Age-adjusted lung cancer death rates also were calculated by classifying workers by the levels of insoluble Cr(III) and total chromium exposure. From the data presented, it appears that for a fixed level of insoluble Cr(III), the lung cancer risk appears to increase as the total chromium increases (Ex. 7–11).

Mancuso (Ex. 23) updated the 1975 study. As of December 31, 1993, 283 (85%) cohort members had died and 49 could not be found. Of the 102 cancer deaths, 66 were lung cancers. The age-adjusted lung cancer death rate per 100,000 ranged from 187.9 (based upon four deaths) to 1,254.1 (based upon 15 deaths) for insoluble Cr(III) exposure categories ranging from 0.25–0.49 to 4.00–5.00 mg/m^3 years. For the highest exposure to insoluble Cr(III) (6.00+ mg/m^3 years) the age-adjusted lung cancer death rate per 100,000 fell slightly to 1,045.5 based upon seven deaths.

The age-adjusted lung cancer death rate per 100,000 ranged from 99.7 (based upon five deaths) to 2,848.3 (based upon two deaths) for soluble Cr(VI) exposure categories ranging from <0.25 to 4.00+ mg/m^3 years. For total chromium, the age-adjusted lung cancer death rate per 100,000 ranged from 64.7 (based upon two deaths) to 1,106.7 (based upon 21 deaths) for exposure categories ranging from <0.50 to 6.00+ mg/m^3 years.

To investigate whether the increase in the lung cancer death rate was due to one form of chromium compound (presumed insoluble Cr(III) or soluble Cr(VI)), age-adjusted lung cancer mortality rates were calculated by classifying workers by the levels of exposure to insoluble Cr(III) and total chromium. For a fixed level of insoluble Cr(III), the lung cancer rate appears to increase as the total chromium increases for each of the six total chromium exposure categories, except for the 1.00–1.99 mg/m^3-years category. For the fixed exposure categories for total chromium, increasing exposures to levels of insoluble Cr(III) showed an increased age-adjusted death rate from lung cancer in three of the six total chromium exposure categories.

For a fixed level of soluble Cr(VI), the lung cancer death rate increased as total chromium categories of exposure increased for three of the six gradients of soluble Cr(VI). For the fixed exposure categories of total chromium, the increasing exposure to specific levels of soluble Cr(VI) led to an increase in two of the six total chromium exposure categories. Mancuso concluded that the relationship of lung cancer is not confined solely to either soluble or insoluble chromium. Unfortunately, it is difficult to attribute these findings specifically to Cr(III) [as insoluble chromium] and Cr(VI) [as soluble chromium] since it is likely that some slightly soluble and insoluble Cr(VI) as well as Cr(III) contributed to the insoluble chromium measurement.

Luippold *et al.* conducted a retrospective cohort study of 493 former employees of the chromate production plant in Painesville, Ohio (Ex. 31–18–4). This Painesville cohort does not overlap with the Mancuso cohort and is defined as employees hired beginning in 1940 who worked for a minimum of one year at Painesville and did not work at any other facility owned by the same company that used or produced Cr(VI). An exception to the last criterion was the inclusion of workers who subsequently were employed at a company plant in North Carolina (number not provided). Four cohort members were identified as female. The cohort was followed for the period January 1, 1941 through December 31, 1997. Thirty-two percent of the cohort worked for 10 or more years.

Information on potential confounders was limited. Smoking status (yes/no) was available for only 35% of the cohort from surveys administered between 1960 and 1965 or from employee medical files. For those employees where smoking data were available, 78% were smokers (responded yes on at least one survey or were identified as smokers from the medical file). Information on race also was limited, the death certificate being the primary source of information.

Results of the vital status follow-up were: 303 deaths; 132 presumed alive and 47 vital status unknown. Deaths were coded to the 9th revision of the International Classification of Diseases. Cause of death could not be located for two decedents. For five decedents the cause of death was only available from data collected by Mancuso and was recoded from the 7th to the 9th revision of the ICD. There were no lung cancer deaths among the five recoded deaths.

SMRs were calculated based upon two reference populations: The U.S. (white males) and the state of Ohio (white males). Lung cancer SMRs stratified by year of hire, duration of exposure, time since first employment and cumulative exposure group also were calculated.

Proctor *et al.* analyzed airborne Cr(VI) levels throughout the facility for the years 1943 to 1971 (the plant closed April 1972) from 800 area air sampling measurements from 21 industrial hygiene surveys (Ex. 35–61). A job exposure matrix (JEM) was constructed for 22 exposure areas for each month of plant operation. Gaps in the matrix were completed by computing the arithmetic mean concentration from area sampling data, averaged by exposure area over three time periods (1940–1949; 1950–1959 and 1960–1971) which coincided with process changes at the plant (Ex. 31–18–1)

The production of water-soluble sodium chromate was the primary operation at the Painesville plant. It involved a high lime roasting process that produced a water insoluble Cr(VI) residue (calcium chromate) as byproduct that was transported in open conveyors and likely contributed to worker exposure until the conveyors were covered during plant renovations in 1949. The average airborne soluble Cr(VI) from industrial hygiene surveys in 1943 and 1948 was 0.72 mg/m^3 with considerable variability among departments. During these surveys, the authors believe the reported levels may have underestimated total Cr(VI) exposure by 20 percent or less for some workers due to the presence of insoluble Cr(VI) dust.

Reductions in Cr(VI) levels over time coincided with improvements in the chromate production process. Industrial hygiene surveys over the period from 1957 to 1964 revealed average Cr(VI) levels of 270 μg/m^3. Another series of plant renovations in the early 1960s lowered average Cr(VI) levels to 39 μg/m^3 over the period from 1965 to 1972. The highest Cr(VI) concentrations generally occurred in the shipping, lime and ash, and filtering operations while the locker rooms, laboratory, maintenance shop and outdoor raw liquor storage areas had the lowest Cr(VI) levels.

The average cumulative Cr(VI) exposure (mg/m^3-yrs) for the cohort was 1.58 mg/m^3-yrs and ranged from 0.006 to 27.8 mg/m^3-yrs. For those who died from lung cancer, the average Cr(VI) exposure was 3.28 mg/m^3-yrs and ranged from 0.06 to 27.8 mg/m^3-yrs.

According to the authors, 60% of the cohort accumulated an estimated Cr(VI) exposure of 1.00 mg/m^3-yrs or less.

Sixty-three per cent of the study cohort was reported as deceased at the end of the follow-up period (December 31, 1997). There was a statistically significant increase for the all causes of death category based on both the national and Ohio state standard mortality rates (national: O=303; E=225.6; SMR=134; 95% CI: 120–150; state: O=303; E=235; SMR=129; 95% CI: 115–144). Fifty-three of the 90 cancer deaths were cancers of the respiratory system with 51 coded as lung cancer. The SMR for lung cancer is statistically significant using both reference populations (national O= 51; E=19; SMR 268; 95% CI: 200–352; state O=51; E=21.2; SMR 241; 95% CI: 180–317).

SMRs also were calculated by year of hire, duration of employment, time since first employment and cumulative Cr(VI) exposure, mg/m^3-years. The highest lung cancer SMRs were for those hired during the earliest time periods. For the period 1940–1949, the lung cancer SMR was 326 (O=30; E=9.2; 95% CI: 220–465); for 1950–1959, the lung cancer SMR was 275 (O=15; E=5.5; 95% CI: 154–454). For the period 1960–1971, the lung cancer SMR was just under 100 based upon six deaths with 6.5 expected.

Lung cancer SMRs based upon duration of employment (years) increased as duration of employment increased. For those with one to four years of employment, the lung cancer SMR was 137 based upon nine deaths (E=6.6; 95% CI: 62–260); for five to nine years of employment, the lung cancer SMR was 160 (O=8; E=5.0; 95% CI: 69–314). For those with 10–19 years of employment, the lung cancer SMR was 169 (O=7; E=4.1; 95% CI: 68–349), and for those with 20 or more years of employment, the lung cancer SMR was 497 (O=27; E=5.4; 95% CI: 328–723).

Analyses of cumulative Cr(VI) exposure found the lung cancer SMR (based upon the Ohio standard) in the highest exposure group (2.70–27.80 mg/m^3-yrs) was 463 (O=20; E=4.3; 95% CI: 183–398). In the 1.05–2.69 mg/m^3-yrs cumulative exposure group, the lung cancer SMR was 365 based upon 16 deaths (E=4.4; 95% CI: 208–592). For the cumulative exposure groups 0.49–1.04, 0.20–0.48 and 0.00–0.19, the lung cancer SMRs were 91 (O=4; E=4.4; 95% CI: 25–234; 184 (O=8; E=4.4; 95% CI: 79–362) and 67 (O=3; E=4.5; 95% CI: 14–196). A test for trend showed a strong relationship between lung cancer mortality and cumulative Cr(VI) exposure (p=0.00002). The authors claim that the SMRs are also consistent with a threshold effect since there was no statistically significant trend for excess lung cancer mortality with cumulative Cr(VI) exposures less than about 1 mg/m^3-yrs. The issue of whether the cumulative Cr(VI) exposure-lung cancer response is best represented by a threshold effect is discussed further in preamble section VI on the quantitative risk assessment.

The Painesville cohort is small (482 employees). Excluded from the cohort were six employees who worked at other chromate plants after Painesville closed. However, exceptions were made for employees who subsequently worked at the company's North Carolina plant (number not provided) because exposure data were available from the North Carolina plant. Subsequent exposure to Cr(VI) by other terminated employees is unknown and not taken into account by the investigators. Therefore, the extent of the bias introduced is unknown.

The 10% lost to follow-up (47 employees) in a cohort of this size is striking. Four of the forty-seven had ''substantial'' follow-up that ended in 1997 just before the end date of the study. For the remaining 43, most were lost in the 1950s and 1960s (most is not defined). Since person-years are truncated at the time individuals are lost to follow up, the potential implication of lost person years could impact the width of the confidence intervals.

The authors used U.S. and Ohio mortality rates for the standards to compute the expectations for the SMRs, stating that the use of Ohio rates minimizes bias that could occur from regional differences in mortality. It is unclear why county rates were not used to address the differences in regional mortality.

c. Other Cohort Studies. The first study of cancer of the respiratory system in the U.S. chromate producing industry was reported by Machle and Gregorius (Ex. 7–2). The study involved a total of 11,000 person-years of observation between 1933 and 1947. There were 193 deaths; 42 were due to cancer of the respiratory system. The proportion of respiratory cancer deaths among chromate workers was compared with proportions of respiratory cancer deaths among Metropolitan Life Insurance industrial policyholders. A non-significant excess respiratory cancer among chromate production workers was found. No attempt was made to control for confounding factors (*e.g.*, age). While some exposure data are presented, the authors state that one cannot associate tumor rates with tasks (and hence specific exposures) because of ''shifting of personnel'' and the lack of work history records.

Baetjer reported the results of a case-control study based upon records of two Baltimore hospitals (Ex. 7–7). A history of working with chromates was determined from these hospital records and the proportion of lung cancer cases determined to have been exposed to chromates was compared with the proportion of controls exposed. Of the lung cancer cases, 3.4% had worked in a chromate manufacturing plant, while none of the controls had such a history recorded in the medical record. The results were statistically significant and Baetjer concluded that the data confirmed the conclusions reached by Machle and Gregorius that ''the number of deaths due to cancer of the lung and bronchi is greater in the chromate-producing industry than would normally be expected'' (Ex. 7–7, p. 516).

As a part of a larger study carried out by the U.S. Public Health Service, the morbidity and mortality of male workers in seven U.S. chromate manufacturing plants during the period 1940–1950 was reported (Exs. 7–1; 7–3). Nearly 29 times as many deaths from respiratory cancer (excluding larynx) were found among workers in the chromate industry when compared to mortality rates for the total U.S. for the period 1940–1948. The lung cancer risk was higher at the younger ages (a 40-fold risk at ages 15–45; a 30-fold risk at ages 45–54 and a 20-fold risk at ages 55–74). Analysis of respiratory cancer deaths (excluding larynx) by race showed an observed to expected ratio of 14.29 for white males and 80 for nonwhite males.

Taylor conducted a mortality study in a cohort of 1,212 chromate workers followed over a 24 year (1937–1960) period (Ex. 7–5). The workers were from three chromate plants that included approximately 70% of the total population of U.S. chromate workers in 1937. In addition, the plants had been in continuous operation for the study period (January 1, 1937 to December 31, 1960). The cohort was followed utilizing records of Old Age and Survivors Disability Insurance (OASDI). Results were reported both in terms of SMRs and conditional probabilities of survival to various ages comparing the mortality experience of chromate workers to the U.S. civilian male population. No measures of chromate exposure were reported although results are provided in terms of duration of employment. Taylor concluded that not only was there an excess in mortality from respiratory cancer, but from other causes as well, especially as duration of employment increased.

In a reanalysis of Taylor's data, Enterline excluded those workers born prior to 1889 and analyzed the data by follow-up period using U.S. rates (Ex. 7–4). The SMR for respiratory cancer for all time periods showed a nine-fold excess (O=69 deaths; E=7.3). Respiratory cancer deaths comprised 28% of all deaths. Two of the respiratory cancer deaths were malignant neoplasms of the maxillary sinuses, a number according to Enterline, ''greatly in excess of that expected based on the experience of the U.S. male population.'' Also slightly elevated were cancers of the digestive organs (O=16; E=10.4) and non-malignant respiratory disease (O=13; E=8.9).

Pastides *et al.* conducted a cohort study of workers at a North Carolina chromium chemical production facility (Ex. 7–93). Opened in 1971, this facility is the largest chromium chemical production facility in the United States. A low-lime process was used since the plant began operation. Three hundred and ninety eight workers employed for a minimum of one year between September 4, 1971 and December 31, 1989 comprised the study cohort. A self-administered employee questionnaire was used to collect data concerning medical history, smoking, plant work history, previous employment and exposure to other potential chemical hazards. Personal air monitoring results for Cr(VI) were available from company records for the period February 1974 through April 1989 for 352 of the 398 cohort members. A job matrix utilizing exposure area and calendar year was devised. The exposure means from the matrix were linked to each employee's work history to produce the individual exposure estimates by multiplying the mean Cr(VI) value from the matrix by the duration (time) in a particular exposure area (job). Annual values were summed to estimate total cumulative exposure.

Personal air monitoring indicated that TWA Cr(VI) air concentrations were generally very low. Roughly half the samples were less than 1 $\mu g/m^3$, about 75 percent were below 3 $\mu g/m^3$, and 96 percent were below 25 $\mu g/m^3$. The average worker's age was 42 years and mean duration of employment was 9.5 years. Two thirds of the workers had accumulated less than 0.01 $\mu g/m^3$-yr cumulative Cr(VI) exposure. SMRs were computed using National, State (not reported) and county mortality rates (eight adjoining North Carolina counties, including the county in which the plant is located). Two of the 17 recorded deaths in the cohort were from lung cancers. The SMRs for lung cancer were 127 (95% CI: 22–398) and 97 (95% CI: 17–306) based on U.S. and North Carolina county mortality rates, respectively. The North Carolina cohort is still relatively young and not enough time has elapsed to reach any conclusions regarding lung cancer risk and Cr(VI) exposure.

In 2005, Luippold *et al.* published a study of mortality among two cohorts of chromate production workers with low exposures (Ex. 47–24–2). Luippold *et al.* studied a total of 617 workers with at least one year of employment, including 430 at the North Carolina plant studied by Pastides *et al.* (1994) (''Plant 1'') and 187 hired after the 1980 institution of exposure-reducing process and work practice changes at a second U.S. plant (''Plant 2''). A high-lime process was never used at Plant 1, and workers drawn from Plant 2 were hired after the institution of a low lime process, so that exposures to calcium chromate in both cohorts were likely minimal. Personal air-monitoring measures available from 1974 to 1988 for the first plant and from 1981 to 1998 for the second plant indicated that exposure levels at both plants were low, with overall geometric mean concentrations below 1.5 $\mu g/m^3$ and area-specific average personal air sampling values not exceeding 10 $\mu g/m^3$ for most years (Ex. 47–24–2, p. 383).

Workers were followed through 1998. By the end of follow-up, which lasted an average of 20.1 years for workers at Plant 1 and 10.1 years at Plant 2, 27 cohort members (4%) were deceased. There was a 41% deficit in all-cause mortality when compared to all-cause mortality from age-specific state reference rates, suggesting a strong healthy worker effect. Lung cancer was 16% lower than expected based on three observed vs. 3.59 expected cases, also using age-specific state reference rates (Ex. 47–24–2, p. 383). The authors stated that ''[t]he absence of an elevated lung cancer risk may be a favorable reflection of the postchange environment'', but cautioned that longer follow-up allowing an appropriate latency for the entire cohort would be required to confirm this conclusion (Ex. 47–24–2, p. 381). OSHA received several written testimony regarding this cohort during the post-hearing comment period. These are discussed in section VI.B.7 on the quantitative risk assessment.

A study of four chromate producing facilities in New Jersey was reported by Rosenman (Ex. 35–104). A total of 3,408 individuals were identified from the four facilities over different time periods (plant A from 1951–1954; plant B from 1951–1971; plant C from 1937–1964 and plant D 1937–1954). No Cr(VI) exposure data was collected for this study. Proportionate mortality ratios (PMRs) and proportionate cancer mortality ratios (PCMRs), adjusted by race, age, and calendar year, were calculated for the three companies (plants A and B are owned by one company). Unlike SMRs, PMRs are not based on the expected mortality rates in a standardized population but, instead, merely represent the proportional distribution of deaths in the cohort relative to the general U.S. population. Analyses were done evaluating duration of work and latency from first employment.

Significantly elevated PMRs were seen for lung cancer among white males (170 deaths, PMR=1.95; 95% CI: 1.67–2.27) and black males (54 deaths, PMR=1.88; 95% CI: 1.41–2.45). PMRs were also significantly elevated (regardless of race) for those who worked 1–10, 11–20 and >20 years and consistently higher for white and black workers 11–20 years and >20 years since first hire. The results were less consistent for those with 10 or fewer years since first hire.

Bidstrup and Case reported the mortality experience of 723 workers at three chromate producing factories in Great Britain (Ex. 7–20). Lung cancer mortality was 3.6 times that expected (O=12; E=3.3) for England and Wales. Alderson *et al.* conducted a follow-up of workers from the three plants in the U.K. (Bolton, Rutherglen and Eaglescliffe) originally studied by Bidstrup (Ex. 7–22). Until the late 1950s, all three plants operated a ''high-lime'' process. This process potentially produced significant quantities of calcium chromate as a by-product as well as the intended sodium dichromate. Process changes occurred during the 1940s and 1950s. The major change, according to the author, was the introduction of the ''no-lime'' process, which eliminated unwanted production of calcium chromate. The no-lime process was introduced at Eaglescliffe 1957–1959 and by 1961 all production at the plant was by this process. Rutherglen operated a low-lime process from 1957/1959 until it closed in 1967. Bolton never changed to the low lime process. The plant closed in 1966. Subjects were eligible for entry into the study if they had received an X-ray examination at work and had been employed for a minimum of one year between 1948 and 1977. Of the 3,898 workers enumerated at the three plants, 2,715 met the cohort entrance criteria, (alive: 1,999; deceased: 602; emigrated: 35; and lost to follow-up: 79). Those lost to follow-up were not included in the analyses. Eaglescliffe contributed the greatest number of subjects to the study (1,418). Rutherglen contributed the largest number of total deaths (369, or 61%). Lung cancer comprised the majority of cancer deaths and was statistically significantly elevated for the entire cohort (O=116; E=47.96; SMR= 240; p <0.001). Two deaths from nasal cancer were observed, both from Rutherglen.

SMRs were computed for Eaglescliffe by duration of employment, which was defined based upon plant process updates (those who only worked before the plant modification, those who worked both before and after the modifications, or those who worked only after the modifications were completed). Of the 179 deaths at the Eaglescliffe plant, 40 are in the pre-change group; 129 in the pre-/post-change and 10 in the post-change. A total of 36 lung cancer deaths occurred at the plant, in the pre-change group O=7; E=2.3; SMR=303; in the pre-/post-change group O=27; E=13; SMR=2.03 and in the post-change group O=2; E=1.07; SMR=187.

In an attempt to address several potential confounders, regression analysis examined the contributions of various risk factors to lung cancer. Duration of employment, duration of follow-up and working before or after plant modification appear to be greater risk factors for lung cancer, while age at entry or estimated degree of chromate exposure had less influence.

Davies updated the work of Alderson, *et al.* concerning lung cancer in the U.K. chromate producing industry (Ex. 7–99). The study cohort included payroll employees who worked a minimum of one year during the period January 1, 1950 and June 30, 1976 at any of the three facilities (Bolton, Eaglescliffe or Rutherglen). Contract employees were excluded unless they later joined the workforce, in which case their contract work was taken into account.

Based upon the date of hire, the workers were assigned to one of three groups. The first, or ''early'' group, consists of workers hired prior to January 1945 who are considered long term workers, but do not comprise a cohort since those who left or died prior to 1950 are excluded. The second group, ''pre-change'' workers, were hired between January 1, 1945 to December 31, 1958 at Rutherglen or to December 31, 1960 at Eaglescliffe. Bolton employees starting from 1945 are also termed pre-change. The cohort of pre-change workers is considered incomplete since those leaving 1946–1949 could not be included and because of gaps in the later records. For those who started after 1953 and for all men staying 5+ years, this subcohort of pre-change workers is considered complete. The third group, ''post-change'' workers, started after the process changes at Eaglescliffe and Rutherglen became fully effective and are considered a ''complete'' cohort. A ''control'' group of workers from a nearby fertilizer facility, who never worked in or near the chromate plant, was assembled.

A total of 2,607 employees met the cohort entrance criteria. As of December 31, 1988, 1,477 were alive, 997 dead, 54 emigrated and 79 could not be traced (total lost to follow-up: 133). SMRs were calculated using the mortality rates for England and Wales and the mortality rates for Scotland. Causes of death were ascertained for all but three decedents and deaths were coded to the revision of the International Classification of Diseases in effect at the time of death. Lung cancer in this study is defined as those deaths where the underlying cause of death is coded as 162 (carcinoma of the lung) or 239.1 (lung neoplasms of unspecified nature) in the 9th revision of the ICD. Two deaths fell into the latter category. The authors attempted to adjust the national mortality rates to allow for differences based upon area and social class.

There were 12 lung cancer deaths at Bolton, 117 at Rutherglen, 75 at Eaglescliffe and one among staff for a total of 205 lung cancer deaths. A statistically significant excess of lung cancer deaths (175 deaths) among early and pre-change workers is seen at Rutherglen and Eaglescliffe for both the adjusted and unadjusted SMRs. For Rutherglen, for the early period based upon 68 observed deaths, the adjusted SMR was 230 while the unadjusted SMR was 347 (for both SMRs p<0.001). For the 41 pre-change lung cancer deaths at Rutherglen, the adjusted SMR was 160 while the unadjusted SMR was 242 (for both SMRs p<0.001). At Eaglescliffe, there were 14 lung cancer deaths in the early period resulting in an adjusted SMR of 196 and an unadjusted SMR of 269 (for both SMRs p<0.05). For the pre-change period at Eaglescliffe, the adjusted SMR was 195 and the unadjusted was 267 (p<0.001 for both SMRs). At Bolton there is a non-significant excess among pre-change men. There are no apparent excesses in the post-change groups, the staff groups or in the non-exposed fertilizer group.

There is a highly significant overall excess of nasal cancers with two cases at Eaglescliffe and two cases at Rutherglen (O=4, Eadjusted=0.26; SMR=1538). All four men with nasal cancer had more than 20 years of exposure to chromates.

Aw reported on two case-control studies conducted at the previously studies Eaglescliffe plant (Ex. 245). In 1960, the plant, converted from a ''high-lime'' to a ''no-lime'' process, reducing the likelihood of calcium chromate formation. As of March 1996, 2,672 post-change workers had been employed, including 891 office personnel. Of the post-change plant personnel, 56% had been employed for more than one year. Eighteen lung cancer cases were identified among white male post-change workers (13 deceased; five alive). Duration of employment for the cases ranged from 1.5 to 25 years with a mean of 14.4. Sixteen of the lung cancer cases were smokers.

In the first case-control study reported, the 15 lung cancer cases identified up to September 1991 were matched to controls by age and hire date (five controls per case). Cases and controls were compared based upon their job categories within the plant. The results showed that cases were more likely to have worked in the kiln area than the controls. Five of the 15 cases had five or more years in the kiln area where Cr(VI) exposure occurred vs. six of the 75 controls. A second case-control study utilized the 18 lung cancer cases identified in post change workers up to March 1996. Five controls per case were matched by age (+/−5 years), gender and hire date. Both cases and controls had a minimum of one year of employment. A job exposure matrix was being constructed that would allow the investigators to ''estimate exposure to hexavalent chromates for each worker in the study for all the jobs done since the start of employment at the site until 1980.'' Starting in 1970 industrial hygiene sampling was performed to determine exposure for all jobs at the plant. Cr(VI) exposure levels for the period between 1960 and 1969 were being estimated based on the recall of employees regarding past working conditions relative to current conditions from a questionnaire. The author stated that preliminary analysis suggests that the maximum recorded or estimated level of exposure to Cr(VI) for the cases was higher than that of the controls. However, specific values for the estimated Cr(VI) exposures were not reported.

Korallus *et al.* conducted a study of 1,140 active and retired workers with a minimum of one year of employment between January 1, 1948 and March 31, 1979 at two German chromate production plants (Ex. 7–26). Workers employed prior to January 1, 1948 (either active or retired) and still alive at that date were also included in the cohort. The primary source for determining cause of death was medical records. Death certificates were used only when medical records could not be found. Expected deaths were calculated using the male population of North Rhineland-Westphalia. Elevated SMRs for cancer of the respiratory system (50 lung cancers and one laryngeal cancer) were seen at both plants (O=21; E=10.9; SMR=192 and O=30; E=13.4; SMR=224).

Korallus *et al.* reported an update of the study. The cohort definition was expanded to include workers with one year of employment between January 1, 1948 and December 31, 1987 (Ex. 7–91). One thousand four hundred and seventeen workers met the cohort entrance criteria and were followed through December 31, 1988. While death certificates were used, where possible, to obtain cause of death, a majority of the cause of death data was obtained from hospital, surgical and general practitioner reports and autopsies because of Germany's data protection laws. Smoking data for the cohort were incomplete.

Process modifications at the two plants eliminated the high-lime process by January 1, 1958 at one location and January 1, 1964 at the second location. In addition, technical measures were introduced which led to reductions in the workplace air concentrations of chromate dusts. Cohort members were divided into pre- and post-change cohorts, with subcohorts in the pre-change group. SMRs were computed with the expected number of deaths derived from the regional mortality rates (where the plants are located). One plant had 695 workers (279 in the pre-change group and 416 in the post change group). The second plant had 722 workers (460 in the pre-change group and 262 in the post-change group). A total of 489 deaths were ascertained (225 and 264 deaths). Of the cohort members, 6.4% were lost to follow-up.

Lung cancer is defined as deaths coded 162 in the 9th revision of the International Classification of Diseases. There were 32 lung cancer deaths at one plant and 43 lung cancer deaths at the second plant. Lung cancer SMRs by date of entry (which differ slightly by plant) show elevated but declining SMRs for each plant, possibly due to lower Cr(VI) exposure as a result of improvements in production process. The lung cancer SMR for those hired before 1948 at Plant 1 is statistically significant (O=13; SMR=225; 95% CI: 122–382). The overall lung cancer SMR for Plant 1 is also statistically significantly elevated based upon 32 deaths (SMR=175; 95% CI: 120–246). At Plant 2, the only lung cancer SMR that is not statistically significant is for those hired after 1963 (based upon 1 death). Lung cancer SMRs for those hired before 1948 (O=23; SMR=344; 95% CI: 224–508) and for those hired between 1948 and 1963 (O=19; SMR=196; 95% CI: 1.24–2.98) are statistically significantly elevated. The overall lung cancer SMR at Plant 2 based upon 43 deaths is 239 (95% CI: 177–317). No nasal cavity neoplasms were found. A statistically significant SMR for stomach cancer was observed at Plant 2 (O=12; SMR=192; 95% CI: 104–324).

Recently, the mortality experience of the post-change workers identified by Korallus *et al.* was updated in a study by Birk *et al.* (Ex. 48–4). The study cohort consisted of 901 post-change male workers from two German chromate production plants (*i.e.* 472 workers and 262 workers, respectively) employed for at least one year. Review of employment records led to the addition of employees to the previous Korallus cohort. Mortality experience of the cohort was evaluated through 1998. A total of 130 deaths were ascertained, of which 22 were due to cancer of the lung. Four percent of the cohort was lost to follow-up. Specific cause of death could not be determined for 14 decedents. The mean duration of Cr(VI) exposure was 10 years and the mean time since first exposure was 17 years. The proportion of workers who ever smoked was 65 percent.

The cohort lacked sufficient job history information and air monitoring data to develop an adequate job-exposure matrix required to estimate individual airborne exposures (Ex. 48–1–2). Instead, the researchers used the over 12,000 measurements of urinary chromium from routine biomonitoring of plant employees collected over the entire study period to derive individual cumulative urinary chromium estimates as an exposure surrogate. The approximate geometric average of all urinary chromium measurements in the two German plants from 1960 to 1998 was 7–8 µg/dl (Ex. 48–1–2, Table 5). There was a general plant-wide decline in average urinary chromium over time from 30 to 50 µg/dl in the 1960s to less than 5 µg/dl in the 1990s (Ex. 48–4, Figure 1). However, there was substantial variation in urinary chromium by work location and job group.

The study reported a statistically significant deficit in all cause mortality (SMR=80 95% CI: 67–95) and mortality due to heart disease (SMR=66 95% CI: 45–93) based on the age- and calendar year-adjusted German national population rates indicating a healthy worker population. However, the SMR for lung cancer mortality was elevated (SMR=148 95% CI: 93–225) against the same reference population (Ex. 48–4, Table 2). There was a statistically significant two-fold excess lung cancer mortality (SMR=209; 95% CI: 108–365; 12 observed lung cancer deaths) among workers in the highest cumulative exposure grouping (*i.e.* >200 µg Cr/L-yr). There was no increase in lung cancer mortality in the lower exposure groups, but the number of lung cancer deaths was small (*i.e.* ≤5 deaths) and the confidence intervals were wide.

There were no obvious trends in lung cancer mortality with employment duration or time since first employed, but the results were, again, limited by the small number of study subjects per group. Logistic regression analysis showed that cumulative urinary chromium ≥ 200 µg Cr/L-yr was associated with a significantly higher risk of lung cancer death (OR=6.9; 95% CI: 2.6–18.2) when compared against workers exposed to lower cumulative urinary chromium exposures. This risk was unchanged after controlling for smoking status indicating that the elevated risks were unlikely to be confounded by smoking. Including a peak exposure score to the regression analysis did not result in additional risk beyond that associated with cumulative exposure alone. Some commenters felt this German post-change cohort provided evidence for an exposure threshold below which there is no risk of lung cancer. This issue is addressed in Section VI.B.7 of the quantitative risk assessment.

DeMarco *et al.* conducted a cohort study of chromate production workers in northern Italy to assess the existence of excess risk of respiratory cancer, specifically lung cancer (Ex. 7–54). The cohort was defined as males who worked for a minimum of one year from 1948 to 1985 and had at least 10 years of follow-up. Five hundred forty workers met the cohort definition. Vital status follow-up, carried out through June 30, 1985, found 427 cohort members alive, 110 dead and three lost to follow-up. Analysis utilizing SMRs based on Italian national rates was conducted. Of the 110 deaths, 42 were cancer deaths. The statistically significant SMR for lung cancer based upon 14 observed deaths with 6.46 expected was 217 (95% CI: 118–363).

Exposure estimates were based upon the duration of cumulative exposure and upon a risk score (low, medium, high and not assessed) assigned to the department in which the worker was primarily employed. A committee assigned the scores, based upon knowledge of the production process or on industrial hygiene surveys taken in

1974, 1982 and 1984. The risk score is a surrogate for the workplace concentrations of Cr(VI) in the different plant departments. Since no substantial changes had been made since World War II, the assumption was made that exposures remained relatively stable. Lung cancer SMRs based upon type of exposure increased with level of exposure (Low: O=1; E=1.43; SMR=70; Medium: O=5; E=202; SMR=2.48; High: O=6; E=1.4; SMR=420; Not Assessed: O=2; E=1.6; SMR=126). Only the SMR for those classified as having worked in departments characterized as high exposure was statistically significant at the $p<0.05$ level.

A cohort study of workers at a chromium compounds manufacturing plant in Tokyo, Japan by Satoh *et al.* included males employed between 1918 and 1975 for a minimum of one year and for whom the necessary data were available (Ex. 7–27). Date and cause of death data were obtained from the death certificate (85%) or from other ''reliable'' written testimony (15%). Of the 1,061 workers identified, 165 were excluded from the study because information was missing. A total of 896 workers met the cohort inclusion criteria and were followed through 1978. The causes of 120 deaths were ascertained. SMRs based on age-cause specific mortality for Japanese males were calculated for four different time periods (1918–1949; 1950–1959; 1960–1969 and 1970–1978) and for the entire follow-up period (1918–1978). An elevated SMR for lung cancer is seen for the entire follow-up period (O=26; E=2.746; SMR=950). A majority of the lung cancer deaths (20) occurred during the 1970–1978 interval.

Results from the many studies of chromate production workers from different countries indicate a relationship between exposure to chromium and malignant respiratory disease. The epidemiologic studies done between 1948 and 1952 by Machle and Gregorius (Ex. 7–2), Mancuso and Hueper (Ex. 7–12) and Brinton, *et al.* (Ex. 7–1) suggest a risk for respiratory cancer among chromate workers between 15 and 29 times expectation. Despite the potential problems with the basis for the calculations of the expectations or the particular statistical methods employed, the magnitude of the difference between observed and expected is powerful enough to overcome these potential biases.

It is worth noting that the magnitude of difference in the relative risks reported in a mortality study among workers in three chromate plants in the U.K. (Ex.7–20) were lower than the relative risks reported for chromate workers in the U.S. during the 1950s and 1960s. The observed difference could be the result of a variety of factors including different working conditions in the two countries, a shorter follow-up period in the British study, the larger lost-to-follow-up in the British study or the different statistical methods employed. While the earlier studies established that there was an excess risk for respiratory cancer from exposure to chromium, they were unable to specify either a specific chromium compound responsible or an exposure level associated with the risk. Later studies were able to use superior methodologies to estimate standardized lung cancer mortality ratios between chromate production cohorts and appropriate reference populations (Exs. 7–14; 7–22; 7–26; 7–99; 7–91). These studies generally found statistically increased lung cancer risk of around two-fold. The studies usually found trends with duration of employment, year of hire, or some production process change that tended to implicate chromium exposure as the causative agent.

Some of the most recent studies were able to use industrial hygiene data to reconstruct historical Cr(VI) exposures and show statistically significant associations between cumulative airborne Cr(VI) and lung cancer mortality (Exs. 23; 31–22–11; Ex. 31–18–4). Gibb *et al.* found the significant association between Cr(VI) and lung cancer was evident in models that accounted for smoking. The exposure'response relationship from these chromate production cohorts provide strong evidence that occupational exposure to Cr(VI) dust can increase cancer in the respiratory tract of workers.

The Davies, Korallus, (German cohort), Luippold (2003), and Luippold (2005) studies examine mortality patterns at chromate producing facilities where one production process modification involved conversion from a high-lime to a low-lime or a lime-free process (Exs. 7–99; 7–91; 31–18–4). In addition to process modification, technical improvements also were implemented that lowered Cr(VI) exposure. One of the plants in the Davies study retained the high-lime process and is not discussed. The lung cancer SMRs for one British plant and both of the German plants decline from early, to pre-change to post change time periods. In the remaining British plants, the lung cancer SMR is basically identical for the early and pre-change period, but does decline in the post-change time period. The lung cancer SMR in the Luippold 2003 cohort also declined over time as the amount of lime was reduced in the roasting process. Other modifications at the Painesville plant that reduced airborne Cr(VI) exposure, such as installation of covered conveyors and conversion from batch to continuous process, occurred at the same time (Ex. 35–61). The workers in the Luippold (2005) study were not exposed to Cr(VI) in facilities using a high-lime process. This study did not show excess risk; however, this may be a consequence of short follow-up time (< 20 years for most workers) or the small size of the study (< 4 expected lung cancers), as discussed further in Section VI.B.7. In general, it is not clear whether reduced levels of the high-lime byproduct, calcium chromate, or the roasting/leaching end product, sodium dichromate, that resulted from the various process changes is the reason for the decrease in lung cancer SMRs in these cohorts. It should be noted that increased lung cancer risk was experienced by workers at the Baltimore plant (*e.g.*, Hayes and Gibb cohorts) even though early air monitoring studies suggest that a high lime process was probably not used at this facility (Ex. 7–17).

2. Evidence From Chromate Pigment Production Workers

Chromium compounds are used in the manufacture of pigments to produce a wide range of vivid colors. Lead and zinc chromates have historically been the predominant hexavalent chromium pigments, although others such as strontium and barium chromate have also been produced. These chromates vary considerably in their water solubility with lead and barium chromates being the most water insoluble. All of the above chromates are less water-soluble than the highly water-soluble sodium chromate and dichromate that usually serve as the starting material for chromium pigment production. The reaction of sodium chromate or dichromate with the appropriate zinc or lead compound to form the corresponding lead or zinc chromate takes place in solution. The chromate pigment is then precipitated, separated, dried, milled, and packaged. Worker exposures to chromate pigments are greatest during the milling and packaging stages.

There have been a number of cohort studies of chromate pigment production workers from the United States, the United Kingdom, France, Germany, the Netherlands, Norway and Japan. Most of the studies found significantly elevated lung cancers in workers exposed to Cr(VI) pigments over many years when compared against standardized reference populations. In general, the studies of chromate pigment workers lack the historical exposure data found in some of the chromate production cohorts. The consistently higher lung cancers across several worker cohorts exposed to the less water-soluble Cr(VI) compounds complements the lung cancer findings from the studies of workers producing highly water soluble chromates and adds to the further evidence that occupational exposure to Cr(VI) compounds should be regarded as carcinogenic. A summary of selected human epidemiologic studies in chromate production workers is presented in Table V–2.

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TABLE V-2: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Chromate Pigment Production

Reference/Exhibit Number	**Study Population**	**Reference Population**	**Chromium (VI) Exposure**	**Lung Cancer Risk**
Langard & Vigander (1983, Ex. 7-36) Langard & Vigander (1975, Ex. 7-33)	133 Norwegian chromium pigment production workers employed between 1948 and 1972; 24 workers with 3+ years exposure to chromate dust; follow up through 1980	Cancer incidence from Norwegian Cancer Registry 1955-1976	Lead and zinc chromates with Some sodium dichromate as starting material; Cr(VI) levels between 10 and 30 $\mu g/m^3$ 1975-1980. No reporting <1975	-O/E of 44 for subcohort of 24 workers based on 6 cancer cases. -5 of 6 cases were exposed primarily to zinc chromate
Davies (1984, Ex. 7-42) Davies (1979, Ex. 7-41)	1152 British chromate pigment workers from 3 plants with a minimum of 1 year employment between 1930-June, 1975; follow up through 1981	Mortality of England and Wales	Factory A: chromates - primarily lead; some zinc; minor barium Factory B: mostly lead and zinc chromates; minor strontium. Factory C: lead chromate only No Cr(VI) levels reported	-O/E of 2.2 ($p<0.05$) for high exposed in Factory A 1932-1954; 21 deaths -O/E of 4.4 ($p<0.05$) for high exposed in Factory B 1948-1967; 11 deaths -O/E of 1.1 (NS) for exposed Factory C 1946-1967; 7 deaths
Hayes et al. (1989, Ex. 7-46) Sheffet et al. (1982, Ex. 7-48)	1,946 male pigment workers from New Jersey facility employed for a minimum of one month between 1940 and 1969; follow up through March, 1982	U.S. Mortality	-Primarily lead chromate with some zinc chromate -Cr(VI) levels in later years reported to be >500 $\mu g/m^3$ for exposed workers	-O/E of 1.2 (NS) for entire cohort based on 41 deaths - O/E of 1.5 ($p<0.5$) for workers employed >10 yr based on 23 deaths -Upward trend (p<,0.01) with duration of exposure
Equitable Environmental Health (1983, Ex. 2-D-1) Equitable Environmental Health (1976, Ex. 2-D-3)	574 male chromate workes from three plants (West Virginia, New Jersey or Kentucky) with a minimum of 6 months of exposure to lead chromate prior to 1974.	U.S. white male mortality rates	-West Virginia: lead chromates - Kentucky: chromates- mostly lead, some zinc, minor strontium and barium -New Jersey: mostly lead and some zinc chromate -Median Cr(VI) in 1975 reported to equal or exceed 52 $\mu g/m^3$	-O/E of 1.30 (NS) for West Virginia plant based on 3 deaths -O/E of 2.16 (NS) for Kentucky plant based on 2 deaths -O/E of 2.31 ($p<.05$) for New Jersey plant based on 9 deaths
Deschamps et al. (1995, Ex. 35-234) Haguenoer et al. (1981, Ex. 7-44)	294 male pigment workers from French facility employed for a minimum of six months between 1958 and 1987	Death rates from northern France	-Mostly lead chromate with some zinc chromate -Cr(VI) levels in 1981 between 2 and 180 $\mu g/m^3$	-O/E of 3.6 ($p<0.01$) based on 18 deaths - Upward trend ($p<0.01$) with duration of exposure

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

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Langard and Vigander updated a cohort study of lung cancer incidence in 133 workers employed by a chromium pigment production company in Norway (Ex. 7–36). The cohort was originally studied by Langard and Norseth (Ex. 7–33). Twenty four men had more than three years of exposure to chromate dust. From 1948, when the company was founded, until 1951, only lead chromate pigment was produced.

From 1951 to 1956, both lead chromate and zinc chromate pigments were produced and from 1956 to the end of the study period in 1972 only zinc chromate was produced. Workers were exposed to chromates both as the pigment and its raw material, sodium dichromate.

The numbers of expected lung cancers in the workers were calculated using the age-adjusted incidence rates for lung cancer in the Norwegian male population for the period 1955–1976. Follow-up using the Norwegian Cancer Registry through December 1980, found the twelve cancers of which seven were lung cancers. Six of the seven lung cancers were observed in the subcohort of 24 workers who had been employed for more than three years before 1973. There was an increased lung cancer incidence in the subcohort based on an observed to expected ratio of 44 (O=6; E=0.135). Except for one case, all lung cancer cases were exposed to zinc chromates and only sporadically to other chromates. Five of the six cases were known to be smokers or ex-smokers. Although the authors did not report any formal statistical comparisons, the extremely high age-adjusted standardized incidence ratio suggests that the results would likely be statistically significant.

Davies reported on a cohort study of English chromate pigment workers at three factories that produced chromate pigments since the 1920s or earlier (Ex. 7–41). Two of the factories produced both zinc and lead chromate. Both products were made in the same sheds and all workers had mixed exposure to both substances. The only product at the third factory was lead chromate.

Cohort members are defined as males with a minimum of one year of employment first hired between 1933 and 1967 at plant A; 1948 and 1967 at plant B and 1946–1961 at plant C. The analysis excludes men who entered employment later than 1967 because of the short follow-up period. Three hundred and ninety six (396) men from Factory A, 136 men from Factory B and 114 men from Factory C were followed to mid-1977. Ninety-four workers with 3–11 months employment during 1932–1945 at Factory A were also included. Expectations were based upon calendar time period-, gender- and age-specific national cancer death rates for England and Wales. The author adjusted the death rates for each factory for local differences, but the exact methods of adjustment were not explicit.

Exposure to chromates was assigned as high for those in the dry departments where pigments were ground, blended and packed; medium for those in the wet departments where precipitates were washed, pressed and stove dried and in maintenance or cleaning which required time in various departments; or low for those jobs which the author states involved ''slight exposure to chromates such as most laboratory jobs, boiler stoking, painting and bricklaying'' (Ex. 7–41, p. 159). The high and medium exposure categories were combined for analytical purposes.

For those entering employment from 1932 to 1954 at Factory A, there were 18 lung cancer deaths in the high/medium exposure group, with 8.2 deaths expected. The difference is significant at p<.01. In the low exposure group, the number of observed and expected lung cancer deaths was equal (two deaths). There were no lung cancer deaths at Factory A for those hired between 1955–1960 and 1961–1967.

For those entering employment between 1948 and 1967 at Factory B, there were seven observed lung cancer deaths in the high/medium exposure group with 1.4 expected which is statistically significant at p<.001. At Factory C (which manufactured only lead chromate), there was one death in the high/medium exposure group and one death in the low exposure group for those beginning employment between 1946 and 1967.

The author points out that:

> There has been no excess lung cancer mortality amongst workers with chromate exposure rated as ''low'', nor among those exposed only to lead chromate. High and medium exposure-rated workers who in the past had mixed exposure to both lead and zinc chromate have experienced a marked excess of lung cancer deaths, even if employed for as little as one year (Ex. 7–41, p. 157).

It is the author's opinion that the results ''suggest that the manufacture of zinc chromate may involve a lung cancer hazard'' (Ex. 7–41, p. 157).

Davies updated the lung cancer mortality at the three British chromate pigment production factories (Ex. 7–42). The follow-up was through December 31, 1981. The cohort was expanded to include all male workers completing one year of service by June 30, 1975 but excluded office workers.

Among workers at Factory A with high and medium exposure, mortality was statistically significantly elevated over the total follow-up period among entrants hired from 1932 to 1945 (O/E=2.22). A similar, but not statistically significant, excess was seen among entrants hired from 1946 to 1954 (O/E=2.23). The results for Factory B showed statistically significantly elevated lung cancer mortality among workers classified with medium exposures entering service during the period from 1948 to 1960 (O/E=3.73) and from 1961 to 1967 (O/E=5.62). There were no lung cancer deaths in the high exposure group in either time period. At Factory C, analysis by entry date (early entrant and the period 1946–1960) produced no meaningful results since the number of deaths was small. When the two periods are combined, the O/E was near unity. The author concluded that in light of the apparent absence of risk at Factory C, ''it seems reasonable to suggest that the hazard affecting workers with mixed exposures at factories A and B * * * is attributable to zinc chromates'' (Ex. 7–42, p. 166). OSHA disagrees with this conclusion, as discussed in section V.9.

Davies also studied a subgroup of 57 chromate pigment workers, mostly employed between 1930 and 1945, who suffered clinical lead poisoning (Ex. 7–43). Followed through 1981, there was a statistically significantly elevated SMR for lung cancer based upon four cases (O=4; E=2.8; SMR=145).

Haguenoer studied 251 French zinc and lead chromate pigment workers employed for six months or more between January 1, 1958 and December 31, 1977 (Ex. 7–44). As of December 31, 1977, 50 subjects were identified as deceased. Cause of death was obtained for 30 of the 50 deaths (60%). Lung cancer mortality was significantly elevated based on 11 fatalities (SMR=461; 95% CI: 270–790). The mean time from first employment until detection of cancer was 17 years. The mean duration of employment among cases was 15 years.

The Haguenoer cohort was followed up in a study by Deschamps *et al.* (Ex. 234). Both lead and zinc chromate pigments were produced at the plant until zinc chromate production ceased in 1986. The cohort consisted of 294 male workers employed for at least six months between 1958 and 1987. At the end of the follow-up, 182 cohort members were alive, 16 were lost to follow-up and 96 were dead. Because of French confidentiality rules, the cause of death could not be obtained from the death certificate; instead physicians and hospital records were utilized. Using cause of death data from sources other than death certificates raises the potential for misclassification bias. Cause of death could not be obtained for five decedents. Data on smoking habits was not available for a number of workers and was not used in the analysis.

Since individual work histories were not available, the authors made the assumption that the exposure level was the same for all workers during their employment at the plant. Duration of employment was used as a surrogate for exposure. Industrial hygiene measurements taken in 1981 provide some idea of the exposure levels at the plant. In the filtration department, Cr(VI) levels were between 2 and 3 μg/m^3; in the grinding department between 6 and 165 μg/m^3; in the drying and sacking department between 6 and 178 μg/m^3; and in the sacks marking department more than 2000 μg/m^3.

The expected number of deaths for the SMR analysis was computed from age-adjusted death rates in the northern region of France where the plant was located. There was a significant increase in lung cancer deaths based on 18 fatalities with five expected (SMR=360; 95% CI: 213–568). Using duration of employment as a surrogate for exposure, statistically significant SMRs were seen for the 10–15 years of exposure (O=6, SMR=720, 95% CI: 264–1568), 15–20 years (O=4, SMR=481, 95% CI: 131–1231), and 20+ years (O=6, SMR=377, 95% CI: 1.38–8.21) time intervals. There was a significantly elevated SMR for brain cancer based upon two deaths (SMR=844, 95% CI: 102–3049). There was a non-statistically significant increase for digestive tract cancer (O=9, SMR=130) consisting of three esophageal cancers, two stomach cancers and four colon cancers.

Equitable Environmental Health, Inc., on behalf of the Dry Color Manufacturers Association, undertook a historical prospective mortality study of workers involved in the production of lead chromate (Exs. 2–D–3; 2–D–1). The cohort was defined as male employees who had been exposed to lead chromate for a minimum of six months prior to December 1974 at one of three facilities in West Virginia, Kentucky or New Jersey. The New Jersey facility had a unit where zinc chromate was produced dating back to 1947 (Ex. 2–D–3). Most workers rotated through this unit and were exposed to both lead and zinc chromates. Two men were identified at the New Jersey facility with exposure solely to lead chromate; no one with exposure only to zinc chromate was identified.

Subsequent review of the data found that the Kentucky plant also produced zinc chromates from the late 1930s to early 1964. During the period 1961–1962, zinc chromates accounted for approximately 12% of chromate production at the plant. In addition, strontium chromate and barium chromate also were produced at the plant.

The cohort consisted of 574 male employees from all three plants (Ex. 2–D–1). Eighty-five deaths were identified with follow up through December 1979. Six death certificates were not obtained. SMRs were reported based on U.S. white male death rates. There were 53 deaths from the New Jersey plant including a statistically significant SMR for cancer of the trachea, bronchus and lung based upon nine deaths (E=3.9; SMR=231; 95% CI: 106–438). One lung cancer decedent worked solely in the production of lead chromates. Three of the lung cancer deaths were black males. In addition, there were six deaths from digestive system cancers, five of which were stomach cancers reported at the New Jersey plant. The SMR for stomach cancer was statistically significantly elevated (O=5; E=0.63; SMR=792; 99% CI: 171–2243). There were 21 deaths from the West Virginia plant, three of which were cancer of the trachea, bronchus and lung (E=2.3; SMR=130; 95% CI: 27–381). There were 11 deaths at the Kentucky plant, two of which were cancer of the trachea, bronchus and lung (E=0.9; SMR=216; 95% CI: 26–780).

Sheffet *et al.* examined the lung cancer mortality among 1,946 male employees in a chromate pigment factory in Newark, NJ, who were exposed to both lead chromate and zinc chromate pigments (Ex. 7–48). The men worked for a minimum of one month between January 1, 1940 and December 31, 1969. As of March 31, 1979, a total of 321 cohort members were identified as deceased (211 white males and 110 non-white males). Cause of death could not be ascertained for 37 white males and 12 non-white males. The proportion of the cohort lost to follow up was high (15% of white males and 20% of non-white males).

Positions at the plant were classified into three categories according to intensity of exposure: high (continuous exposure to chemical dust), moderate (occasional exposure to chemical dust or to dry or wet pigments) and low (infrequent exposure by janitors or office workers). Positions were also classified by type of chemical exposure: chromates, other inorganic substances, and organics. The authors state that in almost all positions individuals ‘‘who were exposed to any chemicals were also exposed to hexavalent chromium in the form of airborne lead and zinc chromates (Ex. 7–48, p. 46).’’ The proportion of lead chromate to zinc chromate was approximately nine to one. Calculations, based upon air samples during later years, give an estimate for the study period of more than 2000 μg airborne chromium/m^3 for the high exposure category, between 500 and 2000 μg airborne chromium/m^3 and less than 100 μg airborne chromium/m^3 for the low exposure category. Other suspected carcinogens present in the workplace air at much lower levels were nickel sulfate and nickel carbonate.

Because of the large proportion of workers lost to follow-up (15% of white males and 20% of non-white males) and the large numbers of unknown cause of death (21% of white males and 12% of non-white males), the authors calculated three separate mortality expectations based upon race-, gender-, age-, and time-specific U.S. mortality ratios. The first expectation was calculated upon the assumption that those lost to follow-up were alive at the end of the study follow-up period. The second expectation was calculated on the assumption that those whose vital status was unknown were lost to follow-up as of their employment termination date. The third expectation was calculated excluding those of unknown vital status from the cohort. Deaths with unknown cause were distributed in the appropriate proportions among known causes of death which served as an adjustment to the observed deaths. The adjusted deaths were used in all of the analyses.

A statistically significant ratio for lung cancer deaths among white males (O/E=1.6) was observed when using the assumption that either the lost to follow-up were assumed lost as of their termination date or were excluded from the cohort (assumptions two and three above). The ratio for lung cancer deaths for non-white males results in an identical O/E of 1.6 for all three of the above scenarios, none of which was statistically significant.

In addition, the authors also conducted Proportionate Mortality Ratio (PMR) and Proportionate Cancer Mortality Ratio (PCMR) analyses. For white males, the lung cancer PMR was 200 and the lung cancer PCMR was 160 based upon 25.5 adjusted observed deaths (21 actual deaths). Both were statistically significantly elevated at the $p<.05$ level. For non-white males, the lung cancer PMR was 200 and the lung cancer PCMR was 150 based upon 11.2 adjusted observed deaths (10 actual deaths). The lung cancer PMR for non-white males was statistically significantly elevated at the $p<.05$ level. Statistically significantly elevated PMRs and PCMRs for stomach cancer in white males were reported (PMR=280; PCMR=230) based upon 6.1 adjusted observed deaths (five actual).

The Sheffet cohort was updated in a study by Hayes *et al.* (Ex. 7–46). The follow up was through December 31, 1982. Workers employed as process operators or in other jobs which involved direct exposure to chromium dusts were classified as having exposure to chromates. Airborne chromium concentrations taken in ''later years'' were estimated to be >500 μg g/m³ for ''exposed'' jobs and >2000 μg/m³ for ''highly exposed'' jobs.

The cohort included 1,181 white and 698 non-white males. Of the 453 deaths identified by the end of the follow-up period, 41 were lung cancers. For the entire study group, no statistically significant excess was observed for lung cancer (SMR=116) or for cancer at any other site. Analysis by duration of employment found a statistically significant trend (p=.04) for lung cancer SMRs (67 for those employed <1 year; 122 for those employed 1–9 years and 151 for those employed 10+ years).

Analysis of lung cancer deaths by duration of employment in chromate dust associated jobs found no elevation in risk for subjects who never worked in these jobs (SMR=92) or for subjects employed less than one year in these jobs (SMR=93). For those with cumulative employment of 1–9 and 10+ years in jobs with chromate dust exposure, the SMRs were 176 (nine deaths) and 194 (eight deaths) respectively.

Frentzel-Beyme studied the mortality experience of 1,396 men employed for more than six months in one of five factories producing lead and zinc chromate pigments located in Germany and the Netherlands (Ex. 7–45). The observed deaths from the five factories were compared with the expected deaths calculated on the basis of mortality figures for the region in which the plant was located. Additional analysis was conducted on relevant cohorts which included workers with a minimum of 10 years exposure, complete records for the entire staff, and exclusion of foreign nationals. Jobs were assigned into one of three exposure categories: High (drying and milling of the filtered pigment paste), medium (wet processes including precipitation of the pigment, filtering and maintenance, craftsmen and cleaning) and low or trivial exposure (storage, dispatch, laboratory personnel and supervisors).

There were 117 deaths in the entire cohort of which 19 were lung cancer deaths (E=9.3). The lung cancer SMRs in the relevant cohort analyses were elevated at every plant; however, in only one instance was the increased lung cancer SMR statistically significant, based upon three deaths (SMR=386, p<0.05). Analysis by type of exposure is not meaningful due to the small number of lung cancer deaths per plant per exposure classification.

Kano *et al.* conducted a study of five Japanese manufacturers who produced lead chromates, zinc chromate, and/or strontium chromate to assess if there was an excess risk of lung cancer (Ex. 7–118). The cohort consisted of 666 workers employed for a minimum of one year between 1950 and 1975. At the end of 1989, 604 subjects were alive, five lost to follow-up and 57 dead. Three lung cancer deaths were observed in the cohort with 2.95 expected (SMR=102; 95% CI: 0.21–2.98). Eight stomach cancer deaths were reported with a non-statistically significant SMR of 120.

Following the publication of the proposed rule, the Color Pigment Manufacturers Association requested that OSHA reconsider its preliminary conclusions with respect to the health effects of lead chromate color pigments (Ex. 38–205). They relied on the Davies (Ex. 7–43), Cooper [Equitable Environmental Health, Inc] (Ex. 2–D–1) and Kano (Ex. 14–1–B) epidemiologic studies as the only available data on worker cohorts exposed to lead chromate in the absence of other chromates commonly found in pigment production (*e.g.*, zinc chromate). The CPMA's comments regarding the Davies, Cooper and Kano studies and OSHA's response to them are discussed in section V.B.9.a.

3. Evidence from Workers in Chromium Plating

Chrome plating is the process of depositing chromium metal onto the surface of an item using a solution of chromic acid. The items to be plated are suspended in a diluted chromic acid bath. A fine chromic acid mist is produced when gaseous bubbles, released by the dissociation of water, rise to the surface of the plating bath and burst. There are two types of chromium electroplating. Decorative or ''bright'' involves depositing a thin (0.5–1 μm) layer of chromium over nickel or nickel-type coatings to provide protective, durable, non-tarnishable surface finishes. Decorative chrome plating is used for automobile and bicycle parts. Hard chromium plating produces a thicker (exceeding 5 μm) coating which makes it resistant and solid where friction is usually greater, such as in crusher propellers and in camshafts for ship engines. Limited air monitoring indicates that Cr(VI) levels are five to ten times higher during hard plating than decorative plating (Ex. 35–116).

There are fewer studies that have examined the lung cancer mortality of chrome platers than of soluble chromate production and chromate pigment production workers. The largest and best described cohort studies investigated chrome plating cohorts in the United Kingdom (Exs. 7–49; 7–57; 271; 35–62). They generally found elevated lung cancer mortality among the chrome platers, especially those engaged in chrome bath work, when compared to various reference populations. The studies of British chrome platers are summarized in Table V–3.

TABLE V.3: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Chromium Plating

Reference/Exhibit Number	**Study Population**	**Reference Population**	**Chromium (VI) Exposure**	**Lung Cancer Risk**
Sorahan & Harrington (2000, Ex. 35-62) Royle (1975, Ex. 7-49)	920 male platers employed in 54 plants in Yorkshire, UK for a minimum of three months between 1969 and 1972; follow up through 1997	-Mortality rates for the general population of England and Wales -Age-, sex-matched comparison group unexposed to Cr(VI)	-Chromic acid mist with some nickel and cadmium co-exposure -Cr(VI) levels in 1970 reported to range from <30 $\mu g/m^3$ to >100 $\mu g/m^3$	-O/E of 1.85 (p=0.001) based on 60 deaths and general pop -O/E of 1.39 (p=0.06) based on unexposed comparison group -No upward trend with duration of exposure
Sorahan et al. (1998, Ex. 35-271) Sorahan et al. (1987, Ex. 7-57)	1,762 platers employed for a minimum of six months between 1946 and 1975 from a Midlands, UK plant; follow up through 1995.	Mortality rates for the general population of England and Wales	-Chromic acid mist with nickel co-exposure -No reported Cr(VI) exposure levels	-O/E of 1.6 (p<0.01) for male chrome bath workers based on 40 deaths -O/E of 0.66 (NS) for other chrome workers based on 9 deaths -Upward trend (p<0.05) with duration of chrome bath work

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

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Cohort studies of chrome platers in Italy, the United States, and Japan are also discussed in this subsection. Co-exposure to nickel, another suspected carcinogen, during plating operations can complicate evaluation of an association between Cr(VI) and an increased risk of lung cancer in chrome platers. Despite this, the International Agency for Research on Cancer concluded that the epidemiological studies provide sufficient evidence for carcinogenicity of Cr(VI) as encountered in the chromium plating industry; the same conclusion reached for chromate production and chromate pigment production (Exs. 18–1; 35–43). The findings implicate the highly water-soluble chromic acid as an occupational carcinogen. This adds to the weight of evidence that water-soluble (*e.g.*, sodium chromates, chromic acid) and water-insoluble forms (*e.g.*, lead and zinc chromates) of Cr(VI) are able to cause cancer of the lower respiratory tract.

Royle reported on a cohort mortality study of 1,238 chromium platers employed for a minimum of three consecutive months between February 20, 1969 and May 31, 1972 in 54 plating plants in West Riding, Yorkshire, England (Ex. 7–49). A control population was enumerated from other departments of the larger companies where chromium plating was only a portion of the companies' activities and from the former and current employees of two industrial companies in York where information on past workers was available. Controls were matched for gender, age (within two years) and date last known alive. In addition, 229 current workers were matched for smoking habits.

As of May 1974, there were 142 deaths among the platers (130 males and 12 females) and 104 deaths among the controls (96 males and 8 females). Among the male platers, there were 24 deaths from cancer of the lung and pleura compared to 13 deaths in the control group. The difference was not statistically significant. There were eight deaths from gastrointestinal cancer among male platers versus four deaths in the control group. The finding was not statistically significant.

The Royle cohort was updated by Sorahan and Harrington (Ex. 35–62). Chrome plating was the primary activity at all 54 plants, however 49 of the plants used nickel and 18 used cadmium. Also used, but in smaller quantities according to the authors, were zinc, tin, copper, silver, gold, brass or rhodium. Lead was not used at any of the plants. Four plants, including one of the largest, only used chromium. Thirty-six chrome platers reported asbestos exposure versus 93 comparison workers.

Industrial hygiene surveys were carried out at 42 plants during 1969–1970. Area air samples were done at breathing zone height. With the exception of two plants, the chromic acid air levels were less than 30 μg/m^3. The two exceptions were large plants, and in both the chromic acid levels exceeded 100 μg/m^3.

The redefined cohort consisted of 1087 platers (920 men and 167 women) from 54 plants employed for a minimum of three months between February 1969 and May 31, 1972 who were alive on May 31, 1972. Mortality data were also available for a comparison group of 1,163 workers (989 men and 174 women) with no chromium exposure. Both groups were followed for vital status through 1997.

The lung cancer SMR for male platers was statistically significant (O=60; E=32.5; SMR=185; 95% CI: 141–238). The lung cancer SMR for the comparison group, while elevated, was not statistically significant (O=47; E=36.9; SMR=127; 95% CI: 94–169). The only statistically significant SMR in the comparison group was for cancer of the pleura (O=7; E=0.57; SMR=1235; 95% CI: 497–2545).

Internal regression analyses were conducted comparing the mortality rates of platers directly with those of the comparison workers. For these analyses, lung cancers mentioned anywhere on the death certificate were considered cases. The redefinition resulted in four additional lung cancer cases in the internal analyses. There was a statistically significant relative risk of 1.44 (p<0.05) for lung cancer mortality among chrome platers that was slightly reduced to 1.39 after adjustment for smoking habits and employment status. There was no clear trend between lung cancer mortality and duration of Cr(VI) exposure. However, any positive trend may have been obscured by the lack of information on worker employment post-1972 and the large variation in chromic acid levels among the different plants.

Sorahan reported the experience of a cohort of 2,689 nickel/chromium platers from the Midlands, U.K. employed for a minimum of six months between 1946 and 1975 and followed through December 1983 (Ex. 7–57). There was a statistically significant lung cancer SMR for males (O=63; E=40; SMR=158; p<0.001). The lung cancer SMR for women, while elevated (O=9; E=8.1; SMR=111), was not statistically significant. Other statistically significant cancer SMRs for males included: stomach (O=21; E=11.3; SMR=186; p<0.05); liver (O=4; E=0.6; SMR=667; p<0.01); and nasal cavities (O=2; E=0.2; SMR=1000; p<0.05). While there were several elevated SMRs for women, none were statistically significant. There were nine lung cancers and one nasal cancer among the women.

Analysis by type of first employment (*i.e.*, chrome bath workers vs. other chrome work) resulted in a statistically significant SMR for lung cancer of 199 (O=46; E=23.1; p<0.001) for chrome bath workers and a SMR of 101 for other chrome work. The SMR for cancer of the stomach for male chrome bath workers was also statistically significantly elevated (O=13; E=6.3; SMR=206; p<0.05); for stomach cancer in males doing other chrome work, the SMR was 160 with 8 observed and 5 expected. Both of the nasal cancers in males and the one nasal cancer in women were chrome bath workers. The nasal cancer SMR for males was statistically significantly elevated (O=2; E=0.1; SMR=2000; p<0.05).

Regression analysis was used to examine evidence of association of several types of cancers and Cr(VI) exposure duration among the cohort. There was a significant positive association between lung cancer mortality and exposure duration as a chrome bath worker controlling for gender as well as year and age at the start of employment. There was no evidence of an association between other cancer types and duration of Cr(VI) exposure. There was no positive association between duration of exposure to nickel bath work and cancer of the lung. The two largest reported SMRs were for chrome bath workers 10–14 years (O=13; E=3.8; SMR=342; p<0.001) and 15–19 years (O=12; E=4.9; SMR=245; p<0.01) after starting employment. The positive associations between lung cancer mortality and duration of chrome bath work suggests Cr(VI) exposure may be responsible for the excess cancer risk.

Sorahan *et al.* reported the results of a follow-up to the nickel/chromium platers study discussed above (Ex. 271). The cohort was redefined and excluded employees whose personnel records could not be located (650); those who started chrome work prior to 1946 (31) and those having no chrome exposure (236). The vital status experience of 1,762 workers (812 men and 950 women) was followed through 1995. The expected number of deaths was based upon the mortality of the general population of England and Wales.

There were 421 deaths among the men and 269 deaths among the women, including 52 lung cancers among the men and 17 among the women. SMRs were calculated for different categories of chrome work: Period from first chrome work; year of starting chrome work, and cumulative duration of chrome work categories. Poison regression modeling was employed to investigate lung cancer in relation to type of chrome work and cumulative duration of work.

A significantly elevated lung cancer SMR was seen for male workers with some period of chrome bath work (O=40; E=25.4; SMR=157; 95% CI: 113–214, $p<0.01$). Lung cancer was not elevated among male workers engaged in other chrome work away from the chromic acid bath (O=9; E=13.7; SMR=66; 95% CI: 30–125). Similar lung cancer mortality results were found for female chrome bath workers (O=15; E=8.6; SMR=175; 95% CI: 98–285; $p<0.06$). After adjusting for sex, age, calendar year, year starting chrome work, period from first chrome work, and employment status, regression modeling showed a statistically significant positive trend ($p<0.05$) between duration of chrome bath work and lung cancer mortality risk. The relative lung cancer risk for chrome bath workers with more than five years of Cr(VI) exposure (*i.e.*, relative to the risk of those without any chrome bath work) was 4.25 (95% CI: 1.83–9.37).

Since the Sorahan cohort consists of nickel/chromium workers, the question arises of the potential confounding of nickel. In the earlier study, 144 of the 564 employees with some period of chrome bath work had either separate or simultaneous periods of nickel bath employment. According to the authors, there was no clear association between cancer deaths from stomach, liver, respiratory system, nose and larynx, and lung and bronchus and the duration of nickel bath employment. In the follow-up report, the authors re-iterate this result stating, ''findings for lung cancer in a cohort of nickel platers (without any exposure to chrome plating) from the same factory are unexceptional'' (Ex. 35–271, p. 241).

Silverstein *et al.* reported the results of a cohort study of hourly employees and retirees with at least 10 years of credited pension service in a Midwestern plant manufacturing hardware and trim components for use primarily in the automobile industry (Ex. 7–55). Two hundred thirty eight deaths occurred between January 1, 1974 and December 31, 1978. Proportional Mortality Ratio (PMR) analysis adjusted for race, gender, age and year of death was conducted. For white males, the PMR for cancer of the lung and pleura was 1.91 ($p<0.001$) based upon 28 deaths. For white females, the PMR for cancer of the lung and pleura was 3.70 ($p<0.001$) based upon 10 deaths.

White males who worked at the plant for less than 15 years had a lung cancer PMR of 1.65. Those with 15 or more years at the plant had a lung cancer PMR of 2.09 ($p<0.001$). For white males with less than 22.5 years between hire and death (latency) the lung cancer PMR was 1.78 ($p<0.05$) and for those with 22.5 or more years, the PMR was 2.11 ($p<0.01$).

A case-control analysis was conducted on the Silverstein cohort to examine the association of lung cancer risk with work experience. Controls were drawn from cardiovascular disease deaths (ICD 390–458, 8th revision). The 38 lung cancer deaths were matched to controls for race and gender. Odds ratios (ORs) were calculated by department depending upon the amount of time spent in the department (ever/never; more vs. less than one year; and more vs. less than five years). Three departments showed increasing odds ratios with duration of work; however, the only statistically significant result was for those who worked more than five years in department 5 (OR=9.17, p=0.04, Fisher's exact test). Department 5 was one of the major die-casting and plating areas of the plant prior to 1971.

Franchini *et al.* conducted a mortality study of employees and retirees from nine chrome plating plants in Parma, Italy (Ex. 7–56). Three plants produced hard chrome plating. The remaining six plants produced decorative chromium plates. A limited number of airborne chromium measurements were available. Out of a total of 10 measurements at the hard chrome plating plants, the air concentrations of chromium averaged 7 $\mu g/m^3$ (range of 1–50 $\mu g/m^3$) as chromic acid near the baths and 3 $\mu g/m^3$ (range of 0–12 $\mu g/m^3$) in the middle of the room.

The cohort consisted of 178 males (116 from the hard chromium plating plants and 62 from the bright chromium plating plants) who had worked for at least one year between January 1, 1951 and December 31, 1981. In order to allow for a 10-year latency period, only those employed before January 1972 were included in further analysis. There were three observed lung cancer deaths among workers in the hard chrome plating plants, which was significantly greater than expected (O=3; E=0.6; $p<0.05$). There were no lung cancer deaths among decorative chrome platers.

Okubo and Tsuchiya conducted a study of plating firms with five or more employees in Tokyo (Exs. 7–51; 7–52). Five hundred and eighty nine firms were sent questionnaires to ascertain information regarding chromium plating experience. The response rate was 70.5%. Five thousand one hundred seventy platers (3,395 males and 1,775 females) met the cohort entrance criteria and were followed from April 1, 1970 to September 30, 1976. There were 186 deaths among the cohort; 230 people were lost to follow-up after retirement. The cohort was divided into two groups: Chromium platers who worked six months or more and a control group with no exposure to chromium (clerical, unskilled workers). There were no deaths from lung cancer among the chromium platers.

The Okubo cohort was updated by Takahashi and Okubo (Ex. 265). The cohort was redefined to consist of 1,193 male platers employed for a minimum of six months between April 1970 and September 1976 in one of 415 Tokyo chrome plating plants and who were alive and over 35 years of age on September 30, 1976. The only statistically significant SMR was for lung cancer for all platers combined (O=16; E=8.9; SMR=179; 95% CI: 102–290). The lung cancer SMR for the chromium plater subcohort was 187 based upon eight deaths and 172 for the nonchromium plater subcohort, also based upon eight deaths. The cohort was followed through 1987. Itoh *et al.* updated the Okubo metal plating cohort through December 1992 (Ex. 35–163). They reported a lung cancer SMR of 118 (95% CI: 99–304).

4. Evidence From Stainless Steel Welders

Welding is a term used to describe the process for joining any materials by fusion. The fumes and gases associated with the welding process can cause a wide range of respiratory exposures which may lead to an increased risk of lung cancer. The major classes of metals most often welded include mild steel, stainless and high alloy steels and aluminum. The fumes from stainless steel, unlike fumes from mild steel, contain nickel and Cr(VI). There are several cohort and case-control studies as well as two meta analyses of welders potentially exposed to Cr(VI). In general, the studies found an excess number of lung cancer deaths among stainless steel welders. However, few of the studies found clear trends with Cr(VI) exposure duration or cumulative Cr(VI). In most studies, the reported excess lung cancer mortality among stainless steel welders was no greater than mild steel welders, even though Cr(VI) exposure is much greater during stainless steel welding. This weak association between lung cancer and indices of exposure limits the evidence provided by these studies. Other limitations include the co-exposures to other potential lung carcinogens, such as nickel, asbestos, and cigarette smoke, as well as possible healthy worker effects and exposure misclassification in some studies, which may obscure a relationship betweeen Cr(VI) and lung cancer risk. These limitations are discussed further in sections VI.B.5, VI.E.3, and VI.G.4.

Nevertheless, these studies add some further support to the much stronger link between Cr(VI) and lung cancer found in soluble chromate production workers, chromate pigment production workers, and chrome platers. The key studies are summarized in Table V–4.

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TABLE V-4: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Stainless Steel Welding

Reference/Exhibit Number	Study Population	Reference Population	Chromium (VI) Exposure	Lung Cancer Risk
Moulin (1997, Ex. 35-285)	Meta analysis of epidemiological studies of lung cancer risk among welders in five categories including stainless steel welding and mild steel welding	Stainless steel welding cohort studies: Simonato et al., 1991; Polednak et al., 1981 case control studies: Hull et al., 1989; Gerin et al., 1984; Kjuus et al. 1986.	Stainless steel welders exposed to higher Cr(VI) than mild steel welders	-RR of 1.50 ($p<0.05$) for stainless steel welders based on combined 114 deaths from five studies -RR of 1.50 ($p<0.05$) for mild steel welders based on combined 137 deaths from four studies
Sjogren et al. (1994, Ex. 7-113)	Meta analysis of epidemiological studies of exposure to stainless steel welding fumes and lung cancer.	Stainless steel welding cohort studies: Moulin et al., 1993; Sjogren et al., 1987 case control studies: Lauritsen et al., 1996; Gerin et al., 1984; Kjuus et al. 1986	Cr(VI) exposure was not part of the analysis	RR of 1.94 ($p<0.05$) for stainless steel welders based on combined 70 deaths from five studies
Simonato et al. (1991, Ex.7-114) Gerin et al. (1993, Ex. 35-220)	Cohort of 11,092 male welders from 135 companies in nine European countries. Cohort entrance criteria varied by country.	Age and sex specific mortality rates computed using the WHO mortality data bank.	Average cumulative Cr(VI) exposures estimated between 0.05 to 1.5 mg/ m^3 - yr based on job process matrix	-O/E of 1.23 (NS) for primarily stainless steel welders based on 20 deaths -Upward trend ($p<0.05$) with time since first exposure -No trend with cumulative exposure
Moulin et al. (1993, Ex. 7-92)	Cohort of 2,721 French male welders from 13 factories with a minimum of one year of employment from 1975 to 1988.	6,683 unexposed manual workers from 13 factories with a minimum of one year of employment from 1975 to 1988	-Primarily manual metal arc welding -Cr(VI) exposures not recorded	-O/E of 1.03 (NS) for primarily stainless steel welders based on 2 deaths -No trend with exposure duration
Hansen et al. (1996, Ex. 35-247)	Cohort of 10,059 male welders and other steel workers from 79 Danish companies employed for a minimum of one year between 1964 and 1984.	National cancer incidence rates from the Danish Cancer Registry.	Cr(VI) exposure not recorded	-O/E of 2.38 (NS) for stainless steel only welders based on 5 deaths -No trend with exposure duration
Lauritsen et al. (1996, Ex. 35-291)	Nested case-control study of 94 lung cancer deaths from Hansen study.	439 eligible controls who were not cases and did not have respiratory disease or unknown malignancy as cause of death	Cr(VI) exposure not recorded	-OR of 1.3 (NS) for stainless steel only welders -No trend with exposure duration
Sjogren et al (1987, Ex. 7-95)	Cohort of 234 male stainless steel welders and 208 male railway track welders. Minimum employment was 5 years between 1950 and 1965. Follow-up through 1984	Mortality rates for Swedish males	Median Cr level for stainless steel welding was 57 $\mu g/m^3$ and for gas shielded welding [railway welders] was 5 $\mu g/m^3$ in Sweden during 1975	-O/E of 2.5 (NS) for stainless steel welders based on 5 deaths -O/E of 0.3 (NS) for railway welders based on 1 death

Kjuus et al (1986, Ex. 7-72)	A hospital-based case-control study of 176 male incident lung cancer cases admitted to two hospitals in Norway during 1979-1983.	186 controls admitted to the same hospitals in Norway during 1979-1983 and matched to cases for age +/- 5 years.	Cr(VI) exposure not recorded	-OR of 3.0 (p <0.05, adjusted for smoking) for stainless steel welding based on 16 deaths -Welding not significant in logistic model with smoking, asbestos
Hull, et al (1989, Ex. 35-243)	Case-control study of 85 lung cancer cases in white male welders identified through the LA County tumor registry (1972-1987).	Controls were 74 welders with non-pulmonary malignancies	No direct Cr(VI) exposure measurements recorded	-OR of 0.9 (NS) for stainless steel welding based on 34 cases -OR of 1.3 (NS) for manual metal arc welding on stainless steel based on 61 cases

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

BILLING CODE 4510–26–C

Sjogren *et al.* reported on the mortality experience in two cohorts of welders (Ex. 7–95). The cohort characterized as ''high exposure'' consisted of 234 male stainless steel welders with a minimum of 5 years of employment between 1950 and 1965. An additional criterion for inclusion in the study was assurance from the employer that asbestos had not been used or had been used only occasionally and never in a dust-generating way. The cohort characterized as ''low exposure'' consisted of 208 male railway track welders working at the Swedish State Railways for at least 5 years between 1950 and 1965. In 1975, air pollution in stainless steel welding was surveyed in Sweden. The median time weighted average (TWA) value for Cr(VI) was 110 μg CrO_3/m^3 (57 μg/m^3 measured as CrVI). The highest concentration was 750 μg CrO_3/m^3 (390 μg/m^3 measured as CrVI) found in welding involving coated electrodes. For gas-shielded welding, the median Cr(VI) concentration was 10 μg CrO_3/m^3 (5.2 μg/m^3 measured as CrVI) with the highest concentration measured at 440 μg CrO_3/m^3 (229 μg/m^3 measured as CrVI). Follow-up for both cohorts was through December 1984. The expected number of deaths was based upon Swedish male death rates. Of the 32 deaths in the ''high exposure'' group, five were cancers of the trachea, bronchus and lung (E=2.0; SMR=249; 95% CI: 0.80–5.81). In the low exposure group, 47 deaths occurred, one from cancer of the trachea, bronchus and lung.

Polednak compiled a cohort of 1,340 white male welders who worked at the Oak Ridge nuclear facilities from 1943 to 1977 (Ex. 277). One thousand fifty-nine cohort members were followed through 1974. The cohort was divided into two groups. The first group included 536 welders at a facility where nickel-alloy pipes were welded; the second group included 523 welders of mild steel, stainless steel and aluminum materials. Smoking data were available for 33.6% of the total cohort. Expectations were calculated based upon U.S. mortality rates for white males. There were 17 lung cancer deaths in the total cohort (E=11.37; SMR=150; 95% CI: 87–240). Seven of the lung cancer deaths occurred in the group which routinely welded nickel-alloy materials (E=5.65; SMR=124; 95% CI: 50–255) versus 10 lung cancer deaths in the ''other'' welders (E=6.12; SMR=163; 95% CI: 78–300).

Becker *et al.* compiled a cohort of 1,213 stainless steel welders and 1,688 turners from 25 German metal processing factories who had a minimum of 6 months employment during the period 1950–1970 (Exs. 227; 250; 251). The data collected included the primary type of welding (*e.g.*, arc welding, gas-shielded welding, etc.) used by each person, working conditions, average daily welding time and smoking status. The most recent follow-up of the cohort was through 1995. Expected numbers were developed using German mortality data. There were 268 deaths among the welders and 446 deaths among the turners. An elevated, but non-statistically significant, lung cancer SMR (O=28; E=23; SMR=121.5; 95% CI: 80.7–175.6) was observed among the welders. There were 38 lung cancer deaths among the turners with 38.6 expected, resulting in a SMR slightly below unity. Seven deaths from cancer of the pleura (all mesotheliomas) occurred among the welders with only 0.6 expected (SMR=1,179.9; 95% CI: 473.1–2,430.5), compared to only one death from cancer of the pleura among the turners, suggesting that the welders had exposure to asbestos. Epidemiological studies have shown that asbestos exposure is a primary cause of pleural mesotheliomas.

The International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) cosponsored a study on welders. IARC and WHO compiled a cohort of 11,092 male welders from 135 companies in nine European countries to investigate the relationship between the different types of exposure occurring in stainless steel, mild steel and shipyard welding and various cancer sites, especially lung cancer (Ex. 7–114). Cohort entrance criteria varied by country. The expected number of deaths was compiled using national mortality rates from the WHO mortality data bank.

Results indicated the lung cancer deaths were statistically significant in the total cohort (116 cases; E=86.81; SMR=134; 95% CI: 110–160). Cohort members were assigned to one of four subcohorts based upon type of welding activity. While the lung cancer SMRs were elevated for all of the subcohorts, the only statistically significant SMR was for the mild steel-only welders (O=40; E=22.42; SMR=178; 95% CI: 127–243). Results for the other subgroups were: shipyard welders (O=36; E=28.62; SMR=126; 95% CI: 88–174); ever stainless steel welders (O=39; E=30.52; SMR=128; 95% CI: 91–175); and predominantly stainless steel welders (O=20; E=16.25; SMR=123; 95% CI: 75–190). When analyzed by subcohort and time since first exposure, the SMRs increased over time for every group except shipyard welders. For the predominantly stainless steel welder subcohort, the trend to increase with time was statistically significant ($p < .05$).

An analysis was conducted of lung cancer mortality in two stainless steel welder subgroups (predominantly and ever) with a minimum of 5 years of employment. Cumulative Cr(VI) was computed from start of exposure until 20 years prior to death. A lung cancer SMR of 170, based upon 14 cases, was observed in the stainless steel ever subgroup for those welders with ≥0.5 mg-years/m^3 Cr(VI) exposure; the lung cancer SMR for those in the <0.5 mg-years/m^3 Cr(VI) exposure group was 123 (based upon seven cases). Neither SMR was statistically significant. For the predominantly stainless steel welders, which is a subset of the stainless steel ever subgroup, the corresponding SMRs were 167 (≥0.5 mg-years/m^3 Cr(VI) exposure) based upon nine cases and 191 (<0.5 mg-years/m^3 Cr(VI) exposure) based upon three cases. Neither SMR was statistically significant.

In conjunction with the IARC/WHO welders study, Gerin *et al.* reported the development of a welding process exposure matrix relating 13 combinations of welding processes and base metals used to average exposure levels for total welding fumes, total chromium, Cr(VI) and nickel (Ex. 7–120). Quantitative estimates were derived from the literature supplemented by limited monitoring data taken in the 1970s from only 8 of the 135 companies in the IARC/WHO mortality study. An exposure history was constructed which included hire and termination dates, the base metal welded (stainless steel or mild steel), the welding process used and changes in exposure over time. When a detailed welding history was not available for an individual, the average company welding practice profile was used. In addition, descriptions of activities, work force, welding processes and parameters, base metals welded, types of electrodes or rods, types of confinement and presence of local exhaust ventilation were obtained from the companies.

Cumulative dose estimates in mg/m^3 years were generated for each welder's profile (number of years and proportion of time in each welding situation) by applying a welding process exposure matrix associating average concentrations of welding fumes (mg/m^3) to each welding situation. The corresponding exposure level was multiplied by length of employment and summed over the various employment periods involving different welding situations. No dose response relationship was seen for exposure to Cr(VI) for either those who were ''ever stainless steel welders'' or those who were ''predominantly stainless steel welders''. The authors note that if their exposure estimates are correct, the study had the power to detect a significant result in the high exposure group for Cr(VI). However, OSHA believes that there is likely to be substantial exposure misclassification in this study, as discussed further in section VI.G.4.

The IARC/WHO multicenter study is the sole attempt to undertake even a semi-quantified exposure analysis of stainless steel welders' potential exposure to nickel and Cr(VI) for <5 and ≥0.5 mg-years/m^3 Cr(VI) exposures. The IARC/WHO investigators noted that there was more than a twofold increase in SMRs between the long (≥20 years since first exposure) and short (<20 years since first exposure) observation groups for the predominantly stainless steel welders ''suggesting a relation of lung cancer mortality with the occupational environment for this group'' (Ex. 7–114, p. 152). The authors conclude that the increase in lung cancer mortality does not appear to be related to either duration of exposure or cumulative exposure to total fume, chromium, Cr(VI) or nickel.

Moulin compiled a cohort of 2,721 French male welders and an internal comparison group of 6,683 manual workers employed in 13 factories (including three shipyards) with a minimum of one year of employment from 1975 to 1988 (Ex. 7–92). Three controls were selected at random for each welder. Smoking data were abstracted from medical records for 86.6% of welders and 86.5% of the controls. Smoking data were incorporated in the lung cancer mortality analysis using methods suggested by Axelson. Two hundred and three deaths were observed in the welders and 527 in the comparison group. A non-statistically significant increase was observed in the lung cancer SMR (O=19; E=15.33; SMR=124; 95% CI: 0.75–1.94) for the welders. In the control group, the lung cancer SMR was in deficit (O=44; E=46.72; SMR=94; 95% CI: 0.68–1.26). The resulting relative risk was a non-significant 1.3. There were three deaths from pleural cancer in the comparison group and none in the welders, suggesting asbestos exposure in the comparison group. The welders were divided into four subgroups (shipyard welders, mild steel only welders, ever stainless steel welders and stainless steel predominantly Cr(VI) welders). The highest lung cancer SMR was for the mild steel welders O=9; SMR of 159). The lowest lung cancer SMRs were for ever stainless steel welders (O=3; SMR= 92) and for stainless steel predominantly Cr(VI) welders (O=2; SMR= 103). None of the SMRs are statistically significant.

Hansen conducted a study of cancer incidence among 10,059 male welders, stainless steel grinders and other metal workers from 79 Danish companies (Ex. 9–129). Cohort entrance criteria included: alive on April 1, 1968; born before January 1, 1965; and employed for at least 12 months between April 1, 1964 and December 31, 1984. Vital status follow-up found 9,114 subjects alive, 812 dead and 133 emigrated. A questionnaire was sent to subjects and proxies for decedents/emigrants in an attempt to obtain information about lifetime occupational exposure, smoking and drinking habits. The overall response rate was 83%. The authors stated that no major differences in smoking habits were found between exposure groups with or without a significant excess of lung cancer.

The expected number of cancers was based on age-adjusted national cancer incidence rates from the Danish Cancer Registry. There were statistically significantly elevated Standardized Incidence Ratios (SIRs) for lung cancer in the welding (any kind) group (O=51; E=36.84; SIR=138; 95% CI: 103–181) and in the mild steel only welders (O=28; E=17.42; SIR=161; 95% CI: 107–233). The lung cancer SIR for mild steel ever welders was 132 (O=46; E=34.75; 95% CI: 97–176); for stainless steel ever welders 119 (O=23; E=19.39; 95% CI: 75–179) and for stainless steel only welders 238 (O=5; E=2.10; 95% CI: 77–555).

Laurtitsen reported the results of a nested case-control conducted in conjunction with the Hansen cancer incidence study discussed above (Exs. 35–291; 9–129). Cases were defined as the 94 lung cancer deaths. Controls were defined as anyone who was not a case, but excluded deaths from respiratory diseases other than lung cancer (either as an underlying or a contributing cause of death), deaths from ''unknown malignancies'' and decedents who were younger than the youngest case. There were 439 decedents eligible for use as controls.

The crude odds ratio (OR) for welding ever (yes/no) was 1.7 (95% CI: 1.0–2.8). The crude OR for mild steel welding only was 1.3 (95% CI: 0.8–2.3) and for stainless steel welding only the crude OR was 1.3 (95% CI: 0.3–4.3). When analyzed by number of years exposed, ''ever'' stainless steel welding showed no relationship with increasing number of years exposed. The highest odds ratio (2.9) was in the lowest category (1–5 years) based upon seven deaths; the lowest odds ratio was in the highest category (21+ years) based upon three deaths.

Kjuus *et al.* conducted a hospital-based case-control study of 176 male incident lung cancer cases and 186 controls (matched for age, +/−5 years) admitted to two county hospitals in southeast Norway during 1979–1983 (Ex. 7–72). Subjects were classified according to exposure status of main occupation and number of years in each exposure category and assigned into one of three exposure groups according to potential exposure to respiratory carcinogens and other contaminants. A statistically significantly elevated risk ratio for lung cancer (adjusted for smoking) for the exposure factor ''welding, stainless, acid proof'' of 3.3 ($p<0.05$) was observed based upon 16 lung cancer deaths. The unadjusted odds ratio is not statistically significant (OR=2.8). However, the appropriateness of the analysis is questionable since the exposure factors are not discrete (a case or a control may appear in multiple exposure factors and therefore is being compared to himself). In addition, the authors note that several exposure factors were highly correlated and point out specifically that one-half of the cases ''exposed to either stainless steel welding fumes or fertilizers also reported moderate to heavy asbestos exposure.'' When put into a stepwise logistic regression model, exposure to stainless steel fumes, which was initially statistically significant, loses its significance when smoking and asbestos are first entered into the model.

Hull *et al.* conducted a case-control study of lung cancer in white male welders aged 20–65 identified through the Los Angeles County tumor registry (Southern California Cancer Surveillance Program) for the period 1972 to 1987 (Ex. 35–243). Controls were welders 40 years of age or older with non-pulmonary malignancies. Interviews were conducted to obtain information about sociodemographic data, smoking history, employment history and occupational exposures to specific welding processes, metals welded, asbestos and confined space welding. Interviews were completed for 90 (70%) of the 128 lung cancer cases and 116 (66%) of the controls. Analysis was conducted using 85 deceased cases and 74 deceased controls after determining that the subject's vital status influenced responses to questions concerning occupational exposures. The crude odds ratio (ever vs. never exposed) for stainless steel welding, based upon 34 cases, was 0.9 (95% CI: 0.3–1.4). For manual metal arc welding on stainless steel, the crude odds ratio was 1.3 (95% CI: 0.6–2.3) based upon 61 cases.

While the relative risk estimates in both cohort and case-control of stainless steel welders are elevated, none are statistically significant. However, when combined in two meta-analyses, a small but statistically significant increase in lung cancer risk was reported. Two meta-analyses of welders have been published. Moulin carried out a meta-analysis of epidemiologic studies of lung cancer risk among welders, taking into account the role of asbestos and smoking (Ex. 35–285). Studies published between 1954 and 1994 were reviewed. The inclusion criteria were clearly defined: only the most recent updates of cohort studies were used and only the mortality data from mortality/morbidity studies were included. Studies that did not provide the information required by the meta-analysis were excluded.

Five welding categories were defined (shipyard welding, non-shipyard welding, mild steel welding, stainless steel welding and all or unspecified welding). The studies were assigned to a welding category (or categories) based upon the descriptions provided in the paper's study design section. The combined relative risks (odds ratios, standardized mortality ratios, proportionate mortality ratios and standardized incidence ratios) were calculated separately for the population-based studies, case-control studies, and cohort studies, and for all the studies combined.

Three case-control studies (Exs. 35–243; 7–120; 7–72) and two cohort studies (Exs. 7–114; 35–277) were included in the stainless steel welding portion of the meta-analysis. The combined relative risk was 2.00 (O=87; 95% CI: 1.22–3.28) for the case-control studies and 1.23 (O=27; 95% CI: 0.82–1.85) for the cohort studies. When all five studies were combined, the relative risk was 1.50 (O=114; 95% CI: 1.10–2.05).

By contrast, the combined risk ratio for the case-control studies of mild steel welders was 1.56 (O=58; 95% CI: 0.82–2.99) (Exs. 7–120; 35–243). For the cohort studies, the risk ratio was 1.49 (O=79; 95% CI: 1.15–1.93) (Exs. 35–270; 7–114). For the four studies combined, the risk ratio was 1.50 (O=137; 95% CI: 1.18–191). The results for the stainless steel welders and the mild steel welders are basically the same.

The meta-analysis by Sjogren of exposure to stainless steel welding fumes and lung cancer included studies published between 1984 and 1993, which took smoking and potential asbestos exposure into account (Ex. 7–113). Five studies met the author's inclusion criteria and were included in the meta-analysis: two cohort studies, Moulin *et al.* (Ex. 35–283) and Sjogren *et al.* (Ex. 7–95); and three case-control studies, Gerin, *et al.* (Ex. 7–120, Hansen *et al.* (Ex. 9–129) and Kjuus *et al.* (Ex. 7–72). The calculated pooled relative risk for welders exposed to stainless steel welding fumes was 1.94 (95% CI: 1.28–2.93).

5. Evidence from Ferrochromium Workers

Ferrochromium is produced by the electrothermal reduction of chromite ore with coke in the presence of iron in electric furnaces. Some of the chromite ore is oxidized into Cr(VI) during the process. However, most of the ore is reduced to chrome metal. The manufacture of ferroalloys results in a complex mixture of particles, fumes and chemicals including nickel, Cr(III) and Cr(VI). Polycyclic aromatic hydrocarbons (PAH) are released during the manufacturing process. The co-exposure to other potential lung carcinogens combined with the lack of a statistically significant elevation in lung cancer mortality among ferrochromium workers were limitations in the key studies. Nevertheless, the observed increase in the relative risks of lung cancer add some further support to the much stronger link between Cr(VI) and lung cancer found in soluble chromate production workers, chromate pigment production workers, and chrome platers. The key studies are summarized in Table V–5.

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TABLE V-5: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Ferrochromium Production

Reference/Exhibit Number	**Study Population**	**Reference Population**	**Chromium (VI) Exposure**	**Lung Cancer Risk**
Axelsson et al. (1980, Ex. 7-62)	1932 Swedish males employed at least one year in a ferrochromium between 1930 to 1975	Swedish county mortality and incidence rates	"Recent" job-specific Cr(VI) levels estimated at 10 to 250 $\mu g/m^3$	-O/E of 0.7 (NS) for ferrochromium workers based on 5 cases -No trend with job-specific Cr(VI)
Langard et al. (1990, Ex. 7-37)	1235 males employed at least one year who started working prior to 1965 in a Norway ferrochromium plant Follow-up through 1985.	-Norwegian Cancer Registry -Subcohort of ferrosilicon workers at same plant not exposed to Cr(VI)	Avg total Cr exposure was 50 $\mu g/m^3$ in 1975 with 11 to 33 % soluble Cr(VI)	-O/E of 1.5 (NS) for ferrochromium workers based on 10 cases -O/E of 0.3 for ferrosilicon workers based on 2 cases

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

BILLING CODE 4510–26–C

Langard *et al.* conducted a cohort study of male workers producing ferrosilicon and ferrochromium for more than one year between 1928 and 1977 at a plant located on the west coast of Norway (Exs. 7–34; 7–37). The cohort and study findings are summarized in Table V.5. Excluded from the study were workers who died before January 1, 1953 or had an unknown date of birth. The cohort was defined in the 1980 study as 976 male employees who worked for a minimum of one year prior to January 1, 1960. In the 1990 study, the cohort definition was expanded to include those hired up to 1965.

Production of ferrosilicon at the plant began in 1928 and ferrochromium production began in 1932. Job characterizations were compiled by combining information from company personnel lists and occupational histories contained in medical records and supplemented with information obtained via interview with long-term employees. Ten occupational categories were defined. Workers were assigned to an occupational category based upon the longest time in a given category.

Industrial hygiene studies of the plant from 1975 indicated that both Cr(III) and Cr(VI) were present in the working environment. The ferrochromium furnance operators were exposed to measurements of 0.04–0.29 mg/m^3 of total chromium. At the charge floor the mean concentration of total chromium was 0.05 mg/m^3, 11–33% of which was water soluble. The water soluble chromium was considered to be in the hexavalent state.

Both observed and expected cases of cancer were obtained via the Norwegian Cancer Registry. The observation period for cancer incidence was January 1, 1953 to December 31, 1985. Seventeen incident lung cancers were reported in the 1990 study (E=19.4; SIR=88). A deficit of lung cancer incidence was observed in the ferrosilicon group (O=2; E=5.8; SIR=35). In the ferrochromium group there were a significant excess of lung cancer; 10 observed lung cancers with 6.5 expected (SIR=154).

Axelsson *et al.* conducted a study of 1,932 ferrochromium workers to examine whether exposure in the ferrochromium industry could be associated with an increased risk of developing tumors, especially lung cancer (Ex. 7–62). The study cohort and findings are summarized in Table V.5. The study cohort was defined as males employed at a ferrochromium plant in Sweden for at least one year during the period January 1, 1930 to December 31, 1975.

The different working sites within the industry were classified into four groups with respect to exposure to Cr(VI) and Cr(III). Exposure was primarily to metallic and trivalent chromium with estimated levels ranging from 0–2.5 mg/m^3. Cr(VI) was also present in certain operations with estimated levels ranging from 0–0.25 mg/m^3. The highest exposure to Cr(VI) was in the arc-furnace operations. Cr(VI) exposure also occurred in a chromate reduction process during chromium alum production from 1950–1956. Asbestos-containing materials had been used in the plant. Cohort members were classified according to length and place of work in the plant.

Death certificates were obtained and coded to the revision of the International Classification of Diseases in effect at the time of death. Data on cancer incidence were obtained from the Swedish National Cancer Registry. Causes of death in the cohort for the period 1951–1975 were compared with causes of death for the age-adjusted male population in the county in which the plant was located.

There were seven cases of cancers of the trachea, bronchus and lung and the pleura with 5.9 expected (SIR=119) for the period 1958–1975. Four of the seven cases in the lung cancer group were maintenance workers and two of the four cases were pleural mesotheliomas. In the arc furnace group, which was thought to have the highest potential exposure to both Cr(III) and Cr(VI), there were two cancers of the trachea, bronchus and lung and the pleura. One of the cases was a mesothelioma. Of the 380 deaths that occurred during the period 1951–1975, five were from cancer of the trachea, bronchus and lung and the pleura (E=7.2; SMR=70). For the ‘‘highly’’ exposed furnace workers, there was one death from cancer of the trachea, bronchus and lung and the pleura.

Moulin *et al.* conducted a cohort mortality study in a French ferrochromium/stainless steel plant to determine if exposure to chromium compounds, nickel compounds and polycyclic aromatic hydrocarbons (PAHs) results in an increased risk of lung cancer (Ex. 282). The cohort was defined as men employed for at least one year between January 1, 1952 and December 31, 1982; 2,269 men met the cohort entrance criteria. No quantitative exposure data were available and no information on the relative amounts of Cr(VI) and Cr(III) was provided. In addition, some workers were also exposed to other carcinogens, such as silica and asbestos. The authors estimated that 75.7% of the cohort had been exposed to combinations of PAH, nickel and chromium compounds. Of the 137 deaths identified, the authors determined 12 were due to cancer of the trachea, bronchus and lung (E=8.56; SMR=140; 95% CI: 0.72–2.45). Eleven of the 12 lung cancers were in workers employed for at least one year in the ferrochromium or stainless steel production workshops (E=5.4; SMR=204; 95% CI: 1.02–3.64).

Pokrovskaya and Shabynina conducted a cohort mortality study of male and female workers employed ‘‘some time’’ between 1955 and 1969 at a chromium ferroalloy production plant in the U.S.S.R (Ex. 7–61). Workers were exposed to both Cr(III) and Cr(VI) as well as to benzo [a] pyrene. Neither the number of workers nor the number of cancer deaths by site were provided. Death certificates were obtained and the deaths were compared with municipal mortality rates by gender and 10 year age groups. The investigators state that they were able to exclude those in the comparison group who had chromium exposures in other industries. The lung cancer SMR for male chromium ferroalloy workers was 440 in the 30–39 year old age group and 660 in the 50–59 year old age group (p=0.001). There were no lung cancer deaths in the 40–49 and the 60–69 year old age groups. The data suggest that these ferrochromium workers may have been had an excess risk of lung cancer.

The association between Cr(VI) exposure in ferrochromium workers and the incidence of respiratory tract cancer these studies is difficult to assess because of co-exposures to other potential carcinogens (*e.g.*, asbestos, PAHs, nickel, etc.), absence of a clear exposure-response relationship and lack of information on smoking. There is suggestive evidence of excess lung cancer mortality among Cr(VI)-exposed ferrochromium workers in the Norwegian (Langard) cohort when compared to a similar unexposed cohort of ferrosilicon workers. However, there is little consistency for this finding in the Swedish (Axelsson) or French (Moulin) cohorts.

6. Evidence From Workers in Other Industry Sectors

There are several other epidemiological studies that do not fit into the five industry sectors previously reviewed. These include worker cohorts in the aerospace industry, paint manufacture, and leather tanning operations, among others. The two cohorts of aircraft manufacturing workers are summarized in Table V–6. All of the cohorts had some Cr(VI) exposure, but certain cohorts may have included a sizable number of workers with little or no exposure to Cr(VI). This creates an additional complexity in assessing whether the study findings support a Cr(VI) etiology for cancer of the respiratory system.

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TABLE V-6: SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM

Aircraft Manufacture

Reference/Exhibit Number	**Study Population**	**Reference Population**	**Chromium (VI) Exposure**	**Lung Cancer Risk**
Alexander et al. (1996, Ex. 31-16-3)	2429 aerospace workers with a minimum six months employment in Washington State from 1974 to 1994. Median age at end of study was 42 years with median 9 years follow-up	Incidence rates from regional cancer surveillance system registry	Painters/sanders exposed to zinc strontium and lead chromates Platers/tank tenders exposed primarily to chromic acid Median cumulative chromate exposure between 0.01 and 0.18 mg/m^3 – yr based on 1974 to 1994 data	-O/E of 0.8 (NS) for aerospace cohort based on 15 deaths -No clear trend with chromate exposure
Boice et al. (1999, Ex. 31-16-4) Marano et al. (2000, Ex. 47-19-5)	77,965 workers employed for minimum of one year in California aircraft manufacturing plant on or after 1960. Follow-up through 1996.	Mortality rates for white population of California and for non-white U.S. population	8 percent of cohort had potential for routine Cr(VI) exposure as painters and platers mean Cr(VI) exposure levels of 0.78 μg/m^3 from 1978-1991 air sampling	-O/E of 1.02 (NS) for workers with routine Cr(VI) exposures based on 87 deaths -upward trend (NS) with duration of exposure -O/E of 0.71 ($p<0.05$) for non-factory workers

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

BILLING CODE 4510–26–C

Alexander *et al.* conducted a cohort study of 2,429 aerospace workers with a minimum of six months of cumulative employment in jobs involving chromate exposure during the period 1974 through 1994 (Ex. 31–16–3). Exposure estimates were based on industrial hygiene measurements and work history records. Jobs were classified into categories of ''high'' (spray painters, decorative painters), ''moderate'' (sanders/maskers, maintenance painters) and ''low'' (chrome platers, surface processors, tank tenders, polishers, paint mixers) exposure. Each exposure category was assigned a summary TWA exposure based upon the weighted TWAs and information from industrial hygienists. The use of respiratory protection was accounted for in setting up the job exposure matrix. The index of cumulative total chromium exposure (reported as μg/m³ chromate TWA-years) was computed by multiplying the years in each job by the summary TWAs for each exposure category.

In addition to cumulative chromate exposure, chromate exposure jobs were classified according to the species of chromate. According to the authors, in painting operations the exposure is to chromate pigments with moderate and low solubility such as zinc chromate, strontium chromate and lead chromate; in sanding and polishing operations the same chromate pigments exist as dust; while platers and tank tenders are exposed to chromium trioxide, which is highly soluble.

Approximately 26% of the cohort was lost to follow-up. Follow-up on the cohort was short (average 8.9 years per cohort member). Cases were identified through the Cancer Surveillance System (CSS) at the Fred Hutchinson Cancer Research Center in Seattle, Washington. CSS records primary cancer diagnoses in 13 counties in western Washington. Expected numbers were calculated using race-, gender-, age- and calendar-specific rates from the Puget Sound reference population for 1974 through 1994. Fifteen lung cancer cases were identified with an overall standardized incidence ratio (SIR) of 80 (95% CI: 0.4–1.3). The SIRs for lung cancer by cumulative years of employment in the ''high exposure'' painting job category were based upon only three deaths in each of the cumulative years categories (<5 and ≥5); years of employment was inversely related to the risk of lung cancer. For those in the ''low exposure'' category, the SIRs were 130 for those who worked less than five years in that category (95% CI: 0.2–4.8) and 190 for those who worked five years or more (95% CI: 0.2–6.9). However, there were only two deaths in each category. The SIR for those who worked ≥5 years was 270 (95% CI: 0.5–7.8), but based only on three deaths.

Boice *et al.* conducted a cohort mortality study of 77,965 workers employed for a minimum of one year on or after January 1960 in aircraft manufacturing (Ex. 31–16–4). Routine exposures to Cr(VI) compounds occurred primarily while operating plating and coating process equipment or when using chromate based primers or paints. According to the authors, 3,634 workers, or 8% of the cohort, had the potential for routine exposure to chromate and 3,809 workers, or 8.4%, had the potential for intermittent exposure to chromate. Limited chromate air sampling was conducted between 1978 and 1991. The mean full shift air measurement was 1.5 μg CrO_3/m³ (0.78 μg Cr(VI)/m³) indicating fairly low airborne Cr(VI) in the plant (Ex. 47–19–5).

Follow up of the cohort was through 1996. Expectations were calculated based on the general population of California for white workers, while general population rates for the U.S. were used for non-white workers. For the 3,634 cohort members who had potential for routine exposure to chromates, the lung cancer SMR (race and gender combined) was 102 based upon 87 deaths (95% CI: 82–126). There was a slight non-significant positive trend (p value >2.0) for lung cancer with duration of potential exposure. The SMR was 108 (95% CI: 75–157) for workers exposed to chromate for ≥5 years. Among the painters, there were 41 deaths from lung cancer yielding a SMR of 111 (95% CI: 80–151). For those who worked as a process operator or plater the SMR for lung cancer was 103 based upon 38 deaths (95% CI: 73–141).

OSHA believes the Alexander (Ex. 31–16–3) and the Boice *et al.* (Ex. 31–16–4) studies have several limitations. The Alexander cohort has few lung cancers (due in part to the young age of the population) and lacks smoking data. The authors note that these factors ''[limit] the overall power of the study and the stability of the risk estimates, especially in exposure-related subanalyses'' (Ex. 31–16–3, p. 1256). Another limitation of the study is the 26.3% of cohort members lost to follow-up. Boice *et al.* is a large study of workers in the aircraft manufacturing industry, but was limited by a lack of Cr(VI) exposure measurement during the 1960s and most of the 1970s. I was also limited by a substantial healthy worker survivor effect that may have masked evidence of excess lung cancer mortality in Cr(VI) exposed workers (Ex. 31–16–4). These studies are discussed further in section VI, including section VI.B.6 (Alexander cohort) and section VI.G.4.a (Alexander and Boice cohorts).

Dalager *et al.* conducted a proportionate mortality study of 977 white male spray painters potentially exposed to zinc chromate in the aircraft maintenance industry who worked at least three months and terminated employment within ten years prior to July 31, 1959 (Ex. 7–64). Follow-up was through 1977. The expected numbers of deaths were obtained by applying the cause-specific proportionate mortality of U.S. white males to the total numbers of deaths in the study group by five year age groups and five year time intervals. Two hundred and two deaths were observed. There were 21 deaths from cancer of the respiratory system (PMR=184), which was statistically significant. The Proportionate Cancer Mortality Ratio for cancer of the respiratory system was not statistically significant (PCMR= 146). Duration of employment as a painter with the military as indicated on the service record was used as an estimate of exposure to zinc chromate pigments, which were used as a metal primer. The PMRs increased as duration of employment increased (<5 years, O=9, E=6.4, PMR=141; 5–9 years, O=6, E=3, PMR=200; and 10+ years, O=6, E=2, PMR=300) and were statistically significant for those who worked 10 or more years.

Bertazzi *et al.* studied the mortality experience of 427 workers employed for a minimum of six months between 1946 and 1977 in a plant manufacturing paint and coatings (Ex. 7–65). According to the author, chromate pigments represented the ''major exposure'' in the plant. The mortality follow-up period was 1954–1978. There were eight deaths from lung cancer resulting in a SMR of 227 on the local standard (95% CI: 156–633) and a SMR of 334 on the national standard (95% CI: 106–434). The authors were unable to differentiate between exposures to different paints and coatings. In addition, asbestos was used in the plant and may be a potential confounding exposure.

Morgan conducted a cohort study of 16,243 men employed after January 1, 1946 for at least one year in the manufacture of paint or varnish (Ex. 8–4). Analysis was also conducted for seven subcohorts, one of which was for work with pigments. Expectations were calculated based upon the mortality experience of U.S. white males. The SMR for cancer of the trachea, bronchus and lung was below unity based upon 150 deaths. For the pigment subcohort, the SMR for cancer of the trachea, bronchus and lung was 117 based upon 43 deaths. In a follow-up study of the subcohorts, case-control analyses were conducted for several causes of death including lung cancer (Ex. 286). The details of matching were not provided. The authors state that no significant excesses of lung cancer risk by job were found. No odds ratios were presented.

Pippard *et al.* conducted a cohort mortality study of 833 British male tannery workers employed in 1939 and followed through December 31, 1982 (Ex. 278). Five hundred and seventy three men worked in tanneries making vegetable tanned leathers and 260 men worked in tanneries that made chrome tanned leathers. The expected number of deaths was calculated using the mortality rates of England and Wales as a whole. The lung cancer SMR for the vegetable tanned leather workers was in deficit (O=31; E=32.6; 95% CI: 65–135), while the lung cancer SMR for the chrome tanned leather workers was slightly elevated but not statistically significant (O=13; E=12; SMR=108; 95% CI: 58–185).

In a different study of two U.S. tanneries, Stern *et al.* investigated mortality in a cohort of all production workers employed from January 1, 1940 to June 11, 1979 at tannery A (N=2,807) and from January 1, 1940 to May 1, 1980 at tannery B (N=6,558) (Ex. 7–68). Vital status was followed through December 31, 1982. There were 1,582 deaths among workers from the two tanneries. Analyses were conducted employing both U.S. mortality rates and the mortality rates for the state in which the plant is located. There were 18 lung/pleura cancer deaths at tannery A and 42 lung/pleura cancer deaths at tannery B. The lung cancer/pleura SMRs were in deficit on both the national standard and the state standard for both tanneries. The authors noted that since the 1940s most chrome tanneries have switched to the one-bath tanning method in which Cr(VI) is reduced to Cr(III).

Blot *et al.* reported the results of a cohort study of 51,899 male workers of the Pacific Gas & Electric Company alive in January 1971 and employed for at least six months before the end of 1986 (Ex. 239). A subset of the workers were involved in gas generator plant operations where Cr(VI) compounds were used in open and closed systems from the 1950s to early 1980s. One percent of the workers (513 men) had worked in gas generator jobs, with 372 identified from post-1971 listing at the company's three gas generator plants and 141 from gas generator job codes. Six percent of the cohort members (3,283) had trained at one of the gas generator plants (Kettleman).

SMRs based on national and California rates were computed. Results in the paper are based on the California rates, since the overall results reportedly did not differ substantially from those using the national rates. SMRs were calculated for the entire cohort and for subsets defined by potential for gas generator plant exposure. No significant cancer excesses were observed and all but one cancer SMR was in deficit. There were eight lung cancer deaths in the gas generator workers (SMR=81; 95% CI: 0.35–1.60) and three lung cancer deaths among the Kettleman trainees (SMR=57; 95% CI: 0.12–1.67). There were no deaths from nasal cancer among either the gas generator workers or the Kettleman trainees. The risk of lung cancer did not increase with length of employment or time since hire.

Rafnsson and Johannesdottir conducted a study of 450 licensed masons (cement finishers) in Iceland born between 1905 and 1945, followed from 1951 through 1982 (Ex. 7–73). Stonecutters were excluded. Expectations were based on the male population of Iceland. The SMR for lung cancer was 314 and is statistically significant based upon nine deaths (E=2.87; 95% CI: 1.43–5.95). When a 20 year latency was factored into the analysis, the lung cancer SMR remained statistically significant (O=8; E=2.19; SMR=365; 95% CI: 1.58–7.20).

Svensson *et al.* conducted a cohort mortality study of 1,164 male grinding stainless steel workers employed for three months or more during the period 1927–1981 (Ex.266). Workers at the facility were reportedly exposed to chromium and nickel in the stainless steel grinding process. Records provided by the company were used to assign each worker to one of three occupational categories: those considered to have high exposure to chromium, nickel as well as total dust, those with intermediate exposure, and those with low exposure. Mortality rates for males in Blekinge County, Sweden were used as the reference population. Vital status follow-up was through December 31, 1983. A total of 194 deaths were observed (SMR=91). No increased risk of lung cancer was observed (SMR=92). The SMR for colon/rectum cancer was 2.47, but was not statistically significant.

Cornell and Landis studied the mortality experience of 851 men who worked in 26 U.S. nickel/chromium alloy foundries between 1968 and 1979 (Ex. 7–66). Standardized Proportionate Mortality Ratio (SPMR) analyses were done using both an internal comparison group (foundry workers not exposed to nickel/chromium) and the mortality experience of U.S. males. The SPMR for lung cancer was 105 (O=60; E=56.9). No nasal cancer deaths were observed.

Brinton *et al.* conducted a case-control study of 160 patients diagnosed with primary malignancies of the nasal cavity and sinuses at one of four hospitals in North Carolina and Virginia between January 1, 1970 and December 31, 1980 (Ex. 8–8). For each case determined to be alive at the time of interview, two hospital controls were selected matched on vital status, hospital, year of admission (±2 years), age (±5 years), race and state economic area or county or usual residence. Excluded from control selection were malignant neoplasms of the buccal cavity and pharynx, esophagus, nasal cavity, middle ear and accessory sinuses, larynx, and secondary neoplasms. Also excluded were benign neoplasms of the respiratory system, mental disorders, acute sinusitis, chronic pharyngitis and nasopharyngitis, chronic sinusitis, deflected nasal septum or nasal polyps. For those cases who were deceased at the time of interview, two different controls were selected. One control series consisted of hospital controls as described previously. The second series consisted of decedents identified through state vital statistics offices matched for age (±5 years), sex, race, county of usual residence and year of death. A total of 193 cases were identified and 160 case interviews completed. For those exposed to chromates, the relative risk was not significantly elevated (OR=5.1) based upon five cases. According to the authors, chromate exposure was due to the use of chromate products in the building industry and in painting, rather than the manufacture of chromates.

Hernberg *et al.* reported the results of a case-control study of 167 living cases of nasal or paranasal sinus cancer diagnosed in Denmark, Finland and Sweden between July 1, 1977 and December 31, 1980 (Exs. 8–7; 7–71). Controls were living patients diagnosed with malignant tumors of the colon and rectum matched for country, gender and age at diagnosis (±3 years) with the cases. Both cases and controls were interviewed by telephone to obtain occupational histories. Patients with work-related exposures during the ten years prior to their illness were excluded. Sixteen cases reported exposure to chromium, primarily in the "stainless steel welding" and "nickel" categories, versus six controls (OR=2.7l; 95% CI: 1.1–6.6).

7. Evidence From Experimental Animal Studies

Most of the key animal cancer bioassays for chromium compounds were conducted before 1988. These studies have been critically reviewed by the IARC in the Monograph Chromium, Nickel, and Welding (Ex. 35–43). OSHA reviewed the key animal cancer bioassays in the NPRM (69 FR at 59341–59347) and requested any additional data in experimental animals that were considered important to evaluating the carcinogenicity of Cr(VI). The discussion below describes these studies along with any new study information received during the public hearing and comment periods.

In the experimental studies, Cr(VI) compounds were administered by various routes including inhalation, intratracheal instillation, intrabronchial implantation, and intrapleural injection, as well as intramuscular and subcutaneous injection. For assessing human health effects from occupational exposure, the most relevant route is inhalation. However, as a whole, there were very few inhalation studies. In addition to inhalation studies, OSHA is also relying on intrabronchial implantation and intratracheal instillation studies for hazard identification because these studies examine effects directly administered to the respiratory tract, the primary target organ of concern, and they give insight into the relative potency of different Cr(VI) compounds. In comparison to studies examining inhalation, intrabronchial implantation, and intratracheal instillation, studies using subcutaneous injection and intramuscular administration of Cr(VI) compounds were of lesser significance but were still considered for hazard identification.

In its evaluation, OSHA took into consideration the exposure regimen and experimental conditions under which the experiments were performed, including the exposure level and duration; route of administration; number, species, strain, gender, and age of the experimental animals; the inclusion of appropriate control groups; and consistency in test results. Some studies were not included if they did not contribute to the weight of evidence, lacked adequate documentation, were of poor quality, or were less relevant to occupational exposure conditions (*e.g.*, some intramuscular injection studies).

The summarized animal studies are organized by Cr(VI) compound in order of water solubility as defined in section IV on Chemical Properties (*i.e.*, Cr(VI) compounds that are highly soluble in water; Cr(VI) compounds that are slightly soluble in water, and Cr(VI) compounds that insoluble in water). Solubility is an important factor in determining the carcinogenicity of Cr(VI) compounds (Ex. 35–47).

a. Highly Water Soluble Cr(VI) Compounds

Multiple animal carcinogenicity studies have been conducted on highly water soluble sodium dichromate and chromic acid. The key studies are summarized in Table V–7.

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TABLE V-7: SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM

Highly Water Soluble Chromates

Compound	Route	Sex/Species/ Strain (# in exposed groups)	Dose Administered[1] and Observation Periods	Tumor Incidence	Reference/Exhibit #
Chromic acid (Chromium trioxide)	Inhalation	Female ICR mice (50 per exposed group)	3.6 mg Cr(VI)/m^3 for 30 min per day, 2 d/wk up to 12 mo. Histopatholoical evaluation at periods up to 18 mo	-Lung tumors: 7/48 vs 2/20 for control -5 benign adenomas and 2 adenocarcinomas	Adachi et al. (1986, Ex. 35-26-1)
	Inhalation	Female C57BL mice (23 examined at 12 mo; 20 examined at 18 mo)	1.8 mg Cr(VI)/m^3 for 120 min 2 x week for 12 months Histopatholoical evaluation at 12 and 18 mo	Nasal papilloma: 6/20 ($p<0.05$) at 18 mo; Lung adenoma: 1/20 (NS) at 18 mo	Adachi (1987, Ex. 35-219)
	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group)	1.0 mg Cr(VI) as single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined) : 2/100 (N.S.)	Levy et al. (1986, Ex. 11-2)
Sodium dichromate	Inhalation	Male Wistar rats (20 per exposed group)	0.025, 0.050 and 0.10 mg Cr(VI)/m^3 22-23 hr/day, 7 d/wk for 18 months; evaluated at up to30 months	Lung tumors: 0.025 mg/m^3- 0/18; 0.05 mg/m^3- 0/18; 0.1 mg/m^3 -3/19 (NS)	Glaser et al. (1986, Ex. 10-11)
	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group)	0.8 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 1/100 (NS)	Levy et al. (1986, Ex. 11-2)
	Intratracheal	Male/female Sprague Dawley rats (40 per exposed group)	5 x weekly: 0.0034, 0.017, 0.086 mg Cr(VI)/kg bw for 30 mo 1x weekly: 0.017, 0.086, 0.43 mg Cr(VI)/kg bw for 30 mo	Lung tumors (M/F combined)- 5 x weekly: 0/80 in all groups 1 x weekly: 0.017 mg/kg -0/80; 0.086 mg/kg-1/80; 0.43 mg/kg-14/80 ($p<0.01$)	Steinhoff et al. (1986, Ex. 11-7)

[1] doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible

Not Statistically Significant – NS

Male/Female – M/F

BILLING CODE 4510–26–C

Chromic acid (Chromium trioxide). In a study by Adachi *et al.*, ICR/JcI mice were exposed by inhalation to 3.63 mg/m^3 for 30 minutes per day, two days per week for up to 12 months (Ex. 35–26–1). The mice were observed for an additional six months. The authors used a miniaturized chromium electroplating system to generate chromic acid for the study. The authors found there were elevations in lung adenomas at 10–14 months (3/14 vs. 0/10) and lung adenocarcinomas at 15–18 months (2/19 vs. 0/10), but the results were not statistically significant. The small number of animals (*e.g.* 10–20 per group) used in this study limited its power to detect all but a relatively high tumor incidence (*e.g.* >20%) with statistical precision. Statistically significant increases in nasal papillomas were observed in another study by Adachi *et al.*, in which C57B1 mice were exposed by inhalation to 1.81 mg/m^3 chromic acid for 120 min per day, two days per week for up to 12 months (Ex. 35–26). At 18 months, the tumor incidence was 6/20 in exposed animals vs. 0/20 in the control animals ($p<0.05$).

In separate but similar studies, Levy *et al.* and Levy and Venitt, using similar exposure protocol, conducted bronchial implantation experiments in which 100 male and female Porton-Wistar rats were dosed with single intrabronchial implantations of 2 mg chromic acid (1.04 mg Cr(VI)) mixed 50:50 with cholesterol in stainless steel mesh pellets (Exs. 11–2; 11–12). The authors found no statistically significant increases in lung tumors, although Levy *et al.* found a bronchial carcinoma incidence of 2/100 in exposed rats compared with 0/100 in control rats. Levy and Venitt found a bronchial carcinoma incidence of 1/100 accompanied by a statistically significant increase in squamous metaplasia, a lesion believed capable of progressing to carcinoma. There was no statistically significant increase in the incidence of squamous metaplasia in control rats or rats treated with Cr(III) compounds in the same study. This finding suggests that squamous metaplasia is specific to Cr(VI) and is not evoked by a non-specific stimuli, the implantation procedure itself, or treatment with Cr(III) containing materials.

Similar to Levy *et al.* and Levy and Venitt studies, Laskin *et al.* gave a single intrabronchial implantation of 3–5 mg chromic acid mixed 50:50 with cholesterol in stainless steel mesh pellets to 100 male and female Porton-Wistar rats (Ex. 10–1). The rats were observed for 2 years. No tumors were identified in the treated or control animals (0/100 vs. 0/24).

Sodium dichromate. Glaser *et al.* exposed male Wistar rats to aerosolized sodium dichromate by inhalation for 22–23 hours per day, seven days per week for 18 months (Exs. 10–10; 10–11). The rats were held for an additional 12 months at which point the study was terminated. Lung tumor incidences among groups exposed to 25, 50, and 100 μg Cr(VI)/m^3 were 0/18, 0/18, and 3/19, respectively, vs. 0/37 for the control animals. Histopathology revealed one adenocarcinoma and two adenomas in the highest group. The slightly elevated tumor incidence at the highest dose was not statistically significant. A small number of animals (20 per group) were used in this study limiting its power to detect all but a relatively high tumor incidence (*e.g.* >20%) with statistical precision. In addition, the administered doses used in this study were fairly low, such that the maximum tolerated dose (*i.e.*, the maximum dose level that does not lead to moderate reduction in body weight gain) may not have been achieved. Together, these factors limit the interpretation of the study.

In an analysis prepared by Exponent and submitted by the Chrome Coalition, Exponent stated that ''inhalation studies of Glaser *et al.* support a position that exposures to soluble Cr(VI) at concentrations at least as high as the current PEL (*i.e.*, 52 μg/m^3) do not cause lung cancer'' (Ex. 31–18–1, page 2). However, it should be noted that the Glaser *et al.* studies found that 15% ($^3/_{19}$) of the rats exposed to an air concentration just above the current PEL developed lung tumors, and that the elevated tumor incidence was not statistically significant in the highest dose group because the study used a small number of animals. OSHA believes the Glaser study lacks the statistical power to state with sufficient confidence that Cr(VI) exposure does not cause lung cancer at the current PEL, especially when given the elevated incidence of lung tumors at the next highest dose level.

Steinhoff *et al.* studied the carcinogenicity of sodium dichromate in Sprague-Dawley rats (Ex. 11–7). Forty male and 40 female Sprague-Dawley rats were divided into two sets of treatment groups. In the first set, doses of 0.01, 0.05 or 0.25 mg/kg body weight in 0.9% saline were instilled intratracheally five times per week. In the second set of treatment groups, 0.05, 0.25 or 1.25 mg/kg body weight in 0.9% saline doses were instilled intratracheally once per week. Duration of exposure in both treatment groups was 30 months. The total cumulative dose for the lowest treatment group of animals treated once per week was the same as the lowest treatment group treated five times per week. Similarly, the medium and high dose groups treated once per week had total doses equivalent to the medium and high dose animals treated five times per week, respectively. No increased incidence of lung tumors was observed in the animals dosed five times weekly. However, in the animals dosed once per week, tumor incidences were 0/80 in control animals, 0/80 in the 0.05 mg/kg exposure group, 1/80 in the 0.25 mg/kg exposure group and 14/80 in the 1.25 mg/kg exposure group ($p <0.01$). The tumors were malignant in 12 of the 14 animals in the 1.25 mg/kg exposure group. Tracheal instillation at the highest dose level (*i.e.* 1.25 mg/kg) caused emphysematous lesions and pulmonary fibrosis in the lungs of Cr(VI)-treated rats. A similar degree of lung damage did not occur at the lower dose levels. Exponent commented that the Steinhoff and Glaser results are evidence that the risk of lung cancer from occupational exposure does not exist below a threshold Cr(VI) air concentration of approximately 20 μg/m^3 (Ex. 38–233–4). This comment is addressed in Section VI.G.2.c.

In separate but similar studies, Levy *et al.* and Levy and Venitt implanted stainless steel mesh pellets filled with a single dose of 2 mg sodium dichromate (0.80 mg Cr(VI)) mixed 50:50 with cholesterol in the bronchi of male and female Porton-Wistar rats (Exs. 11–2; 11–12). Control groups (males and females) received blank pellets or pellets loaded with cholesterol. The rats were observed for two years. Levy *et al.* and Levy and Venitt reported a bronchial tumor incidence of 1/100 and 0/89, respectively, for exposed rats. However, the latter study reported a statistically significant increase in squamous metaplasia, a lesion believed capable of progressing to carcinoma, among exposed rats when compared to unexposed rats. There were no bronchial tumors or squamous metaplasia in any of the control animals and no significant increases in lung tumors were observed in the two studies.

b. Slightly Water Soluble Cr(VI) Compounds

Animal carcinogenicity studies have been conducted on slightly water soluble calcium chromate, strontium chromate, and zinc chromates. The key studies are summarized in Table V–8.

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TABLE V-8: SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM

Slightly Water Soluble Chromates

Compound	**Route**	**Sex/Species/ Strain (# in exposed groups)**	**Dose Administered[1] and Observation Periods**	**Tumor Incidence**	**Reference/Exhibit #**
Calcium chromate	Inhalation	Male/female C57BL/6 mice (136 per group)	4.3 mg Cr(VI)/m^3, 5 hr/d, 5d/wk over animal lifetime	Lung adenoma (M/F combined): 14/272 vs 5/272 for controls	Nettesheim et al. (1971, Ex. 10-8)
	Intrabronchial	Male/female Porton-Wistar rats (100 per group)	0.67 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 25/100 ($p<0.01$)	Levy et al. (1986, Ex. 11-2)
	Intratracheal	Male/female Sprague Dawley rats (40 per group)	5 x weekly: 0.083 mg Cr(VI)/kg bw for 30 mo 1 x weekly: 0.41.mg Cr(VI)/kg bw for 30 mo	Lung tumors (M/F combined)– 5 x weekly: 0.083 mg/kg- 6/80 ($p<0.01$) 1 x weekly: 0.41 mg/kg-13/80 ($p<0.01$)	Steinhoff et al. (1986, Ex. 11-7)
	Intratracheal	Male Sprague Dawley rats (50 per exposed group)	0.67 mg Cr(VI)/kg bw x 13 installations over 20 wks and evaluated at 2 to 2.5 yr	Lung tumors: 1/44 (NS)	Snyder et al. (1997, Ex. 31-18-12)
Strontium chromates (two different compounds)	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group)	0.48 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 43/99 & 62/99 ($p<0.01$)	Levy et al. (1986, Ex. 11-2)
Zinc chromates (three different compounds)	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group)	0.42 to 0.52 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 3/61 ($p<0.05$), 5/100 ($p<0.05$), 3/100 ($p=0.07$)	Levy et al. (1986, Ex. 11-2) Levy and Venitt (1986, Ex. 11-12)
Zinc tetroxychromate	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group)	0.18 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 1/100 (NS)	Levy et al. (1986, Ex. 11-2)

[1] doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible

Not Statistically significant – NS

Male/Female – M/F

BILLING CODE 4510–26–C

Calcium chromate. Nettesheim *et al.* conducted the only available inhalation carcinogenicity study with calcium chromate showing borderline statistical significance for increased lung adenomas in C57B1/6 mice exposed to 13 mg/m^3 for 5 hours per day, 5 days per week over the life of the mice. The tumor incidences were 6/136 in exposed male mice vs. 3/136 in control male mice and 8/136 in exposed female mice vs. 2/136 in control female mice (Ex. 10–8).

Steinhoff *et al.* observed a statistically significant increase in lung tumors in Sprague-Dawley rats exposed by intratracheal instillation to 0.25 mg/kg body weight calcium chromate in 0.9% saline five times weekly for 30 months (Ex. 11–7). Tumors were found in 6/80 exposed animals vs. 0/80 in unexposed controls ($p<0.01$). Increased incidence of lung tumors was also observed in those rats exposed to 1.25 mg/kg calcium chromate once per week (14/80 vs. 0/80 in controls) for 30 months. At the highest dose, the authors observed 11 adenomas, one adenocarcinoma, and two squamous carcinomas. The total administered doses for both groups of dosed animals (1 × 1.25 mg/kg and 5 × 0.25 mg/kg) were equal, but the tumor incidence in the rats exposed once per week was approximately double the incidence in rats exposed to the same weekly dose divided into five smaller doses. The authors suggested that the dose-rate for calcium chromate compounds may be important in determining carcinogenic potency and that limiting higher single exposures may offer greater protection against carcinogenicity than reducing the average exposure alone.

Snyder *et al.* administered Cr(VI)-contaminated soil of defined aerodynamic diameter (2.9 to 3.64 micron) intratracheally to male Sprague-Dawley rats (Ex. 31–18–12). For the first six weeks of treatment, the rats were instilled with weekly suspensions of 1.25 mg of material per kg body weight, followed by 2.5 mg/kg every other week, until treatments were terminated after 44 weeks. The investigation included four exposure groups: control animals (50 rats), rats administered Cr(VI)-contaminated soil (50 rats), rats administered Cr(VI)-contaminated soil supplemented with calcium chromate (100 rats), and rats administered calcium chromate alone (100 rats). The total Cr(VI) dose for each group was: control group (0.000002 mg Cr(VI)/kg), soil alone group (0.324 mg Cr(VI)/kg), soil plus calcium chromate group (7.97 mg Cr(VI)/kg), and calcium chromate alone group (8.70 mg Cr(VI)/kg). No primary tumors were observed in the control group or the chromium contaminated soil group. Four primary tumors of the lung were found in the soil plus calcium chromate group and one primary lung tumor was observed in the group treated with calcium chromate alone; however, these incidences did not reach statistical significance.

Statistically significant increases in the incidence of bronchial carcinoma in rats exposed to calcium chromate through intrabronchial instillation were reported by Levy *et al.* (Ex. 11–2) and Levy and Venitt (Ex. 11–12). These studies, using a similar protocol, implanted a single dose of 2 mg calcium chromate (0.67 mg Cr(VI)) mixed 50:50 with cholesterol in stainless steel pellets into the bronchi of Porton-Wistar rats. Levy *et al.* and Levy and Venitt found bronchial carcinoma incidences of 25/100 and 8/84, respectively, following a 24-month observation. The increased incidences were statistically significant when compared to the control group. Levy and Venitt also reported statistically significant increases in squamous metaplasia in the calcium chromate-treated rats (Ex. 11–12).

Laskin *et al.* observed 8/100 tumors in rats exposed to a single dose of 3–5 mg calcium chromate mixed with cholesterol in stainless steel mesh pellets implanted in the bronchi (Ex. 10–1). Animals were observed for a total of 136 weeks. The sex, strain, and species of the rats were not specified in the study. Tumor incidence in control animals was 0/24. Although tumor incidence did not reach statistical significance in this study, OSHA agrees with the IARC evaluation that the incidences are due to calcium chromate itself rather than background variation.

Strontium chromate. Strontium chromate was tested by intrabronchial implantation and intrapleural injection. In a study by Levy *et al.*, two strontium chromate compounds mixed 50:50 with cholesterol in stainless steel mesh pellets were administered by intrabronchial instillation of a 2 mg (0.48 mg Cr(VI)) dose into 100 male and female Porton-Wistar rats (Ex. 11–2). Animals were observed for up to 136 weeks. The strontium chromate compounds induced bronchial carcinomas in 43/99 (Sr, 42.2%; CrO_4, 54.1%) and 62/99 rats (Sr, 43.0%; Cr, 24.3%)], respectively, compared to 0/100 in the control group. These results were statistically significant. The strontium chromates produced the strongest carcinogenic response out of the 20 Cr(VI) compounds tested by the intrabronchial implantation protocol. Boeing Corporation commented that the intrabronchial implantation results with strontium chromate should not be relied upon in an evaluation of carcinogenicity and that the data is inconsistent with other Cr(VI) studies (Ex. 38–106–2, p. 26). This comment is discussed in the Carcinogenic Effects Conclusion Section V.B.9 dealing with the carcinogenicity of slightly soluble Cr(VI) compounds.

In the study by Hueper, strontium chromate was administered by intrapleural injection (doses unspecified) lasting 27 months (Ex. 10–4). Local tumors were observed in 17/28 treated rats vs. 0/34 for the untreated rats. Although the authors did not examine the statistical significance of tumors, the results clearly indicate a statistical significance.

Zinc chromate compounds. Animal studies have been conducted to examine several zinc chromates of varying water solubilities and composition. In separate, but similarly conducted studies, Levy *et al.* and Levy and Venitt studied two zinc chromate powders, zinc potassium chromate, and zinc tetroxychromate (Exs. 11–2; 11–12). Two milligrams of the compounds were administered by intrabronchial implantation to 100 male and female Porton-Wistar rats. Zinc potassium chromate (0.52 mg Cr(VI)) produced a bronchial tumor incidence of 3/61 which was statistically significant ($p<0.05$) when compared to a control group (Ex. 11–12). There was also an increased incidence of bronchial tumors (5/100, $p=0.04$; 3/100, $p=0.068$) in rats receiving the zinc chromate powders (0.44 mg Cr(VI)). Zinc tetroxychromate (0.18 mg Cr(VI)) did not produce a statistically significant increase in tumor incidence (1/100) when compared to a control group. These studies show that most slightly water soluble zinc chromate compounds elevated incidences of tumors in rats.

Basic potassium zinc chromate was administered to mice, guinea pigs and rabbits via intratracheal instillation (Ex. 35–46). Sixty-two Strain A mice were given six injections of 0.03 ml of a 0.2% saline suspension of the zinc chromate at six week intervals and observed until death. A statistically significant increase in tumor incidence was observed in exposed animals when compared to controls (31/62 vs. 7/18). Statistically significant effects were not observed among guinea pigs or rabbits. Twenty-one guinea pigs (sex and strain not given) received six injections of 0.3 ml of a 1% suspension of zinc chromate at three monthly intervals and observed until death. Results showed pulmonary adenomas in only 1/21 exposed animals vs. 0/18 in controls. Seven rabbits (sex and strain not given) showed no increase in lung tumors when given 3–5 injections of 1 ml of a saline suspension of 10 mg zinc chromate at 3-month intervals. However, as noted by IARC, the small numbers of animals used in the guinea pig and rabbit experiments (as few as 13 guinea pigs and 7 rabbits per group) limit the power of the study to detect increases in cancer incidence.

Hueper found that intrapleural injection of slightly water soluble zinc yellow (doses were unspecified) resulted in statistically significant increases in local tumors in rats (sex, strain, and age of rat unspecified; dose was unspecified). The incidence of tumors in exposed rats was 22/33 vs. 0/34 in controls (Ex. 10–4).

Maltoni *et al.* observed increases in the incidence of local tumors after subcutaneous injection of slightly water soluble zinc yellow in 20 male and 20 female Sprague-Dawley rats (statistical significance was not evaluated) (Ex. 8–37). Tumor incidences were 6/40 in 20% CrO_3 dosed animals at 110 weeks and 17/40 in 40% CrO_3 dosed animals at 137 weeks compared to 0/40 in control animals.

c. Water Insoluble Cr(VI) Compounds

There have been a number of animal carcinogenicity studies involving implantation or injection of principally water insoluble zinc, lead, and barium chromates. The key studies are summarized in Table V–9.

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TABLE V-9: SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM

Water Insoluble Chromates

Compound	**Route**	**Sex/Species/ Strain (# in exposed groups)**	**Dose Administered[1] and Observation Periods**	**Tumor Incidence**	**Reference/Exhibit #**
Lead chromates (seven different compounds)	Intrabronchial	Male/female Porton- Wistar rats (50 per exposed group)	0.25 to 0.32 mg Cr(VI) as single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 0-1/100 (N.S.)	Levy et al. (1986, Ex. 11-2)
Lead chromates (three different compounds)	Subcutaneous	Male/female Sprague Dawley rats (20 per exposed group)	1.5 to 4.8 mg Cr(VI) as a single dose in water and evaluated after 2 years	Sarcomas at injection site (M/F combined): 26-36/40 vs 0/40 for controls	Maltoni et al. (1974, Ex. 8-25) Maltoni (1976, Ex. 5-2)
Lead chromate	Intramuscular	Male/female Fischer 344 rats (25 per exposed group)	1.29 mg Cr(VI) in trioctyanoin 1 x mo for 9 mo and evaluated at up to 2 yr	Sarcomas at injection site (M/F combined): 31/47 vs 0/44 for controls	Furst et al. (1976, Ex. 10-2)
		Female NIH-Swiss mice (25 per exposed group)	0.72 mg Cr(VI) in trioctyanoin 1 x mo for 4 mo and evaluated at up to 2 yr	Sarcomas at injection site: 0/22 (NS)	
Barium chromate	Intrabronchial	Male/female Porton- Wistar rats (50 per exposed group)	0.37 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years	Bronchial carcinoma (M/F combined): 0/100 (NS)	Levy et al. (1986, Ex. 11-2)

[1] doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible

Not Statistically significant – NS

Male/Female – M/F

BILLING CODE 4510–26–C

Lead chromate and lead chromate pigments. Levy et al. examined the carcinogenicity of lead chromate and several lead chromate-derived pigments in 100 male and female Porton-Wistar rats after a single intrabronchial implantation followed by a two year observation period (Ex. 11–12). The rats were dosed with two mg of a lead chromate compound and lead chromate pigments, which were mixed 50:50 with cholesterol in stainless steel mesh pellets and implanted in the bronchi of experimental animals. The lead chromate and lead chromate pigment compositions consisted of the following: lead chromate (35.8% CrO_4; 0.32 mg Cr(VI)), primrose chrome yellow (12.6% Cr; 0.25 mg Cr(VI)), molybdate chrome orange (12.9% Cr; 0.26 mg Cr(VI)), light chrome yellow (12.5% Cr; 0.25 mg Cr(VI)), supra LD chrome yellow (26.9% CrO_3; 0.28 mg Cr(VI)), medium chrome yellow (16.3% Cr; 0.33 mg Cr(VI)) and silica encapsulated medium chrome yellow (10.5% Cr; 0.21 mg Cr(VI)). No statistically significant tumors were observed in the lead chromate group compared to controls (1/98 vs. 0/100), primrose chrome yellow group (1/100 vs. 0/100), and supra LD chrome yellow group (1/100 vs. 0/100). The authors also noted no tumors in the molybdate chrome orange group, light chrome yellow group, and silica encapsulated medium chrome yellow group.

Maltoni (Ex. 8–25), Maltoni (Ex. 5–2), and Maltoni *et al.* (Ex. 8–37) examined the carcinogenicity of lead chromate, basic lead chromate (chromium orange) and molybdenum orange in 20 male and 20 female Sprague-Dawley rats by a single subcutaneous administration of the lead chromate compound in water. Animals were observed for 117 to 150 weeks. After injection of 30 mg lead chromate, local injection site sarcomas were observed in 26/40 exposed animals vs. 0/60 and 1/80 in controls. Although the authors did not examine the statistical significance of sarcomas, the results clearly indicate a statistical significance. Animals injected with 30 mg basic lead chromate (chromium orange) were found to have an increased incidence of local injection site sarcomas (27/40 vs. 0/60 and 1/80 in controls). Animals receiving 30 mg molybdenum orange in 1 ml saline were also found to have an increased incidence of local injection site sarcomas (36/40 vs. 0/60 controls).

Carcinogenesis was observed after intramuscular injection in a study by Furst *et al.* (Ex. 10–2). Fifty male and female Fischer 344 rats were given intramuscular injections of 8 mg lead chromate in trioctanoin every month for nine months and observed up to 24 months. An increase in local tumors at the injection site (fibrosarcomas and rhabdomyosarcomas) was observed (31/47 in treated animals vs. 0/22 in controls). These rats also had an increased incidence of renal carcinomas (3/23 vs. 0/22 in controls), but IARC noted that the renal tumors may be related to the lead content of the compound. In the same study, 3 mg lead chromate was administered to 25 female NISH Swiss weanling mice via intramuscular injection every 4 months for up to 24 months. In the exposed group, the authors observed three lung alveologenic carcinomas after 24 months of observation and two lymphomas after 16 months of observation. Two control groups were used: an untreated control group (22 rats) and a vehicle injected control group (22 rats). The authors noted that one alveologenic carcinoma and one lymphoma were observed in each control group. The Color Pigment Manufacturers Association (CPMA) commented that the lack of elevated tumor incidence in the intrabronchial implantation studies confirmed that lead chromate was not carcinogenic and that the positive injection studies by the subcutaneous, intrapleural, and intramuscular routes were of questionable relevance (Ex. 38–205, p. 93). This comment is further discussed in the Carcinogenic Effects Conclusion Section V.B.9 dealing with the carcinogenicity of lead chromate.

Barium chromate. Barium chromate was tested in rats via intrabronchial, intrapleural and intramuscular administration. No excess lung or local tumors were observed (Ex. 11–2; Ex. 10–4; Ex. 10–6).

d. Summary. Several Cr(VI) compounds produced tumors in laboratory animals under a variety of experimental conditions using different routes of administration. The animals were generally given the test material(s) by routes other than inhalation (*e.g.*, intratracheal administration, intramuscular injection, intrabronchial implantation, and subcutaneous injection). Although the route of administration may have differed from that found in an occupational setting, these studies have value in the identification of potential health hazards associated with Cr(VI) and in assessing the relative potencies of various Cr(VI) compounds.

OSHA believes that the results from Adachi *et al.* (Ex. 35–26–1), Adachi *et al.* (Ex. 35–26), Glaser *et al.* (Ex. 10–4), Glaser *et al.* (Ex. 10–10), Levy *et al.* (Ex. 11–2), and Steinhoff *et al.* (Ex. 11–7) studies provide valuable insight on the carcinogenic potency of Cr(VI) compounds in laboratory animals. Total dose administered, dose rate, amount of dosage, dose per administration, number of times administered, exposure duration and the type of Cr(VI) compound are major influences on the observed tumor incidence in animals. It was found that slightly water soluble calcium, strontium, and zinc chromates showed the highest incidence of lung tumors, as indicated in the results of the Steinhoff and Levy studies, even when compared to similar doses of the more water soluble sodium chromates and chromic acid compounds. The highly insoluble lead chromates did not produce lung tumors by the intrabronchial implantation procedure but did produce tumors by subcutaneous injection and intramuscular injection.

8. Mechanistic Considerations

Mechanistic information can provide insight into the biologically active form(s) of chromium, its interaction with critical molecular targets, and the resulting cellular responses that trigger neoplastic transformation. There has been considerable scientific study in recent years of Cr(VI)-initiated cellular and molecular events believed to impact development of respiratory carcinogenesis. Much of the research has been generated using *in vitro* techniques, cell culture systems, and animal administrations. The early mechanistic data were reviewed by IARC in 1990 (Ex. 35–43). Recent experimental research has identified several biological steps critical to the mode of action by which Cr(VI) transforms normal lung cells into a neoplastic phenotype. These are: (a) Cellular uptake of Cr(VI) and its extracellular reduction, (b) intracellular Cr(VI) reduction to produce biologically active products, (c) damage to DNA, and (d) activation of signaling pathways in response to cellular stress. Each step will be described in detail below.

a. Cellular Uptake and Extracellular Reduction. The ability of different Cr(VI) particulate forms to be taken up by the bronchoalveolar cells of the lung is an essential early step in the carcinogenic process. Particle size and solubility are key physical factors that influence uptake into these cells. Large particulates (>10 μm) are generally deposited in the upper nasopharygeal region of the respiratory tract and do not reach the bronchoalveolar region of the lungs. Smaller Cr(VI) particulates will increasingly reach these lower regions and come into contact with target cells.

Once deposited in the lower respiratory tract, solubility of Cr(VI) particulates becomes a major influence on disposition. Highly water soluble Cr(VI), such as sodium chromate and chromic acid, rapidly dissolves in the fluids lining the lung epithelia and can be taken up by lung cells via facilitated diffusion mediated by sulfate/phosphate anion transport channels (Ex. 35–148). This is because Cr(VI) exists in a tetrahedral configuration as a chromate oxyanion similar to the physiological anions, sulfate and phosphate (Ex. 35–

231). Using cultured human epithelial cells, Liu *et al.* showed that soluble Cr(VI) uptake was time- and dose-dependant over a range of 1 to 300 µm in the medium with 30 percent of the Cr(VI) transported into the cells within two hours and 67 percent at 16 hours at the lowest concentration (Ex. 31–22–18).

Water insoluble Cr(VI) particulates do not readily dissolve into epithelial lining fluids of the bronchoalveolar region. This has led to claims that insoluble chromates, such as lead chromate pigments, are not bioavailable and, therefore, are unable to cause carcinogenesis (Ex. 31–15). However, several scientific studies indicate that insoluble Cr(VI) particulates can come in close contact with the bronchoalveolar epithelial cell surface, allowing enhanced uptake into cells. Wise *et al.* showed that respirable lead chromate particles adhere to the surface of rodent cells in culture causing cell-enhanced dissolution of the chromate ion as well as phagocytosis of lead chromate particles (Exs. 35–68; 35–67). The intracellular accumulation was both time- and dose-dependant. Cellular uptake resulted in damage to DNA, apoptosis (*i.e.*, form of programmed cell death), and neoplastic transformation (Ex. 35–119). Singh *et al.* showed that treatment of normal human lung epithelial cells with insoluble lead chromate particulates (0.4 to 2.0 µg/cm^2) or soluble sodium chromate (10 µM) for 24 hours caused Cr(VI) uptake, Cr-DNA adduct formation, and apoptosis (Ex. 35–66). The proximate genotoxic agent in these cell systems was determined to be the chromate rather than the lead ions (Ex. 35–327). Elias *et al.* reported that cell-enhanced particle dissolution and uptake was also responsible for the cytotoxicity and neoplastic transformation in Syrian hamster embryo cells caused by Cr(VI) pigments, including several complex industrial chrome yellow and molybdate orange pigments (Ex. 125). These studies are key experimental evidence in the determination that water-insoluble Cr(VI) compounds, as well as water soluble Cr(VI) compounds, are to be regarded as carcinogenic agents. This determination is further discussed in the next section (see V.B.9).

Reduction to the poorly permeable Cr(III) in the epithelial lining fluid limits cellular uptake of Cr(VI). Ascorbic acid and glutathione (GSH) are believed to be the key molecules responsible for the extracellular reduction. Cantin *et al.* reported high levels of GSH in human alveolar epithelial lining fluid and Susuki *et al.* reported significant levels of ascorbic acid in rat lung lavage fluids (Exs. 35–147; 35–143). Susuki and Fukuda studied the kinetics of soluble Cr(VI) reduction with ascorbic acid and GSH *in vitro* and following intratracheal instillation (Ex. 35–90). They reported that the rate of reduction was proportional to Cr(VI) concentration with a half-life of just under one minute to several hours. They found the greatest reduction rates with higher levels of reductants. Ascorbic acid was more active than GSH. Cr(VI) reduction was slower *in vivo* than predicted from *in vitro* and principally involved ascorbic acid, not GSH. This research indicates that extracellular Cr(VI) reduction to Cr(III) is variable depending on the concentration and nature of the reductant in the epithelial fluid lining regions of the respiratory tract. De Flora *et al.* determined the amount of soluble Cr(VI) reduced *in vitro* by human bronchiolar alveolar fluid and pulmonary alveolar macrophage fractions over a short period and used these specific activities to estimate an ‘‘overall reducing capacity’’ of 0.9–1.8 mg Cr(VI) and 136 mg Cr(VI) per day per individual, respectively (Ex. 35–140).

De Flora, Jones, and others have interpreted the extracellular reduction data to mean that very high levels of Cr(VI) are required to ‘‘overwhelm’’ the reductive defense mechanism before target cell uptake can occur and, as such, impart a ‘‘threshold’’ character to the exposure-response (Exs. 35–139; 31–22–7). However, the threshold capacity concept does not consider that facilitated lung cell uptake and extracellular reduction are dynamic and parallel processes that happen concurrently. If their rates are comparable then some cellular uptake of Cr(VI) would be expected, even at levels that do not ‘‘overwhelm’’ the reductive capacity. Based on the *in vitro* kinetic data, it would appear that such situations are plausible, especially when concentrations of ascorbic acid are low. Unfortunately, there has been little systematic study of the dose-dependence of Cr(VI) uptake in the presence of physiological levels of ascorbate and GSH using experimental systems that possess active anion transport capability. The implications of extracellular reduction on the shape of Cr(VI) dose—lung cancer response curve is further discussed in Section VI.G.2.c.

Wise *et al.* did study uptake of a single concentration of insoluble lead chromate particles (0.8 µg/cm^2) and soluble sodium chromate (1.3 µM) in Chinese hamster ovary cells co-treated with a physiological concentration (1mM) of ascorbate (Ex. 35–68). They found that the ascorbate substantially reduced, but did not eliminate, chromate ion uptake over a 24 hour period. Interestingly, ascorbate did not affect phagocytic uptake of lead chromate particles, although it eliminated the Cr(VI)-induced clastogenesis (*e.g.*, DNA strand breakage and chromatid exchange) as measured under their experimental conditions.

Singh *et al.* suggested that cell surface interactions with insoluble lead chromate particulates created a concentrated microenvironment of chromate ions resulting in higher intracellular levels of chromium than would occur from soluble Cr(VI) (Ex. 35–149). Cell membrane-enhanced uptake of Cr(VI) is consistent with the intratracheal and intrabronchial instillation studies in rodents that show greater carcinogenicity with slightly soluble (*e.g.*, calcium chromate and strontium chromate) than with the highly water-soluble chromates (*e.g.*, sodium chromate and chromic acid) (Ex. 11–2).

Finally, Cr(VI) deposited in the tracheobronchial and alveolar regions of the respiratory tract is cleared by the mucocilliary escalator (soluble and particulate Cr(VI)) and macrophage phagocytosis (particulate Cr(VI) only). In most instances, these clearance processes take hours to days to completely clear Cr(VI) from the lung, but it can take considerably longer for particulates deposited at certain sites. For example, Ishikawa *et al.* showed that some workers had substantial amounts of chromium particulates at the bifurcations of the large bronchii for more than two decades after cessation of exposure (Ex. 35–81). Mancuso reported chromium in the lungs of six chromate production workers who died from lung cancer (as cited in Ex. 35–47). The interval between last exposure to Cr(VI) until autopsy ranged from 15 months to 16 years. Using hollow casts of the human tracheobronchial tree and comparing particle deposition with reported occurrence of bronchogenic tumors, Schlesinger and Lippman were able to show good correlations between sites of greatest deposition and increased incidence of bronchial tumors (Ex. 35–102).

b. Intracellular Reduction of Cr(VI). Once inside the cell, the hexavalent chromate ion is rapidly reduced to intermediate oxidation states, Cr(V) and Cr(IV), and the more chemically stable Cr(III). Unlike Cr(VI), these other chromium forms are able to react with DNA and protein to generate a variety of adducts and complexes. In addition, reactive oxygen species (ROS) are produced during the intracellular reduction of Cr(VI) that are also capable of damaging DNA. These reactive intermediates, and not Cr(VI) itself, are considered to be the ultimate genotoxic agents that initiate the carcinogenic process.

After crossing the cell membrane, Cr(VI) compounds can be non-enzymatically converted to Cr(III) by several intracellular reducing factors (Ex. 35–184). The most plentiful electron donors in the cell are GSH, and other thiols, such as cysteine, and ascorbate. Connett and Wetterhahn showed that a Cr(VI)-thioester initially forms in the presence of GSH (Ex. 35–206). A two-phase reduction then occurs with rapid conversion to Cr(V) and glutathionyl radical followed by relatively slower reduction to Cr(III) that requires additional molecules of GSH. Depletion of cellular GSH and other thiols is believed to retard complete reduction of Cr(VI) to Cr(III), allowing buildup of intermediates Cr(V) and Cr(IV). The molecular kinetics of the Cr(VI) to Cr(III) reduction with ascorbate is less well understood but can also involve intermediate formation of Cr(V) and free radicals (Ex. 35–184).

Another important class of intracellular Cr(VI) reductions are catalyzed by flavoenzymes, such as GSH reductase, lipoyl dehydrogenase, and ferredoxin-NADP oxidoreductase. The most prominent among these is GSH reductase that uses NADPH as a cofactor in the presence of molecular oxygen (O_2) to form Cr(V)-NADPH complexes. During the reaction, O_2 undergoes one electron reduction to the superoxide radical (O_2^-) which produces hydrogen peroxide (H_2O_2) through the action of the enzyme superoxide dismutase. The Cr(V)-NADPH can then react with H_2O_2 to regenerate Cr(VI) giving off hydroxyl radicals, a highly reactive oxygen species, by a Fenton-like reaction. It is, therefore, possible for a single molecule of Cr(VI) to produce many molecules of potentially DNA damaging ROS through a repeated reduction/oxidation cycling process. Shi and Dalal used electron spin resonance (ESR) to establish formation of Cr(V)-NADPH and hydroxyl radical in an *in vitro* system (Ex. 35–169; 35–171). Sugiyama *et al.* reported Cr(V) formation in cultured Chinese hamster cells treated with soluble Cr(VI) (Ex.35–133). Using a low frequency ESR, Liu *et al.* provided evidence of Cr(V) formation *in vivo* in mice injected with soluble Cr(VI) (Ex. 35–141–28).

Several studies have documented that Cr(VI) can generate Cr(V) and ROS in cultured human lung epithelial cells and that this reduction/oxidation pathway leads to DNA damage, activation of the p53 tumor suppressor gene and stress-induced transcription factor NF-κB, cell growth arrest, and apoptosis (Exs. 35–125; 35–142; 31–22–18; 35–135). Leonard *et al.* used ESR spin trapping, catalase, metal chelators, free radical scavengers, and O_2-free atmospheres to show that hydroxyl radical generation involves a Fenton-like reaction with soluble potassium dichromate (Ex. 31–22–17) and insoluble lead chromate (Ex.35–137) *in vitro.* Liu *et al.* showed that the Cr(IV)/Cr(V) compounds are also able to generate ROS with H_2O_2 in a Fenton reduction/oxidation cycle *in vitro* (Ex. 35–183).

Although most intracellular reduction of Cr(VI) is believed to occur in the cytoplasm, Cr(VI) reduction can also occur in mitochondria and the endoplasmic reticulum. Cr(VI) reduction can occur in the mitochondria through the action of the electron transport complex (Ex. 35–230). The microsomal cytochrome P–450 system in the endoplasmic reticulum also enzymatically reduces Cr(VI) to Cr(V), producing ROS through reduction/oxidation cycling as described above (Ex. 35–171).

c. Genotoxicity and Damage to DNA. A large number of studies have examined multiple types of genotoxicity in a wide range of experimental test systems. Many of the specific investigations have been previously reviewed by IARC (Ex. 35–43), Klein (Ex. 35–134), ATSDR (Ex. 35–41), and the K.S. Crump Group (Ex. 35–47) and will only be briefly summarized here. The body of evidence establishes that both soluble and insoluble forms of Cr(VI) cause structural DNA damage that can lead to genotoxic events such as mutagenisis, clastogenisis, inhibition of DNA replication and transcription, and altered gene expression, all of which probably play a role in neoplastic transformation. The reactive intermediates and products that occur from intracellular reduction of Cr(VI) cause a wide variety of DNA lesions. The type(s) of DNA damage that are most critical to the carcinogenic process is an area of active investigation.

Many Cr(VI) compounds are mutagenic in bacterial and mammalian test systems (Ex. 35–118). In the bacterial Salmonella typhimurium strains, soluble Cr(VI) caused base pair substitutions at A–T sites as well as frame shift mutations (Ex. 35–161). Nestmann *et al.* also reported forward and frame shift mutations in Salmonella typhimurium with pre-solubilized lead chromate (Ex. 35–162). Several Cr(VI) compounds have produced mutagenic responses at various genetic loci in mammalian cells (Ex. 12–7). Clastogenic damage, such as sister chromatid exchange and chromosomal aberrations, have also been reported for insoluble Cr(VI) and soluble Cr(VI) (Exs. 35–132; 35–115). Mammalian cells undergo neoplastic transformation following treatment with soluble Cr(VI) or insoluble Cr(VI), including a number of slightly soluble zinc and insoluble lead chromate pigments (Exs. 12–5; 35–186).

Genotoxicity has been reported from Cr(VI) administration to animals *in vivo.* Soluble Cr(VI) induced micronucleated erythrocytes in mice following intraperitoneal (IP) administration (Ex. 35–150). It also increased the mutation frequency in liver and bone marrow following IP administration to lacZ transgenic mice (Exs. 35–168; 35–163). Izzotti *et al.* reported DNA damage in the lungs of rats exposed to soluble Cr(VI) by intratracheal instillation (Ex. 35–170). Intratracheal instillation of soluble Cr(VI) produced a time- and dose-dependant elevation in mutant frequency in the lung of Big Blue transgenic mice (Ex. 35–174). Oral administration of soluble Cr(VI) in animals did not produce genotoxicity in several studies probably due to route-specific differences in absorption. OSHA is not aware of genotoxicity studies from *in vivo* administration of insoluble Cr(VI). Studies of chromosomal and DNA damage in workers exposed to Cr(VI) vary in their findings. Some studies reported higher levels of chromosomal aberrations, sister chromatid exchanges, or DNA strand breaks in peripheral lymphocytes of stainless steel welders (Exs. 35–265; 35–160) and electroplaters (Ex. 35–164). Other studies were not able to find excess damage in DNA from the blood lymphocytes of workers exposed to Cr(VI) (Exs. 35–185; 35–167). These reports are difficult to interpret since co-exposure to other genotoxic agents (*e.g.*, other metals, cigarette smoke) likely existed and the extent of Cr(VI) exposures were not known.

Because of the consistent positive response across multiple assays in a wide range of experimental systems from prokaryotic organisms (*e.g.*, bacteria) to human cells *in vitro* and animals *in vivo*, OSHA regards Cr(VI) as an agent able to induce carcinogenesis through a genotoxic mode of action. Both soluble and insoluble forms of Cr(VI) are reported to cause genotoxicity and neoplastic transformation. On the other hand, Cr(III) compounds do not easily cause genotoxicity in intact cellular systems, presumably due to the inability of Cr(III) to penetrate cell membranes (Exs. 12–7; 35–186).

There has been a great deal of research to identify the types of damage to DNA caused by Cr(VI), the reactive intermediates that are responsible for the damage, and the specific genetic lesions critical to carcinogenesis. It was shown that Cr(VI) was inactive in DNA binding assays with isolated nuclei or purified DNA (Ex. 35–47). However, Cr(III) was able to produce DNA protein cross-links, sister chromatid exchanges, and chromosomal aberrations in an acellular system. Zhitkovich *et al.* showed that incubation of Chinese hamster ovary cells with soluble Cr(VI) produced ternary complexes of Cr(III) cross-linked to cysteine, other amino acids, or glutathione and the DNA phosphate backbone (Ex. 312). Utilizing the pSP189 shuttle vector plasmid, they showed these DNA-Cr(III)-amino acid cross-links were mutagenic when introduced in human fibroblasts (Ex. 35–131).

Another research group showed that plasmid DNA treated with Cr(III) produced intrastrand crosslinks and the production of these lesions correlated with DNA polymerase arrest (Ex. 35–126). The same intrastrand crosslinks and DNA polymerase arrest could also be induced by Cr(VI) in the presence of ascorbate as a reducing agent to form Cr(III) (Ex. 35–263). These results were confirmed in a cell system by treating human lung fibroblasts with soluble Cr(VI), isolating genomic DNA, and demonstrating dose-dependent guanine-specific arrest in a DNA polymerase assay (Ex. 35–188). Cr(V) may also form intrastrand crosslinks since Cr(V) interacts with DNA *in vitro* (Ex. 35–178). The Cr(V)-DNA crosslinks are probably readily reduced to Cr(III) in cell systems. Intrastrand crosslinks have also been implicated in inhibition of RNA polymerase and DNA topoisomerase, leading to cell cycle arrest, apoptosis and possibly other disturbances in cell growth that contribute to the carcinogenic pathway (Ex. 35–149).

DNA strand breaks and oxidative damage result from the one electron reduction/oxidation cycling of Cr(VI), Cr(V), and Cr(IV). Shi *et al.* showed that soluble Cr(VI) in the presence of ascorbate and H_2O_2 caused DNA double strand breaks and 8-hydroxy deoxyguanine (8-OHdG, a marker for oxidative DNA damage) in vitro (Ex. 35–129). Leonard *et al.* showed that the DNA strand breaks were reduced by several experimental conditions including an O_2-free atmosphere, catabolism of H_2O_2 by catalase, ROS depletion by free radical scavengers, and chelation of Cr(V). They concluded that the strand breaks and 8-OHdG resulted from DNA damage caused by hydroxyl radicals from Cr(VI) reduction/oxidation cycling (Ex. 31–22–17). Generation of ROS-dependant DNA damage could also be shown with insoluble Cr(VI) (Ex. 35–137). DNA strand breaks and related damage caused by soluble Cr(VI) have been reported in Chinese hamster cells (Ex. 35–128), human fibroblasts (Ex. 311), and human prostate cells (Ex. 35–255). Pretreatment of Chinese hamster cells with a metal chelator suppressed Cr(V) formation from Cr(VI) and decreased DNA strand breaks (Ex. 35–197). Chinese hamster cells that developed resistance to H_2O_2 damage also had reduced DNA strand breaks from Cr(VI) treatment compared to the normal phenotype (Ex. 35–176).

Several researchers have been able to modulate Cr(VI)-induced DNA damage using cellular reductants such as ascorbate, GSH and the free radical scavenger tocopherol (vitamin E). This has provided insight into the relationships between DNA damage, reduced chromium forms and ROS. Sugiyama *et al.* showed that Chinese hamster cells pretreated with ascorbate decreased soluble Cr(VI)-induced DNA strand damage (*e.g.*, alkali-labile sites), but enhanced DNA-amino acid crosslinks (Ex. 35–133). Standeven and Wetterhahn reported that elimination of ascorbate from rat lung cytosol prior to *in vitro* incubation with soluble Cr(VI) completely inhibited Cr-DNA binding (Ex. 35–180). However, not all types of Cr-DNA binding are enhanced by ascorbate. Bridgewater *et al.* found that high ratios of ascorbate to Cr(VI) actually decreased intrastrand crosslinks *in vitro* while low ratios induced their formation (Ex. 35–263). This finding is consistent with research by Stearns and Watterhahn who showed that excessive ascorbate relative to Cr(VI) leads to two-electron reduction of Cr(III) and formation of Cr(III)-DNA monoadducts and DNA-Cr(III)-amino acid crosslinks (Ex. 35–166). Low amounts of ascorbate primarily cause one-electron reduction to intermediates Cr(V) and Cr(IV) that form crosslinks with DNA and ROS responsible for DNA strand breaks, alkali-labile sites, and clastogenic damage. This explains the apparent paradox that extracellular Cr(VI) reduction by ascorbate to Cr(III) reduces Cr(VI)-induced DNA binding but intracellular Cr(VI) reduction by ascorbate to Cr(III) enhances Cr-DNA binding. The aforementioned studies used soluble forms of Cr(VI), but Blankenship *et al.* showed that ascorbate pretreatment inhibited chromosomal aberrations in Chinese hamster ovary cells caused by both insoluble lead chromate particles as well as soluble Cr(VI) (Ex. 35–115). Pretreatment with the free radical scavenger tocopherol also inhibits chromosomal aberrations and alkali-labile sites in Cr(VI)-treated cells (Exs. 35–115; 35–128).

Studies of the different types of DNA damage caused by Cr(VI) and the modulation of that damage inside the cell demonstrate that Cr(VI) itself is not biologically active. Cr(VI) must undergo intracellular reduction to Cr(V), Cr(IV), and Cr(III) before the damage to DNA can occur. The evidence suggests that Cr(III) can cause DNA-Cr-amino acid, DNA-Cr-DNA crosslinks and Cr-DNA monoadducts. Cr(V) and possibly Cr(IV) contribute to intrastrand crosslinks and perhaps other Cr-DNA binding. ROS generated during intracellular reduction of Cr(VI) lead to lesions such as chromosomal aberrations, DNA strand breaks, and oxidative DNA damage. The specific DNA lesions responsible for neoplastic transformation have yet to be firmly established so all forms of DNA damage should, at this time, be regarded as potential contributors to carcinogenicity.

d. Cr(VI)-induced Disturbances in the Regulation of Cell Replication. Recent research has begun to elucidate how Cr(VI)-induced oxidative stress and DNA lesions trigger cell signaling pathways that regulate the cell growth cycle. The complex regulation of the cell growth cycle by Cr(VI) involves activation of the p53 protein and other transcription factors that respond to oxidative stress and DNA damage. The cellular response ranges from a temporary pause in the cell cycle to terminal growth arrest (*i.e.*, viable cells that have lost the ability to replicate) and a programmed form of cell death, known as apoptosis. Apoptosis involves alterations in mitochondrial permeability, release of cytochrome c and the action of several kinases and caspases. Less is known about the molecular basis of terminal growth arrest. Terminal growth arrest and apoptosis serve to eliminate further growth of cells with unrepaired Cr(VI)-induced genetic damage. However, it is believed that cells which escape these protective mechanisms and regain replicative competence eventually become resistant to normal growth regulation and can transform to a neoplastic phenotype (Exs. 35–121; 35–122; 35–120).

Blankenship *et al.* first described apoptosis as the primary mode of cell death following a two hour treatment of Chinese hamster ovary cells with high concentrations (>150 μM) of soluble Cr(VI) (Ex. 35–144). Apoptosis also occurs in human lung cells following short-term treatment with soluble Cr(VI)

(Ex. 35–125) as well as longer term treatment (*e.g.*, 24 hours) with lower concentrations of soluble Cr(VI) (*e.g.*, 10 μM) and insoluble Cr(VI) in the form of lead chromate (Ex. 35–166). Ye *et al.* found that the Cr(VI) treatment that caused apoptosis also activated expression of p53 protein (Ex. 35–125). This apoptotic response was substantially reduced in a p53-deficient cell line treated with Cr(VI), suggesting that the p53 activation was required for apoptosis. Other studies using p53 null cells from mice and humans confirmed that Cr(VI)-induced apoptosis is p53-dependent (Ex. 35–225).

The p53 protein is a transcription factor known to be activated by DNA damage, lead to cell cycle arrest, and regulate genes responsible for either DNA repair or apoptosis. Therefore, it is likely that the p53 activation is a response to the Cr(VI)-induced DNA damage. Apoptosis (*i.e.*, programmed cell death) is triggered once the Cr(VI)-induced DNA damage becomes too extensive to successfully repair. In this manner, apoptosis serves to prevent replication of genetically damaged cells.

Several researchers have gone on to further elucidate the molecular pathways involved in Cr(VI)-induced apoptosis. ROS produced by intracellular Cr(VI) reduction/oxidation cycling have been implicated in the activation of p53 and apoptosis (Exs. 35–255; 35–122). Using specific inhibitors, Pritchard *et al.* showed that mitochondrial release of cytochrome c is critical to apoptotic death from Cr(VI) (Ex. 35–159). Cytochrome c release from mitochondria could potentially result from either direct membrane damage caused by Cr(VI)-induced ROS or indirectly by enhanced expression of the p53-dependent apoptotic proteins, Bax and Nova, known to increase mitochondrial membrane permeability.

Cr(VI) causes cell cycle arrest and reduces clonogenic potential (*i.e.*, normal cell growth) at very low concentrations (*e.g.*, 1 μM) where significant apoptosis is not evident. Xu *et al.* showed that human lung fibroblasts treated with low doses of Cr(VI) caused guanine-guanine intrastrand crosslinks, guanine-specific polymerase arrest, and inhibited cell growth at the G_1/S phase of the cell cycle (Ex. 35–188). Zhang *et al.* described a dose-dependent increase in growth arrest at the G_2/M phase of the cell cycle in a human lung epithelial cell line following 24 hour Cr(VI) treatment over a concentration range of 1 to 10 μM (Ex. 35–135). The cell cycle arrest could be partially eliminated by reducing production of Cr(VI)-induced ROS. Apoptosis was not detected in these cells until a concentration of 25 μM Cr(VI) had been reached. These data suggest that low cellular levels of Cr(VI) are able to cause DNA damage and disrupt the normal cell growth cycle.

Pritchard *et al.* studied the clonogenicity over two weeks of human fibroblasts treated 24 hours with soluble Cr(VI) concentrations from 1 to 10 μM (Ex. 35–120). They reported a progressive decline in cell growth with increasing Cr(VI) concentration. Terminal growth arrest (*i.e.*, viable cells that have lost the ability to replicate) was primarily responsible for the decrease in clonogenic survival below 4 μM Cr(VI). At higher Cr(VI) concentrations, apoptosis was increasingly responsible for the loss in clonogenicity. Pritchard *et al.* and other research groups have suggested that a subset of cells that continue to replicate following Cr(VI) exposure could contain unrepaired genetic damage or could have become intrinsically resistant to processes (*e.g.*, apoptosis, terminal growth arrest) that normally control their growth (Exs. 35–121; 35–122; 35–120). These surviving cells would then be more prone to neoplastic progression and have greater carcinogenic potential.

e. Summary. Respirable chromate particulates are taken up by target cells in the bronchoalveolar region of the lung, become intracellularly reduced to several reactive genotoxic species able to damage DNA, disrupt normal regulation of cell division and cause neoplastic transformation. Scientific studies indicate that both water soluble and insoluble Cr(VI) can be transported into the cell. In fact, cell surface interactions with slightly soluble and insoluble chromates may create a concentrated microenvironment of chromate ion, especially in the case of the slightly soluble Cr(VI) compounds that more readily dissociate. The higher concentration of chromate ion in close proximity to the lung cells will likely result in higher intracellular Cr(VI) than would occur from the highly water-soluble chromates. This is consistent with the studies of respiratory tract carcinogenesis in animals that indicate the most tumorigenic chromates had low to moderate water solubility. Once inside the cell, Cr(VI) is converted to several lower oxidation forms able to bind to and crosslink DNA. ROS are produced during intracellular reduction/oxidation of Cr(VI) that further damage DNA. These structural lesions are functionally translated into a impaired DNA replication, mutagenesis, and altered gene expression that ultimately lead to neoplastic transformation.

9. Conclusion

In the NRPM, OSHA preliminarily concluded that the weight of evidence supports the determination that all Cr(VI) compounds should be regarded as carcinogenic to workers (69 FR at 59351). This conclusion included the highly water soluble chromates, such as sodium chromate, sodium dichromate, and chromic acid; chromates of slight and intermediate water solubility such as calcium chromate, strontium chromates, and many zinc chromates (e.g. zinc yellow); and chromates that have very low water solubility and are generally considered to be water insoluble such as barium chromate and lead chromates. The strongest evidence supporting this conclusion comes from the many cohort studies reporting excess lung cancer mortality among workers engaged in the production of soluble chromates (Exs. 7–14; 31–22–11; 23; 31–18–4), chromate pigments (Exs. 7–36; 7–42; 7–46), and chrome plating (Exs. 35–62; 35–271). Chromate production workers were principally exposed to the highly soluble sodium chromate and dichromate (Ex. 35–61) although lesser exposure to other chromates, such as highly soluble chromic acid and slightly soluble calcium chromate probably occurred. Pigment production workers were principally exposed Cr(VI) in the form of lead and zinc chromates. Significantly elevated lung cancer mortality was found in two British chromium electroplating cohorts (Exs. 35–62; 35–271). These workers were exposed to Cr(VI) in the form of chromic acid mist. Therefore, significantly elevated lung cancer rates have been observed in working populations exposed to a broad range of Cr(VI) compounds.

Cellular research has shown that both highly water soluble (e.g. sodium chromate) Cr(VI) and water insoluble (e.g. lead chromate) Cr(VI) enter lung cells (see Section V.8.a) and undergo intracellular reduction to several lower oxidation forms able to bind to and crosslink DNA as well as generate reactive oxygen species that can further damage DNA (see Section V.8.b). Soluble and insoluble Cr(VI) compounds are reported to cause mutagenesis, clastogenesis, and neoplastic transformation across multiple assays in a wide range of experimental systems from prokaryotic organisms to human cells *in vitro* and animals *in vivo* (see Section V.8.c).

The carcinogenicity of various Cr(VI) compounds was examined after instillation in the respiratory tract of rodents. Slightly water soluble Cr(VI) compounds, strontium chromate, calcium chromate, and some zinc chromates produced a greater incidence of respiratory tract tumors than highly water soluble (e.g. sodium dichromate and chromic acid) and water insoluble (e.g. barium chromate and lead chromates) Cr(VI) compounds under similar experimental protocol and conditions (see Section V.7). This likely reflects the greater tendency for chromates of intermediate water solubility to provide a persistent high local concentration of solubilized Cr(VI) in close proximity to the target cell. Highly soluble chromates rapidly dissolve and diffuse in the aqueous fluid lining the epithelia of the lung. Thus, these chromates are less able to achieve the higher local concentrations within close proximity of the lung cell surface than the slightly water soluble chromates. However, it has been shown that water-soluble Cr(VI) can still enter lung cells, damage DNA, and cause cellular effects consistent with carcinogenesis (Ex. 31–22–18; 35–125; 35–135; 35–142). Like the slightly water soluble chromates, water insoluble Cr(VI) particulates are able to come in close contact with the lung cell surface and slowly dissolve into readily absorbed chromate ion. For example, water insoluble lead chromate has been shown to enter human airway cells both through extracellular solubilization as chromate ion (Exs. 35–66; 35–327; 47–12–3) as well as internalization as unsolubilized particulate (Exs. 35–66; 47–19–7). However, the rate of solubilization and uptake of water insoluble Cr(VI) is expected to be more limited than chromates with moderate solubility. Once chromate ion is inside lung cells, studies have shown that similar cellular events believed critical to initiating neoplastic transformation occur regardless of whether the source is a highly soluble or insoluble Cr(VI) compound (Ex. 35–327).

a. Public Comment on the Carcinogenicity of Cr(VI) Compounds

In the NRPM, OSHA requested comment on whether currently available epidemiologic and experimental studies supported the determination that all Cr(VI) compounds possess carcinogenic potential and solicited additional information that should be considered in evaluating relative carcinogenic potency of the different Cr(VI) compounds (69 FR 59307). Several comments supported the view that sufficient scientific evidence exists to regard all Cr(VI) compounds as potential occupational carcinogens (Exs. 38–106–2; 38–222; 39–73–2; 40–10–2; 42–2). The AFL–CIO stated that ''* * * the agency has fully demonstrated that Cr(VI) is a human carcinogen and that exposed workers are at risk of developing lung cancer'' (Ex. 38–222). NIOSH stated that ''the epidemiologic and experimental studies cited by OSHA support the carcinogenic potential of all Cr(VI) compounds (i.e. water soluble, insoluble, and slightly soluble)'' (Ex. 40–10–2, p. 4). Peter Lurie of Public Citizen testified:

> As we heard repeatedly in the course of this hearing, scientific experts, in fact, agree. They agree that the most reasonable approach to the regulation is to consider them all [Cr(VI) compounds] to be carcinogenic (Tr. 710).

Several commenters agreed that the evidence supported the qualitative determination that Cr(VI) compounds were carcinogenic but wished to make clear that the information was inadequate to support quantitative statements about relative potency of the individual chromates (Exs. 38–106–2; 40–10–2; 42–2). For example, the Boeing Company in their technical comments stated:

> The available data does support the conclusion that the low solubility hexavalent chromium compounds [e.g. strontium chromate] can cause cancer but evidence to support a quantitative comparison of carcinogenic potency based on differences in solubility is lacking (Ex. 38–106–2, p. 18).

Pigment Manufacturers' Comments on Carcinogenicity of Lead Chromate—One group that did not regard all Cr(VI) compounds as occupational carcinogens was the color pigment manufacturers who manufacture and market lead chromate pigments which are primarily used in industrial coatings and colored plastic articles. The color pigment manufacturers maintain that their lead chromate products are unreactive in biological systems, are not absorbed into the systemic circulation by any route, and can not enter lung cells (Ex. 38–205, p. 14). Their principal rationale is that lead chromate is virtually insoluble in water, is unable to release chromate ion into aqueous media, and therefore, is incapable of interacting with biological systems (Exs. 38–205, p. 95; 38–201–1, p. 9). The color pigment manufacturers assert that their lead chromate pigment products are double encapsulated in a resin/plastic matrix surrounded by a silica coating and that the encapsulated pigment becomes even less ''bioavailable'' than unencapsulated ''less stabilized'' lead chromates. They believe the extreme stability and non-bioavailable nature of their products makes them a non-carcinogenic form of Cr(VI) (Ex. 38–205, p. 106).

According to the Color Pigment Manufacturers Association (CPMA), several pieces of scientific evidence support their position, namely, the lack of a significant excess of lung cancer mortality in three cohorts of pigment workers engaged in the production of water-insoluble lead chromate (Ex. 38–205, pp. 88–91) and the lack of statistically significant elevated tumor incidence following a single instillation of lead chromate in the respiratory tract of rats (Ex. 38–205, pp. 88–92). They dismiss as irrelevant other animal studies that produced statistically significant increases in tumors when lead chromate was repeatedly injected by other routes. In addition, CPMA claims that the lead chromate used in cellular studies that report genotoxicity was reagent grade, was contaminated with soluble chromate, and was inappropriately solubilized using strong acids and bases prior to treatment (Exs. 38–205, pp. 93–94; 47–31, pp. 9–13). They are especially critical of studies conducted by the Environmental and Genetic Toxicology group at the University of Southern Maine that report lead chromate particulates to be clastogenic in human lung cells (Exs. 34–6–1; 38–205, pp. 98–102 & appendix D; 47–22). Instead, they rely on two *in vitro* studies of lead chromate pigments that report a lack of genotoxicity in cultured bacterial and hamster ovary cells, respectively (Exs. 47–3 Appendix C; 38–205, p. 94).

OSHA addresses many of the CPMA claims in other sections of the preamble. The bioavailability issue of encapsulated lead chromate is addressed in Section V.A.2. The CPMA request to consider the lack of excess lung cancer mortality among pigment workers exposed exclusively to lead chromate is discussed in Section V.B.2. The CPMA assertions that animal studies are evidence that lead chromates are not carcinogenic to workers are addressed in Section V.B.7. The studies documenting uptake of lead chromate into lung cells are described in Section V.B.8.a. Section V.B.8.c describes evidence that lead chromate is genotoxic. As requested by CPMA, OSHA will pull these responses together and expand on their concerns below.

Lung Cancer Mortality in Pigments Workers Exposed to Lead Chromate—Comments and testimony from NIOSH and others cite evidence of excess lung cancer among pigment workers and support the results of OSHA's preliminary risk assessment for color pigments in general and for lead chromate in particular (Tr. 135–146, 316, 337, Ex. 40–18–1, p. 2). However, comments submitted by the CPMA and the Dominion Colour Corporation (DCC) attributed the excess lung cancer risk observed in pigment worker studies to zinc chromate (Tr. 1707, 1747, Exs. 38–201–1, p. 13; 38–205, p. 90; 40–7, p. 92). For example, the CPMA stated that:

> When lead chromate and zinc chromate exposures occur simultaneously, there appears to be a significant cancer hazard. However, when lead chromate pigments alone are the source of chromium exposure, a significant carcinogenic response has never been found (Ex. 40–7, p. 92).

The latter statement refers to the Davies *et al.* (1984) study of British pigment workers, the Cooper *et al.* (1983) study of U.S. pigment workers, and the Kano *et al.* (1993) study of pigment workers in Japan, all of which calculated separate observed and expected lung cancer deaths for workers exposed exclusively to lead chromate (Ex. 38–205, p. 89). DCC and the Small Business Administration's Office of Advocacy similarly stated that the excess lung cancer risk observed among workers exposed to both zinc chromate and lead chromate cannot necessarily be attributed to lead chromate (Exs. 38–201–1, p. 13; 38–7, p. 4).

OSHA agrees with CPMA and DCC that the excess lung cancer observed in most pigment worker studies taken alone cannot be considered conclusive evidence that lead chromate is carcinogenic. Given that the workers were exposed to both zinc chromate and lead chromate, it is not possible to draw strong conclusions about the effects of either individual compound using only these studies. However, based on the overall weight of available evidence, OSHA believes that the excess lung cancer found in these studies is most likely attributable to lead chromate as well as zinc chromate exposure. Lead chromate was the primary source of Cr(VI) for several worker cohorts with excess lung cancer (*e.g.*, Davies *et al.* (1984), Factory A; Hayes *et al.* (1989); and Deschamps *et al.* (1995)) (Exs. 7–42; 7–46; 35–234), and as previously discussed, there is evidence from animal and mechanistic studies supporting the carcinogenicity of both zinc chromate and lead chromate. Considered in this context, the elevated risk of lung cancer observed in most chromate pigment workers is consistent with the Agency's determination that all Cr(VI) compounds—including lead chromate—should be regarded as carcinogenic.

Moreover, OSHA disagrees with the CPMA and DCC interpretation of the data on workers exposed exclusively to lead chromate. In the Preamble to the Proposed Rule, OSHA stated that ''[t]he number of lung cancer deaths [in the Davies, Cooper, and Kano studies] is too small to be meaningful'' with respect to the Agency's determination regarding the carcinogenicity of lead chromate (FR 69 at 59332). The CPMA subsequently argued that:

> [b]y this rationale, OSHA could never conclude that a compound such as lead chromate pigment exhibits no carcinogenic potential because there can never be enough lung cancer deaths to produce a ''meaningful'' result. This is an arbitrary and obviously biased assessment which creates an insurmountable barrier. Since the lead chromate pigments did not create an excess of lung cancer, there cannot be a significant enough mortality from lung cancer to be meaningful (Ex. 38–205, p. 90).

OSHA believes that these comments reflect a misunderstanding of the sense in which the Davies, Cooper, and Kano studies are too small to be meaningful, and also a misunderstanding of the Agency's position.

Contrary to CPMA's argument, a study with no excess in lung cancer mortality can provide evidence of a lack of carcinogenic effect if the confidence limits for the measurement of effect are close to the null value. In other words, the measured effect must be close to the null and the study must have a high level of precision. In the case of the Davies, Cooper, and Kano studies, the standardized mortality ratio (SMR) is the measurement of interest and the null value is an SMR of 1. Table V.10 below shows that the SMRs for these study populations are near or below 1; however, the 95% confidence intervals for the SMRs are quite wide, indicating that the estimated SMRs are imprecise. The Kano data, for example, are statistically consistent with a ''true'' SMR as low as 0.01 or as high as 2.62. The results of these studies are too imprecise to provide evidence for or against the hypothesis that lead chromate is carcinogenic.

Table V.10: Summary of Lead Chromate Cohort Studies

Study	Number of Workers	Person-Years of Observation	Oberved/Expected Lung Cancer Deaths	SMR (95% C.I.)
Davies (Plant C, high/med exposure)	180	3395	4/5.07	0.79 (0.20 - 2.00)
Davies (Plant C, low exposure)	34	813	3/1.38	2.17 (0.4- 6.3)
Cooper (Plant 1)	246	4768	3/2.31	1.30 (0.27 - 3.81)
Kano (workers exposed only to Pb Cr(VI)	not reported	not reported	1/2.14	0.47 (0.01 - 2.62)

This lack of precision may be partly explained by the small size of the studies, as reflected in the low numbers of expected lung cancers. However, it is the issue of precision, and not the number of lung cancer deaths *per se*, that led OSHA to state in the preamble to the proposed rule that the Davies, Cooper, and Kano studies cannot serve as the basis of a meaningful analysis of lead chromate carcinogenicity (Exs. 7–42; 2–D–1; 7–118). In contrast, a study population that has confidence limits close to or below 1 would provide evidence to support the DCC claim that ''* * * if lead chromate pigments possess any carcinogenic potential at all, it must be extremely small'' (Ex. 38–201–1, p. 14) at the exposure levels experienced by that population. While this standard of evidence has not been met in the epidemiological literature for pigment workers exposed exclusively to lead chromate (*i.e.*, the Davies, Cooper, and Kano studies), it is hardly an ''insurmountable barrier'' that sets up an impossible standard of proof for those who contend that lead chromate is not carcinogenic.

Some comments suggested that the Davies, Cooper, and Kano studies should be combined to derive a summary risk measure for exposure to lead chromate (see *e.g.* Ex. 38–201–1, pp. 13–14). However, OSHA believes that these studies do not provide a suitable basis of meta-analysis. There is little information with which to assess factors recognized by epidemiologists as key to meta-analysis, for example sources of bias or confounding in the individual studies and comparability of exposures and worker characteristics across studies, and to verify certain conditions required for comparability of SMRs across these studies (see *e.g. Modern Epidemiology*, Rothman and Greenland, p. 655). In addition, the inclusion criteria and length of follow-up differ across the three studies. Finally, each of the studies is extremely small. Even if it were appropriate to calculate a 'summary' SMR based on them, the precision of this SMR would not be much improved compared to those of the original studies.

In their written testimony, DCC suggested that OSHA should aggregate the data from the Davies, Cooper, and Kano studies in order to determine whether there is a discrepancy between the results of these three studies, taken together, and OSHA's preliminary risk assessment (Ex. 38–201–1, pp. 13–14). DCC performed a calculation to compare OSHA's risk model with the observed lung cancer in the three cohorts. DCC stated that:

> OSHA estimates a chromate worker's risk of dying from lung cancer due to occupational exposure as about one chance in four * * * [Assuming that there were about] 200 workers in the Kano study, the total in the three studies would be 600. A calculation of one quarter would be 150 deaths. To compensate for a working life of less than OSHA's 45 years [an assumption of 20 years] provides * * * a refined estimate of about 70 deaths. An observed number less than this could be due either to exposures already in practice averaging much less than the current PEL of 52, or to lead chromate having much less potential (if any) for carcinogenicity than other chromates. In any event the actual incidence of death from lung cancer would appear to be no more than one tenth of OSHA's best estimate (Ex. 38–201–1, pp. 15–16).

The method suggested by DCC is not an appropriate way to assess the carcinogenicity of lead chromate, to identify a discrepancy between the pigment cohort results and OSHA's risk estimates, or to determine an exposure limit for lead chromate. Among other problems, DCC's calculation does not make a valid comparison between OSHA's risk estimates and the results of the Davies, Cooper, and Kano studies. OSHA's 'best estimate' of lung cancer risk for any given Cr(VI)-exposed population depends strongly on factors including exposure levels, exposure duration, population age, and length of follow-up. The 'one in four' prediction cited by DCC applies to one specific risk scenario (lifetime risk from 45 years of occupational exposure at the previous PEL of 52 μg/m^3). OSHA's best estimate of risk would be lower for a population with lower exposures (as noted by DCC), shorter duration of exposure, or less than a lifetime of follow-up. Without adequate information to adjust for each of these factors, a valid comparison cannot be drawn between OSHA's risk predictions and the results of the lead chromate cohort studies.

The importance of accounting for cohort age and follow-up time may be illustrated using information provided in the Cooper *et al.* study. As shown in Table V–11 below, approximately three-fourths of the Cooper et al. Plant 1 cohort members were less than 60 years old at the end of follow-up.

Table V-11: Followup of Workers in Cooper et al. (Plant 1)

year of birth	number of workers	age at end of followup*	percent of cohort
1950 - 1954	8	25 - 29	3.3%
1945 - 1949	18	30 - 34	7.3%
1940 - 1944	19	35 - 39	7.7%
1935 - 1939	19	40 - 44	7.7%
1930 - 1934	29	45 - 49	11.8%
1925 - 1929	53	50 - 54	21.5%
1920 - 1924	36	55 - 59	14.6%
1915 - 1919	33	60 - 64	13.4%
1910 - 1914	17	65 - 69	6.9%
1905 - 1909	8	70 - 74	3.3%
1900 - 1904	5	75 - 79	2.0%
1895 - 1899	1	80 - 84	0.4%

* age of follow-up based on birthyear, assuming survival and follow-up to 1979;

actual follow-up will be shorter for 14 deceased workers and 9 lost to follow-up

For a population of 600 with approximately the same distribution of follow-up time as described in the Cooper et al. publication (e.g., 0.4% of workers are followed to age 84, 2% to age 79, etc.), OSHA's risk model predicts about 3–15 excess lung cancers (making the DCC assumption that workers are exposed for 20 years at 52 μg/m^3), rather than the 70 deaths calculated by the DCC. If the workers were typically exposed for less than 20 years or at levels lower than 52 μg/m^3, OSHA s model would predict still lower risk. A precise comparison between OSHA's risk model and the observed lung cancer risk in the Davies, Cooper and Kano cohorts is not possible without demographic, work history and exposure information on the lead chromate workers. (In particular, note that year 2000 background lung cancer rates were used in the calculation above, as it was not feasible to reconstruct appropriate reference rates without work history information on the cohorts.) However, this exercise illustrates that DCC's assertion of a large discrepancy between OSHA's risk model and the available data on workers exposed exclusively to lead chromate is not well-founded. To make a valid comparison between the OSHA risk model and the lung cancer observed in the lead chromate cohorts would require more information on exposure and follow-up than is available for these cohorts.

OSHA received comments and testimony from NIOSH and others supporting of the Agency's interpretation of the epidemiological literature on Cr(VI) color pigments, including lead chromate (Tr. 135–146, 316, 337, Ex. 40–18–1, p. 2). At the hearing, Mr. Robert Park of NIOSH stated that the available studies of workers exposed to chromate pigments show ''* * * a general pattern of excess [lung cancer] * * *'' and pointed out that ''[i]n several of the studies, lead [chromate] was by far the major component of production, like 90 percent * * * So I don't think there is any epidemiological evidence at this point that gets lead off the hook'' (Tr. 337). Regarding the lack of statistically significant excess lung cancer in several pigment worker cohorts, Mr. Park identified study attributes that may have obscured an excess in lung cancer, such as the high percentage of workers lost to follow-up among immigrant workers in the Davies et al. study (Tr. 337) or a healthy worker effect in the Hayes et al. study (Tr. 316). Dr. Paul Schulte of NIOSH explained that

> * * * a lot of these studies that appear to be negative were either of low power or had [some] other kind of conflicting situation [so] that we can't really consider them truly negative studies (Tr. 338).

Dr. Herman Gibb testified that the epidemiological studies relied on by CPMA and DCC to question the carcinogenicity of lead chromate have very low expected numbers of lung cancer deaths, so they ''* * * really don't have a lot of ability to be able to detect a risk'' (Tr. 135–136). Public Citizen agreed with OSHA's preliminary conclusion that lead chromate is carcinogenic. Based on the major pigment worker cohorts identified by OSHA in the Preamble to the Proposed Rule, Public Citizen's Health Research Group concluded that

> * * * inadequately-powered studies, the standardized mortality ratios for exposed workers are significantly elevated (range 1.5–4.4) and a relationship between extent of exposure (whether measured by duration of exposure or factory) generally emerges; [moreover,] [t]hese studies must be placed in the context * * * of the animal carcinogenicity studies * * * and the mechanistic studies reviewed by OSHA (Ex. 40–18–1, p. 2).

Tumor Incidence in Experimental Animals Administered Lead Chromate—CPMA also claims that the absence of evidence for carcinogenicity found among the three cited cohorts of lead chromate pigment workers ''* * * is further confirmed by the rat implantation studies of Levy'' (Ex. 38–205, p. 98). They argue that these studies which involved implantation into rat lungs ''* * * indicated no increased incidence of tumors for lead chromate pigment, although more soluble chromates exhibited varying degrees of carcinogenicity'' (Ex. 38–205, p. 93). They dismissed other animal studies involving intramuscular and subcutaneous injection of lead chromate which did report increased incidence of tumors because they believe these techniques

> * * * are of questionable relevance in relation to human workplace exposure conditions in industry, whereas tests involving implantation in rat lung * * * are relevant to inhalation in industrial exposures (Ex. 38–205, p. 93).

In a more recent submission, CPMA remarked that the intramuscular and subcutaneous injection studies with lead chromate were contradictory and ''* * * problematic in that false positive results frequently occur during the study procedure (Ex. 47–31, p. 13).

The rat implantation studies of Levy involved the surgical placement of a Cr(VI)-containing pellet in the left bronchus of an anesthetized rat (Exs. 10–1; 11–12; 11–2). This pellet procedure was an attempt to deliver Cr(VI) compounds directly to the bronchial epithelium and mimic continuous chronic *in vivo* dosing at the tissue target site in order to assess the relative ability of different Cr(VI) compounds to induce bronchogenic carcinoma. Histopathological evaluation of the rat lung was conducted after a two year exposure time. In most cases, approximately 100 rats were implanted with a single pellet for each Cr(VI) test compound. The total lifetime dose of Cr(VI) received by the animal was generally between 0.2 and 1.0 mg depending on the compound. The amount of Cr(VI) that actually leached from the cholesterol pellet and remained near the lung tissue was never determined. At least 20 different commercially relevant Cr(VI) compounds ranging from water insoluble to highly water soluble were tested using this intrabronchial implantation protocol.

The results of these studies are described in preamble section V.B.7 and tables V–7, V–8, and V–9. Reagent grade lead chromate and six different lead chromate pigments were tested. The lead chromate pigments were a variety of different chrome yellows, including a silica encapsulated chrome yellow, and molybdenum orange. The incidence of bronchogenic cancer in the rats under this set of experimental conditions was one percent or less for all the lead chromates tested. This incidence was not statistically different from the negative controls (i.e. rats implanted with a cholesterol pellet containing no test compound) or rats administered either the water-insoluble barium chromate or the highly soluble chromic acid and sodium dichromate. The percent incidence of bronchogenic cancer in lead chromate-treated rats was substantially less than that of rats treated with slightly soluble strontium chromates (about 52 percent) and calcium chromate (24 percent). The type of bronchogenic cancer induced in these experiments was almost entirely squamous cell carcinomas.

OSHA does not agree with the CPMA position that absence of a significant tumor incidence in the intrabronchial implantation studies confirms that lead chromates lack carcinogenic activity and, therefore, should not be subject to the OSHA Cr(VI) standard. The bioassay protocol used approximately 100 test animals per experimental group. This small number of animals limits the power of the bioassay to detect tumor incidence below three to four percent with an acceptable degree of statistical confidence. Three of the lead chromates, in fact, produced a tumor incidence of about one percent (e.g. 1 tumor in 100 rats examined) which was not statistically significant. The researchers only applied a single 2 mg [approximately 0.3 mg Cr(VI)] dose of lead chromate to the bronchus of the rats. Since it was not experimentally confirmed that the lead chromate pigments were able to freely leach from the cholesterol pellet, the amount of Cr(VI) actually available to the lung tissue is not entirely clear. Therefore, OSHA believes a more appropriate interpretation of the study findings is that lead chromates delivered to the respiratory tract at a dose of about 0.3 mg Cr(VI) (maybe lower) lead to a less than three percent tumor incidence.

However, OSHA agrees that the intrabronchial implantation protocol does provide useful information regarding the relative carcinogenicity of different Cr(VI) compounds once they are delivered and deposited in the respiratory tract. No other study examines the carcinogenicity of such a broad range of commercial Cr(VI) compounds under the same experimental conditions in the relevant target organ to humans (i.e. respiratory tract) following *in vivo* administration. OSHA agrees with CPMA that the results of this study provide credible evidence that water insoluble lead chromates are less carcinogenic than some of the more moderately soluble chromates. Specifically, this includes the slightly soluble zinc chromates (e.g. zinc yellow, zinc potassium chromates, basic zinc chromates) as well as strontium chromate and calcium chromate. Intrabronchial implantation of chromic acid and other highly soluble Cr(VI) salts, such as sodium chromates, did not induce a significant number of tumors. Therefore, these experiments do not indicate lead chromate are less carcinogenic than the highly water soluble Cr(VI) compounds.

If the histopathology data from the intrabronchial implantation is examined more closely, all lead chromates increased the incidence of squamous metaplasia relative to controls, and, for some lead chromates, squamous dysplasia of the bronchial epithelium occurred (Table 2, Ex. 11–2). Squamous metaplasia and dysplasia are generally considered to be transformed cellular states from which a neoplasm (e.g. carcinomas) can arise (Ex. 11–12). Increased squamous metaplasia was common among all tested Cr(VI) compounds but not among Cr(III)-containing materials or the negative controls (Ex. 11–12). The increased metaplasia induced by lead chromates is unlikely to be due to bronchial inflammation since the degree of inflammation was no greater than that observed in the cholesterol-implanted controls (Table 2, Ex. 11–2).

The squamous metaplasia and dysplasia in the rat lung model following low dose lead chromate administration is consistent with a low carcinogenic response (e.g. incidence of one percent or less) not able to be detected under the conditions of the animal bioassay. This explanation is supported by studies (discussed later in the section) that show lead chromate can enter lung cells, damage DNA, and cause genotoxic events leading to neoplastic transformation.

Lead chromate carcinogenicity is also supported by the animal studies that CPMA dismisses as problematic and of questionable relevance. These studies administered lead chromates to rodents by either the subcutaneous (Exs. 8–25, 5–2, 8–37) or intramuscular routes (Ex. 10–2). While OSHA agrees that these routes may be less relevant to occupational inhalation than implantation in the respiratory tract, the studies exposed rats to a larger dose of lead chromate. The higher amounts of Cr(VI) produced a significant incidence of tumors at the injection site (see section V.B.7.c).

The lead chromate pigments, chrome yellow and chrome orange, induced injection site rhabdomyosarcomas and fibrosarcomas in 65 percent of animals following a single 30 mg injection in a saline suspension (Ex. 8–37). The rats received a roughly ten fold higher dose of Cr(VI) than in the intrabronchial bioassay. Rats injected with saline alone did not develop injection site tumors. Only two percent or less of rats receiving equal quantities of the inorganic pigments iron yellow and iron red developed these tumors. The iron oxides are not considered to be carcinogenic and do not give a significant neoplastic response in this bioassay. OSHA has no reason to believe the experimental procedure was problematic or given to frequent false positives.

A similarly high incidence (i.e. 70 percent) of the same injection site sarcomas were found in an independent study in which rats were injected intramuscularly with reagent grade lead chromate once a month for nine months (Ex. 10–2). Each injection contained approximately 1.3 mg of Cr(VI) and the total dose administered was over 30 times higher than the intrabronchial implantation. The lead chromate was administered in a glycerin vehicle. The vehicle produced less than a two percent incidence of injection site sarcomas when administered alone.

Contrary to statements by Eurocolour (Ex. 44–3D), lead chromate did produce a low incidence of site-of-contact tumors in rats in an earlier study when administered by either intramuscular or intrapleural implantation (Ex. 10–4). There was no tumor incidence in the control animals. The dose of lead chromate in this early publication was not stated.

Based on the increase in pre-neoplastic changes from the single low dose intrabronchial implantation and the high incidence of malignant tumors resulting from larger doses administered by subcutaneous and intramuscular injection, it is scientifically reasonable to expect that larger doses of lead chromate may have produced a higher incidence of tumors in the more relevant intrabronchial implantation procedure. The highly soluble sodium dichromate produced a small (statistically insignificant) incidence of squamous cell carcinoma (i.e. one percent) upon single low dose intrabronchial implantation similar to the lead chromates (Ex. 11–2). In another study, sodium dichromate caused a significant 17 percent increase in the incidence of respiratory tract tumors when instilled once a week for 30 months in the trachea of rats (Ex. 11–7). The weekly-administered dose for this repeated instillation was about ⅕th the dose of that used in the intrabronchial implantation assay but the total administered dose after 30 months was about 25 times higher. Rats that received a lower total dose of sodium dichromate or the same total dose in more numerous instillations (i.e. lower dose rate) developed substantially fewer tumors that were statistically indistinguishable from the saline controls. A third study found a 15 percent increase (not statistically significant) in lung tumor incidence when rats repeatedly inhaled aerosolized sodium dichromate for 18 months at the highest air concentrations tested (Ex. 10–11). These sodium dichromate studies are further described in section V.B.7.a. The findings suggest that the lack of significant carcinogenic activity in the intrabronchial implantation study reflects, in part, the low administered dose employed in the bioassay.

In his written testimony to OSHA, Dr. Harvey Clewell directly addressed the issue of interpreting the absence of carcinogenicity in an animal study as it relates to significant risk.

> First, the ability to detect an effect depends on the power of the study design. A statistically-based No Observed Adverse Effect Level (NOAEL) in a toxicity study does not necessarily mean that there is no risk of adverse effect. For example, it has been estimated that a NOAEL in a typical animal study can actually be associated with the presence of an effect in as many as 10% to 30% of the animals. Thus the failure to observe a statistically significant increase in tumor incidence at a particular exposure does not rule out the presence of a substantial carcinogenic effect at that exposure * * *. Similarly the failure of Levy et al. (1986) to detect an increase in tumors following intrabronchial instillation of lead chromate does not in itself demonstrate a lack of carcinogenic activity for that compound. It only demonstrates a lower activity than for other compounds that showed activity in the same experimental design. Presumably this lower activity is primarily due to its low solubility; evidence of solubilization, cellular uptake, and carcinogenic activity of this compound [i.e. lead chromate] is provided in other studies (Maltoni et al. 1974, Furst et al., 1976, Blankenship et al., 1997; Singh et al., 1999; Wise et al., 2004) (Ex. 44.5, p. 13–14).

OSHA agrees with Dr. Clewell that the inability to detect a statistically significant incidence of tumors in one study that administers a single low dose of lead chromate to a limited number of animals is not evidence that this Cr(VI) compound lacks carcinogenic activity. This is especially true when there exists an elevation in pre-neoplastic lesions and other studies document significant tumor incidence in animals administered higher doses of lead chromate.

Cellular Uptake and Genotoxicity of Lead Chromate—CPMA disputes the many studies that report lead chromate to be genotoxic or clastogenic in cellular test systems (Exs. 35–162; 12–5; 35–119; 35–188; 35–132; 35–68; 35–67; 35–115; 35–66; 47–22–1; 47–12–3; 35–327; 35–436). They claim that the studies inappropriately solubilized the lead chromate ‘‘ * * * in non-biological conditions such as strong alkali or strong acid that causes the chemical breakdown of the lead chromate crystal’’ (Ex. 38–205, p. 94) and the ‘‘lead chromate had been dissolved * * * using aggressive substances’’ (Ex. 38–205, p. 99). In a later submission, CPMA states state that some of the cellular studies used reagent grade lead chromate that is only ≥98 percent pure and may contain up to 2 percent soluble chromate (Ex. 47–31, p. 11). They speculate that the interactions (e.g. chromate ion uptake, chromosomal aberrations, DNA adducts, etc.) described in studies using cell cultures treated with lead chromate are either due to the presumed contamination of soluble chromate or some other undefined ‘‘reactive nature’’ of lead chromate. CPMA adds that ‘‘ * * * the studies referenced by OSHA [that use reagent grade lead chromate] have no relevance to occupational exposures to commercial lead chromate pigments’’ (Ex. 38–205, p. 11–12).

OSHA agrees that studies involving lead chromate pre-solubilized in solutions of hydrochloric acid, sodium hydroxide or other strong acids and bases prior to treatment with cells are not particularly relevant to the inhalation of commercial lead chromate particulates. However, several relevant cellular studies have demonstrated that lead chromate particulates suspended in biological media and not can enter lung cells, damage DNA, and cause altered gene expression as described below.

Beginning in the late 1980s, there has been a consistent research effort to characterize the genotoxic potential of lead chromate particulate in mammalian cells. The lead chromate was not pre-solubilized prior to cell treatment in any of these investigations. In most of the studies, lead chromate particles were rinsed with water and then acetone. The rinses cleansed the particles of water- and acetone-soluble contaminants before cell treatment. This served to remove any potential water-soluble Cr(VI) present that might confound the study results. In most instances, the lead chromate particles were filtered, stirred or sonicated in suspension to break up the aggregated particles into monomeric lead chromate particulates. These lead chromate particulates were primarily less than 5 μm in diameter. This is consistent with the inhaled particle size expected to deposit in the bronchial and alveolar regions of the lung where lung cancer occurs. Air-dried lead chromate particulates were introduced to the cell cultures in a suspension of either saline-based media or acetone. Lead chromate particulate is considered to be insoluble in both solvents so significant solubilization is not expected during the process of creating a homogenous suspension.

The initial research showed that lead chromate particulate morphologically transformed mouse and hamster embryo cells (Exs. 35–119; 12–5). One study tested a variety of lead chromate pigments of different types (e.g. chrome yellows, chrome oranges, molybdate oranges) as well as reagent grade lead chromate (Ex. 12–5). The transformed cells displayed neoplastic properties (e.g. growth in soft agar) and were tumorigenic when injected into animals (Ex. 35–119; 12–5). While lead chromate particulate transformed mouse embryo cells, it is important to note that lead chromate particulate was not found to be mutagenic in these cells suggesting that other types of genetic lesions (e.g. clastogenicity) may be involved (Ex. 35–119).

Follow-on research established that lead chromate particulate caused DNA-protein crosslinks, DNA strand breaks, and chromosomal aberrations (i.e. chromatid deletions and achromatic lesions combined) in mammalian cells rather than DNA nucleotide binding often associated with base substitution and frameshift mutations captured in a standard Ames assay (Exs. 35–132; 35–188). This distinguishes lead chromate particulate from high concentrations of soluble Cr(VI) compounds or pre-solubilized lead chromate which can cause these mutations.

Lead chromate particulate enters mammalian embryo cells by two distinct pathways (Ex. 35–68). It partially dissolves in the culture medium (i.e. biological saline solution) to form chromate ion, which is then transported into the cell. The rate of particle dissolution was shown to be time- and concentration-dependent. The measured chromate ion concentration was consistent with that predicted from the lead chromate solubility constant in water. Lead chromate particulates were shown to adhere to the embryo cell surface enhancing chromate ion solubilization leading to sustained intracellular chromium levels and measurable chromosomal damage (Ex. 35–67).

Lead chromate particulates are also internalized into embryo cells, without dissolution, by a phagocytic process (Ex. 35–68). The lead chromate particles appeared to remain undissolved in tight vacuoles (*i.e.* phagosomes) within the cell over a 24 hour period. Treatment of embryo cells with lead chromate particulates in the presence of a reducing agent (*i.e.* ascorbate) substantially reduced cellular uptake of dissolved chromate ions and the chromosomal damage, but did not impact the internalization of lead chromate particulates (Ex. 35–68). This suggests that chromosomal damage by lead chromate was the result of extracellular particle dissolution and not internalization under the particular experimental conditions. Embryo cell treatment with large amounts of lead glutamate that produced high intracellular lead in the absence of Cr(VI) did not cause chromosomal damage further implicating intracellular chromium as the putative clastogenic agent (Ex. 35–67).

As the ability to maintain human tissue cells in culture improved in the 1990s, dissolution and internalization of lead chromate particulates, uptake of chromate ion, and the resulting chromosomal damage were verified in human lung cells (Exs. 35–66; 47–22–1; 47–12–3; 35–327; 35–436). Lead chromate particulates are internalized, form chromium adducts with DNA, and trigger dose-dependent apoptosis in human small airway epithelial cells (Ex. 35–66). They also cause dose-dependent increases in intracellular chromium, internalized lead chromate particulates and chromosomal damage in human lung fibroblasts (Exs. 47–22–1; 47–12–3). The chromosomal damage from lead chromate in these human lung cells is dependent on the extracellular dissolution and cell uptake of the chromate, rather than lead, in a manner similar to dilute concentrations of the highly soluble sodium chromate (Ex. 47–12–3; 35–327). Another water insoluble Cr(VI) compound, barium chromate particulate, produces very similar responses in human lung fibroblasts (Ex. 35–328). Human lung macrophages can phagocytize lead chromate particulates and trigger oxidation-reduction of Cr(VI) to produce reactive oxygen species capable of damaging DNA and altering gene expression (Ex. 35–436).

OSHA finds these recent studies to be carefully conceived and executed by reputable academic laboratories. The scientific findings have been published in well-respected peer reviewed molecular cancer and toxicology journals, such as Carcinogenesis (Exs. 12–5, 35–68), Cancer Research (Ex. 35–119), Toxicology and Applied Pharmacology (Exs. 35–66; 25–115), and Mutation Research (Exs. 35–132; 47–22–1; 35–327). Contrary to statements by CPMA, the results indicate that lead chromate particulates are able to dissociate in the presence of biological media without the aid of aggressive substances. The resulting chromate ion is bioavailable to enter lung cells, damage genetic material and initiate events critical to carcinogenesis. These effects can not be attributed to small amounts of soluble chromate contaminants since these substances are usually removed as part of the test compound preparation prior to cell treatment.

As one of the study authors, Dr. John Wise of the University of Southern Maine, stated in his post-hearing comments:

> At no time did we dissolve lead chromate particles prior to administration. At the initial onset of the administration of lead chromate particles in our studies, the cells encountered intact lead chromate particles. Any dissolution that occurred was the natural result of the fate of lead chromate particles in a biological environment (Ex. 47–12, p. 3).

Other scientists concurred that the methods and findings of the cellular research with lead chromate were reasonable. Dr. Kathleen MacMahon, a biologist from NIOSH stated:

> NIOSH believes that the methods that were used in the [lead chromate] studies were credible and we support the results and conclusions from those studies (Tr. 342).

Dr. Clewell said:

> As I recall, it [lead chromate particles] was suspended in acetone and ultrasonically shaken to reduce it to submicron particles, which seems like a reasonably good thing to do. There are actually a couple of studies besides the Wise studies that have looked at the question of the uptake of lead chromate. I have looked at those studies and I don't really see any basic flaws in what they did. It is obviously a challenge to reproduce inhalation exposure *in vitro* (Tr. 180–181).

Chromosal Aberrations and Lead Chromate—Several submissions contained testimony from another researcher, Dr. Earle Nestmann of CANTOX Health Sciences International, that criticized the methodology and findings of a study published by the research group at the University of Southern Maine (Exs. 34–6–1; 38–205D; 47–12–1; 47–22). Dr. Nestmann viewed as inappropriate the practice of combining the chromatid deletions and achromatic lesions together as chromosomal aberrations. He indicated the standard practice was to score these two types of lesions separately and that only the deletions had biological relevance. According to Dr. Nestmann, achromatic lesions are chromatid gaps (i.e. lesion smaller than the width of one chromatid) that have no clastogenic significance and serve to inflate the percentage of cells with chromosomal aberrations (i.e. chromatid deletions or breaks). Dr. Nestmann criticized the studies for not including a positive control group that shows the experimental system responds to a 'true' clastogenic effect (i.e. a compound that clearly increases chromosomal deletions without contribution from chromatid gaps).

Dr. John Wise, the Director of the research laboratory at the University of Southern Maine, responded that distinguishing chromatid gaps from breaks is a subjective distinction (e.g. requiring judgment as to the width of a lesion relative to the width of a chromatid) and pooling these lesions simply reduces this potential bias (Ex. 47–12; 47–12–1). He stated that there is no consensus on whether gaps should or should not be scored as a chromosomal aberration and that gaps have been included as chromosomal aberrations in other publications. Dr. Wise also points out that achromatic lesions have not been shown to lack biological significance and that the most recent research indicates that they may be related to DNA strand breaks, a scientifically accepted genotoxic endpoint. Dr. Wise further believed that a positive control was unnecessary in his experiments since the purpose was not to determine whether lead chromate was a clastogenic agent, which had already been established by other research. Rather, the purpose of his studies was to assess Cr(VI) uptake and chromosomal damage caused by water-insoluble lead chromate compared to that of highly water soluble sodium chromate using a relevant *in vitro* cell model (i.e. human lung cells).

OSHA is not in a position to judge whether achromatic lesions should be scored as a chromosomal aberration. However, OSHA agrees with Dr. Nestmann that combining gaps and breaks together serves to increase the experimental response rate in the studies. Given the lack of consensus on the issue, it would have been of value to record these endpoints separately. OSHA is not aware of data that show achromatic gaps to be of no biological significance. The experimental data cited above indicate that soluble and insoluble Cr(VI) compounds clearly increase achromatic gaps in a concentration-dependent manner. The chromatid lesions (gaps and breaks) may be chromosomal biomarkers indicative of genetic damage that is critical to neoplastic transformation. Furthermore, OSHA agrees with Dr. Wise that other evidence establishes lead chromate as an agent able to cause DNA damage and transform cells. The Agency considers the use of sodium chromate-treated cells in the above set of experiments to be the appropriate comparison group and does not find the absence of an additional positive control group to be a technical deficiency of the studies. OSHA considers the research conducted at the University of Southern Maine documenting chromosomal damage in human lung cells following treatment with lead chromate particulates to be consistent with results from other studies (see Section V.B.8) and, thus, contributes to the evidence that water insoluble lead chromate, like other chromates, is able to enter lung cells and damage DNA.

In post-hearing comments, CPMA provided a Canadian research laboratory report that tested the lead chromate Pigment Yellow 34 for chromosomal aberrations in a hamster embryo cell system (Ex. 47–3, appendix C). The research was sponsored by DCC and its representative Dr. Nestmann. Lead chromate particles over the concentration range of 0.1 μ/cm^2 to 10 μ/cm^2 were reported to not induce chromosomal aberrations under the experimental test conditions. Chromatid structural and terminal gaps were not scored as aberrations in this study, even though the percentage of cells with these lesions increased in a dose-dependent manner from two percent in the absence of lead chromate to over thirteen percent in cells treated with 1 μ/cm^2 lead chromate pigment particles.

This result is consistent with other experimental data that show lead chromate particulates cause chromosomal lesions when administered to mammalian embryo cells (Exs. 35–188; 35–132; 35–68; 35–67). The key difference is how the various researchers interpreted the data. The George Washington University group (i.e. Pateirno, Wise, Blankenship *et al.*) considered the dose-dependent achromatic lesions (i.e. chromatid gaps) as a clastogenic event and included them as chromosomal damage. The Canadian test laboratory (i.e. Nucrotechnics) reported achromatic lesions but did not score them as chromosomal aberrations. Reporting achromatic lesions but not scoring them as chromosomal aberrations is consistent with regulatory test guidelines as currently recommended by EPA and OECD. The Nucrotechnics data suggest that the tested lead chromate pigment caused a similar degree of chromosomal damage (i.e. dose-dependent achromatic lesions and chromosomal aberrations combined) in mammalian cells. This result was similar to results produced by reagent grade lead chromate in previous studies.

Mutagenicity and Lead Chromate—CPMA also relied on a study that reported a lack of mutagenicity for lead chromate pigments in a bacterial assay using Salmonella Typhimurium TA 100 (Ex. 11–6). As previously mentioned, this assay specifically measures point and frameshift mutations usually caused by DNA adduct formation. The assay is not sensitive to chromosomal damage, DNA strand breaks, or DNA crosslinks most commonly found with low concentrations of Cr(VI) compounds. Large amounts (50 to 500 µg/plate) of highly soluble sodium dichromate and slightly soluble calcium, strontium, and zinc chromates, were found to be mutagenic in the study, but not the water insoluble barium chromate and lead chromate pigments. However, mutagenicity was observed when the acidic chelating agent, nitrilotriacetic acid (NTA), was added to the assay to help solubilize the water insoluble Cr(VI) compounds. The chelating agent was unable to solubilize sufficient amounts of lead chromate pigments to cause bacterial mutagenicity, if these pigments were more than five percent encapsulated (weight to weight) with amorphous silica.

OSHA finds the results of this study to be consistent with the published literature that shows Cr(VI) mutagenicity requires high concentrations of solubilized chromate ion (Exs. 35–118; 35–161). Large amounts of water-soluble and slightly soluble Cr(VI) compounds produce a mutagenic response in most studies since these Cr(VI) compounds can dissociate to achieve a high concentration of chromate ion. Insoluble lead chromate usually needs to be pre-solubilized under acidic or alkaline conditions to achieve sufficient chromate ion to cause mutagenicity (Ex. 35–162). The above study found highly and slightly soluble chromates to be mutagenic as well as water insoluble lead chromate pigments pre-solubilized with NTA. The lack of mutagenicity for silica encapsulated lead chromate pigments under these experimental conditions is likely the result of their greater resistance to acidic digestion than unencapsulated lead chromate pigment.

Failure to elicit a mutagenic response in a bacterial assay, with or without NTA, is not a convincing demonstration that chromate ion can not partially dissociate from encapsulated lead chromate in biological media, enter mammalian cells, and elicit other types of genotoxicity. As described above, chromosomal damage, believed to result from DNA strand breaks and crosslinks, appears to be the critical genotoxic endpoint for low concentrations of Cr(VI) compounds. Research has shown that lead chromate and lead chromate pigment particulates in biological media can cause chromosomal lesions and cell transformation without the aid of strongly acidic or basic substances (Exs. 12–5; 35–119; 35–188; 35–132; 35–68; 35–67; 47–12–3; 35–327). While silica-encapsulated lead chromate pigments have not been as thoroughly investigated as the unencapsulated pigments or reagent grade lead chromate, one study reported that lead silicochromate particles did have low solubility in biological culture media and transformed hamster embryo cells (Ex. 12–5).

Information is not available in the record to adequately demonstrate the efficiency and stability of the encapsulation process, despite OSHA statements that such information would be of value in its health effects evaluation and its request for such information (69 FR 59315–59316, 10/4/2004; Ex. 2A). In the absence of data to the contrary, OSHA believes it prudent and plausible that encapsulated lead chromate pigments are able to partially dissociate into chromate ion available for lung cell uptake and/or be internalized in a manner similar to other lead chromate particulates. The resulting intracellular Cr(VI) leads to genotoxic damage and cellular events critical to carcinogenesis.

Public Comments on Carcinogenicity of Slightly Water Soluble Cr(VI) Compounds—In its written comments to the NPRM, Boeing Corporation stated that ‘‘there is no persuasive scientific evidence for OSHA's repeated assertion that low solubility hexavalent chromium compounds [e.g. strontium and zinc chromates] are more potent carcinogens than [highly] soluble [Cr(VI)] compounds’’ (Ex. 38–106, p. 2). Boeing and others in the aerospace industry are users of certain slightly soluble Cr(VI) compounds, particularly strontium chromate, found in the protective coatings applied to commercial and military aircraft.

Boeing argues that OSHA, along with IARC, ACGIH and others, have exclusively relied on intrabronchial implantation studies in animals that are both not representative of inhalation exposures in the workplace and are not consistent with the available animal inhalation data (Ex. 38–106–2, p. 26). Boeing asserts that there is no evidence that slightly soluble chromates behave differently in terms of their absorption kinetics than highly soluble chromates when instilled in the lungs of rats (Ex. 38–106–2, p. 19). Boeing believes the OSHA position that slightly soluble Cr(VI) compounds are retained in the lung, associate with cells, and cause high uptake or high local concentrations to be inconsistent with other data showing these Cr(VI) compounds quickly disperse in water (Ex. 38–106–2, p. 26). Boeing concludes:

> There is no basis for the conclusion that low solubility [i.e. slightly soluble] chromates could be more potent than [highly] soluble, and some evidence the opposite may be the case. As a worst case OSHA should conclude that there is inadequate evidence to conclude that [highly] soluble and low-solubility compounds differ in carcinogenic potency. It is critical that OSHA maintain a distinction between low-solubility chromates and highly insoluble chromates based on this data. (Ex. 38–106–2, p. 26)

As noted earlier, OSHA as well as other commenters agree with Boeing that the animal intrabronchial and intratracheal instillation studies are not appropriate for quantitatively predicting lung cancer risk to a worker breathing Cr(VI) dust and aerosols. However, many stakeholders disagreed with the Boeing view and believed these animal studies can be relied upon as qualitative evidence of relative carcinogenic potency. CPMA, which relies on the rat intrabronchial implantation results as evidence that lead chromate is non-carcinogenic, states ‘‘tests involving implantation in rat lung, as carried out by Levy *et al.* in 1986, are relevant to inhalation in industrial exposures’’ (Ex. 38–205, p. 93). In their opening statement NIOSH agreed with the preliminary OSHA determination that ‘‘the less water soluble [Cr(VI)] compounds may be more potent than the more water soluble [Cr(VI)] compounds’’ (Tr. 299). NIOSH identified the rat intrabronchial implantation findings as the basis for their position that the slightly soluble Cr(VI) compounds appear to be more carcinogenic than the more soluble and insoluble Cr(VI) compounds (Tr. 334). Dr. Clewell testified that:

> Some animal studies suggest the solubility of hexavalent chromium compounds influences their carcinogenic potency with slightly soluble compounds having the higher potencies than highly soluble or insoluble compounds. However, the evidence is inadequate to conclude that specific hexavalent chromium compounds are not carcinogenic. Moreover the designs of the studies were not sufficient to quantitatively

estimate comparative potencies (Ex. 44–5, p. 15).

Respiratory Tract Instillation of Slightly Soluble Cr(VI) Compounds in Rats—OSHA agrees that animal intrabronchial and intratracheal implantation studies provide persuasive evidence that slightly soluble Cr(VI) are more carcinogenic than the highly soluble Cr(VI) compounds. As mentioned previously, these studies provide useful information regarding the relative carcinogenicity of different Cr(VI) compounds once they are delivered and deposited in the respiratory tract. For example, one study examined the carcinogenicity of over twenty different Cr(VI) compounds in rats, spanning a broad range of solubilities, under the same experimental conditions in the relevant target organ to humans (i.e. respiratory tract) following *in vivo* administration (Ex. 11–2). A single administration of each Cr(VI) test compound was instilled in the lower left bronchus of approximately 100 rats. The results were dramatic. Roughly 50 and 25 percent of the rats receiving the slightly soluble strontium and calcium chromates, respectively, developed bronchogenic carcinoma. No other Cr(VI) compounds produced more than five percent tumor incidence. The highly soluble sodium dichromate under the same experimental conditions caused bronchogenic carcinoma in only a single rat.

The higher relative potency of the slightly soluble calcium chromate compared to the highly soluble sodium dichromate was confirmed in another study in which each test compound was instilled at a low dose level (i.e., 0.25 mg/kg) in the trachea of 80 rats five times weekly for 30 months (Ex. 11–7). Using this experimental protocol, 7.5 percent of the slightly soluble calcium chromate-treated animals developed brochioalveolar adenomas while none of the highly soluble sodium dichromate-treated rats developed tumors. The tumor incidence at this lower dose level occurred in the absence of serious lung pathology and is believed to reflect the tumorigenic potential of the two Cr(VI) compounds at workplace exposures of interest to OSHA. On the other hand, a five-fold higher dose level that caused severe damage and chronic inflammation to the rat lungs produced a similar fifteen percent lung tumor incidence in both calcium and sodium chromate treated rats. OSHA, as well as the study authors, believe the later tumor response with the higher dose level did not result from direct Cr(VI) interaction with cellular genes, but, instead, was primarily driven by the cellular hyperplasia secondary to the considerable damage to the lung tissue. Boeing also seems to attribute this result to tissue damage stating ‘‘most of the tumors were found in areas of chronic inflammation and scarring, suggesting an effect that is secondary to tissue damage’’ (Ex. 38–106–2, p. 21).

OSHA does not agree with some study interpretations advanced by Boeing in support of their position that slightly soluble Cr(VI) compounds are no more carcinogenic than highly soluble Cr(VI). For example, Boeing claims that the intrabronchial implantation experiments cannot be relied upon because the results do not correspond to findings from animal inhalation studies (Ex. 38–106–2, p. 24–25). The primary basis for the Boeing comparison were two rodent bioassays that reported tumor incidence from the inhalation of different Cr(VI) compounds (Exs. 10–8; 10–11). In one study over 200 mice inhaled slightly soluble calcium chromate powder for five hours per day, five days per week for roughly two years (Ex. 10–8). In the other study, 19 rats inhaled an aqueous sodium dichromate liquid aerosol virtually around the clock for 22 hours a day, seven days a week for eighteen months (Ex. 10–11). The two studies reported a similar tumor incidence despite the lower total weekly Cr(VI) dose of sodium dichromate in the second study. OSHA believes the vastly different experimental protocols employed in these studies do not allow for a legitimate comparison of carcinogenic potency between Cr(VI) compounds. First, mouse and rat strains can differ in their susceptibility to chemical-induced lung tumors. Second, the proportion of respirable Cr(VI) may differ between a liquid aerosol of aqueous sodium dichromate mist and an aerosol solid calcium chromate particles suspended in air. Third, the opportunity for Cr(VI) clearance will undoubtedly differ between a Cr(VI) dose inhaled nearly continuously (e.g., 22 hours per day, seven days a week) and inhaled intermittently (e.g., five hours a day, five days a week) over the course of a week. These experimental variables can be expected to have a major influence on tumor response and, thus, will obscure a true comparison of carcinogenic potency. Boeing acknowledges that ‘‘these [inhalation] studies used very different protocols and are not directly comparable’’ (Ex. 38–106–2, p.24). On the other hand, slightly soluble Cr(VI) compounds were found to cause a greater incidence of lung tumors than highly soluble Cr(VI) compounds in two independent studies in which the test compounds were instilled under the same dosing regime in the same rodent models in research specifically designed to assess relative Cr(VI) carcinogenic potency (Exs. 11–2; 11–7). Therefore, OSHA believes any apparent lack of correspondence between animal inhalation and instillation studies is due to an inability to compare inhalation data from vastly different experimental protocols and should not diminish the relevance of the instillation findings.

Epidemiological Studies of Slightly Soluble Cr(VI) Compounds—Boeing further argues that the greater carcinogenic potency experienced by rats intrabronchially instilled with slightly soluble chromates compared to rats instilled with highly soluble and water-insoluble Cr(VI) compounds ‘‘do not correspond qualitatively to observed lung cancer in occupational exposure’’ (Ex. 38–106–2, p. 21). Several other industry stakeholders disagree. In explaining the excess lung cancer mortality among pigment production workers, CPMA commented:

> [water-insoluble] Lead chromate pigments must be differentiated from [slightly soluble] zinc chromate corrosion inhibitor additives, which are consistently shown to be carcinogenic in various studies. When [water insoluble] lead chromate and [slightly soluble] zinc chromate exposures occur simultaneously, there appears to be a significant cancer hazard. However, when lead chromate pigments alone are the source of chromium exposure, a significant cancer response has never been found (Ex. 38–205, p. 91).

In explaining the excess lung cancer mortality among chromate production workers in the Gibb and Luippold cohorts, the Electric Power Research Institute states that:

> One important distinction is that workers of the historical chromate production industry were exposed to sparingly soluble forms of calcium chromate in the roast mix, which are recognized to have greater carcinogenic potential as compared to soluble forms of Cr(VI) based on animal implantation studies (Ex. 38–8, p. 12).

Deborah Proctor of Exponent also testified:

> Several studies of chromate production worker cohorts have demonstrated that the excess cancer risk is reduced when less lime is added to the roast mixture, reducing worker exposure to the sparingly soluble calcium chromate compounds’’ (Ex. 40–12–5).

OSHA believes there is merit to the above comments that workplace exposure to slightly soluble Cr(VI) compounds may have contributed to the higher lung cancer mortality in both pigments workers producing mixed zinc and lead chromate pigments as well as chromate production workers exposed to calcium chromate from high lime production processes in the 1930s and 1940s. Other factors, such as greater Cr(VI) exposure, probably also contributed to the higher lung cancer mortality observed in these cohorts. In any case, these epidemiological findings support the Boeing contention that the epidemiological findings are inconsistent with the results from animal intrabronchial implantation studies (Ex. 38–106–2, p. 26).

Clearance, Retention, and Dissolution of Slightly Soluble Cr(VI) Compounds in the Lung—Boeing argues that animal experiments that examined the absorption, distribution and excretion of Cr(VI) compounds after intratracheal instillation of Cr(VI) compounds in rats do not show that highly soluble Cr(VI) is cleared more rapidly or retained in the lung for shorter periods than slightly soluble Cr(VI) compounds (Ex. 38–106–2, p. 18–19). The results of one study found that larger amounts of water-insoluble lead chromate were retained in the lungs of rats at both 30 minutes and at 50 days after instillation than for highly soluble sodium chromate or slightly soluble zinc chromate (Ex. 35–56). Although the authors concluded that slightly soluble zinc chromate was more slowly absorbed from the lung than the highly soluble sodium chromate, the excretion and distribution of the absorbed chromium from the zinc and sodium chromate instillations was similar. Furthermore, there was little difference in the amounts of zinc and sodium chromate retained by the lung at the two extreme time points (e.g., 30 minutes and 50 days) measured in the study. OSHA agrees with Boeing that these findings indicate slower clearance and longer retention in the lung of the water insoluble lead chromate relative to highly soluble sodium chromate, but not in the case of the slightly soluble zinc chromate. Slower clearance and longer residence time in the lung will generally enhance carcinogenic potential assuming other dosimetric variables such as lung deposition, Cr(VI) concentration at the lung cell surface, and dissociation into chromate ion are unchanged.

Boeing asserts that a study of strontium chromate dissociation from paint primer contradicts the notion that slightly soluble are more likely than highly soluble Cr(VI) compounds to concentrate and dissociate at the lung cell surface (Ex. 38–106–2, p. 25). This experimental research found that roughly 75 and 85 percent of strontium chromate contained in metal surface primer coating particles was solubilized in water after one and 24 hours, respectively (Ex. 31–2–1). The primer particles were generated using a high volume, low pressure spray gun according to manufacturer specifications, and collected in water impingers. The authors concluded that their study demonstrated that chromate dissociation from primer particles into the aqueous fluid lining lung cells would be modestly hindered relative to highly water soluble Cr(VI) aerosols.

The slower dissociation of the slightly soluble Cr(VI) compound, strontium chromate, plausibly explains its higher carcinogenicity in animal implantation studies. The 'modest hindrance' allows the undissociated chromate to achieve higher concentrations at the surface of the lung cells facilitating chromate transport into the cell. The unhindered, instantaneous dispersion of highly water soluble chromates in aqueous fluid lining of the respiratory tract is less likely to achieve a high chromate concentration at the lung cell membrane. OSHA believes the results of the above study support, not contradict, that slightly soluble Cr(VI) may lead to higher chromium uptake into lung cells than highly soluble Cr(VI) compounds.

In summary, slightly soluble Cr(VI) compounds have consistently caused higher lung tumor incidence in animal instillation studies specifically designed to examine comparative carcinogenic potency in the respiratory tract. The higher carcinogenic activity of slightly soluble Cr(VI) is consistent with cellular studies that indicate that chromate dissociation in close proximity to the lung cell surface may be a critical feature to efficient chromate ion uptake. This is probably best achieved by Cr(VI) compounds that have intermediate water solubility rather than by highly water-soluble Cr(VI) that rapidly dissolves and diffuses in the aqueous fluid layers lining the respiratory tract. The higher carcinogenicity of slightly soluble Cr(VI) may contribute, along with elevated Cr(VI) workplace exposures, to the greater lung cancer mortality in certain occupational cohorts exposed to both slightly soluble and other forms of Cr(VI). The vastly different study protocols employed in the few animal inhalation bioassays do not allow a valid comparison of lung tumor incidence between slightly soluble and highly soluble Cr(VI) compounds.

b. Summary of Cr(VI) Carcinogenicity

After carefully considering all the epidemiological, animal and mechanistic evidence presented in the rulemaking record, OSHA regards all Cr(VI) compounds as agents able to induce carcinogenesis through a genotoxic mode of action. This position is consistent with findings of IARC, EPA, and ACGIH that classified Cr(VI) compounds as known or confirmed human carcinogens. Based on the above animal and experimental evidence, OSHA believes that slightly soluble Cr(VI) compounds are likely to exhibit a greater degree of carcinogenicity than highly water soluble or water insoluble Cr(VI) when the same dose is delivered to critical target cells in the respiratory tract of the exposed worker. In its evaluation of different Cr(VI) compounds, ACGIH recommended lower occupational exposure limits for the slightly soluble strontium chromate (TLV of 0.5 $\mu g/m^3$) and calcium chromate (TLV of 1 $\mu g/m^3$) than either water insoluble (TLV of 10 $\mu g/m^3$) or water soluble (TLV of 50 $\mu g/m^3$) forms of Cr(VI) based on the animal instillation studies cited above. While these animal instillation studies are useful for hazard identification and qualitative determinations of relative potency, they cannot be used to determine a reliable quantitative estimate of risk for human workers breathing these chromates during occupational exposure. This was due to use of inadequate number of dose levels (e.g., single dose level) or a less appropriate route of administration (e.g., tracheal instillation).

It is not clear from the animal or cellular studies whether the carcinogenic potency of water insoluble Cr(VI) compounds would be expected to be more or less than highly water soluble Cr(VI). However, it was found that a greater percentage of water insoluble lead chromate remains in the lungs of rats for longer periods than the highly water soluble sodium chromate when instilled intratracheally at similar doses (Ex. 35–56). Since water insoluble lead chromate can persist for long periods in the lung and increase intracellular levels of Cr and damage DNA in human lung cells at low doses (e.g., 0.1 $\mu g/cm^2$), OSHA believes that based on the scientific evidence discussed above it is reasonable to regard the water insoluble Cr(VI) to be of similar carcinogenic potency to highly soluble Cr(VI) compounds. No convincing scientific evidence was introduced into the record that shows lead chromate to be less carcinogenic than highly soluble chromate compounds.

C. Non-cancer Respiratory Effects

The following sections describe the evidence from the literature on nasal irritation, nasal ulcerations, nasal perforations, asthma, and bronchitis following inhalation exposure to water soluble Cr(VI) compounds. The evidence clearly demonstrates that workers can develop impairment to the respiratory system (nasal irritation, nasal ulceration, nasal perforation, and asthma) after workplace exposure to Cr(VI) compounds below the previous PEL.

It is very clear from the evidence that workers may develop nasal irritation, nasal tissue ulcerations, and nasal septum perforations at occupational exposures level at or below the current PEL of 52 μg/m³. However, it is not clear what occupational exposure levels lead to the development of occupational asthma or bronchitis.

1. Nasal Irritation, Nasal Tissue Ulcerations and Nasal Septum Perforations

Occupational exposure to Cr(VI) can lead to nasal tissue ulcerations and nasal septum perforations. The nasal septum separates the nostrils and is composed of a thin strip of cartilage. The nostril tissue consists of an overlying mucous membrane known as the mucosa. The initial lesion after Cr(VI) exposure is characterized by localized inflammation or a reddening of the affected mucosa, which can later lead to atrophy. This may progress to an ulceration of the mucosa layer upon continued exposure (Ex. 35–1; Ex. 7–3). If exposure is discontinued, the ulcer progression will stop and a scar may form. If the tissue damage is sufficiently severe, it can result in a perforation of the nasal septum, sometimes referred to chrome hole. Individuals with nasal perforations may experience a range of signs and symptoms, such as a whistling sound, bleeding, nasal discharge, and infection. Some individuals may experience no noticeable effects.

Several cohort and cross-sectional studies have described nasal lesions from airborne exposure to Cr(VI) at various electroplating and chrome production facilities. Most of these studies have been reviewed by the Center for Disease Control's Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile for chromium (Ex. 35–41). OSHA reviewed the studies summarized in the profile, conducted its own literature search, and evaluated studies and comments submitted to the rulemaking record. In its evaluation, OSHA took into consideration the exposure regimen and experimental conditions under which the studies were performed, including exposure levels, duration of exposure, number of animals, and the inclusion of appropriate control groups. Studies were not included if they did not contribute to the weight of evidence either because of inadequate documentation or because of poor quality. This section only covers some of the key studies and reviews. OSHA has also identified two case reports demonstrating the development of nasal irritation and nasal septum perforations, and these case reports are summarized as well. One case report shows how a worker can develop the nasal perforations from direct contact (*i.e.*, touching the inner surface of the nose with contaminated fingers).

Lindberg and Hedenstierna examined the respiratory symptoms and effects of 104 Swedish electroplaters (Ex. 9–126). Of the 104 electroplaters, 43 were exposed to chromic acid by inhalation. The remaining 61 were exposed to a mixture of chromic acid and nitric acid, hydrochloric acid, boric acid, nickel, and copper salts. The workers were evaluated for respiratory symptoms, alterations in the condition of the nasal tissue, and lung function. All workers were asked to fill out a detailed questionnaire on their history of respiratory symptoms and function. Physicians performed inspections of the nasal passages of each worker. Workers were given a pulmonary function test to assess lung function. For those 43 workers exposed exclusively to chromic acid, the median exposure time was 2.5 years, ranging from 0.2 to 23.6 years. The workers were divided into two groups, a low exposure group (19 workers exposed to eight-hour time weighted average levels below 2 μg/m³) and a high exposure group (24 workers exposed to eight-hour time weighted average levels above 2 μg/m³). Personal air sampling was conducted on 11 workers for an entire week at stations close to the chrome baths to evaluate peak exposures and variations in exposure on different days over the week. Nineteen office employees who were not exposed to Cr(VI) were used as controls for nose and throat symptoms, and 119 auto mechanics (no car painters or welders) whose lung function had been evaluated using similar techniques to those used on Cr(VI) exposed workers were used as controls for lung function.

The investigators reported nasal tissue ulcerations and septum perforations in a group of workers exposed to chromic acid as Cr(VI) at peak exposure ranging from 20 μg/m³ to 46 μg/m³. The prevalence of ulceration/perforation was statistically higher than the control group. Of the 14 individuals in the 20–46 μg/m³ exposure group, 7 developed nasal ulcerations. In addition to nasal ulcerations, 2 of the 7 also had nasal perforations. Three additional individuals in this group developed nasal perforations in the absence of ulcerations. None of the 14 workers in the 20–46 μg/m³ exposure group were reported to have nasal tissue atrophy in the absence of the more serious ulceration or perforation.

At average exposure levels from 2 μg/m³ to 20 μg/m³, half of the workers complained of ''constantly running nose,'' ''stuffy nose,'' or ''there was a lot to blow out.'' (Authors do not provide details of each complaint). Nasal tissue atrophy, in the absence of ulcerations or perforations, was observed in 66 percent of occupationally exposed workers (8 of 12 subjects) at relatively low peak levels ranging from 2.5 μg/m³ to 11 μg/m³. No one exposed to levels below 1 μg/m³ (time-weighted average, TWA) complained of respiratory symptoms or developed lesions.

The authors also reported that in the exposed workers, both forced vital capacity and forced expiratory volume in one second were reduced by 0.2 L, when compared to controls. The forced mid-expiratory flow diminished by 0.4 L/second from Monday morning to Thursday afternoon in workers exposed to chromic acid as Cr(VI) at daily TWA average levels of 2 μg/m³ or higher. The effects were small, not outside the normal range and transient. Workers recovered from the effects after two days. There was no difference between the control and exposed group after the weekend. The workers exposed to lower levels (2 μg/m³ or lower, TWA) showed no significant changes.

Kuo *et al.* evaluated nasal septum ulcerations and perforations in 189 electroplaters in 11 electroplating factories (three factories used chromic acid, six factories used nickel-chromium, and two factories used zinc) in Taiwan (Ex. 35–10). Of the 189 workers, 26 used Cr(VI), 129 used nickel-chromium, and 34 used zinc. The control group consisted of electroplaters who used nickel and zinc. All workers were asked to fill out a questionnaire and were given a nasal examination including a lung function test by a certified otolaryngologist. The authors determined that 30% of the workers (8/26) that used chromic acid developed nasal septum perforations and ulcerations and 38% (10/26) developed nasal septum ulcers. Using the Mantel Extension Test for Trends, the authors also found that chromium electroplaters had an increased likelihood of developing nasal ulcers and perforations compared to electroplating workers using nickel-chromium and zinc. Personal sampling of airborne Cr(VI) results indicated the highest levels (32 μg/m³ ± 35 μg/m³, ranging from 0.1 μg/m³–119 μg/m³) near the electroplating tanks of the Cr(VI) electroplating factories (Ex. 35–11). Much lower personal sampling levels were reported in the ''other areas in the manufacturing area'' and in the ''administrative area'' (TWA 0.16 ± 0.10 μg/m^3) of the Cr(VI) electroplating plant. The duration of sampling was not indicated. The lung function tests showed that Cr(VI) electroplaters had significantly lower forced vital capacity and forced expiratory volume when compared to other exposure groups.

Cohen *et al.* examined respiratory symptoms of 37 electroplaters following inhalation exposure to chromic acid (Ex. 9–18). The mean length of employment for the 37 electroplaters was 26.9 months (range from 0.3 to 132 months). Fifteen workers employed in other parts of the plant were randomly chosen for the control group (mean length of employment was 26.1 months; range from 0.1 to 96). All workers were asked to fill out a questionnaire on their respiratory history and to provide details about their symptoms. An otolaryngologist then examined each individual's nasal passages and identified ulcerations and perforations. Air samples to measure Cr(VI) were collected for electroplaters. The air sampling results of chromic acid as Cr(VI) concentrations for electroplaters was a mean of 2.9 μg/m^3 (range from non-detectable to 9.1 μg/m^3). The authors found that 95% of the electroplaters developed pathologic changes in nasal mucosa. Thirty-five of the 37 workers who were employed for more than 1 year had nasal tissue damage. None of these workers reported any previous job experience involving Cr(VI) exposure. Four workers developed nasal perforations, 12 workers developed ulcerations and crusting of the septal mucosa, 11 workers developed discoloration of the septal mucosa, and eight workers developed shallow erosion of septal mucosa. The control group consisted of 15 workers who were not exposed to Cr(VI) at the plant. All but one had normal nasal mucosa. The one individual with an abnormal finding was discovered to have had a previous Cr(VI) exposure while working in a garment manufacturing operation as a fabric dyer for three years. In addition to airborne exposure, the authors observed employees frequently wiping their faces and picking their noses with contaminated hands and fingers. Many did not wear any protective gear, such as gloves, glasses, or coveralls.

Lucas and Kramkowsi conducted a Health Hazard Evaluation (HHE) on 11 chrome platers in an industrial electroplating facility (Ex. 3–84). The electroplaters worked for about 7.5 years on average. Physicians evaluated each worker for chrome hole scars, nasal septum ulceration, mucosa infection, nasal redness, perforated nasal septum, and wheezing. Seventeen air samples for Cr(VI) exposure were collected in the chrome area. Cr(VI) air concentrations ranged from 1 to 20 μg/m^3, with an average of 4 μg/m^3. In addition to airborne exposure, the authors observed workers being exposed to Cr(VI) by direct ''hand to nose'' contact, such as touching the nose with contaminated hands. Five workers had nasal mucosa that became infected, two workers had nasal septum ulcerations, two workers had atrophic scarring (author did not provide explanation), possibly indicative of presence of past ulcerations, and four workers had nasal septum perforations.

Gomes evaluated 303 employees from 81 electroplating operations in Sao Paulo, Brazil (Ex. 9–31). Results showed that more than two-thirds of the workers had nasal septum ulcerations and perforations following exposure to chromic acid at levels greater than 100 μg/m^3, but less than 600 μg/m^3 (precise duration of exposure was not stated). These effects were observed within one year of employment.

Lin *et al.* examined nasal septum perforations and ulcerations in 79 electroplating workers from seven different chromium electroplating factories in Taipei, Taiwan (Ex.35–13). Results showed six cases of nasal septum perforations, four having scar formations, and 38 cases of nasal septum ulcerations following inhalation exposure to chromic acid. Air sampling near the electroplating tanks had the highest range of chromic acid as Cr(VI) (mean of 28 μg/m^3; range from 0.7 to 168.3 μg/m^3). In addition to airborne exposures, the authors also observed direct ''hand to nose'' contact where workers placed contaminated fingers in their nose. The authors attributed the high number of cases to poor industrial hygiene practices in the facilities. Five of the seven factories did not have adequate ventilation systems in place. Workers did not wear any PPE, including respirators.

Bloomfield and Blum evaluated nasal tissue damage and nasal septum perforations in 23 workers employed at six chromium electroplating plants (Ex. 9–13). They found that daily exposure to chromic acid as Cr(VI) at levels of 52 μg/m^3 or higher can lead to nasal tissue damage. Three workers developed nasal ulcerations, two workers had nasal perforations, nine workers had nose bleeds, and nine workers had inflamed mucosa.

Kleinfeld and Rosso found that seven out of nine of chrome electroplaters had nasal septum ulcerations (Ex. 9–41). The nine workers were exposed to chromic acid as Cr(VI) by inhalation at levels ranging from 93 μg/m^3 to 728 μg/m^3. Duration of exposure varied from two weeks to one year. Nasal septum ulcerations were noted in some workers who had been employed for only one month.

Royle, using questionnaire responses from 997 British electroplaters exposed to chromic acid, reported a significant increase in the prevalence of nasal ulcerations. The prevalence increased the longer the worker was exposed to chromic acid (*e.g.*, from 14 cases with exposure less than one year to 62 cases with exposure over five years) (Ex. 7–50). In all but 2 cases, air samples revealed chromic acid concentrations of 0.03 mg/m^3 (*i.e.*, 30 μg/m^3).

Gibb *et al.* reported nasal irritations, nasal septum bleeding, nasal septum ulcerations and perforations among a cohort of 2,350 chrome production workers in a Baltimore plant (Ex. 31–22–12). A description of the cohort is provided in detail in the cancer health effects section V.B. of this preamble. The authors found that more than 60% of the cohort had experienced nasal ulcerations and irritations, and that the workers developed these effects for the first time within the first three months of being hired (median). Gibb *et al.* found that the median annual exposure to Cr(VI) during first diagnosis of irritated and/or ulcerated nasal septum was 10 μg/m^3. About 17% of the cohort reported nasal perforations. Based on historical data, the authors believe that the nasal findings are attributable to Cr(VI) exposure.

Gibb *et al.* also used a Proportional Hazard Model to evaluate the relationship between Cr(VI) exposure and the first occurrence of each of the clinical findings. Cr(VI) data was entered into the model as a time dependent variable. Other explanatory variables were calendar year of hire and age of hire. Results of the model indicated that airborne Cr(VI) exposure was associated with the occurrence of nasal septum ulceration ($p = 0.0001$). The lack of an association between airborne Cr(VI) exposure and nasal perforation and bleeding nasal septum may reflect the fact that Cr(VI) concentrations used in the model represent annual averages for the job, in which the worker was involved in at the time of the findings, rather than a short-term average. Annual averages do not factor in day-to-day fluctuations or extreme episodic occurrences. Also, the author believed that poor housekeeping and hygiene practices may have contributed to these health effects as well as Cr(VI) air borne concentrations.

Based on their hazard model, Gibb *et al.* estimated the relative risks for nasal septum ulcerations would increase 1.2 for each 52 µg of Cr(VI)/m^3 increase in Cr(VI) air levels. They found a reduction in the incidence of nasal findings in the later years. They found workers from the earlier years who did not wear any PPE had a greater risk of developing respiratory problems. They believe that the reduction in ulcerations was possibly due to an increased use of respirators and protective clothing and improved industrial hygiene practices at the facility.

The U.S. Public Health Service conducted a study of 897 chrome production workers in seven chromate producing plants in the early 1950s (Ex. 7–3). The findings of this study were used in part as justification for the current OSHA PEL. Workers were exposed by inhalation to various water soluble chromates and bichromate compounds. The total mean exposure to the workers was a TWA of 68 µg/m^3. Of the 897 workers, 57% (or 509 workers) were found to have nasal septum perforations. Nasal septum perforations were even observed in workers during their first year on the job.

Case reports provide further evidence that airborne exposure and direct ‘‘hand to nose’’ contact of Cr(VI) compounds lead to the development of nasal irritation and nasal septum perforations.

For example, a 70-year-old man developed nasal irritation, incrustation, and perforation after continuous daily exposure by inhalation to chromium trioxide (doses were not specified, but most likely quite high given the nature of his duties). This individual inhaled chromium trioxide daily by placing his face directly over an electroplating vessel. He worked in this capacity from 1934 to 1982. His symptoms continued to worsen after he stopped working. By 1991, he developed large perforations of the nasal septum and stenosis (or constriction) of both nostrils by incrustation (Ex. 35–8).

Similarly, a 30-year-old female jigger (a worker who prepares the items prior to electroplating by attaching the items to be plated onto jigs or frames) developed nasal perforation in her septum following continuous exposure (doses in this case were not provided) to chromic acid mists. She worked adjacent to the automated Cr(VI) electroplating shop. She was also exposed to chromic acid from direct contact when she placed her contaminated fingers in her nose. Her hands became contaminated by handling wet components in the jigging and de-jigging processes (Ex. 35–24).

Evidence of nasal septum perforations has also been demonstrated in experimental animals. Adachi exposed 23 C57BL mice to chromic acid by inhalation at concentrations of 1.81 mg Cr(VI)/m^3 for 120 min per day, twice a week and 3.63 mg Cr(VI)/m^3 for 30 minutes per day, two days per week for up to 12 months (Ex. 35–26). Three of the 23 mice developed nasal septum perforations in the 12 month exposure group.

Adachi *et al.* also exposed 50 ICR female mice to chromic acid by inhalation at concentrations of 3.18 mg Cr(VI)/m^3 for 30 minutes per day, two days per week for 18 months (Ex. 35–26–1). The authors used a miniaturized chromium electroplating system to mimic electroplating processes and exposures similar to working experience. Nasal septum perforations were found in six mice that were sacrificed after 10 months of exposure. Of those mice that were sacrificed after 18 months of exposure, nasal septum perforations were found in three mice.

2. Occupational Asthma

Occupational asthma is considered ‘‘a disease characterized by variable airflow limitation and/or airway hyperresponsiveness due to causes and conditions attributable to a particular occupational environment and not to stimuli encountered outside the workplace’’ (Ex. 35–15). Asthma is a serious illness that can damage the lungs and in some cases be life threatening. The common symptoms associated with asthma include heavy coughing while exercising or when resting after exercising, shortness of breath, wheezing sound, and tightness of chest (Exs. 35–3; 35–6).

Cr(VI) is considered to be an airway sensitizer. Airway sensitizers cause asthma through an immune response. The sensitizing agent initially causes production of specific antibodies that attach to cells in the airways. Subsequent exposure to the sensitizing agent, such as Cr(VI), can trigger an immune-mediated narrowing of the airways and onset of bronchial inflammation. All exposed workers do not become sensitized to Cr(VI) and the asthma only occurs in sensitized individuals. It is not clear what occupational exposure levels of Cr(VI) compounds lead to airway sensitization or the development of occupational asthma.

The strongest evidence of occupational asthma has been demonstrated in four case reports. OSHA chose to focus on these four case reports because the data from other occupational studies do not exclusively implicate Cr(VI). The four case reports have the following in common: (1) The worker has a history of occupational exposure exclusively to Cr(VI); (2) a physician has confirmed a diagnosis that the worker has symptoms consistent with occupational asthma; and (3) the worker exhibits functional signs of air restriction (*e.g.*, low forced expiratory volume in one second or low peak expiratory flow rate) upon bronchial challenge with Cr(VI) compounds. These case reports demonstrate, through challenge tests, that exposure to Cr(VI) compounds can cause asthmatic responses. The other general case reports below did not use challenge tests to confirm that Cr(VI) was responsible for the asthma; however, these reports came from workers similarly exposed to Cr(VI) such that Cr(VI) is likely to have been a contributing factor in the development of their asthmatic symptoms.

DaReave reported the case of a 48-year-old cement floorer who developed asthma from inhaling airborne Cr(VI) (Ex. 35–7). This worker had been exposed to Cr(VI) as a result of performing cement flooring activities for more than 20 years. The worker complained of dyspnea, shortness of breath, and wheezing after work, especially after working in enclosed spaces. The Cr(VI) content in the cement was about 12 ppm. A bronchial challenge test with potassium dichromate produced a 50% decrease in forced expiratory volume in one second. The occupational physician concluded that the worker's asthmatic condition, triggered by exposure to Cr(VI) caused the worker to develop bronchial constriction.

LeRoyer reported a case of a 28-year-old roofer who developed asthma from breathing dust while sawing material made of corrugated fiber cement containing Cr(VI) for nine years (Ex. 35–12). This worker demonstrated symptoms such as wheezing, shortness of breath, coughing, rhinitis, and headaches while working. Skin prick tests were all negative. Several inhalation challenges were performed by physicians and immediate asthmatic reactions were observed after nebulization of potassium dichromate. A reduction (by 20%) in the forced expiratory volume in one second after exposure to fiber cement dust was noted.

Novey *et al.* reported a case of a 32-year-old electroplating worker who developed asthma from working with chromium sulfate and nickel salts (Ex. 35–16). He began experiencing coughs, wheezing, and dyspnea within the first week of exposure. Separate inhalation challenge tests given by physicians using chromium sulfate and nickel salts resulted in positive reactions. The worker immediately had difficulty breathing and started wheezing. The challenges caused the forced expiratory volume in 1 second to decrease by 22% and the forced expiratory volume in 1 second/forced vital capacity ratio to decrease from 74.5% to 60.4%. The author believes the worker's bronchial asthma was induced from inhaling chromium sulfate and nickel salts. Similar findings were reported in a different individual by Sastre (Ex.35–20).

Shirakawa and Morimoto reported a case of a 50-year-old worker who developed asthma while working at a metal-electroplating plant (Ex. 35–21). Bronchial challenge by physicians produced positive results when using potassium bichromate, followed by a rapid recovery within 5 minutes, when given no exposures. The worker's forced expiratory volume in one second dropped by 37% after inhalation of potassium bichromate. The individual immediately began wheezing, coughing with dyspnea, and recovered without treatment within five minutes. The author believes that the worker developed his asthma from inhaling potassium bichromate.

In addition to the case reports confirming that Cr(VI) is responsible for the development of asthma using inhalation challenge tests, there are several other case reports of Cr(VI) exposed workers having symptoms consistent with asthma where the symptoms were never confirmed by using inhalation challenge tests.

Lockman reported a case of a 41-year-old woman who was occupationally exposed to potassium dichromate during leather tanning (Ex. 35–14). The worker developed an occupational allergy to potassium dichromate. This allergy involved both contact dermatitis and asthma. The physicians considered other challenge tests using potassium dichromate as the test agent (*i.e.*, peak expiratory flow rate, forced expiratory volume in 1 second and methacholine or bronchodilator challenge), but the subject changed jobs before the physicians could administer these tests. Once the subject changed jobs, all her symptoms disappeared. It was not confirmed whether the occupational exposure to Cr(VI) was the cause of the asthma.

Williams reported a 23-year-old textile worker who was occupationally exposed to chromic acid. He worked near two tanks of chromic acid solutions (Ex. 35–23) and inhaled fumes while frequently walking through the room with the tanks. He developed both contact dermatitis and asthma. He believes the tank was poorly ventilated and was the source of the fumes. He stopped working at the textile firm on the advice of his physician. After leaving, his symptoms improved greatly. No inhalation bronchial challenge testing was conducted to confirm that chromic acid was causing his asthmatic attacks. However, as noted above, chromic acid exposure has been shown to lead to occupational asthma, and thus, chromic acid was likely to be a causative agent in the development of asthma.

Park *et al.* reported a case of four workers who worked in various occupations involving exposure to either chromium sulfate or potassium dichromate (Ex. 35–18). Two worked in a metal electroplating factory, one worked at a cement manufacturer, and the other worked in construction. All four developed asthma. One individual had a positive response to a bronchial provocation test (with chromium sulfate as the test agent). This individual developed an immediate reaction, consisting of wheezing, coughing and dyspnea, upon being given chromium sulfate as the test agent. Peak expiratory flow rate decreased by about 20%. His physician determined that exposure to chromium sulfate was contributing to his asthma condition. Two other individuals had positive reactions to prick skin tests with chromium sulfate as the test agent. Two had positive responses to patch tests using potassium dichromate as the testing challenge agent. Only one out of four underwent inhalation bronchial challenge testing (with a positive result to chromium sulfate) in this report.

3. Bronchitis

In addition to nasal ulcerations, nasal septum perforations, and asthma, there is also limited evidence from reports in the literature of bronchitis associated with Cr(VI) exposure. It is not clear what occupational exposure levels of Cr(VI) compounds would lead to the development of bronchitis.

Royle found that 28% (104/288) of British electroplaters developed bronchitis upon inhalation exposure to chromic acid, as compared to 23% (90/299) controls (Ex. 7–50). The workers were considered to have bronchitis if they had symptoms of persistent coughing and phlegm production. In all but two cases of bronchitis, air samples revealed chromic acid at levels of 0.03 mg/m^3. Workers were asked to fill out questionnaires to assess respiratory problems. Self-reporting poses a problem in that the symptoms and respiratory health problems identified were not medically confirmed by physicians. Workers in this study believe they were developing bronchitis, but it is not clear from this study whether the development of bronchitis was confirmed by physicians. It is also difficult to assess the bronchitis health effects of chromic acid from this study because the study results for the exposed (28%) and control groups (23%) were similar.

Alderson *et al.* reported 39 deaths of chromate production workers related to chronic bronchitis from three chromate producing factories (Bolton, Eaglescliffe, and Rutherglen) from 1947 to 1977 (Ex. 35–2). Neither the specific Cr(VI) compound nor the extent or frequency with which the workers were exposed were specified. However, workers at all three factories were exposed to sodium chromate, chromic acid, and calcium chromate at one time or another. The authors did not find an excess number of bronchitis related deaths at the Bolton and Eaglescliffe factories. At Rutherglen, there was an excess number of deaths (31) from chronic bronchitis with a ratio of observed/expected of 1.8 ($p<0.001$). It is difficult to assess the respiratory health effects of Cr(VI) compounds from this study because there are no exposure data, there are no data on smoking habits, nor is it clear the extent, duration, and amount of specific Cr(VI) compound to which the workers were exposed during the study.

While the evidence supports an association between bronchitis and Cr(VI) exposure is limited, studies in experimental animals demonstrate that Cr(VI) compounds can cause lung irritation, inflammation in the lungs, and possibly lung fibrosis at various exposure levels. Glaser *et al.* examined the effects of inhalation exposure of chromium (VI) on lung inflammation and alveolar macrophage function in rats (Ex. 31–18–9). Twenty, 5-week-old male TNO–W–74 Wistar rats were exposed via inhalation to 25–200 µg Cr(VI)/m^3 as sodium dichromate for 28 days or 90 days for 22 hours per day, 7 days per week in inhalation chambers. Twenty, 5-week-old male TNO–W–74 Wistar rats also served as controls. All rats were killed at the end of the inhalation exposure period. The authors found increased lung weight in the 50–200 µg/m^3 groups after the 90-day exposure period. They also found that 28-day exposure to levels of 25 and 50 µg/m^3 resulted in ''activated'' alveolar macrophages with stimulated phagocytic activities. A more pronounced effect on the activation of alveolar macrophages was seen during the 90-day exposure period of 25 and 50 μg/m^3.

Glaser *et al.* exposed 150 male, 8-week-old Wistar rats (10 rats per group) continuously by inhalation to aerosols of sodium dichromate at concentrations of 50, 100, 200, and 400 μg Cr(VI)/m^3 for 22 hours per day, 7 days a week, for continuous exposure for 30 days or 90 days in inhalation chambers (Ex. 31–18–11). Increased lung weight changes were noticeable even at levels as low as 50 and 100 μg Cr(VI)/m^3 following both 30 day and 90 day exposures. Significant accumulation of alveolar macrophages in the lungs was noted in all of the exposure groups. Lung fibrosis occurred in eight rats exposed to 100 μg Cr(VI)/m^3 or above for 30 days. Most lung fibrosis disappeared after the exposure period had ceased. At 50 μg Cr(VI)/m^3 or higher for 30 days, a high incidence of hyperplasia was noted in the lung and respiratory tract. The total protein in bronchoalveolar lavage (BAL) fluid, albumin in BAL fluid, and lactate dehydrogenase in BAL fluid were significant at elevated levels of 200 and 400 μg Cr(VI)/m^3 in both the 30 day and 90 day exposure groups (as compared to the control group). These responses are indicative of severe injury in the lungs of animals exposed to Cr(VI) dose levels of 200 μg Cr(VI)/m^3 and above. At levels of 50 and 100 μg Cr(VI)/m^3, the responses are indicative of mild inflammation in the lungs. The authors concluded that these results suggest that the severe inflammatory reaction may lead to more chronic and obstructive lesions in the lung.

4. Summary

Overall, there is convincing evidence to indicate that Cr(VI) exposed workers can develop nasal irritation, nasal ulcerations, nasal perforations, and asthma. There is also some limited evidence that bronchitis may occur when workers are exposed to Cr(VI) compounds at high levels. Most of the studies involved exposure to water-soluble Cr(VI) compounds. It is very clear that workers may develop nasal irritations, nasal ulcerations, and nasal perforations at levels below the current PEL of 52 μg/m^3. However, it is not clear what occupational exposure levels lead to disorders like asthma and bronchitis.

There are numerous studies in the literature showing nasal irritations, nasal perforations, and nasal ulcerations resulting from Cr(VI) inhalation exposure. It also appears that direct hand-to-nose contact (*i.e.*, by touching inner nasal surfaces with contaminated fingers) can contribute to the incidence of nasal damage. Additionally, some studies show that workers developed these nasal health problems because they did not wear any PPE, including respiratory protection. Inadequate area ventilation and sanitation conditions (lack of cleaning, dusty environment) probably contributed to the adverse nasal effects.

There are several well documented case reports in the literature describing occupational asthma specifically triggered by Cr(VI) in sensitized workers. All involved workers who frequently suffered symptoms typical of asthma (e.g. dyspnea, wheezing, coughing, etc.) while working in jobs involving airborne exposure to Cr(VI). In some of the reports, a physician diagnosed bronchial asthma triggered by Cr(VI) after specific bronchial challenge with a Cr(VI) aerosol produced characteristic symptoms and asthmatic airway responses. Several national and international bodies, such as the National Institute for Occupational Safety and Health, the World Health Organization's International Programme on Chemical Safety, and the United Kingdom Health and Safety Executive have recognized Cr(VI) as an airway sensitizer that can cause occupational asthma. Despite the widespread recognition of Cr(VI) as an airway sensitizer, OSHA is not aware of any well controlled occupational survey or epidemiological study that has found a significantly elevated prevalence of asthma among Cr(VI)-exposed workers. The level of Cr(VI) in the workplace that triggers the asthmatic condition and the number of workers at risk are not known.

The evidence that workers breathing Cr(VI) can develop respiratory disease that involve inflammation, such as asthma and bronchitis is supported by experimental animal studies. The 1985 and 1990 Glaser *et al.* studies show that animals experience irritation and inflammation of the lungs following repeated exposure by inhalation to water-soluble Cr(VI) at air concentrations near the previous PEL of 52 μg/m^3.

D. Dermal Effects

Occupational exposure to Cr(VI) is a well-established cause of adverse health effects of the skin. The effects are the result of two distinct processes: (1) Irritant reactions, such as skin ulcers and irritant contact dermatitis, and (2) delayed hypersensitivity (allergic) reactions. Some evidence also indicates that exposure to Cr(VI) compounds may cause conjunctivitis.

The mildest skin reactions consist of erythema (redness), edema (swelling), papules (raised spots), vesicles (liquid spots), and scaling (Ex. 35–313, p. 295). The lesions are typically found on exposed areas of the skin, usually the hands and forearms (Exs. 9–9; 9–25). These features are common to both irritant and allergic contact dermatitis, and it is generally not possible to determine the etiology of the condition based on histopathologic findings (Ex. 35–314). Allergic contact dermatitis can be diagnosed by other methods, such as patch testing (Ex. 35–321, p. 226). Patch testing involves the application of a suspected allergen to the skin, diluted in petrolatum or some other vehicle. The patch is removed after 48 hours and the skin examined at the site of application to determine if a reaction has occurred.

Cr(VI) compounds can also have a corrosive, necrotizing effect on living tissue, forming ulcers, or ''chrome holes'' (Ex. 35–315). This effect is apparently due to the oxidizing properties of Cr(VI) compounds (Ex. 35–318, p. 623). Like dermatitis, chrome ulcers generally occur on exposed areas of the body, chiefly on the hands and forearms (Ex. 35–316). The lesions are initially painless, and are often ignored until the surface ulcerates with a crust which, if removed, leaves a crater two to five millimeters in diameter with a thickened, hardened border. The ulcers can penetrate deeply into tissue and become painful. Chrome ulcers may penetrate joints and cartilage (Ex. 35–317, p. 138). The lesions usually heal in several weeks if exposure to Cr(VI) ceases, leaving a flat, atrophic scar (Ex. 35–318, p.623). If exposure continues, chrome ulcers may persist for months (Ex. 7–3).

It is generally believed that chrome ulcers do not occur on intact skin (Exs. 35–317, p. 138; 35–315; 35–25). Rather, they develop readily at the site of small cuts, abrasions, insect bites, or other injuries (Exs. 35–315; 35–318, p. 138). In experimental work on guinea pigs, Samitz and Epstein found that lesions were never produced on undamaged skin (Ex. 35–315). The degree of trauma, as well as the frequency and concentration of Cr(VI) application, was found to influence the severity of chrome ulcers.

The development of chrome ulcers does not appear to be related to the sensitizing properties of Cr(VI). Edmundson provided patch tests to determine sensitivity to Cr(VI) in 56 workers who exhibited either chrome ulcers or scars (Ex. 9–23). A positive response to the patch test was found in only two of the workers examined.

Parkhurst first identified Cr(VI) as a cause of allergic contact dermatitis in 1925 (Ex. 9–55). Cr(VI) has since been confirmed as a potent allergen. Kligman (1966) used a maximization test (a skin test for screening possible contact allergens) to assess the skin sensitizing potential of Cr(VI) compounds (Ex. 35–327). Each of the 23 subjects was sensitized to potassium dichromate. On a scale of one to five, with five being the most potent allergen, Cr(VI) was graded as five (*i.e.*, an extreme sensitizer). This finding was supported by a guinea pig maximization test, which assigned a grade of four to potassium chromate using the same scale (Ex. 35–328).

1. Prevalence of Dermal Effects

Adverse skin effects from Cr(VI) exposure have been known since at least 1827, when Cumin described ulcers in two dyers and a chromate production worker (Ex. 35–317, p. 138). Since then, skin conditions resulting from Cr(VI) exposure have been noted in a wide range of occupations. Work with cement is regarded as the most common cause of Cr(VI)-induced dermatitis (Exs. 35–313, p. 295; 35–319; 35–320). Other types of work where Cr(VI)-related skin effects have been reported include chromate production, chrome plating, leather tanning, welding, motor vehicle assembly, manufacture of televisions and appliances, servicing of railroad locomotives, aircraft production, and printing (Exs. 31–22–12; 7–50; 9–31; 9–100; 9–63; 9–28; 9–95; 9–54; 35–329; 9–97; 9–78; 9–9; 35–330). Some of the important studies on Cr(VI)-related dermal effects in workers are described below.

a. Cement Dermatitis

Many workers develop cement dermatitis, including masons, tile setters, and cement workers (Ex. 35–318, p. 624). Cement, the basic ingredient of concrete, may contain several possible sources of chromium (Exs. 35–317, p.148; 9–17). Clay, gypsum, and chalk that serve as ingredients may contain traces of chromium. Ingredients may be crushed using chrome steel grinders that, with wear, contribute to the chromium content of the concrete. Refractory bricks in the kiln and ash residues from the burning of coal or oil to heat the kiln serve as additional sources. Trivalent chromium from these sources can be converted to Cr(VI) in the kiln (Ex. 35–317. p. 148).

The prevalence of cement dermatitis in groups of workers with regular contact with wet cement has been reported to be from 8 to 45 percent depending on the countries of origin, type of construction industry, and criteria used to diagnose dermatitis (Exs. 46–74, 9–131; 35–317, 9–57, 40–10–10). Cement dermatitis can be caused by direct irritation of the skin, by sensitization to Cr(VI), or both (Ex. 35–317, p. 147). The reported proportion of allergic and irritant contact dermatitis varies considerably depending on the information source. In a review of 16 different data sets, Burrows (1983) found that, on average, 80% of cement dermatitis cases were sensitized to Cr(VI) (Ex. 35–317, p. 148). The studies were mostly conducted prior to 1970 on European construction workers. More recent occupational studies suggest that Cr(VI) allergy may make up a smaller proportion of all dermatitis in construction workers, depending on the Cr(VI) content of the cement. For example, examination of 1238 German and Austrian construction workers in dermatitis units found about half those with occupational dermatitis were skin sensitized to Cr(VI) (Ex. 40–10–10). Several other epidemiological investigations conducted in the 1980s and 1990s also reported that allergic contact dermatitis made up 50 percent or less of all dermatitis cases in various groups of construction workers exposed to wet cement (Ex. 46–74).

Cement is alkaline, abrasive, and hydroscopic (water-absorbing), and it is likely that the irritant effect resulting from these properties interferes with the skin's defenses, permitting penetration and sensitization to take place more readily (Ex. 35–318, p. 624). Dry cement is considered relatively innocuous because it is not as alkaline as wet cement (Exs. 35–317, p. 147; 9–17). When water is mixed with cement the water liberates calcium hydroxide, causing a rise in pH (Ex. 35–317, p. 147).

Flyvholm *et al.* (1996) noted a correlation between the Cr(VI) concentration in the local cement and the frequency of allergic contact dermatitis (Ex. 35–326, p. 278). Because the Cr(VI) content depends partially upon the chromium concentration in raw materials, there is a great variability in the Cr(VI) content in cement from different geographical regions. In locations with low Cr(VI) content, the prevalence of Cr(VI)-induced allergic contact dermatitis was reported to be approximately one percent, while in regions with higher chromate concentrations the prevalence was reported to rise to between 9 to 11% of those exposed (Ex. 35–326, p. 278). For example, only one of 35 U.S. construction workers with confirmed cement dermatitis was reported to have a positive Cr(VI) patch test in a 1970 NIOSH study (Ex. 9–57). However, the same study revealed a low Cr(VI) content in 42 representative cement samples from U.S. companies (e.g 80 percent of the samples with C(VI) < 2 µg/g).

The relationship between Cr(VI) content in cement and the prevalence of Cr(VI)-induced allergic contact dermatitis is supported by the findings of Avnstorp (1989) in a study of Danish workers who had daily contact with wet cement during the manufacture of pre-fabricated concrete products (Ex. 9–131). Beginning in September of 1981, low concentrations of ferrous sulfate were added to all cement sold in Denmark to reduce Cr(VI) to trivalent chromium. Two hundred and twenty seven workers were examined in 1987 for Cr(VI)-related skin effects. The findings from these examinations were compared to the results from 190 workers in the same plants who were examined in 1981. The prevalence of hand eczema had declined from 11.7% to 4.4%, and the prevalence of Cr(VI) sensitization had declined from 10.5% to 2.6%. While the two-to four-fold drop in prevalence was statistically significant, the magnitude of the reduction may be overstated because the amount of exposure time was less in the 1987 than the 1981 group. There is also the possibility that other factors, in addition to ferrous sulfate, may have led to less dermal contact to Cr(VI), such as greater automation or less construction work. However, the study found no significant change in the frequency of irritant dermatitis.

Another study also found lower prevalence of allergic contact dermatitis among Finish construction workers following the 1987 decision to reduce Cr(VI) content of cement used in Finland to less than 2 ppm (Ex. 48–8). Ferrous sulfate was typically added to the cement to meet this requirement. There was a significantly decreased risk of allergic Cr(VI) contact dermatitis reported to the Finnish Occupational Disease Registry post-1987 as compared to pre-1987 (OR=0.4, 95% CI: 0.2–0.7) indicating the occurrence of disease dropped one-third after use of the low Cr(VI) content cement. On the other hand, the occurrence of irritant dermatitis remained stable throughout the study period. Time of exposure was not a significant explanatory variable in the analysis. However, the findings may have been somewhat confounded by changes in diagnostic procedure over time. The Finnish study retested patients previously diagnosed with prior patch test protocols and found several false positives (i.e. false diagnosis of Cr(VI) allergy).

In 2003, the Norwegian National Institute of Occupational Health sponsored an expert peer review of 24 key epidemiological investigations addressing; (1) whether exposure to wet cement containing water soluble Cr(VI) caused allergic contact dermatitis, and (2) whether there was a causal association between reduction of Cr(VI) in cement and reduction in the prevalence of the disease (Ex. 46–74). The panel of four experts concluded that, despite the documented limitations of each individual study, the collective evidence was consistent in supporting ''fairly strong associations between Cr(VI) content in cement and the occurrence of allergic dermatitis * * * it seems unlikely that all these associations reported in the reviewed papers are due to systematic errors only'' (Ex. 46–74, p. 42).

Even though the Norwegian panel felt that the available evidence indicated a relationship between reduced Cr(VI) content of wet cement and lower occurrence of allergic dermatitis, they stated that the epidemiological literature was ''not sufficient to conclude that there is a causal association'' (Ex. 46–74, p. 42). This is somewhat different than the view expressed in a written June 2002 opinion by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) to the European Commission, Directorate for General Health and Consumer Protection (Ex. 40–10–7). In responding to the question of whether it is scientifically justified to conclude that cement containing less than 2 ppm Cr(VI) content could substantially reduce the risk of skin sensitization, the CSTEE stated that ''the available information clearly demonstrates that reduction of chromium VI in cement to less than 2 ppm * * * will reduce the prevalence of allergic contact eczema in workers'' (Ex. 40–10–7, p. 5)

b. Dermatitis Associated With Cr(VI) From Sources Other Than Cement

In 1953 the U.S. Public Health Service reported on hazards associated with the chromium-producing industry in the United States (Ex. 7–3). Workers were examined for skin effects from Cr(VI) exposure. Workers' eyes were also examined for possible effects from splashes of Cr(VI)-containing compounds that had been observed in the plants. Of the 897 workers examined, 451 had skin ulcers or scars of ulcers. Seventeen workers were reported to have skin lesions suggestive of chrome dermatitis. The authors noted that most plants provided adequate washing facilities, and had facilities for providing clean work clothes. A statistically significant increase in congestion of the conjunctiva was also reported in Cr(VI)-exposed workers when compared with non-exposed workers (38.7% vs. 25.8%).

In the Baltimore, Maryland chromate production plant examined by Gibb *et al.* (2000), a substantial number of workers were reported to have experienced adverse skin effects (Ex. 31–22–12). The authors identified a cohort of 2,357 workers first employed at the plant between 1950 and 1974. Clinic and first aid records were examined to identify findings of skin conditions. These clinical findings were identified by a physician as a result of routine examinations or visits to the medical clinic by members of the cohort. Percentages of the cohort with various clinical findings were as follows:

Irritated skin:	15.1%
Dermatitis:	18.5%
Ulcerated skin:	31.6%
Conjunctivitis:	20.0%

A number of factors make these results difficult to interpret. The reported findings are not specifically related to Cr(VI) exposure. They may have been the result of other workplace exposures, or non-workplace factors. The report also indicates the percentage of workers who were diagnosed with a condition during their tenure at the plant; however, no information is presented to indicate the expected incidence of these conditions in a population that is not exposed to Cr(VI).

Measurements of Cr(VI) air concentrations by job title were used to estimate worker exposures. Based on these estimates, the authors used a proportional hazards model to find a statistically significant correlation ($p=0.004$) between ulcerated skin and airborne Cr(VI) exposure. Statistically significant correlations between year of hire and findings of ulcerated skin and dermatitis were also reported. Exposures to Cr(VI) in the plant had generally dropped over time. Median exposure to Cr(VI) at the time of occurrence for most of the findings was said to be about 10 $\mu g/m^3$ Cr(VI) (reported as 20 $\mu g/m^3$ CrO_3). It is unclear, however, what contribution airborne Cr(VI) exposures may have had to dermal effects. Direct dermal contact with Cr(VI) compounds in the plant may have been a contributing factor in the development of these conditions.

Mean and median times on the job prior to initial diagnosis were also reported. The mean time prior to diagnosis of skin or eye effects ranged from 373 days for ulcerated skin to 719 days for irritated skin. Median times ranged from 110 days for ulcerated skin to 221 days for conjunctivitis. These times are notable because many workers in the plant stayed for only a short time. Over 40% worked for less than 90 days. Because these short-term workers did not remain in the workplace for the length of time that was typically necessary for these effects to occur, the results of this study may underestimate the incidence that would occur with a more stable worker population.

Lee and Goh (1988) examined the skin condition of 37 workers who maintained chrome plating baths and compared these workers with a group of 37 control subjects who worked in the same factories but were not exposed to Cr(VI) (Ex. 35–316). Mean duration of employment as a chrome plater was 8.1 (SD±7.9) years. Fourteen (38%) of the chrome platers had some occupational skin condition; seven had chrome ulcers, six had contact dermatitis and one had both. A further 16 (43%) of the platers had scars suggestive of previous chrome ulcers. Among the control group, no members had ulcers or scars of ulcers, and three had dermatitis.

Where ulcers or dermatitis were noted, patch tests were administered to determine sensitization to Cr(VI) and nickel. Of the seven workers with chrome ulcers, one was allergic to Cr(VI). Of the six workers with dermatitis, two were allergic to Cr(VI) and one to nickel. The worker with ulceration and dermatitis was not sensitized to either Cr(VI) or nickel. Although limited by a relatively small study population, this report clearly indicates that Cr(VI)-exposed workers face an increased risk of adverse skin effects. The fact that the majority of workers with dermatitis were not sensitized to Cr(VI) indicates that irritant factors play an important role in the development of dermatitis in chrome plating operations.

Royle (1975) also investigated the occurrence of skin conditions among workers involved in chrome plating (Ex. 7–50). A questionnaire survey completed by 997 chrome platers revealed that 21.8% had experienced skin ulcers, and 24.6% had suffered from dermatitis. No information was presented to indicate the expected incidence in a comparable population that was not exposed to Cr(VI). Of the 54 plants involved in the study, 49 used nickel, another recognized cause of allergic contact dermatitis.

The author examined the relationship between the incidence of these conditions and length of exposure. The plater population was divided into three groups: those with less than one year of Cr(VI) exposure, those with one to five years of Cr(VI) exposure, and those with over five years of Cr(VI) exposure. A statistically significant trend was found between length of Cr(VI) exposure and incidence of skin ulcers. The incidence of dermatitis, on the other hand, bore no relationship to length of exposure.

In 1973, researchers from NIOSH reported on the results of a health hazard investigation of a chrome plating establishment (Ex. 3–5). In the plating area, airborne Cr(VI) concentrations ranged from less than 0.71 to 9.12 μg/m^3 (mean 3.24 μg/m^3; SD=2.48 μg/m^3). Of the 37 exposed workers who received medical examinations, five were reported to have chrome-induced lesions on their hands. Hygiene and housekeeping practices in this facility were reportedly deficient, with the majority of workers not wearing gloves, not washing their hands before eating or leaving the plant, and consuming food and beverages in work areas.

Gomes (1972) examined Cr(VI)-induced skin lesions among electroplaters in Sao Paulo, Brazil (Ex. 9–31). A clinical examination of 303 workers revealed 88 (28.8%) had skin lesions, while 175 (58.0%) had skin and mucus membrane lesions. A substantial number of employers (26.6%) also did not provide personal protective equipment to workers. The author attributed the high incidence of skin ulcers on the hands and arms to inadequate personal protective equipment, and lack of training for employees regarding hygiene practices.

Fleeger and Deng (1990) reported on an outbreak of skin ulcerations among workers in a facility where enamel paints containing chromium were applied to kitchen range parts (Ex. 9–97). A ground coat of paint was applied to the parts, which were then placed on hooks and transported through a curing oven. In some cases, small parts were places on hooks before paint application. Tiny holes in the oven coils apparently resulted in improper curing of the paint, leaving sharp edges and a Cr(VI)-containing residue on the hooks. Most of the workers who handled the hooks reportedly did not wear gloves, because the gloves were said to reduce dexterity and decrease productivity. As a result, cuts from the sharp edges allowed the Cr(VI) to penetrate the skin, leading to ulcerations (Ex. 9–97).

2. Prognosis of Dermal Effects

Cr(VI)-related dermatitis tends to become more severe and persistent with continuing exposure. Once established, the condition may persist even if occupational exposure ceases. Fregert followed up on cases of occupational contact dermatitis diagnosed over a 10-year period by a dermatology service in Sweden. Based on responses to questionnaires completed two to three years after treatment, only 7% of women and 10% of men with Cr(VI)-related allergic contact dermatitis were reported to be healed (Ex. 35–322). Burrows reviewed the condition of patients diagnosed with work-related dermatitis 10–13 years earlier. Only two of the 25 cases (8%) caused by exposure to cement had cleared (Ex. 35–323).

Hogan *et al.* reviewed the literature regarding the prognosis of contact dermatitis, and reported that the majority of patients had persistent dermatitis (Ex. 35–324). It was reported that job changes did not usually lead to a significant improvement for most patients. The authors surveyed contact dermatitis experts around the world to explore their experience with the prognosis of patients suffering from occupational contact dermatitis of the hands. Seventy-eight percent of the 51 experts who responded to the survey indicated that chromate was one of the allergens associated with the worst possible prognosis.

Halbert *et al.* reviewed the experience of 120 patients diagnosed with occupational chromate dermatitis over a 10-year period (Ex. 35–320). The time between initial diagnosis and the review ranged from a minimum of six months to a maximum of nine years. Eighty-four (70%) of patients were reviewed two or more years after initial diagnosis, and 40 (33%) after five years or more. In the majority of cases (78, or 65%), the dermatitis was attributed to work with cement. For the study population as a whole, 76% had ongoing dermatitis at the time of the review.

When the review was conducted, 62 (58%) patients were employed in the same occupation as when initially diagnosed. Fifty-five (89%) of these workers continued to suffer from dermatitis. Fifty-eight patients (48%) changed occupations after their initial diagnosis. Each of these individuals indicated that they had changed occupations because of their dermatitis. In spite of the change, dermatitis persisted in 40 members of this group (69%).

Lips *et al.* found a somewhat more favorable outcome among 88 construction workers with occupational chromate dermatitis who were removed from Cr(VI) exposure (Ex. 35–325). Follow-up one to five years after removal indicated that 72% of the patients no longer had dermatitis. The authors speculated that this result might be due to strict avoidance of Cr(VI) contact. Nonetheless, the condition persisted in a substantial portion of the affected population.

3. Thresholds for Dermal Effects

In a response to OSHA's RFI submitted on behalf of the Chrome Coalition, Exponent indicated that the findings of Fowler *et al.* (1999) and others provide evidence of a threshold for elicitation of allergic contact dermatitis (Ex. 31–18–1, p. 27). Exponent also stated that because chrome ulcers did not develop in the Fowler *et al.* study, ''more aggressive'' exposures appear to be necessary for the development of chrome ulcers.

The Fowler *et al.* study involved the dermal exposure of 26 individuals previously sensitized to Cr(VI) who were exposed to water containing 25 to 29 mg/L Cr(VI) as potassium dichromate (pH 9.4) (Ex. 31–18–5). Subjects immersed one arm in the Cr(VI) solution, while the other arm was immersed in an alkaline buffer solution as a control. Exposure lasted for 30 minutes and was repeated on three consecutive days. Based on examination of the skin, the authors concluded that the skin response experienced by subjects was not consistent with either irritant or allergic contact dermatitis.

The exposure scenario in the Fowler *et al.* study, however, does not take into account certain skin conditions often encountered in the workplace. While active dermatitis, scratches, and skin lesions served as criteria for excluding both initial and continuing participation in the study, it is reasonable to expect that individuals with these conditions will often continue to work. Cr(VI)-containing mixtures and compounds used in the workplace may also pose a greater challenge to the integrity of the skin than the solution used by Fowler *et al.* Wet cement, for example, may have a pH higher than 9.4, and may be capable of abrading or otherwise damaging the skin. As damaged skin is liable to make exposed workers more susceptible to Cr(VI)-induced skin effects, the suggested threshold is likely to be invalid. The absence of chrome ulcers in the Fowler *et al.* study is not unexpected, because subjects with ''fissures or lesions'' on the skin were excluded from the study (Ex. 31–18–5). As discussed earlier, chrome ulcers are not believed to occur on intact skin.

4. Conclusions

OSHA believes that adverse dermal effects from exposure to Cr(VI), including irritant contact dermatitis, allergic contact dermatitis, and skin ulceration, have been firmly established. The available evidence is not sufficient to relate these effects to any given Cr(VI) air concentration. Rather, it appears that direct dermal contact with Cr(VI) is the most relevant factor in the development of dermatitis and ulcers. Based on the findings of Gibb *et al.* (Ex. 32–22–12) and U.S. Public Health Service (Ex. 7–3), OSHA believes that conjunctivitis may result from direct eye contact with Cr(VI).

OSHA does not believe that the available evidence is sufficient to establish a threshold concentration of Cr(VI) below which dermal effects will not occur in the occupational environment. This finding is supported not only by the belief that the exposure scenario of Fowler *et al.* is not consistent with occupational exposures, but by experience in the workplace as well. As summarized by Flyvholm *et al.* (1996), numerous reports have indicated that allergic contact dermatitis occurs in cement workers exposed to Cr(VI) concentrations below the threshold suggested by Fowler *et al.* (1999). OSHA considers the evidence of Cr(VI)-induced allergic contact dermatitis in these workers to indicate that the threshold for elicitation of response suggested by Fowler *et al.* (1999) is not applicable to the occupational environment.

E. Other Health Effects

OSHA has examined the possibility of health effect outcomes associated with Cr(VI) exposure in addition to such effects as lung cancer, nasal ulcerations and perforations, occupational asthma, and irritant and allergic contact dermatitis. Unlike the Cr(VI)-induced toxicities cited above, the data on other health effects do not definitively establish Cr(VI)-related impairments of health from occupational exposure at or below the previous OSHA PEL.

There is some positive evidence that workplace inhalation of Cr(VI) results in gastritis and gastrointestinal ulcers, especially at high exposures (generally over OSHA's previous PEL) (Ex. 7–12). This is supported by ulcerations in the gastrointestinal tract of mice breathing high Cr(VI) concentration for long periods (Ex. 10–8). Other studies reported positive effects but significant information was not reported or the confounders made it difficult to draw positive conclusions (Ex. 3–84; Sassi 1956 as cited in Ex. 35–41). Other studies reported negative results (Exs. 7–14; 9–135).

Likewise, several studies reported increases in renal proteins in the urine of chromate production workers and chrome platers (Exs. 35–107; 5–45; 35–105; 5–57). The Cr(VI) air levels recorded in these workers were usually below the previous OSHA PEL (Exs. 35–107; 5–45). Workers with the highest urinary chromium levels tended to also have the largest elevations in renal markers (Ex. 35–107). One study reported no relationship between chromium in urine and renal function parameters, no relationship with age or with duration of exposure, and no relationship between the presence of chromium skin ulcers and chromium levels in urine or renal function parameters (Ex. 5–57). In most studies, the elevated renal protein levels were restricted to only one or two proteins out of several examined per study, generally exhibited small increases (Ex. 35–105) and the effects appeared to be reversible (Ex. 5–45). In addition, it has been stated that low molecular weight proteinuria can occur from other reasons and cannot by itself be considered evidence of chronic renal disease (Ex. 35–195). Other human inhalation studies reported no changes in renal markers (Exs. 7–27; 35–104). Animal inhalation studies did not report kidney damage (Exs. 9–135; 31–18–11; 10–11; 31–18–10; 10–10). Some studies with Cr(VI) administered by drinking water or gavage were positive for increases in renal markers as well as some cell and tissue damage (Exs. 9–143; 11–10). However, it is not clear how to extrapolate such findings to workers exposed to Cr(VI) via inhalation. Well-designed studies of effects in humans via ingestion were not found.

OSHA did not find information to clearly and sufficiently demonstrate that exposures to Cr(VI) result in significant impairment to the hepatic system. Two European studies, positive for an excess of deaths from cirrhosis of the liver and hepatobiliarity disorders, were not able to separate chromium exposures from exposures to the many other substances present in the workplace. The authors also could not rule out the role of alcohol use as a possible contributor to the disorder (Ex. 7–92; Sassi as cited in Ex. 35–41). Other studies did not report any hepatic abnormalities (Exs. 7–27; 10–11).

The reproductive studies showed mixed results. Some positive reproductive effects occurred in some welding studies. However, it is not clear that Cr(VI) is the causative agent in these studies (Exs. 35–109; 35–110; 35–108; 35–202; 35–203). Other positive studies were seriously lacking in information. Information was not given on exposures, the nature of the reproductive complications, or the women's tasks (Shmitova 1980, 1978 as cited in Ex. 35–41, p. 52). ATSDR states that because these studies were generally of poor quality and the results were poorly reported, no conclusions can be made on the potential for chromium to produce adverse reproductive effects in humans (Ex. 35–41, p. 52). In animal studies, where Cr(VI) was administered through drinking water or diet, positive developmental effects occurred in offspring (Exs. 9–142; 35–33; 35–34; 35–38). However, the doses administered in drinking water or given in the diet were high (*i.e.*, 250, 500, and 750 ppm). Furthermore, strong studies showing reproductive or developmental effects in other situations where employees were working exclusively with Cr(VI) were not found. In fact, the National Toxicology Program (NTP) (Exs. 35–40; 35–42; 35–44) conducted an extensive multigenerational reproductive assessment by continuous breeding where the chromate was administered in the diet. The assessment yielded negative results (Exs. 35–40; 35–42; 35–44). Animal inhalation studies were also negative (Exs. 35–199; 9–135; 10–10; Glaser 1984 as cited in Ex. 31–22–33;). Thus, it cannot be concluded that Cr(VI) is a reproductive toxin for normal working situations.

VI. Quantitative Risk Assessment

A. Introduction

The Occupational Safety and Health (OSH) Act and some landmark court cases have led OSHA to rely on quantitative risk assessment, where possible, to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. Section 6(b)(5) of the Act states that ''The Secretary [of Labor], in promulgating standards dealing with toxic materials or harmful agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' (29 U.S.C. 651 *et seq.*)

In a further interpretation of the risk requirements for OSHA standard setting, the United States Supreme Court, in the 1980 ''benzene'' decision, (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)) ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made that there is a significant risk of material impairment of health at the existing PEL and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that ''before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' [448 U.S. 642]. The Court also stated ''that the Act does not limit the Secretary's power to require the elimination of significant risks'' [488 U.S. 644]. While the Court indicated that the use of quantitative risk analysis was an appropriate means to establish significant risk, they made clear that ''OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty.''

The Court in the Cotton Dust case, (*American Textile Manufacturers Institute* v. *Donovan,* 452 U.S. 490 (1981)) found that Section 6(b)(5) of the OSH Act places benefits to worker health above all other considerations except those making attainment of the health benefits unachievable and, therefore, only feasibility analysis of OSHA health standards is required and not cost-benefit analysis. It reaffirmed its previous position in the ''benzene'' case, however, that a risk assessment is not only appropriate but should be used to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

The determining factor in the decision to perform a quantitative risk assessment is the availability of suitable data for such an assessment. As reviewed in section V.B. on Carcinogenic Effects, there are a substantial number of occupational cohort studies that reported excess lung cancer mortality in workers exposed to Cr(VI) in several industrial operations. Many of these found that workers exposed to higher levels of airborne Cr(VI) for a longer period of time had greater standardized mortality ratios (SMRs) for lung cancer.

OSHA believes that two recently studied occupational cohorts by Gibb *et al.* (Ex. 31–22–11) and Luippold *et al.* (Ex. 33–10) have the strongest data sets on which to quantify lung cancer risk from cumulative Cr(VI) exposure (*i.e.*, air concentration x exposure duration). A variety of exposure-response models were fit to these data, including linear relative risk, quadratic relative risk, log-linear relative risk, additive risk, and Cox proportional hazards models. Using a linear relative risk model on these data to predict excess lifetime risk, OSHA estimated that the lung cancer risk from a 45 year occupational exposure to Cr(VI) at an 8-hour TWA at the previous PEL of 52 $\mu g/m^3$ is 101 to 351 excess deaths per 1000. Quantitative lifetime risk estimates from a working lifetime exposure at several lower alternative PELs under consideration by the Agency were also estimated. The sections below discuss the selection of the appropriate data sets and risk models, the estimation of lung cancer risks based on the selected data sets and models, the uncertainty in the risk estimates, and the key issues that were raised in comments received during the public hearing process.

A preliminary quantitative risk assessment was previously published in the Notice of Proposed Rulemaking (69 FR at 59306, 10/4/2004). This was peer-reviewed by three outside experts in the fields of occupational epidemiology and risk assessment. Their comments were discussed in the NPRM (69 FR at 59385–59388). They commented on the suitability of several occupational data sets for exposure-response analysis, the choice of exposure metric and risk model, the appropriateness of the risk estimates, and the characterization of key issues and uncertainties. The reviewers agreed that the soluble chromate production cohorts described by Gibb *et al.* and Luippold *et al.* provided the strongest data sets for quantitative risk assessment. They concurred that a linear model using cumulative exposure based on time-weighted average Cr(VI) air concentrations by job title and employment history was the most reasonable risk assessment approach. The experts showed less enthusiasm for average monthly Cr(VI) air concentrations as an appropriate exposure metric or for an exposure threshold below which there is no lung cancer risk. They found the range of excess lifetime lung cancer risks presented by OSHA to be sound and reasonable. They offered suggestions regarding issues such as the impact of cigarette smoking and the healthy worker effect on the assessment of risk. OSHA revised the preliminary quantitative risk assessment in several respects based on these peer review comments.

In contrast to the more extensive occupational cohort data on Cr(VI) exposure-response, data from experimental animal studies are less suitable for quantitative risk assessment of lung cancer. Besides the obvious species difference, most of the animal studies administered Cr(VI) to the respiratory tract by less relevant routes, such as instillation or implantation. The few available inhalation studies in animals were limited by a combination of inadequate exposure levels, abbreviated durations, and small numbers of animals per dose group. Despite these limitations, the animal data do provide semi-quantitative information with regard to the relative carcinogenic potency of different Cr(VI) compounds. A more detailed discussion can be found in sections V.B.7 and V.B.9.

The data that relate non-cancer health impairments, such as damage to the respiratory tract and skin, to Cr(VI) exposure are also not well suited for quantitative assessment. There are some data from cross-sectional studies and worker surveys that group the prevalence and severity of nasal damage by contemporary time-weighted average (TWA) Cr(VI) air measurements. However, there are no studies that track either incidence or characterize exposure over time. Nasal damage is also more likely influenced by shorter-term peak exposures that have not been well characterized. While difficult to quantify, the data indicate that the risk of damage to the nasal mucosa will be significantly reduced by lowering the previous PEL, discussed further in section VII on Significance of Risk.

There are even less suitable exposure-response data to assess risk for other Cr(VI)-induced impairments (*e.g.*, mild renal damage, gastrointestinal ulceration). With the possible exception of respiratory tract effects (*e.g.*, nasal damage, occupational asthma), the risk of non-cancer adverse effects that result from inhaling Cr(VI) are expected to be very low, except as a result of long-term regular airborne exposure around or above the previous PEL (52 $\mu g/m^3$). Since the non-cancer effects occur at relatively high Cr(VI) air concentrations, OSHA has concluded that lowering the PEL to reduce the risk of developing lung cancer over a working lifetime will also eliminate or reduce the risk of developing these other health impairments. As discussed in section V.E., adverse effects to the skin primarily result from dermal rather than airborne exposure.

B. Study Selection

The more than 40 occupational cohort studies reviewed in Section VI.B on carcinogenic effects were evaluated to determine the adequacy of the exposure-response information for the quantitative assessment of lung cancer risk associated with Cr(VI) exposure. The key criteria were data that allowed for estimation of input variables, specifically levels of exposure and duration of exposure (*e.g.*, cumulative exposure in mg/m^3-yr); observed numbers of cancers (deaths or incident cases) by exposure category; and expected (background) numbers of cancer deaths by exposure category.

Additional criteria were applied to evaluate the strengths and weaknesses of the available epidemiological data sets. Studies needed to have well-defined cohorts with identifiable cases. Features such as cohort size and length of follow-up affect the ability of the studies to detect any possible effect of Cr(VI) exposure. Potential confounding of the responses due to other exposures was considered. Study evaluation also considered whether disease rates from an appropriate reference population were used to derive expected numbers of lung cancers. One of the most important factors in study evaluation was the ascertainment and use of exposure information (*i.e.*, well-documented historical exposure data). Both level and duration of exposure are important in determining cumulative dose, and studies are often deficient with respect to the availability or use of such information.

Two recently studied cohorts of chromate production workers, the Gibb cohort and the Luippold cohort, were found to be the strongest data sets for quantitative assessment (Exs. 31–22–11; 33–10). Of the various studies, these two had the most extensive and best documented Cr(VI) exposures spanning three or four decades. Both cohort studies characterized observed and expected lung cancer mortality and reported a statistically significant positive association between lung cancer risk and cumulative Cr(VI) exposure. For the remainder of this preamble the Gibb and Luippold cohorts are referred to as the ‘‘preferred cohorts’’, denoting that they are the cohorts used to derive OSHA's model of lung cancer risk from exposure to Cr(VI).

Four other cohorts (Mancuso, Hayes *et al.*, Gerin *et al.*, and Alexander *et al.*) had less satisfactory data for quantitative assessments of lung cancer risk (Exs. 7–11; 23; 7–14; 7–120; 31–16–3). These cohorts include chromate production workers, stainless steel welders, and aerospace manufacturing workers. While the lung cancer response in these cohorts was stratified across multiple exposure groups, there were limitations to these data that affected their reliability for quantitative risk assessment. OSHA therefore did not consider them to be preferred cohorts (*i.e.*, they were not used to derive OSHA's model of lung cancer risk from exposure to Cr(VI)). However, OSHA believes that quantitative analysis of these cohorts provides valuable information to the risk assessment, especially for the purpose of comparison with OSHA's risk model based on the preferred Gibb and Luippold cohorts. Analyses based on the Mancuso, Hayes *et al.*, Gerin *et al.*, and Alexander *et al.* cohorts, referred to as ‘‘additional cohorts’’ for the remainder of this preamble, were compared with the assessments based on the Gibb and Luippold cohorts. The strengths and weaknesses of all six cohorts as a basis for exposure-response analysis are discussed in more detail below.

1. Gibb Cohort

The Gibb *et al.* study was a particularly strong study for quantitative risk assessment, especially in terms of cohort size and historical exposure data (Exs. 31–22–11; 33–11). Gibb *et al.* studied an updated cohort from the same Baltimore chromate production plant previously studied by Hayes *et al.* (see section VI.B.4). The cohort included 2357 male workers (white and non-white) first employed between 1950 and 1974. Follow-up was through the end of 1992 for a total of 70,736 person-years and an average length of 30 years per cohort member. Smoking status and amount smoked in packs per day at the start of employment was available for the majority of the cohort members.

A significant advantage of the Gibb data was the availability of a large number of personal and area sampling measurements from a variety of locations and job titles which were collected over the years during which the cohort members were exposed (from 1950 to 1985, when the plant closed). Using these concentration estimates, a job exposure matrix was constructed giving annual average exposures by job title. Based on the job exposure matrix and work histories for the cohort members, Gibb *et al.* computed the person-years of observation, the observed numbers of lung cancer deaths, and the expected numbers of lung cancer deaths categorized by cumulative Cr(VI) exposure and age of death. They found that cumulative Cr(VI) exposure was a significant predictor of lung cancer risk over the exposure range of 0 to 2.76 (mean±SD = 0.70±2.75) mg/m^3-yr. This included a greater than expected number of lung cancer deaths among relatively young workers. For example, chromate production workers between 40 and 50 years of age with mean cumulative Cr(VI) exposure of 0.41 mg CrO_3/m^3-yr (equivalent to 0.21 mg Cr(VI)/m^3-yr) were about four times more likely to die of lung cancer than a State of Maryland resident of similar age (Ex. 31–22–11, Table V).

The data file containing the demographic, exposure, smoking, and mortality data for the individual cohort members was made available to OSHA (Ex. 295). These data were used in several reanalyses to produce several different statistical exposure-response models and to explore various issues raised in comments to OSHA, such as the use of linear and nonlinear exposure-response models, the difference between modern and historical levels of Cr(VI) exposure, and the impact of including or excluding short-term workers from the exposure-response analysis. The Agency's access to the dataset and to reanalyses of it performed by several different analysts has been a tremendous advantage in its consideration of these and other issues in the development of the final risk assessment.

2. Luippold Cohort

The other well-documented exposure-response data set comes from a second cohort of chromate production workers. Luippold *et al.* studied a cohort of 482 predominantly white, male employees who started work between 1940 and 1972 at the same Painesville, Ohio plant studied earlier by Mancuso (Ex. 33–10) (see subsection VI.B.3). Mortality status was followed through 1997 for a total of 14,048 person-years. The average worker had 30 years of follow-up. Cr(VI) exposures for the Luippold cohort were based on 21 industrial hygiene surveys conducted at the plant between 1943 and 1971, yielding a total of more than 800 area samples (Ex. 35–61). A job exposure matrix was computed for 22 exposure areas for each month of plant operation starting in 1940 and, coupled with detailed work histories available for the cohort members, cumulative exposures were calculated for each person-year of observation. Luippold *et al.* found significant dose-related trends for lung cancer SMRs as a function of year of hire, duration of employment, and cumulative Cr(VI) exposure. Risk assessments on the Luippold *et al.* study data performed by Crump *et al.* had access to the individual data and, therefore, had the best basis for analysis of this cohort (Exs. 31–18–1; 35–205; 35–58).

While the Luippold cohort was smaller and less racially diverse than the Gibb cohort, the workforce contained fewer transient, short-term employees. The Luippold cohort consisted entirely of workers employed over one year. Fifty-five percent worked for more than five years. In comparison, 65 percent of the Gibb cohort worked for less than a year and 15 percent for more than five years at the Baltimore plant. There was less information about the smoking behavior (smoking status available for only 35 percent of members) of the Luippold cohort than the Gibb cohort.

One aspect that the Luippold cohort had in common with the Gibb cohort was extensive and well-documented air monitoring of Cr(VI). The quality of exposure information for both the Gibb and Luippold cohorts was considerably better than that for the Mancuso, Hayes *et al.*, Gerin *et al.*, and Alexander *et al.* cohorts. The cumulative Cr(VI) exposures for the Luippold cohort, which ranged from 0.003 to 23 (mean±SD = 1.58±2.50) mg Cr(VI)/m^3-yr, were generally higher but overlapped those of the Gibb cohort. The use of individual work histories to define exposure categories and presentation of mean cumulative doses in the exposure groups provided a strong basis for a quantitative risk assessment. The higher cumulative exposure range and the longer work duration of the Luippold cohort serve to complement quantitative data available on the Gibb cohort.

3. Mancuso Cohort

Mancuso (Ex. 7–11) studied the lung cancer incidence of an earlier cohort of 332 white male employees drawn from the same plant in Painesville, Ohio that was evaluated by the Luippold group. The Mancuso cohort was first employed at the facility between 1931 and 1937 and followed up through 1972, when the plant closed. Mancuso (Ex. 23) later extended the follow-up period through 1993, yielding a total of 12,881 person-years of observation for an average length of 38.8 years and a total of 66 lung cancer deaths. Since the Mancuso workers were first employed in the 1930s and the Luippold workers were first employed after 1940, the two cohorts are completely different sets of individuals.

A major limitation of the Mancuso study is the uncertainty of the exposure data. Mancuso relied exclusively on the air monitoring reported by Bourne and Yee (Ex. 7–98) conducted over a single short period of time during 1949. Bourne and Yee presented monitoring data as airborne insoluble chromium, airborne soluble chromium, and total airborne chromium by production department at the Painesville plant. The insoluble chromium was probably Cr(III) compounds with some slightly water-soluble and insoluble chromates. The soluble chromium was probably highly water-soluble Cr(VI). Mancuso (Exs. 7–11; 23) calculated cumulative exposures (mg/m^3-yr) for each cohort member based on the 1949 mean chromium concentrations, by production department, under the assumption that those levels reflect exposures during the entire duration of employment for each cohort member, even though employment may have begun as early as 1931 and may have extended to 1972. Due to the lack of air measurements spanning the full period of worker exposure and the lack of adequate methodology to distinguish chromium valence states (*i.e.*, Cr(VI) vs. Cr(III)), the exposure data associated with the Mancuso cohort were not as well characterized as data from the Luippold or Gibb cohorts.

Mancuso (Exs. 7–11; 23)reported cumulative exposure-related increases in age-adjusted lung cancer death rates for soluble, insoluble, or total chromium. Within a particular range of exposures to insoluble chromium, lung cancer death rates also tended to increase with increasing total cumulative chromium. However, the study did not report whether these tendencies were statistically significant, nor did it report the extent to which exposures to soluble and insoluble chromium were correlated. Thus, it is possible that the apparent relationship between insoluble chromium (*e.g.*, primarily Cr(III)) and lung cancer may have arisen because both insoluble chromium concentrations and lung cancer death rates were positively correlated with Cr(VI) concentrations. Further discussion with respect to quantitative risk estimation from the Mancuso cohort is provided in section VI.E.1 on additional risk assessments.

4. Hayes Cohort

Hayes *et al.* (Ex. 7–14) studied a cohort of employees at the same chromate production site in Baltimore examined by Gibb *et al.* The Hayes cohort consisted of 2101 male workers who were first hired between 1945 and 1974, excluding those employed for less than 90 days. The Gibb cohort had different but partially overlapping date criteria for first employment (1950–1974) and no 90 day exclusion. Hayes *et al.* reported SMRs for respiratory tract cancer based on workers grouped by time of hire, employment duration, and high or low exposure groups. Workers who had ever worked at an older plant facility and workers whose location of employment could not be determined were combined into a single exposure group referred to as ''high or questionable'' exposure. Workers known to have been employed exclusively at a newer renovated facility built in 1950 and 1951 were considered to have had ''low'' exposure. A dose-response was observed in the sense that higher SMRs for respiratory cancer were observed among long-term workers (workers who had worked for three or more years) than among short-term workers.

Hayes *et al.* did not quantify occupational exposure to Cr(VI) at the time the cohort was studied, but Braver *et al.* (Ex. 7–17) later estimated average cumulative soluble chromium (presumed by the authors to be Cr(VI)) exposures for four subgroups of the Hayes cohort first employed between 1945 and 1959. The TWA Cr(VI) concentrations were determined from a total of 555 midget impinger air measurements that were collected at the older plant from 1945 to 1950. The cumulative exposures for the subgroups were estimated from the yearly average Cr(VI) exposure for the entire plant and the subgroups' average duration of employment rather than job-specific Cr(VI) concentrations and individual work histories. Such ''group level'' estimation of cumulative exposure is less appropriate than the estimation based on individual experiences as was done for the Gibb and Luippold cohorts.

A more severe limitation of this study is that exposures attributed to many workers in the newly renovated facility at the Baltimore site throughout the 1950s were based on chromium measurements from an earlier period (*i.e.*, 1949–1950) at an older facility. Samples collected at the new facility and reviewed by Gibb *et al.* (Exs. 25, 31–22–12) show that the exposures in the new facility were substantially lower than assumed by Braver *et al.* Braver *et al.* (Ex. 7–17) discussed a number of other potential sources of uncertainty in the Cr(VI) exposure estimates, such as the possible conversion to Cr(III) during sample collection and the likelihood that samples may have been collected mainly in potential problem areas.

5. Gerin Cohort

Gerin *et al.* (Ex. 7–120) developed a job exposure matrix that was used to estimate cumulative Cr(VI) exposures for male stainless steel welders who were part of the International Agency for Research on Cancer's (IARC) multi-center historical cohort study (Ex. 7–114). The IARC cohort included 11,092 welders. However, the number of cohort members who were stainless steel welders, for which Cr(VI) exposures were estimated, could not be determined from their report. Gerin *et al.* used occupational hygiene surveys reported in the published literature, including a limited amount of data collected from 8 of the 135 companies that employed welders in the cohort, to estimate typical eight-hour TWA Cr(VI) breathing zone concentrations for various combinations of welding processes and base metal. The resulting exposure matrix was then combined with information about individual work history, including time and length of employment, type of welding, base metal welded, and information on typical ventilation status for each company (*e.g.*, confined area, use of local exhaust ventilation, etc.) to estimate the cumulative Cr(VI) exposure. Individual work histories were not available for about 25 percent of the stainless steel welders. In these cases, information was assumed based on the average distribution of welding practices within the company. The lack of Cr(VI) air measurements from most of the companies in the study and the limitations in individual work practice information for this cohort raise questions concerning the accuracy of the exposure estimates.

Gerin *et al.* reported no upward trend in lung cancer mortality across four cumulative Cr(VI) exposure categories for stainless steel welders, each accumulating between 7,000 and 10,000 person-years of observation. The welders were also known to be exposed to nickel, another potential lung carcinogen. Co-exposure to nickel may obscure or confound the Cr(VI) exposure-response relationship. As discussed further in Sections VI.E.3 and VI.G.4, exposure misclassification in this cohort may obscure an exposure-response relationship. This is the primary reason that the Gerin *et al.* cohort was not considered a preferred cohort (*i.e.*, it was not used to derive OSHA's quantitative risk estimates), although a quantitative analysis of this cohort was performed for comparison with the preferred cohorts.

6. Alexander Cohort

Alexander *et al.* (Ex. 31–16–3) conducted a retrospective cohort study of 2429 aerospace workers employed in jobs entailing chromate exposure (*e.g.*, spray painting, sanding/polishing, chrome plating, etc.) between 1974 and 1994. The cohort included workers employed as early as 1940. Follow-up time was short, averaging 8.9 years per cohort member; in contrast, the Gibb and Luippold cohorts accumulated an average 30 or more years of follow-up. Long-term follow-up of cohort members is particularly important for determining the risk of lung cancer, which typically has an extended latency period of twenty years or more.

Industrial hygiene data collected between 1974 and 1994 were used to classify jobs in categories of ''high'' exposure, ''moderate'' exposure, or ''low'' exposure to Cr(VI). The use of respiratory protection was accounted for when setting up the job exposure matrix. These exposure categories were assigned summary TWA concentrations and combined with individual job history records to estimate cumulative exposures for cohort members over time. As further discussed in section VI.E.4, it was not clear from the study whether exposures are expressed in units of Cr(VI) or chromate (CrO_3). Exposures occurring before 1974 were assumed to be at TWA levels assigned to the interval from 1974 to 1985.

Alexander *et al.* presented lung cancer incidence data for four cumulative chromate exposure categories based on worker duration and the three (high, moderate, low) exposure levels. Lung cancer incidence rates were determined using a local cancer registry, part of the National Cancer Institute (NCI) Surveillance Epidemiology and End Results (SEER) program. The authors reported no positive trend in lung cancer incidence with increasing Cr(VI) exposure. Limitations of this cohort study include the young age of the cohort members (median = 42) and lack of information on smoking. As discussed above, the follow-up time (average < 9 years) was probably too short to capture lung cancers resulting from Cr(VI) exposure. Finally, the available Cr(VI) air measurement data did not span the entire employment period of the cohort (*e.g.*, no data for 1940 to 1974) and was heavily grouped into a relatively small number of ''summary'' TWA concentrations that may not have fully captured individual differences in workplace exposures to Cr(VI). For the above reasons, in particular the insufficient follow-up time for most cohort members, the Alexander cohort was not considered a preferred dataset for OSHA's quantitative risk analysis. However, a quantitative analysis of this cohort was performed for comparison with the preferred cohorts.

7. Studies Selected for the Quantitative Risk Assessment

The epidemiologic database is quite extensive and contains several studies with exposure and response data that could potentially be used for quantitative risk assessment. OSHA considers certain studies to be better suited for quantitative assessment than others. The Gibb and Luippold cohorts are the preferred sources for quantitative risk assessment because they are large, have extensive follow-up, and have documentation of historical Cr(VI) exposure levels superior to the Mancuso, Hayes, Gerin and Alexander cohorts. In addition, analysts have had access to the individual job histories of cohort members and associated exposure matrices. OSHA's selection of the Gibb and Luippold cohorts as the best basis of exposure-response analysis for lung cancer associated with Cr(VI) exposure was supported by a variety of commenters, including for example NIOSH (Tr. 314; Ex. 40–10–2, p. 4), EPRI (Ex. 38–8, p.6), and Exponent (Ex. 38–215–2, p. 15). It was also supported by the three external peer reviewers who reviewed OSHA's preliminary risk assessment, Dr. Gaylor (Ex. 36–1–4–1, p. 24), Dr. Smith (Ex. 36–1–4–2 p. 28), and Dr. Hertz-Picciotto (Ex. 36–1–4–4, pp. 41–42).

The Mancuso cohort and the Hayes cohort were derived from workers at the same plants as Luippold and Gibb, respectively, but have limitations associated with the reporting of quantitative information and exposure estimates that make them less suitable for risk assessment. Similarly, the Gerin and Alexander cohorts are less suitable, due to limitations in exposure estimation and short follow-up, respectively. For these reasons, OSHA did not rely upon the Mancuso, Hayes, Gerin, and Alexander cohorts to derive its exposure-response model for the risk of lung cancer from Cr(VI).

Although the Agency did not rely on the Mancuso, Hayes, Gerin, and Alexander studies to develop its exposure-response model, OSHA believes that evaluating risk among several different worker cohorts and examining similarities and differences between them adds to the overall completeness and quality of the assessment. The Agency therefore analyzed these datasets and compared the results with the preferred Gibb and Luippold cohorts. This comparative analysis is discussed in Section VI.E. In light of the extensive worker exposure-response data, there is little additional value in deriving quantitative risk estimates from tumor incidence results in rodents, especially considering the concerns with regard to route of exposure and study design.

OSHA received a variety of public comments regarding the overall quality of the Gibb and Luippold cohorts and their suitability as the preferred cohorts in OSHA's quantitative risk analysis. Some commenters raised concerns about the possible impact of short-term workers in the Gibb cohort on the risk assessment (Tr. 123; Exs. 38–106, p. 10, 21; 40–12–5, p. 9). The Gibb cohort's inclusion of many workers employed for short periods of time was cited as a ''serious flaw'' by one commenter, who suggested that many lung cancers among short-term workers in the study were caused by unspecified other factors (Ex. 38–106, p. 10, p. 21). Another commenter stated that the Davies cohort of British chromate production workers ''gives greater credence to the Painesville cohort as it showed that brief exposures (as seen in a large portion of the Baltimore cohort) did not have an increased risk of lung cancer'' (Ex. 39–43, p. 1). However, separate analyses of the short-term (< 1 year employment) and longer-term (1 year) Gibb cohort members indicated that restriction of the cohort to workers with tenures of at least one year did not substantially impact estimates of excess lung cancer mortality (Ex. 31–18–15–1 , p. 29). At the public hearing, Ms. Deborah Proctor of Exponent, Inc. stated that ''the short term workers did not affect the results of the study'' (Tr. 1848). OSHA agrees with Ms. Proctor's conclusion, and does not believe that the inclusion of short term workers in the Gibb cohort is a source of substantial uncertainty in the Agency's risk estimates.

Some commenters expressed concern that the Gibb study did not control for smoking (Exs. 38–218, pp. 20–21; 38–265, p. 28; 39–74, p. 3). However, smoking status at the time of employment was ascertained for approximately 90% of the cohort (Ex. 35–435) and was used in statistical analyses by Gibb *et al.*, Environ Inc., and Exponent Inc. to adjust for the effect of smoking on lung cancer in the cohort (Exs. 25; 31–18–15–1; 35–435). NIOSH performed similar analyses using more detailed information on smoking level (packs per day) that was available for 70% of the cohort (Ex. 35–435, p.1100). OSHA believes that these analyses appropriately addressed the potential confounding effect of smoking in the Gibb cohort. Issues and analyses related to smoking are further discussed in Section VI.G.3.

Other issues and uncertainties raised about the Gibb and Luippold cohorts include a lack of information necessary to estimate deposited dose of Cr(VI) for workers in either cohort and a concern that the Luippold exposure data were based on exposures to ''airborne total soluble and insoluble chromium* * * rather than exposures to Cr(VI)'' (Ex. 38–218, pp. 20–21). However, the exposure estimates for the Luippold (2003) cohort were recently developed by Proctor *et al.* using measurements of airborne Cr(VI), not the total chromium measurements used previously in Mancuso *et al.*'s analysis (Exs. 35–58, p. 1149; 35–61). And, while it is true that the Gibb and Luippold (2003) datasets do not lend themselves to construction of deposited dose measures, the extensive Cr(VI) air monitoring data available on these cohorts are more than adequate for quantitative risk assessment. In the case of the Gibb cohort, the exposure dataset is extraordinarily comprehensive and well-documented (Tr. 709–710; Ex. 44–4, p.2), even ''exquisite'' according to one NIOSH expert (Tr. 312). Further discussion of the quality and reliability of the Gibb and Luippold (2003) exposure data and related comments appears in Section VI.G.1.

OSHA received several comments regarding a new epidemiological study conducted by Environ, Inc. for the Industrial Health Foundation, Inc. of workers hired after the institution of process changes and industrial hygiene practices designed to limit exposure to Cr(VI) in two chromate production plants in the United States and two plants in Germany (Exs. 47–24–1; 47–27, pp. 15–16; 47–35–1, pp. 7–8). These commenters suggested that OSHA should use these cohorts to model risk of lung cancer from low exposures to Cr(VI). Unfortunately, the public did not have a chance to comment on this study because documents related to it were submitted to the docket after the time period when new information should have been submitted. However, OSHA reviewed the study and comments that were submitted to the docket. Based on the information submitted, the Agency does not believe that quantitative analysis of these studies would provide additional information on risk from low exposures to Cr(VI).

A cohort analysis based on the U.S. plants is presented in an April 2005 publication by Luippold *et al.* (Ex. 47–24–2). Luippold *et al.* studied a total of 617 workers with at least one year of employment, including 430 at a plant built in the early 1970s (''Plant 1'') and 187 hired after the 1980 institution of exposure-reducing process and work practice changes in a second plant (''Plant 2''). Workers were followed through 1998. Personal air-monitoring measures available from 1974 to 1988 for the first plant and from 1981 to 1998 for the second plant indicated that exposure levels at both plants were low, with overall geometric mean concentrations below 1.5 $\mu g/m^3$ and area-specific average personal air sampling values not exceeding 10 $\mu g/m^3$ for most years (Ex. 47–24–2, p. 383). By the end of follow-up, which lasted an average of 20.1 years for workers at Plant 1 and 10.1 years at Plant 2, 27 cohort members (4%) were deceased. There was a 41% deficit in all-cause mortality when compared to all-cause mortality from age-specific state reference rates, suggesting a strong healthy worker effect. Lung cancer was 16% lower than expected based on three observed vs. 3.59 expected cases, also using age-specific state reference rates (Ex. 47–24–2, p. 383). The authors concluded that ''[t]he absence of an elevated lung cancer risk may be a favorable reflection of the postchange environment. However, longer follow-up allowing an appropriate latency for the entire cohort will be needed to confirm this conclusion'' (Ex. 47–24–2, p. 381).

OSHA agrees with the study authors that the follow-up in this study was not sufficiently long to allow potential Cr(VI)-related lung cancer deaths to occur among many cohort members. The mean times since first exposure of 10 and 20 years for Plant 1 and Plant 2 employees, respectively, suggest that most workers in the cohort may not have completed the '' * * * typical latency period of 20 years or more'' that Luippold *et al.* suggest is required for occupational lung cancer to emerge (Ex. 47–24–2, p. 384). Other important limitations of this study include the striking healthy worker effect on the SMR analysis, and the relatively young age of most workers at the end of follow-up (approximately 90% < 60 years old) (Ex. 47–24–2, p. 383). OSHA also agrees with the study authors' statements that '' * * * the few lung cancer deaths in this cohort precluded * * * [analyses to] evaluate exposure-response relationships * * * '' (Ex. 47–24–2, p. 384).

Although OSHA's model predicts high excess lung cancer risk for highly exposed individuals (*e.g.*, workers exposed for 45 years at the previous PEL of 52 $\mu g/m^3$), the model would predict much lower risks for workers with low exposures, as in the Luippold (2005) cohorts. To provide a point of comparison between the results of the Luippold *et al.* (2005) 'post-change' study and OSHA's risk model, the Agency used its risk model to generate an estimate of lung cancer risk for a population with exposure characteristics approximately similar to the 'post-change' cohorts described in Luippold *et al.* (2005). It should be noted that since this comparative analysis used year 2000 U.S. reference rates were rather than the state-, race-, and gender-specific historical reference mortality rates used by Luippold *et al.* (2005), this risk calculation provides only a rough estimate of expected excess lung cancer risk for the cohort. The derivation of OSHA's risk model (based on the preferred Gibb and Luippold

(2003) cohorts) is described in Sections VI.C.1 and VI.C.2.

It is difficult to tell from the publication what the average level or duration of exposure was for the cohort. However, personal sampling data reported by Luippold *et al.* (2005) had annual geometric mean 8-hour TWA concentrations ''much less'' than 1.5 µg/m^3 in most years (Ex. 47–24–2, p. 383). Most workers also probably had less than 20 years of exposure, given the average follow-up periods of 20 and 10 years reported for the Luippold (2005) Plant 1 and Plant 2, respectively. OSHA assumed that workers had TWA exposures of 1.5 µg/m^3 for 20 years, with the understanding that this assumption would lead to somewhat higher estimates of risk than OSHA s model would predict if the average exposure of the cohort was known. Using these assumptions, OSHA's model predicts a 2–9% excess lung cancer risk due to Cr(VI) exposure, or less than four cancers in the population the size and age of the Luippold 2005 cohort.

Since this analysis used year 2000 U.S. reference rates rather than the state-, race-, and gender-specific historical reference mortality rates used by Luippold *et al.* (2005), this risk calculation provides only a rough estimate of the lung cancer risk that OSHA's model would predict for the cohort. Nevertheless, it illustrates that for a relatively young population with low exposures, OSHA's risk model (derived from the preferred Gibb and Luippold 2003 cohorts) predicts lung cancer risk similar to that observed in the low-exposure Luippold 2005 cohort. The small number of lung cancer deaths observed in Luippold 2005 should not be considered inconsistent with the risk estimates derived using models developed by OSHA based on the Gibb and Luippold (2003) cohorts (Ex. 47–24–2, p. 383).

Some commenters believed that analysis of the unpublished German cohorts would demonstrate that lung cancer risk was only increased at the highest Cr(VI) levels and, therefore, could form the basis for an exposure threshold (Exs. 47–24–1; 47–35–1). Although no data were provided to corroborate their comments, the Society of the Plastics Industry requested that OSHA obtain and evaluate the German study as ''new and available evidence which may suggest a higher PEL than proposed'' (Ex. 47–24–1, p. 4).

Following the close of the comment period, OSHA gained access to a 2002 final contract report by Applied Epidemiology Inc. prepared for the Industrial Health Foundation (Ex. 48–1–1; 48–1–2) and a 2005 prepublication by ENVIRON Germany (Ex. 48–4). The 2002 report contained detailed cohort descriptions, exposure assessments, and mortality analyses of 'post-change' workers from the two German chromate production plants referred to above and two U.S. chromate production plants, one of which is plant 1 discussed in the 2005 study by Luippold *et al.* The mortality and multivariate analyses were performed on a single combined cohort from all four plants. The 2005 prepublication contained a more abbreviated description and analysis of a smaller cohort restricted to the two German plants only. The cohorts are referred to as 'post-change' because the study only selected workers employed after the participating plants switched from a high-lime to a no-lime (or very low lime facility, in the case of U.S. plant 1) chromate production process and implemented industrial hygiene improvements that considerably reduced Cr(VI) air levels in the workplace.

The German cohort consisted of 901 post-change male workers from two chromate production plants employed for at least one year. Mortality experience of the cohort was evaluated through 1998. The study found elevated lung cancer mortality (SMR=1.48 95% CI: 0.93–2.25) when compared to the age- and calendar year-adjusted German national population rates (Ex. 48–4). The cohort lacked sufficient job history information and air monitoring data to develop an adequate job-exposure matrix required to estimate individual airborne exposures (Ex. 48–1–2). Instead, the researchers used the large amount of urinary chromium data from routine biomonitoring of plant employees to analyze lung cancer mortality using cumulative urinary chromium as an exposure surrogate, rather than the conventional cumulative Cr(VI) air concentrations. The study reported a statistically significant two-fold excess lung cancer mortality (SMR=2.09; 95% CI: 1.08–3.65; 12 observed lung cancer deaths) among workers in the highest cumulative exposure grouping (*i.e.* >200 µg Cr/L—yr). There was no increase in lung cancer mortality in the lower exposure groups, but the number of lung cancer deaths was small (*i.e.* <5 deaths) and the confidence intervals were wide. Logistic regression modeling in the multi-plant cohort (*i.e.* German and U.S. plants combined) showed an increased risk of lung cancer in the high (OR=20.2; 95% CI: 6.2–65.4; 10 observed deaths) and intermediate (OR=4.9; 95% CI: 1.5–16.0; 9 deaths) cumulative exposure groups when compared to the low exposure group (Ex. 48–1–2, Table 18). The lung cancer risks remained unchanged when smoking status was controlled for in the model, indicating that the elevated risks were unlikely to be confounded by smoking in this study.

OSHA does not believe that the results of the German study provide a basis on which to establish a threshold exposure below which no lung cancer risk exists. Like the U.S. post-change cohort (*i.e.,* Luippold (2005) cohort) discussed above, small cohort size, few lung cancer cases (*e.g.,* 10 deaths in the three lowest exposure groups combined) and limited follow-up (average 17 years) severely limit the power to detect small increases in risk that may be present with low cumulative exposures. The limited power of the study is reflected in the wide confidence intervals associated with the SMRs. For example, there is no apparent evidence of excess lung cancer (SMR=0.95; 95% CI: 0.26–2.44) in workers exposed to low cumulative urine chromium levels between 40–100 µg Cr/L—yr. However, the lack of precision in this estimate is such that a two-fold increase in lung cancer mortality can not be ruled out with a high degree of confidence. Although the study authors state that the data suggest a possible threshold effect, they acknowledge that ''demonstrating a clear (and statistically significant) threshold response in epidemiological studies is difficult especially [where], as in this study, the number of available cases is relatively small, and the precise estimation of small risks requires large numbers'' (Ex. 48–4, p. 8). OSHA agrees that the number of lung cancer cases in the study is too small to clearly demonstrate a threshold response or precisely estimate small risks.

OSHA has relied upon a larger, more robust cohort study for its risk assessment than the German cohort. In comparison, the Gibb cohort has about five times the person-years of observation (70736 vs. 14684) and number of lung cancer cases (122 vs. 22). The workers, on average, were followed longer (30 vs. 17 years) and a greater proportion of the cohort is deceased (36% vs. 14%). Limited air monitoring from the German plants indicate that average plant-wide airborne Cr(VI) roughly declined from about 35 µg Cr(VI)/m^3 in the mid 1970s to 5 µg Cr(VI)/m^3 in the 1990s (2002 report; Ex. 7–91). This overlaps the Cr(VI) air levels in the Baltimore plant studied by Gibb *et al.* (Ex. 47–8). Furthermore, cumulative exposure estimates for members of the Gibb cohort were individually reconstructed from job histories and Cr(VI) air monitoring data. These airborne Cr(VI) exposures are better suited than urinary chromium for evaluating occupational risk at the permissible exposure limits under consideration by OSHA. An appropriate conversion procedure that credibly predicts time-weighted average Cr(VI) air concentrations in the workplace from urinary chromium measurements is not evident and, thus, would undoubtedly generate additional uncertainty in the risk estimates. For the above reasons, OSHA believes the Gibb cohort provides a stronger dataset than the German cohort on which to assess the existence of a threshold exposure. This and other issues pertaining to the relationship between the cumulative exposure and lung cancer risk are further discussed in section VI.G.1.a.

C. Quantitative Risk Assessments Based on the Gibb Cohort

Quantitative risk assessments were performed on the exposure-response data from the Gibb cohort by three groups: Environ International (Exs. 33–15; 33–12) under contract with OSHA; the National Institute for Occupational Safety and Health (Ex. 33–13); and Exponent (Ex. 31–18–15–1) for the Chrome Coalition. All reported similar risks for Cr(VI) exposure over a working lifetime despite using somewhat different modeling approaches. The exposure-response data, risk models, statistical evaluation, and risk estimates reported by each group are discussed below.

1. Environ Risk Assessments

In 2002, Environ International (Environ) prepared a quantitative analysis of the association between Cr(VI) exposure and lung cancer (Ex. 33–15) , which was described in detail in the Preamble to the Proposed Rule (69 FR at 59364–59365). After the completion of the 2002 Environ analysis, individual data for the 2357 men in the Gibb *et al.* cohort became available. The new data included cumulative Cr(VI) exposure estimates, smoking information, date of birth, race, date of hire, date of termination, cause of death, and date of the end of follow-up for each individual (Ex. 35–295). The individual data allowed Environ to do quantitative risk assessments based on (1) redefined exposure categories, (2) alternate background reference rates for lung cancer mortality, and (3) Cox proportional hazards modeling (Ex. 33–12). These are discussed below and in the 2003 Environ analysis (Ex. 33–12).

The 2003 Environ analysis presented two alternate groupings with ten cumulative Cr(VI) exposure groups each, six more than reported by Gibb *et al.* and used in the 2002 analysis. One alternative grouping was designed to divide the person-years of follow-up fairly evenly across groups. The other alternative allocated roughly the same number of observed lung cancers to each group. These two alternatives were designed to remedy the uneven distribution of observed and expected cases in the Gibb *et al.* categories, which may have caused parameter estimation problems due to the small number of cases in some groups. The new groupings assigned adequate numbers of observed and expected lung cancer cases to all groups and are presented in Table VI–1.

Environ used a five-year lag to calculate cumulative exposure for both groupings. This means that at any point in time after exposure began, an individual's cumulative exposure would equal the product of chromate concentration and duration of exposure, summed over all jobs held up to five years prior to that point in time. An exposure lag is commonly used in exposure-response analysis for lung cancer since there is a long latency period between first exposure and the development of disease. Gibb *et al.* found that models using five- and ten-year lags provided better fit to the mortality data than lags of zero, two and twenty years (Ex. 31–22–11).

Table VI-1

Dose-Response Data From Environ (2003, Ex. 33-12): Observed and Expected Lung Cancer Deaths for Gibb Cohort Grouped by Ten Cumulative Cr(VI) Exposure Categories

	Cumulative Cr(VI) Exposure ($\mu g/m^3$-years)	Mean Cr(VI) Exposure ($\mu g/m^3$-yr)	Person-Years	Observed Lung Cancers	Expected Lung Cancers	
					Maryland Rates	Baltimore Rates
Alternative 1: Roughly Equal Observed Cases per Group	0 - 0.151	0.0246	17982	12	10.3	13.37
	0.151 - 0.686	0.395	9314	12	13.0	16.80
	0.686 - 2.08	1.25	8694	12	10.3	13.55
	2.08 - 4.00	2.96	5963	12	7.38	9.42
	4.00 - 8.32	5.89	5102	12	5.63	7.32
	8.32 - 18.2	12.4	5829	13	7.09	9.21
	18.2 - 52	31.1	6679	13	6.83	9.05
	52 - 182	105	6194	12	5.77	7.73
	182 - 572	314	4118	12	5.79	7.66
	>572	979	945	12	2.07	2.62
Alternative 2: Roughly Equal Number of Person-Years per Group	0 - 0.052	0.00052	14282	4	5.08	6.63
	0.052 - 0.273	0.147	6361	11	9.05	11.58
	0.273 - 0.65	0.455	6278	7	8.71	11.33
	0.65 - 1.43	0.996	6194	11	7.30	9.58
	1.43 - 3.12	2.19	6395	12	8.17	10.52
	3.12 - 6.89	4.59	6207	11	6.90	8.95
	6.89 - 16.1	10.7	6296	17	7.77	10.05
	16.1 -41.6	25.9	6230	12	6.50	8.57
	41.6 - 143	81.5	6287	10	5.56	7.52
	>143	384	6289	27	9.17	11.99
TOTAL			70819.38	122	74.2	96.7

The lower bounds of the ranges are inclusive; the upper bounds are exclusive.

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The 2003 Environ analysis also derived expected cases using lung cancer rates from alternative reference populations. In addition to the State of Maryland lung cancer rates that were used by Gibb *et al.*, Environ used age- and race-specific rates from the city of Baltimore, where the plant was located. Baltimore may represent a more appropriate reference population because most of the cohort members resided in Baltimore and Baltimore residents may be more similar to the cohort members than the Maryland or U.S. populations in their co-exposures and lifestyle characteristics, especially smoking habits and urban-related risk factors. On the other hand, Baltimore may not be the more appropriate reference population if the higher lung cancer rates in the Baltimore population primarily reflect extensive exposure to industrial carcinogens. This could lead to underestimation of risk attributable to Cr(VI) exposure.

The 2003 analysis used two externally standardized models, a relative risk model (model E1 below) and an additive risk model (model E2) defined as follows:

E1. $N_i = C_0 * E_i * (1 + C_1D_i + C_2D_i^2)$

E2. $N_i = C_0 * E_i + PY_i * (C_1D_i + C_2D_i^2)$

where N_i is the predicted number of lung cancers in the i th group; PY_i is the number of person-years for group i; E_i is the expected number of lung cancers in that group, based on the reference population; D_i is the mean cumulative dose for that group; and C_0, C_1, and C_2 are parameters to be estimated. Both models initially included quadratic exposure terms ($C_2D_i^2$) as one way to test for nonlinearity in the exposure-response. Model E1 is a relative risk model, whereas Model E2 is an additive risk model. In the case of additive risk models, the exposure-related estimate of excess risk is the same regardless of the age- and race-specific background rate of lung cancer. For relative risk models, a dose term is multiplied by the appropriate background rate of lung cancer to derive an exposure-related estimate of risk, so that excess risk always depends on the background.

Maximum likelihood techniques were used to estimate the parameters C_0, C_1, and C_2. Likelihood ratio tests were used to determine which of the model parameters contributed significantly to the fit of the model. Parameters were sequentially added to the model, starting with C_1, when they contributed significantly ($p < 0.05$) to improving the fit. Parameters that did not contribute significantly, including the quadratic exposure terms ($C_2D_i^2$), were removed from the models.

Two Cox proportional hazards models were also fit to the individual exposure-response data. The model forms were:

C1. $h(t;z;D) = h_0(t)*\exp(\beta_1 z + \beta_2 D)$

C2. $h(t;z;D) = h_0(t)*[\exp(\beta_1 z)][1 + \beta_2 D]$

where h is the hazard function, which expresses the age-specific rate of lung cancer among workers, as estimated by the model. In addition, t is age, z is a vector of possible explanatory variables other than cumulative dose, D is cumulative dose, $h_0(t)$ is the baseline hazard function (a function of age only), β_2 is the cumulative dose coefficient, and β_1 is a vector of coefficients for other possible explanatory variables—here, cigarette smoking status, race, and calendar year of death (Ex. 35–57). Cox modeling is an approach that uses the experience of the cohort to estimate an exposure-related effect, irrespective of an external reference population or exposure categorization. Because they are internally standardized, Cox models can sometimes eliminate concerns about choosing an appropriate reference population and may be advantageous when the characteristics of the cohort under study are not well matched against reference populations for which age-related background rates have been tabulated. Model C1 assumes the lung cancer response is nonlinear with cumulative Cr(VI) exposure, whereas C2 assumes a linear lung cancer response with Cr(VI) exposure. For the Cox proportional hazards models, C1 and C2, the other possible explanatory variables considered were cigarette smoking status, race, and calendar year of death.

The externally standardized models E1 and E2 provided a good fit to the data ($p \geq 0.40$). The choice of exposure grouping had little effect on the parameter estimates of either model E1 or E2. However, the choice of reference rates had some effect, notably on the ‘‘background’’ parameter, C_0, which was included as a fitted parameter in the models to adjust for differences in background lung cancer rates between cohort members and the reference populations. For example, values of C_0 greater than one ‘‘inflate’’ the base reference rates, reducing the magnitude of excess risks in the model. Such an adjustment was necessary for the Maryland reference population (the maximum likelihood estimate of C_0 was significantly higher than one), but not for the Baltimore city reference population (C_0 was not significantly different from one). This result suggests that the Maryland lung cancer rates may be lower than the cohort's background lung cancer rates, but the Baltimore city rates may adequately reflect the cohort background rates. The inclusion of the C_0 parameter yielded a cumulative dose coefficient that reflected the effect of exposure and not the effect of differences in background rates, and was appropriate.

The model results indicated a relatively consistent cumulative dose coefficient, regardless of reference population. The coefficient for cumulative dose in the models ranged from 2.87 to 3.48 per mg/m^3-yr for the relative risk model, E1, and from 0.0061 to 0.0071 per mg/m^3-person-yr for the additive risk model, E2. These coefficients determine the slope of the linear cumulative Cr(VI) exposure-lung cancer response relationship. In no case did a quadratic model fit the data better than a linear model.

Based on comparison of the models' AIC values, Environ indicated that the linear relative risk model E1 was preferred over the additive risk model E2. OSHA agrees with Environ's conclusion. The relative risk model is also preferred over an additive risk model because the background rate of lung cancer varies with age. It may not be appropriate to assume, as an additive model does, that increased lung cancer risk at age 25, where background risk is relatively low, would be the same (for the same cumulative dose) as at age 65, where background rates are much higher.

The Cox proportional hazards models, C1 and C2, also fit the data well (although the fit was slightly better for model C2 than C1). Recall that for the Cox proportional hazards models, C1 and C2, the other possible explanatory variables considered were cigarette smoking status, race, and calendar year of death. For both models, addition of a term for smoking status significantly improved the fit of the models to the data ($p<0.00001$). The experience with model C1 indicated that race ($p=0.15$) and year of death ($p=0.4$) were not significant contributors when cumulative dose and smoking status were included in the model. Based on results for model C1, race and year of death were not considered by Environ in the linear model C2. The cumulative dose coefficient, β_2, was 1.00 for model C1 and 2.68 for model C2. A more complete description of the models and variables can be found in the 2003 Environ analysis (Ex. 33–12, p. 10).

Lifetable calculations were made of the number of extra lung cancers per 1000 workers exposed to Cr(VI) based on models E1, E2, C1, and C2, assuming a constant exposure from age 20 through a maximum of age 65. The lifetable accounted for both lung cancer risk and competing mortality through age 100. Rates of lung cancer and other mortality for the lifetable calculations were based, respectively, on 2000 U.S. lung cancer and all-cause mortality rates for both sexes and all races. In addition to the maximum likelihood estimates, 95% confidence intervals for the excess lifetime risk were derived. Details about the procedures used to estimate parameters, model fit, lifetable calculations, and confidence intervals are described in the 2003 Environ report (Ex. 33–12, p. 8–9).

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Table VI-2

Environ (2003, Ex. 33-12): Model Predictions of Excess Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Cr(VI) Concentrations, by Model, Reference Population, and Exposure Grouping

Model	**Reference Population**	**Exposure Grouping**	**Cr(VI) Concentration (μg/m^3) [95% Confidence Interval]**						
			0.25	**0.5**	**1.0**	**5**	**10**	**20**	**52**
Relative Risk Model (E1)	Maryland State	Equal Cases/group	1.9 [0.9-3.6]	3.8 [1.8-7.2]	7.5 [3.7-14]	37 [18-69]	72 [36-132]	137 [57-240]	305 [168-471]
		Equal PYRs/group	2.0 [0.6-4.0]	4.0 [1.3-8.0]	8.0 [2.5-16]	39 [12-77]	76 [25-145]	144 [49-258]	318 [120-500]
	Baltimore City	Equal Cases/group	2.1 [1.0-3.6]	4.3 [1.3-8.0]	8.5 [4.1-14]	42 [20-68]	81 [40-130]	153 [78-237]	334 [186-467]
		Equal PYRs/group	2.3 [1.0-3.9]	4.6 [2.0-7.8]	9.1 [4.0-16]	45 [20-75]	86 [39-142]	163 [76-256]	351 [181-493]
Additive Risk Model (E4)	Maryland State	Equal Cases/group	2.4 [1.0-4.0]	4.7 [2.1-8.0]	9.4 [4.1-16]	46 [20-75]	89 [40-146]	170 [79-268]	373 [189-532]
		Equal PYRs/group	2.1 [0.7-3.7]	4.2 [1.5-7.5]	8.4 [3.0-15]	41 [15-72]	80 [29-137]	152 [58-253]	342 [141-511]
	Baltimore City	Equal Cases/group	2.4 [1.2-4.0]	4.8 [2.4-7.9]	10 [4.7-16]	47 [23-76]	92 [46-145]	174 [91-264]	380 [214-530]
		Equal PYRs/group	2.2 [1.0-3.8]	4.4 [2.0-7.5]	8.8 [3.9-15]	43 [19-72]	84 [38-138]	161 [74-254]	356 [181-513]
Cox Model C1	N/A	N/A	0.66 [0.3-0.9]	1.3 [0.6-1.9]	2.7 [1.3-3.8]	15 [6.7-21]	32 [14-49]	N/A	363 [110-606]
Cox Model C2	N/A	N/A	1.8 [0.7-3.4]	3.5 [1.4-6.8]	7.1 [2.7-14]	35 [13-66]	68 [27-125]	129 [52-229]	290 [128-456]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.

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Table VI–2 shows each model's predictions of excess lifetime lung cancer risk from a working lifetime of exposure to various Cr(VI) air levels. The estimates are very consistent regardless of model, exposure grouping, or reference population. The model that appears to generate results least similar to the others is C1, which yielded one of the higher risk estimates at 52 μg/m^3, but estimated the lowest risks for exposure levels of 10 μg/m^3 or lower. The change in magnitude, relative to the other models, is a result of the nonlinearity of this model. Confidence limits for all models, including C1, tend to overlap, suggesting a fair degree of statistical consistency.

2. National Institute for Occupational Safety and Health (NIOSH) Risk Assessment

NIOSH (Ex. 33–13) developed a risk assessment from the Gibb cohort. The NIOSH analysis, like the 2003 Environ assessment, used the cohort individual data files to compute cumulative Cr(VI) exposure. However, NIOSH also explored some other exposure-related assumptions. For example, they performed the dose-response analysis with lag times in addition to the 5-year lag used by Environ. NIOSH also analyzed dose-response using as many as 50 exposure categories, although their report presents data in five cumulative Cr(VI) exposure groupings.

NIOSH incorporated information on the cohort smoking behavior in their quantitative assessments. They estimated (packs/day)-years of cumulative smoking for each individual in the cohort, using information from a questionnaire that was administered at the time of each cohort member's date of hire. To estimate cumulative smoking, NIOSH assumed that the cohort members maintained the level of smoking reported in the questionnaire from the age of 18 through the end of follow-up. Individuals with unknown smoking status were assigned a value equal to the average smoking level among all individuals with known smoking levels (presumably including non-smokers). Individuals who were known to smoke but for whom the amount was unknown were assigned a smoking level equal to the average of all smokers.

NIOSH considered six different relative risk models, fit to the Gibb cohort data by Poisson regression methods. They did not consider additive risk models. The six relative risk models were externally standardized using age- and race-specific U.S. lung cancer rates. Their background coefficients, C_0, explicitly included smoking, race, and age terms to adjust for differences between the cohort and the reference population. These models are described as follows:

NIOSH1a: $N_i = C_0 * Ei * \exp(C_1 D_i)$
NIOSH1b: $N_i = C_0 * Ei * \exp(C_1 D_i{}^{1/2})$
NIOSH1c: $N_i = C_0 * Ei * \exp(1 + C_1 D_i + C_2 D_i{}^2)$
NIOSH1d: $N_i = C_0 * Ei * (1 + Di)^{\alpha}$
NIOSH1e: $N_i = C_0 * Ei * (1 + C_1 D_i)$
NIOSH1f: $N_i = C_0 * Ei * (1 + C_1 D_i{}^{\alpha})$

where the form of the equation has been modified to match the format used in the Environ reports. In addition, NIOSH fit Cox proportional hazard models (not presented) to the lung cancer mortality data using the individual cumulative Cr(VI) exposure estimates.

NIOSH reported that the linear relative risk model 1e generally provided a superior fit to the exposure-response data when compared to the various log linear models, 1a–d. Allowing some non-linearity (*e.g.*, model 1f) did not significantly improve the goodness-of-fit, therefore, they considered the linear relative risk model form 1e (analogous to the Environ model E1) to be the most appropriate for determining their lifetime risk calculations. A similar fit could be achieved with a log-linear power model (model 1d) using log-transformed cumulative Cr(VI) and a piece-wise linear specification for the cumulative smoking term.

The dose coefficient (C_1) for the linear relative risk model 1e was estimated by NIOSH to be 1.444 per μg CrO_3/m^3-yr (Ex. 33–13, Table 4). If the exposures were converted to units of μg Cr(VI)/m^3-yr, the estimated cumulative dose coefficient would be 2.78 (95% CI: 1.04 to 5.44) per μg/m^3-yr. This value is very close to the estimates derived in the Environ 2003 analysis (maximum likelihood estimates ranging from 2.87 to 3.48 for model E1, depending on the exposure grouping and the reference population). Lifetime risk estimates based on the NIOSH-estimated dose coefficient and the Environ lifetable method using 2000 U.S. rates for lung cancer and all cause mortality are shown in Table VI–3. The values are very similar to the estimates predicted by the Environ 2003 analysis (Table VI–3). The small difference may be due to the NIOSH adjustment for smoking in the background coefficient. NIOSH found that excess lifetime risks for a 45-year occupational exposure to Cr(VI) predicted by the best-fitting power model gave very similar risks to the preferred linear relative risk model at TWA Cr(VI) concentrations between 0.52 and 52 μg/m^3 (Ex. 33–13, Table 5). Although NIOSH did not report the results, they stated that Cox modeling produced risk estimates similar to the Poisson regression. The consistency between Cox and Poisson regression modeling is discussed further in section VI.C.4.

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Table VI-3

Model Predictions of Additional Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Cr(VI) Concentrations Based on NIOSH-Estimated Parameters

0.25	**0.5**	**1.0**	**5**	**10**	**20**	**52**
1.8	3.7	7.3	36	70	133	297
[0.7-3.6]	[1.4-7.2]	[2.7-14]	[14-69]	[27-131]	[53-238]	[130-468]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.

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NIOSH reported a significantly higher dose-response coefficient for nonwhite workers than for white workers. That is, nonwhite workers in the Gibb cohort are estimated to have a higher excess risk of lung cancer than white workers, given equal cumulative exposure to Cr(VI). In contrast, no significant race difference was found in the Cox proportional hazards analysis reported by 2003 Environ.

3. Exponent Risk Assessment

In response to OSHA's Request For Information, Exponent prepared an analysis of lung cancer mortality from the Gibb cohort. Like the 2003 Environ and NIOSH analyses, the Exponent analysis relied on the individual worker data. Exponent performed their dose-response analyses based on three different sets of exposure categories using two reference populations and 70,808 person-years of follow-up. A total of four analyses were completed, using (1) Maryland reference rates and the four Gibb *et al.* exposure categories; (2) Baltimore reference rates and the four Gibb *et al.* exposure categories; (3) Baltimore reference rates and six exposure groups defined by Exponent; and (4) Baltimore City reference rates and five exposure categories, obtained by removing the highest of the six groups defined by Exponent from the dose-response analysis. A linear relative risk model without a background correction term (the term C_0 used by Environ and NIOSH) was applied in all of these cases and cumulative exposures were lagged five years (as done by Environ and NIOSH). The analyses showed excess lifetime risk between 6 and 14 per 1000 for workers exposed to 1 μg/m^3 Cr(VI) for 45 years.

The analysis using Maryland reference lung cancer rates and the Gibb *et al.* four-category exposure grouping yielded an excess lifetime risk of 14 per 1000. This risk, which is higher than the excess lifetime risk estimates by Environ and NIOSH for the same occupational exposure, probably results from the absence of a background rate coefficient (C_0) in Exponent's model. As reported in the Environ 2002 and 2003 analyses, the Maryland reference lung cancer rates require a background rate coefficient greater than 1 to achieve the best fit to the exposure-response data. The unadjusted Maryland rates probably underestimate the cohort's background lung cancer rate, leading to overestimation of the risk attributable to cumulative Cr(VI) exposure.

The two analyses that used Baltimore reference rates and either Exponent's six-category exposure grouping or the Gibb *et al.* four-category grouping both resulted in an excess lifetime unit risk of 9 per 1000 for workers exposed to 1 μg/m^3 Cr(VI) for 45 years (Ex. 31–18–15–1, p. 41). This risk is close to estimates reported by Environ using their relative risk model (E1) and Baltimore reference rates for the same occupational exposure (Table VI–2). The Environ analysis showed that, unlike the Maryland-standardized model discussed above, the Baltimore-standardized models had background rate coefficients very close to 1, the ''default'' value assumed by the Exponent relative risk model. This suggests that the Baltimore reference rates may represent the background lung cancer rate for this cohort more accurately than the Maryland reference rates.

The lowest excess lifetime unit risk for workers exposed to 1 μg/m^3 Cr(VI) for 45 years reported by Exponent, at 6 per 1000, was derived from the analysis that excluded the highest of Exponent's six exposure groups. While this risk value is close to the Environ and NIOSH unit risk estimates, the analysis merits some concern. Exponent eliminated the highest exposure group on the basis that most cumulative exposures in this group were higher than exposures usually found in current workplace conditions. However, eliminating this group could exclude possible long-term exposures (*e.g.*, >15 years) below the previous OSHA PEL (52 μg/m^3) from the risk analysis. Moreover, no matter what current exposures might be, data on higher cumulative exposures are relevant for understanding the dose-response relationships.

In addition, the Exponent six category cumulative exposure grouping may have led to an underestimate of the dose effect. The definition of Exponent's six exposure groups was not related to the distribution of cumulative exposure associated with individual person-years, but rather to the distribution of cumulative exposure among the workers at the end of their employment. This division does not result in either a uniform distribution of person-years or observed lung cancer cases among exposure categories. In fact, the six category exposure groupings of both person-years and observed lung cancers were very uneven, with a preponderance of both allocated to the lowest exposure group. This skewed distribution of person-years and observed cases puts most of the power for detecting significant differences from background cancer rates at low exposure levels, where these differences are expected to be small, and reduces the power to detect any significant differences from background at higher exposure concentrations.

4. Summary of Risk Assessments Based on the Gibb Cohort

OSHA finds remarkable consistency among the risk estimates from the various quantitative analyses of the Gibb cohort. Both Environ and NIOSH determined that linear relative risk models generally provided a superior fit to the data when compared to other relative risk models, although the confidence intervals in the non-linear Cox model reported by Environ overlapped with the confidence intervals in their linear models. The Environ 2003 analysis further suggested that a linear additive risk model could adequately describe the observed dose-response data. The risk estimates for NIOSH and Environ's best-fitting models were statistically consistent (compare Tables VI–2 and VI–3).

The choice of reference population had little impact on the risk estimates. NIOSH used the entire U.S. population as the reference, but included adjustment terms for smoking, age and race in its models. The Environ 2003 analysis used both Maryland and Baltimore reference lung cancer rates, and included a generic background coefficient C_0 to adjust for potential differences in background risk between the reference population and the worker cohort. This term was significant in the fitted model when Maryland rates were used for external standardization, but not when Baltimore rates were used. Since no adjustment in the model background term was required to better fit the exposure-response data using Baltimore City lung cancer rates, they may best represent the cohort's true background lung cancer incidence. OSHA considers the inclusion of such adjustment factors, whether specific to smoking, race, and age (as defined by NIOSH), or generic (as defined by Environ), to be appropriate and believes they contribute to accurate risk estimation by helping to correct for confounding risk factors. The Cox proportional hazard models, especially the linear Cox model, yielded risk estimates that were generally consistent with the externally standardized models.

Finally, the number of exposure categories used in the analysis had little impact on the risk estimates. When an appropriate adjustment to the background rates was included, the four exposure groups originally defined by Gibb *et al.* and analyzed in the 2002 Environ report, the six exposure groups defined by Exponent, the two alternate sets of ten exposure categories as defined in the 2003 Environ analysis, and the fifty groups defined and aggregated by NIOSH all gave essentially the same risk estimates. The robustness of the results to various categorizations of cumulative exposure adds credence to the risk projections.

Having reviewed the analyses described in this section, OSHA finds that the best estimates of excess lung cancer risk to workers exposed to the previous PEL (52 μg Cr(VI)/m^3) for a working lifetime are about 300 to 400 per thousand based on data from the Gibb cohort. The best estimates of excess lung cancer risks to workers exposed to other TWA exposure concentrations are presented in Table VI–2. These estimates are consistent with predictions from Environ, NIOSH and Exponent models that applied linear relative and additive risk models based on the full range of cumulative Cr(VI) exposures experienced by the Gibb cohort and used appropriate adjustment terms for the background lung cancer mortality rates.

D. Quantitative Risk Assessments Based on the Luippold Cohort

As discussed earlier, Luippold *et al.* (Exs. 35–204; 33–10) provided information about the cohort of workers employed in a chromate production plant in Painesville, Ohio. Follow-up for the 482 members of the Luippold cohort started in 1940 and lasted through 1997, with accumulation of person-years for any individual starting one year after the beginning of his first exposure. There were 14,048 total person-years of follow-up for the cohort. The person-years were then divided into five exposure groups that had approximately equal numbers of expected lung cancers in each group. Ohio reference rates were used to compute expected numbers of deaths. White male rates were used because the number of women was small (4 out of 482) and race was known to be white for 241 of 257 members of the cohort who died and for whom death certificates were available. The 1960–64 Ohio rates (the earliest available) were assumed to hold for the time period from 1940 to 1960. Rates from 1990–94 were assumed to hold for the period after 1994. For years between 1960 and 1990, rates from the corresponding five-year summary were used. There were significant trends for lung cancer SMR as a function of year of hire, duration of employment, and cumulative Cr(VI) exposure. The cohort had a significantly increased SMR for lung cancer deaths of 241 (95% C.I. 180 to 317).

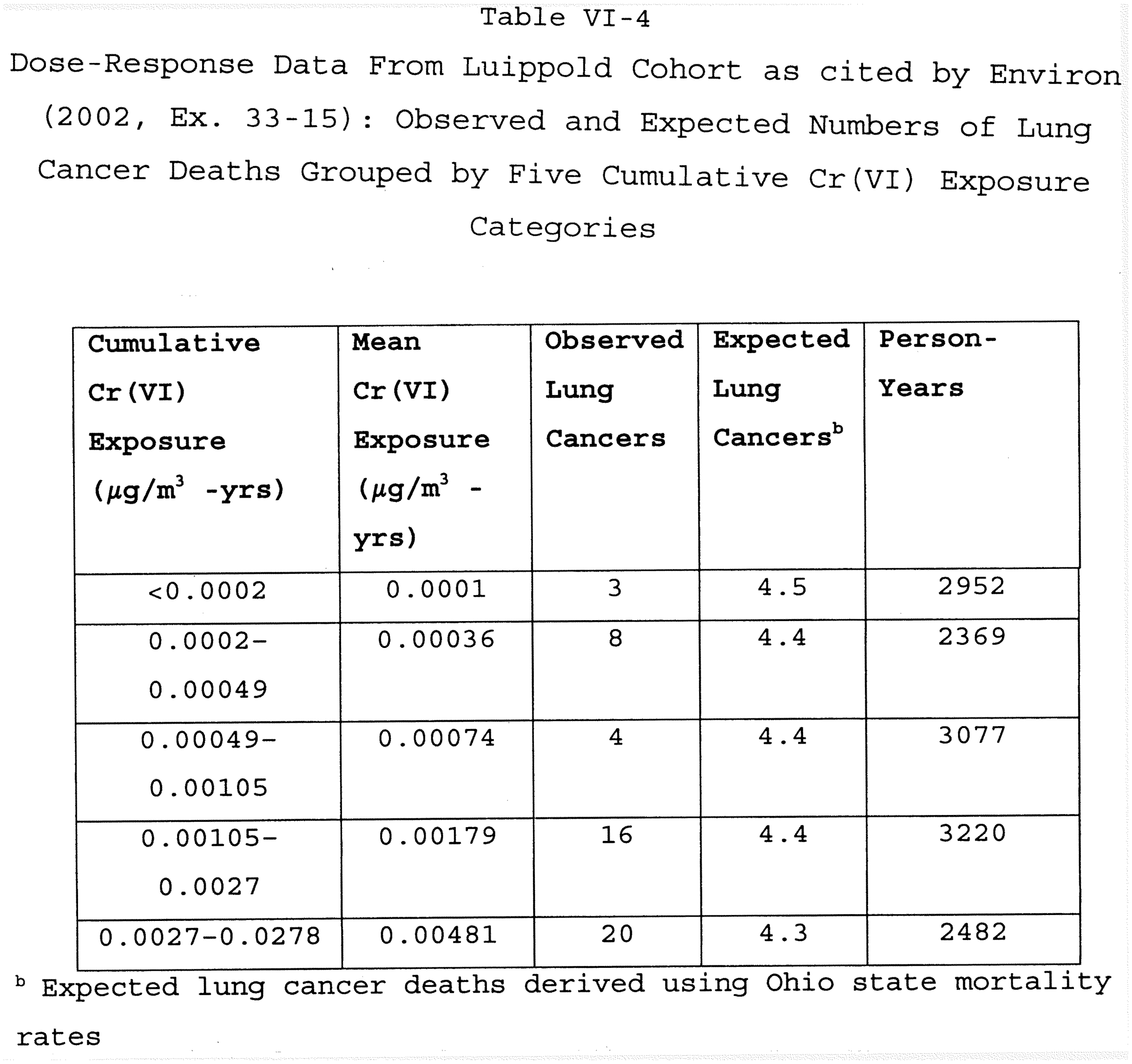

Table VI-4

Dose-Response Data From Luippold Cohort as cited by Environ (2002, Ex. 33-15): Observed and Expected Numbers of Lung Cancer Deaths Grouped by Five Cumulative Cr(VI) Exposure Categories

Cumulative Cr(VI) Exposure ($\mu g/m^3$ -yrs)	**Mean Cr(VI) Exposure ($\mu g/m^3$ -yrs)**	**Observed Lung Cancers**	**Expected Lung Cancers[b]**	**Person-Years**
<0.0002	0.0001	3	4.5	2952
0.0002-0.00049	0.00036	8	4.4	2369
0.00049-0.00105	0.00074	4	4.4	3077
0.00105-0.0027	0.00179	16	4.4	3220
0.0027-0.0278	0.00481	20	4.3	2482

[b] Expected lung cancer deaths derived using Ohio state mortality rates

Environ conducted a risk assessment based on the cumulative Cr(VI) exposure-lung cancer mortality data from Luippold *et al.* and presented in Table VI–4 (Ex. 33–15). Cumulative Cr(VI) exposures were categorized into five groups with about four expected lung cancer deaths in each group. In the absence of information to the contrary, Environ assumed Luippold *et al.* did not employ any lag time in determining the cumulative exposures. The calculated and expected numbers of lung cancers were derived from Ohio reference rates. Environ applied the relative and additive risk models, E1 and E2, to the data in Table VI–4.

Linear relative and additive risk models fit the Luippold cohort data adequately ($p \geq 0.25$). The final models did not include the quadratic exposure coefficient, C_2, or the background rate parameter, C_0, as they did not significantly improve the fit of the models. The maximum likelihood estimates for the Cr(VI) exposure-related parameter, C_1, of the linear relative and additive risk models were 0.88 per mg/m^3-yr and 0.0014 per mg/m^3-person-yr, respectively. The C_1 estimates based on the Luippold cohort data were about 2.5-fold lower than the parameter estimates based on the Gibb cohort data. The excess lifetime risk estimate calculated by Environ for a 45-year working-lifetime exposure to 1 µg Cr(VI)/m^3 (*e.g.*, the unit risk) for both models was 2.2 per 1000 workers (95% confidence intervals from 1.3 to 3.5 per 1000 for the relative risk model and 1.2 to 3.4 per 1000 for the additive risk model) using a lifetable analysis with 1998 U.S. mortality reference rates. These risks were 2.5 to 3-fold lower than the projected unit risks based on the Gibb data set for equivalent cumulative Cr(VI) exposures.

Crump *et al.* (Exs. 33–15; 35–58; 31–18) also performed an exposure-response analysis from the Painesville data. In a Poisson regression analysis, cumulative exposures were grouped into ten exposure categories with approximately two expected lung cancer deaths in each group. The observed and expected lung cancer deaths by Cr(VI) exposure category are shown in Table VI–5. Ohio reference rates were used in calculating the expected lung cancer deaths and cumulative exposures were lagged five years.

Table VI-5

Dose-Response Data From Crump _et al_. (Ex. 35-58): Observed and Expected Numbers of Lung Cancer Deaths for Luippold Cohort Grouped by Ten Cumulative Cr(VI) Exposure Categories

Cumulative Cr(VI) Exposure (µg/m^3 -yrs)	Mean Cr(VI) Exposure (µg/m^3 -yrs)	Observed Lung Cancers	Expected Lung Cancer[b]	Person-Years
0-0.00006	0.0000098	0	2.09	3112
0.00006-0.00018	0.00011	3	2.19	1546
0.00018-0.0003	0.00023	3	2.21	1031
0.0003-0.00046	0.00038	5	2.13	1130
0.00046-0.00067	0.00056	0	2.22	1257
0.00067-0.001	0.00080	4	2.23	1431
0.001-0.00163	0.00125	12	2.23	1493
0.00163-0.0026	0.0021	3	2.18	1291
0.0026-0.00445	0.00327	10	2.18	1248
0.00445-0.029	0.00755	11	2.12	904

The lower bounds of the ranges are inclusive; the upper bounds are exclusive.

[b] Expected lung cancer deaths derived using Ohio state mortality rates

The Crump *et al.* analysis used the same linear relative risk and additive risk models as Environ on the individual data categorized into the ten cumulative exposure groups (Ex. 35–58). Tests for systematic departure from linearity were non-significant for both models ($p \geq 0.11$). The cumulative dose coefficient determined by the maximum likelihood method was 0.79 (95% CI: 0.47 to 1.19) per mg/m^3-yr for the relative risk model and 0.0016 (95% CI: 0.00098 to 0.0024) per mg/m^3-person-yr for the additive risk model, respectively. The authors noted that application of the linear models to five and seven exposure groups resulted in no significant difference in dose coefficients, although the results were not presented. The exposure coefficients reported by Crump *et al.* were very similar to those obtained by Environ above, although different exposure groups were used and Crump *et al.* used a five-year lag for the cumulative exposure calculation. The authors noted that the linear models did not fit the exposure data grouped into ten categories very well (goodness-of-fit $p \leq 0.01$) but fit the data much better with seven exposure groups ($p > 0.3$), replacing the many lower exposure categories where there were few observed and expected cancers with more stable exposure groupings with greater numbers of cancers. The reduction in number of exposure groups did not substantially change the fitted exposure coefficients.

The maximum likelihood estimate for the cumulative exposure coefficient using the linear Cox regression model C2 was 0.66 (90% CI: 0.11 to 1.21), which was similar to the linear [Poisson regression] relative risk model. When the Cox analysis was restricted to the 197 workers with known smoking status and a smoking variable in the model, the dose coefficient for Cr(VI) was nearly identical to the estimate without controlling for smoking. This led the authors to conclude that ''the available smoking data did not suggest that exposure to Cr(VI) was confounded with smoking in this cohort, or that failure to control for smoking had an appreciable effect upon the estimated carcinogenic potency of Cr(VI)'' (Ex. 35–58, p. 1156).

Given the similarity in results, OSHA believes it is reasonable to use the exposure coefficients reported by Crump *et al.* based on their groupings of the individual cumulative exposure data to estimate excess lifetime risk from the Luippold cohort. Table VI–6 presents the excess risk for a working lifetime exposure to various TWA Cr(VI) levels as predicted by Crump *et al.*'s relative and additive risk models using a lifetable analysis with 2000 U.S. rates for all causes and lung cancer mortality. The resulting maximum likelihood estimates indicate that working lifetime exposures to the previous Cr(VI) PEL would result in excess lifetime lung cancer risks around 100 per 1000 (95% C.I. approx. 60–150). The risk estimates based on the Luippold cohort are lower than the risk estimates based on the Gibb cohort, as discussed further in section VI.F.

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Table VI-6

Model Predictions of Additional Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Concentrations of Cr(VI) Based on the Luippold Cohort and Crump Dose Coefficients

Model	**0.25**	**0.5**	**1.0**	**5**	**10**	**20**	**52**
Relative Risk	0.52 [0.31 -0.79]	1.0 [0.62-1.6]	2.1 [1.2-3.1]	10 [6.2-15]	21 [12- 31]	41 [21-60]	101 [62 -147]
Additive Risk	0.55 [0.36- 0.82]	1.1 [0.67-1.6]	2.2 [1.3-3.3]	11 [6.7-16]	22 [13- 32]	43 [27-64]	108 [67 - 155]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.

Maximum likelihood estimates and 95% confidence intervals are shown.

These estimates were derived from the Crump et al. risk models using the exposure coefficients reported in section VI.D and a lifetable using 2000 U.S. mortality rates for all causes and lung cancer.

E. Quantitative Risk Assessments Based on the Mancuso, Hayes, Gerin, and Alexander Cohorts

In addition to the preferred data sets analyzed above, there are four other cohorts with available data sets for estimation of additional lifetime risk of lung cancer. These are the Mancuso cohort, the Hayes cohort, the Gerin cohort, and the Alexander cohort. Environ did exposure-response analysis for all but the Hayes cohort (Ex. 33–15). Several years earlier, the K.S. Crump Division did quantitative assessments on data from the Mancuso and Hayes cohort, under contract with OSHA (Ex.13–5). The U.S. EPA developed quantitative risk assessments from the Mancuso cohort data for its Integrated Risk Information System (Exs. 19–1; 35–52). The California EPA (Ex. 35–54), Public Citizen Health Research Group (Ex. 1), and the U.S. Air Force Armstrong Laboratory (AFAL) for the Department of Defense (Ex. 35–51) performed assessments from the Mancuso data using the 1984 U.S. EPA risk estimates as their starting point. The U.S. EPA also published a risk assessment based on the Hayes cohort data (Ex. 7–102). Until the cohort studies of Gibb *et al.* and Luippold *et al.* became available, these earlier assessments provided the most current projected cancer risks from airborne exposure to Cr(VI). The previous risk assessments were extensively described in the NPRM sections VI.E.1 and VI.E.2 (69 FR at 59375–59378). While the risk estimates from Mancuso, Hayes, Gerin, and Alexander data sets are associated with a greater degree of uncertainty, it is nevertheless valuable to compare them to the risk estimates from the higher quality Gibb and Luippold data sets in order to determine if serious discrepancies exist between them. OSHA believes evaluating consistency in risk among several worker cohorts adds to the overall quality of the assessment.

The Mancuso and Luippold cohorts each worked at the Painesville plant but the worker populations did not overlap due to different selection criteria. Exposure estimates were also based on different industrial hygiene surveys. The Hayes and Gibb cohorts both worked at the Baltimore plant. Even though Cr(VI) exposures were reconstructed from monitoring data measured at different facilities resulting in significantly different exposure-response functions (see section VI.F), there was some overlap in the two study populations. As a result, the projected risks from these data sets can not strictly be viewed as independent estimates. The Gerin and Alexander cohorts were not chromate production workers and are completely independent from the Gibb and Luippold data sets. The quantitative assessment of the four data sets and comparison with the risk assessments based on the Gibb and Luippold cohorts are discussed below.

1. Mancuso Cohort

As described in subsection VII.B.3, the Mancuso cohort was initially defined in 1975 and updated in 1997. The cohort members were hired between 1931 and 1937 and worked at the same Painesville facility as the Luippold cohort workers. However, there was no overlap between the two cohorts since all Luippold cohort workers were hired after 1939. The quantitative risk assessment by Environ used data reported in the 1997 update (Ex. 23, Table XII) in which lung cancer deaths and person-years of follow-up were classified into four groups of cumulative exposure to soluble chromium, assumed to represent Cr(VI) (Ex. 33–15). The mortality data and person-years were further broken down by age of death in five year increments starting with age interval 40 to 44 years and going up to >75 years. No expected numbers of lung cancers were computed, either for the cohort as a whole or for specific groups of person-years. Environ applied an indirect method based on the recorded median age and year of entry into the cohort to estimate age information necessary to derive expected numbers of age- and calendar year-adjusted lung cancers deaths required to complete the risk assessment.

Observed and expected lung cancer deaths by age and cumulative exposure (mg/m^3-yr) are presented in Table 3 of the 2002 Environ report (Ex. 33–15, p. 39). The mean cumulative exposures to soluble Cr(VI) were assumed to be equal to the midpoints of the tabulated ranges. No lag was used for calculating the cumulative exposures. Environ applied externally standardized risk models to these data, similar to those described in section VI.C.1 but using an age-related parameter, as discussed in the 2002 report (Ex. 33–15, p. 39). The externally-standardized linear relative risk model with an age-dependent exposure term provided a superior fit over the other models.

The predicted excess risk of lung cancer from a 45-year working lifetime of exposure to Cr(VI) at the previous OSHA PEL using the best-fitting linear relative risk model is 293 per 1000 workers (95% C.I. 188 to 403). The maximum likelihood estimate from working lifetime exposure to new PEL of 5.0 μg/m^3 Cr(VI) is 34 per 1000 workers (95% C.I. 20 to 52 per 1000). These estimates are close to those predicted from the Gibb cohort but are higher than predicted from the Luippold cohort.

There are uncertainties associated with both the exposure estimates and the estimates of expected numbers of lung cancer deaths for the 1997 Mancuso data set. The estimates of exposure were derived from a single set of measurements obtained in 1949 (Ex. 7–98). Although little prior air monitoring data were available, it is thought that the 1949 air levels probably understate the Cr(VI) concentrations in the plant during some of the 1930s and much of the 1940s when chromate production was high to support the war. The sampling methodology used by Bourne and Yee only measured soluble Cr(VI), but it is believed that the chromate production process employed at the Painesville plant in these early years yielded slightly soluble and insoluble Cr(VI) compounds that would not be fully accounted for in the sampling results (Ex. 35–61). This would imply that risks would be overestimated by use of concentration estimates that were biased low. However, it is possible that the 1949 measurements did not underestimate the Cr(VI) air levels in the early 1930s prior to the high production years. Some older cohort members were also undoubtedly exposed to less Cr(VI) in the 1950s than measured in 1949 survey.

Another uncertainty in the risk assessment for the Mancuso cohort is associated with the post-hoc estimation of expected numbers of lung cancer deaths. The expected lung cancers were derived based on approximate summaries of the ages and assumed start times of the cohort members. Several assumptions were dictated by reliance on the published groupings of results (*e.g.*, ages at entry, calendar year of entry, age at end of follow-up, etc.) as well as by the particular choices for reference mortality rates (*e.g.*, U.S. rates, in particular years close to the approximated time at which the person-years were accrued). Since the validity of these assumptions could not be tested, the estimates of expected numbers of lung cancer deaths are uncertain.

There is also a potential healthy worker survivor effect in the Mancuso cohort. The cohort was identified as workers first hired in the 1930s based on employment records surveyed in the late 1940s (Ex. 2–16). The historical company files in this time period were believed to be sparse and more likely to only identify employees still working at the plant in the 1940s (Ex. 33–10). If there was a sizable number of unidentified short-term workers who were hired but left the plant in the 1930s or who died before 1940 (*i.e.* prior to systematic death registration), then there may have been a selection bias (*i.e.*, healthy worker survivor effect) toward longer-term, healthier individuals (Ex. 35–60). Since the mortality of these long-term ''survivors'' is often more strongly represented in the higher cumulative exposures, it can negatively confound the exposure-response and lead to an underestimation of risk, particularly to shorter-term workers (Ex. 35–63). This may be an issue with the Mancuso cohort, although the magnitude of the potential underestimation is unclear.

Earlier quantitative risk assessments by the K.S. Crump Division, EPA, and others were done on cohort data presented in the 1975 Mancuso report (Ex. 7–11). These assessments did not have access to the 20 additional years of follow-up nor did they have age-grouped lung cancer mortality stratified by cumulative soluble chromium (presumed Cr(VI)) exposure), which was presented later in the 1997 update. Instead, age-grouped lung cancer mortality was stratified by cumulative exposure to total chromium that included not only carcinogenic Cr(VI) but substantial amounts of non-carcinogenic Cr(III). OSHA believes that the Environ quantitative risk assessment is the most credible analysis from the Mancuso cohort. It relied on the updated cohort mortality data and cumulative exposure estimates derived directly from air measurements of soluble chromium.

2. Hayes Cohort

The K.S. Crump Division (Ex. 13–5) assessed risk based on the exposure-response data reported in Table IV by Braver *et al.* (Ex. 7–17) for the cohort studied by Hayes *et al.* (Ex. 7–14). The Hayes cohort overlapped with the Gibb cohort. The Hayes cohort included 734 members, not part of the Gibb cohort, who worked at an older facility from 1945 to 1950 but did not work at the newer production facility built in August 1950. The Hayes cohort excluded 990 members of the Gibb cohort who worked less than 90 days in the new production facility after August 1950. As noted in section VI.B.4, Braver *et al.* derived a single cumulative soluble Cr(VI) exposure estimate for each of four subcohorts of chromate production workers categorized by duration of employment and year of hire by Hayes *et al.* Thus, exposures were not determined for individual workers using a more comprehensive job exposure matrix procedure, as was done for the Gibb and Luippold cohorts. In addition, the exposures were estimated from air monitoring conducted only during the first five of the fifteen years the plant was in operation. Unlike the Mancuso cohort, Hayes *et al.* did not stratify the observed lung cancer deaths by age group. The expected number of lung cancer deaths for each subcohort was based on the mortality statistics from Baltimore.

The K.S. Crump Division applied the externally standardized linear relative risk approach to fit the exposure-response data (Ex. 13–5). The maximum likelihood estimate for the dose coefficient (*e.g.*, projected linear slope of the Cr(VI) exposure-response curve) was 0.75 per mg Cr(VI)/m^3-yr with a 90% confidence bound of between 0.45 and 1.1 per mg Cr(VI)/m^3-yr. These confidence bounds are consistent with the dose coefficient estimate obtained from modeling the Luippold cohort data (0.83, 95% CI: 0.55 to 1.2) but lower than that from the Gibb cohort data (3.5, 95% CI: 1.5 to 6.0). The linear relative risk model fit the Hayes cohort data well (p=0.50). The K.S. Crump Division predicted the excess risk from occupational exposure to Cr(VI) for a 45 year working lifetime at the previous OSHA PEL (52 µg/m^3) to be 88 lung cancer cases per 1000 workers (95% CI: 61 to 141). Predicted excess risk at the new PEL of 5 µg/m^3 is about 9 excess lung cancer deaths per 1000 (95% CI: 6.1 to 16) for the same duration of occupational exposure. These estimates are somewhat lower than the corresponding estimates based on the Gibb cohort data, probably because of the rather high average soluble Cr(VI) level (218 µg/m^3) assumed by Braver *et al.* for plant workers throughout the 1950s. If these assumed air levels led to an overestimate of worker exposure, the resulting risks would be underestimated.

3. Gerin Cohort

Environ (Ex. 33–15) did a quantitative assessment of the observed and expected lung cancer deaths in stainless steel welders classified into four cumulative Cr(VI) exposure groups reported in Tables 2 and 3 of Gerin *et al.* (Ex. 7–120). The lung cancer data came from a large combined multi-center welding study in which a statistically significant excess lung cancer risk was observed for the whole cohort and non-statistically significant elevated lung cancer mortality was found for the stainless steel welder subcohorts (Ex. 7–114). A positive relationship with time since first exposure was also observed for the stainless steel welders (the type of welding with the highest exposure to Cr(VI)) but not with duration of employment.

The exposure-response data from the Gerin study was only presented for those stainless steel welders with at least five years employment. Workers were divided into ''ever stainless steel welders'' and ''predominantly stainless steel welders'' groups. The latter group were persons known to have had extended time welding stainless steel only or to have been employed by a company that predominantly worked stainless steel. As stated in section VI.B.5, the cumulative exposure estimates were not based on Cr(VI) air levels specifically measured in the cohort workers, and therefore are subject to greater uncertainty than exposure estimates from the chromate production cohort studies. Environ restricted their analysis to the ''ever stainless steel welders'' since that subcohort had the greater number of eligible subjects and person-years of follow-up, especially in the important lower cumulative exposure ranges. The person-years, observed numbers of lung cancers, and expected numbers of lung cancers were computed starting 20 years after the start of employment. Gerin *et al.* provided exposure-response data on welders with individual work histories (about two-thirds of the workers) as well as the entire subcohort. Regardless of the subcohort examined, there was no obvious indication of a Cr(VI) exposure-related effect on lung cancer mortality. A plausible explanation for this apparent lack of exposure-response is the potentially severe exposure misclassification resulting from the use of exposure estimates based on the welding literature (rather than exposure measurements at the plants used in the study, which were not available to the authors).

Environ used externally standardized models to fit the data (Ex. 33–15). They assumed that the cumulative Cr(VI) exposure for the workers was at the midpoint of the reported range. A value of 2.5 mg/m^3-yr was assumed for the highest exposure group (*e.g.*, >0.5 mg/m^3-yr), since Gerin *et al.* cited it as the mean value for the group, which they noted to also include the ''predominantly stainless steel welders''. All models fit the data adequately (p>0.28) with exposure coefficients considerably lower than for the Gibb or Luippold cohorts (Ex. 33–15, Table 6). In fact, the 95% confidence intervals for the exposure coefficients overlapped 0, which would be expected when there is no exposure-related trend.

Based on the best fitting model, a linear relative risk model (Ex. 33–15, Table 9, p. 44), the projected excess risk of lung cancer from a working lifetime exposure to Cr(VI) at the previous PEL was 46 (95% CI: 0 to 130) cases per 1000 workers. The 95 percent confidence interval around the maximum likelihood estimate reflects the statistical uncertainty associated with risk estimates from the Gerin cohort.

Following the publication of the proposed rule, OSHA received comments from Exponent (on behalf of a group of steel industry representatives) stating that it is not appropriate to model exposure-response for this cohort because there was not a statistically significant trend in lung cancer risk with estimated exposure, and risk of lung cancer did not increase monotonically with estimated exposure (Ex. 38–233–4, pp. 7–8). OSHA disagrees. Because the best-fitting model tested by Environ fit the Gerin data adequately, OSHA believes that it is reasonable to generate risk estimates based on this model for comparison with the risk estimates based on the Gibb and Luippold cohorts. This allows OSHA to quantitatively assess the consistency between its preferred estimates and risk estimates derived from the Gerin cohort.

In post-hearing comments, Dr. Herman Gibb expressed support for OSHA's approach. Dr. Gibb stated:

> The epidemiologic studies of welders * * * conducted to date have been limited in their ability to evaluate a lung cancer risk. It is conceivable that differences in exposure * * * between [this industry] and the chromate production industry could lead to differences in cancer risk. Because there aren't adequate data with which to evaluate these differences, it is appropriate to compare the upper bounds [on risk] derived from the Gerin *et al.* * * * [study] with those predicted from the chromate production workers to determine if they are consistent.

OSHA agrees with Exponent that the results of the Gerin *et al.* study were different from those of the Luippold (2003) and Gibb cohorts, in that a statistically significant exposure-response relationship and a monotonically increasing lung cancer risk with exposure were not found in Gerin. Also, the maximum likelihood risk estimates based on the Gerin cohort were somewhat lower than those based on the Gibb and Luippold cohorts. However, OSHA believes the lower risk estimates from the Gerin cohort may be explained by the strong potential for bias due to Cr(VI) exposure misclassification and possibly by the presence of co-exposures, as discussed in sections VI.B.5 and VI.G.4. Part of the difference may also relate to statistical uncertainty; note that the 95% confidence intervals (shown in Table VI–7) overlap the lower end of OSHA's range based on the preferred Gibb and Luippold (2003) studies.

4. Alexander Cohort

Environ (Ex. 33–15) did a quantitative assessment of the observed and expected lung cancer incidence among aerospace workers exposed to Cr(VI) classified into four cumulative chromate exposure groups, reported in Table 4 of Alexander *et al.* (Ex. 31–16–3). The authors stated that they derived "estimates of exposure to chromium [VI]" based on the TWA measurements, but later on referred to "the index of cumulative total *chromate* exposure (italics added) reported as μg/m^3 chromate TWA-years" (Ex. 31–16–3, p. 1254). Alexander *et al.* grouped the lung cancer data by cumulative exposure with and without a ten year lag period. They found no statistically significant elevation in lung cancer incidence among the chromate-exposed workers or clear trend with cumulative chromate exposure.

For their analysis, Environ assumed that the cumulative exposures were expressed in μg/m^3-yr of Cr(VI), rather than chromate (CrO_4^{-2}) or chromic acid (CrO_3). Environ used an externally standardized linear relative risk model to fit the unlagged data (Ex. 33–15). An additive risk model could not be applied because person-years of observation were not reported by Alexander *et al.* Environ assumed that workers were exposed to a cumulative Cr(VI) exposure at the midpoint of the reported ranges. For the open-ended high exposure category, Environ assumed a cumulative exposure 1.5 times greater than the lower limit of 0.18 mg/m^3-yr. The model fit the data poorly (p=0.04) and the exposure coefficient was considered to be 0 since positive values did not significantly improve the fit. Given the lack of a positive trend between lung cancer incidence and cumulative Cr(VI) exposure for this cohort, these results are not surprising.

Following the publication of the proposed rule, OSHA received comments from Exponent (on behalf of the Aerospace Industries Association) stating that the Agency should not apply a linear model to the Alexander *et al.* study to derive risk estimates for comparison with the estimates based on the Gibb and Luippold (2003) cohorts (Ex. 38–215–2, p. 10). Due to the poor fit of Environ's exposure-response model to the Alexander cohort data, OSHA agrees with Exponent in this matter. Risk estimates based on Alexander *et al.* are therefore not presented in this risk assessment.

OSHA believes that there are several possible reasons for the lack of a positive association between Cr(VI) exposure and lung cancer incidence in this cohort. First, follow-up time was extremely short, averaging 8.9 years per cohort member. Long-term follow-up of cohort members is particularly important for determining the risk of lung cancer, which typically has an extended latency period of roughly 20 years or more. One would not necessarily expect to see excess lung cancer or an exposure-response relationship among workers who had been followed less than 20 years since their first exposure to Cr(VI), as most exposure-related cancers would not yet have appeared. Other possible reasons that an exposure-response relationship was not observed in the Alexander cohort include the young age of the cohort members (median 42 years at end of follow-up), which also suggests that occupational lung cancers may not yet have appeared among many cohort members. The estimation of cumulative Cr(VI) exposure was also problematic, drawing on air measurement data that did not span the entire employment period of the cohort (there were no data for 1940 to 1974) and were heavily grouped into a relatively small number of "summary" TWA concentrations that did not capture individual differences in workplace exposures to Cr(VI).

F. Summary of Risk Estimates Based on Gibb, Luippold, and Additional Cohorts

OSHA believes that the best estimates of excess lifetime lung cancer risks are derived from the Gibb and Luippold cohorts. Due to their large size and long follow-up, these two cohorts accumulated a substantial number of lung cancer deaths that were extensively examined by several different analyses using a variety of statistical approaches. Cohort exposures were reconstructed from air measurements and job histories over three or four decades. The linear relative risk model fit the Gibb and Luippold data sets well. It adequately fit several epidemiological data sets used for comparative analysis. Environ and NIOSH explored a variety of nonlinear dose-response forms, but none provided a statistically significant improvement over the linear relative risk model.

The maximum likelihood estimates from a linear relative risk model fit to the Gibb data are three- to five-fold higher than estimates based on the Luippold data at equivalent cumulative

Cr(VI) exposures and the confidence limits around the projected risks from the two data sets do not overlap. This indicates that the maximum likelihood estimates derived from one data set are unlikely to describe the lung cancer mortality observed in the other data set. Despite this statistical inconsistency between the risk estimates, the differences between them are not unreasonably great given the potential uncertainties involved in estimating cancer risk from the data (see section VI.G). Since the analyses based on these two cohorts are each of high quality and their projected risks are reasonably close (well within an order of magnitude), OSHA believes the excess lifetime risk of lung cancer from occupational exposure to Cr(VI) is best represented by the range of risks that lie between maximum likelihood estimates of the Gibb and Luippold data sets.

Table VI-7

OSHA Estimates of Excess Lung Cancer Cases per 1000 Workers[a] Exposed to Various Eight Hour TWA Cr(VI) With 95 Percent Confidence Interval Comparisons by Cohort

Exposure Level ($\mu g/m^3$)	Best Estimates of Risk	Preferred Cohorts		Additional Cohorts		
		Gibb	Luippold	Mancuso	Hayes	Gerin
0.25	0.52-2.3	2.3 (1.0-3.9)	0.53 (0.31-0.79)	1.7 (1.0-2.7)	0.45 (0.31-0.75)	0.2 (0.0-0.7)
0.5	1.0-4.6	4.6 (2.0-7.8)	1.1 (0.62-1.6)	3.5 (2.0-5.4)	0.90 (0.62-1.5)	0.5 (0.0-1.4)
1.0	2.1-9.1	9.1 (4.0-16)	2.1 (1.2-3.1)	7.0 (4.1-11)	1.8 (1.2-3.0)	0.9 (0.0-2.8)
5.0	10-45	45 (20-75)	10 (6.2-15)	34 (20-52)	9.0 (6.1-15)	4.5 (0.0-14)
10	21-86	86 (39-142)	21 (12-31)	n/a	18 (12-30)	9.0 (0.0-29)
20	41-164	164 (76-256)	41 (21-60)	n/a	36 (24-51)	18 (0.0-54)
52	101-351	351 (181-493)	101 (62-147)	293 (188-403)	88 (61-141)	46 (0.0-130)

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level. All estimates were recalculated using year 2000 U.S. reference rates, all races, both sexes, for lung cancer and all causes, except for those from Mancuso, for which 1998 rates were used.

[b] OSHA finds that the estimates of risk best supported by the scientific evidence are the ranges bounded by the maximum likelihood estimates from the linear relative risk models presented in Table VI-2 (Baltimore reference population/exposure grouping with equal person-years) for the Gibb cohort and Table VI-6 for the Luippold cohort.

[c] The confidence intervals for the Gibb and Luippold cohorts are from Tables VI-2 and VI-6. The confidence intervals for the Mancuso and Gerin cohorts are derived from parameters reported by Environ (2002, Ex. 33-15). All are from the best fitting linear relative risk models and are 95% confidence intervals. The confidence interval for the Hayes cohort was calculated from the 90 percent confidence interval on the dose coefficient for the linear relative risk model reported by the K.S. Crump Division (1995, Ex. 13-5).

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OSHA's best estimates of excess lung cancer cases from a 45-year working lifetime exposure to Cr(VI) are presented in Table VI–7. As previously discussed, several acceptable assessments of the Gibb data set were performed, with similar results. The 2003 Environ model E1, applying the Baltimore City reference population and ten exposure categories based on a roughly equal number of person-years per group, was selected to represent the range of best risk estimates derived from the Gibb cohort, in part because this assessment employed an approach most consistent with the exposure grouping applied in the Luippold analysis (see Table VI–6). To characterize the statistical uncertainty of OSHA's risk estimates, Table VI–7 also presents the 95% confidence limits associated with the maximum likelihood risk estimates from the Gibb cohort and the Luippold cohort.

OSHA finds that the most likely lifetime excess risk at the previous PEL of 52 μg/m^3 Cr(VI) lies between 101 per 1000 and 351 per 1000, as shown in Table VI–7. That is, OSHA predicts that between 101 and 351 of 1000 workers occupationally exposed for 45 years at the previous PEL would develop lung cancer as a result of their exposure. The wider range of 62 per 1000 (lower 95% confidence bound, Luippold cohort) to 493 per 1000 (upper 95% confidence bound, Gibb cohort) illustrates the range of risks considered statistically plausible based on these cohorts, and thus represents the statistical uncertainty in the estimates of lung cancer risk. This range of risks decreases roughly proportionally with exposure, as illustrated by the risk estimates shown in Table VI–7 for working lifetime exposures at various levels at and below the previous PEL.

The risk estimates for the Mancuso, Hayes, and Gerin data sets are also presented in Table VI–7. (As discussed previously, risk estimates were not derived from the Alexander data set.) The exposure-response data from these cohorts are not as strong as those from the two featured cohorts. OSHA believes that the supplemental assessments for the Mancuso and Hayes cohorts support the range of projected excess lung cancer risks from the Gibb and Luippold cohorts. This is illustrated by the maximum likelihood estimates and 95% confidence intervals shown in Table VI–7. The risk estimates and 95% confidence interval based on the Hayes cohort are similar to those based on the Luippold cohort, while the estimates based on the Mancuso cohort are more similar to those based on the Gibb cohort. Also, OSHA's range of best risk estimates based on the two primary cohorts for a given occupational Cr(VI) exposure overlap the 95 percent confidence limits for the Mancuso, Hayes, and Gerin cohorts. This indicates that the Agency's range of best estimates is statistically consistent with the risks calculated by Environ from any of these data sets, including the Gerin cohort where the lung cancers did not show a clear positive trend with cumulative Cr(VI) exposure.

Several commenters remarked on OSHA's use of both the Gibb cohort and the Luippold cohort to define a preliminary range of risk estimates associated with a working lifetime of exposure at the previous and alternative PELs. Some suggested that OSHA should instead rely exclusively on the Gibb study, due to its superior size, smoking data, completeness of follow-up, and exposure information (Tr. 709–710, 769; Exs. 40–18–1, pp. 2–3; 47–23, p. 3; 47–28, pp. 4–5). Others suggested that OSHA should devise a weighting scheme to derive risk estimates based on both studies but with greater weight assigned to the Gibb cohort (Tr. 709–710, 769, Exs. 40–18–1, pp. 2–3; 47–23, p. 3), arguing that "the use of the maximum likelihood estimate from the Luippold study as the lower bound of OSHA's risk estimates * * * has the effect of making a higher Permissible Exposure Limit (PEL) appear acceptable" (Ex. 40–18–1, p. 3). OSHA disagrees with this line of reasoning. OSHA believes that including all studies that provide a strong basis to model the relationship between Cr(VI) and lung cancer, as the Luippold study does, provides useful information and adds depth to the Agency's risk assessment. OSHA agrees that in some cases derivation of risk estimates based on a weighting scheme is an appropriate approach when differences between the results of the two or more studies are believed to primarily reflect sources of uncertainty or error in the underlying studies. A weighting scheme might then be used to reflect the degree of confidence in their respective results. However, the Gibb and Luippold cohorts were known to be quite different populations, and the difference between the risk estimates based on the two cohorts could partly reflect variability in exposure-response. In this case, OSHA's use of a range of risk defined by the two studies is appropriate for the purpose of determining significance of risk at the previous PEL and the alternative PELs that the Agency considered.

Another commenter suggested that OSHA should derive a "single 'best' risk estimate [taking] into account all of the six quantitative risk estimates" identified by OSHA as featured or supporting risk assessments in the preamble to the proposed rule, consisting of the Gibb and Luippold cohorts as well as studies by Mancuso (Ex. 7–11), Hayes (Ex. 7–14), Gerin (Ex. 7–120), and Alexander (Ex. 31–16–3) (Ex. 38–265, p. 76). The commenter, Mr. Stuart Sessions of Environomics, Inc., proposed that OSHA should use a weighted average of risk estimates derived from all six studies, weighting the Gibb and Luippold studies more heavily than the remaining four ''admittedly weaker studies'' (Ex. 38–265, p. 78). During the public hearing, however, he stated that OSHA may reasonably choose not to include some studies in the development of its quantitative risk model based on certain criteria or qualifications related to the principles of sound epidemiology and risk assessment (Tr. 2484–2485). Mr. Sessions agreed with OSHA that sufficient length of follow-up (≥20 years) is a critical qualification for a cohort to provide an adequate basis for lung cancer risk assessment, admitting that ''if we are dealing with [a] long latency sort of effect and if you only follow them for a few years it wouldn't be showing up with anywhere near the frequency that you would need to get a statistically significant excess risk'' (Tr. 2485). This criterion supports OSHA's decision to exclude the Alexander study as a primary data set for risk assessment, due in part to the inadequate length of follow-up on the cohort (average 8.9 years).

Mr. Sessions also agreed that the quality and comprehensiveness of the exposure information for a study could be a deciding factor in whether it should be used for OSHA's risk estimates (Tr. 2485–2487). As discussed in the preamble to the proposed rule, significant uncertainty in the exposure estimates for the Mancuso and Gerin studies was a primary reason they were not used in the derivation of OSHA's preliminary risk estimates (69 FR at 59362–3). Mancuso relied exclusively on the air monitoring reported by Bourne and Yee (Ex. 7–98) conducted over a single short period of time during 1949 to calculate cumulative exposures for each cohort member, although the cohort definition and follow-up period allowed inclusion of workers employed as early as 1931 and as late as 1972. In the public hearing, Mr. Sessions indicated that reliance on exposure data from a single year would not necessarily ''disqualify'' a study from inclusion in the weighted risk estimate he proposed, if ''for some reason the exposure hasn't changed much over the period of exposure'' (Tr. 2486). However, the Mancuso study provides no evidence that exposures in the Painesville plant were stable over the period of exposure. To the contrary, Mancuso stated that:

> The tremendous progressive increase in production in the succeeding years from zero could have brought about a concomitant increase in the dust concentrations to 1949 that could have exceeded the level of the first years of operation. The company instituted control measures after the 1949 study which markedly reduced the exposure (Ex. 7–11, p. 4).

In the Gerin *et al.* study, cohort members' Cr(VI) exposures were estimated based on total fume levels and fume composition figures from ''occupational hygiene literature and and welding products manufacturers' literature readily available at the time of the study'', supplemented by ''[a] limited amount of industrial hygiene measurements taken in the mid 1970s in eight of the [135] companies'' from which the cohort was drawn (Ex. 7–120, p. S24). Thus, cumulative exposure estimates for workers in this cohort were generally not based on data collected in their particular job or company. Gerin *et al.* explained that the resulting ''global average'' exposure estimates ''obscure a number of between-plant and within-plant variations in specific factors which affect exposure levels and would dilute a dose-response relationship'', including type of activity, * * * special processes, arcing time, voltage and current characteristics, welder position, use of special electrodes or rods, presence of primer paints and background fumes coming from other activities (Ex. 7–120, p. S25).

Commenting on the available welding epidemiology, NIOSH emphasized that wide variation in exposure conditions across employers may exist, and should be a consideration in multi-employer studies (Ex. 47–19, p. 6). Gerin *et al.* recommended refinement and validation of their exposure estimates using ''more complete and more recent quantitative data'' and accounting for variability within and between plants, but did not report any such validation for their exposure-response analysis. OSHA believes that the exposure misclassification in the Gerin study could be substantial. It is therefore difficult to place a high degree of confidence in its results, and it should not be used to derive the Agency's quantitative risk estimates. Comments received from Dr. Herman Gibb support OSHA's conclusion. He stated that epidemiologic studies of welders conducted to date do not include adequate data with which to evaluate lung cancer risk (Ex. 47–8, p. 2).

Finally, Mr. Sessions agreed with OSHA that it is best to rely on ''independent studies on different cohorts of workers'', rather than including the results of two or more overlapping cohorts in the weighted average he proposed (Tr. 2487). As discussed in the preamble to the proposed rule, the Hayes *et al.* and Gibb *et al.* cohorts were drawn from the same Baltimore chromate production plant (FR 69 at 59362). The workers in the subcohort of Hayes *et al.* analyzed by Braver were first hired between 1945 and 1959; the Gibb cohort included workers first hired between 1950 and 1974. Due to the substantial overlap between the two cohorts, it is not appropriate to use the results of the Hayes as well as the Gibb cohort in a weighted average calculation (as proposed by Mr. Sessions).

Having carefully reviewed the various comments discussed above, OSHA finds that its selection of the Gibb and Luippold cohorts to derive a range of quantitative risk estimates is the most appropriate approach for the Cr(VI) risk assessment. Support for this approach was expressed by NIOSH, which stated that ''the strength is in looking at [the Gibb and Luippold studies] together * * * appreciating the strengths of each'' (Tr. 313). Several commenters voiced general agreement with OSHA's study selection, even while disagreeing with OSHA's application of these studies' results to specific industries. Said one commenter, ''[w]e concur with the selection of the two focus cohorts (Luippold *et al.* 2003 and Gibb *et al.* 2000) as the best data available upon which to base an estimate of the exposure-response relationship between occupational exposure to Cr(VI) and an increased lung cancer risk'' (38–8, p. 6); and another, ''[i]t is clear that the data from the two featured cohorts, Gibb *et al.* (2000) and Luippold *et al.* (2003), offer the best information upon which to quantify the risk due to Cr(VI) exposure and an increased risk of lung cancer'' (Ex. 38–215–2, p. 16). Comments regarding the suitability of the Gibb and Luippold cohorts as a basis for risk estimates in specific industries will be addressed in later sections.

G. Issues and Uncertainties

The risk estimates presented in the previous sections include confidence limits that reflect statistical uncertainty. This statistical uncertainty concerns the limits of precision for statistical inference, given assumptions about the input parameters and risk models (*e.g.*, exposure estimates, observed lung cancer cases, expected lung cancer cases, linear dose-response). However, there are uncertainties with regard to the above input and assumptions, not so easily quantified, that may lead to underestimation or overestimation of risk. Some of these uncertainties are discussed below.

1. Uncertainty With Regard to Worker Exposure to Cr(VI)

The uncertainty that may have the greatest impact on risk estimates relates to the assessment of worker exposure. Even for the Gibb cohort, whose exposures were estimated from roughly 70,000 air measurements over a 35-year period, the calculation of cumulative exposure is inherently uncertain. The methods used to measure airborne Cr(VI) did not characterize particle size that determines deposition in the respiratory tract (see section V.A). Workers typically differ from one another with respect to working habits and they may have worked in different areas in relation to where samples are taken. Inter-individual (and intra-facility) variability in cumulative exposure can only be characterized to a limited degree, even with extensive measurement. The impact of such variability is likely less for estimates of long-term average exposures when there were more extensive measurements in the Gibb and Luippold cohorts in the 1960s through 1980s, but could affect the reliability of estimates in the 1940s and 1950s when air monitoring was done less frequently. Exposure estimates that rely on annual average air concentrations are also less likely to reliably characterize the Cr(VI) exposure to workers who are employed for short periods of time. This may be particularly true for the Gibb cohort in which a sizable fraction of cohort members were employed for only a few months.

Like many retrospective cohort studies, the frequency and methods used to monitor Cr(VI) concentrations may also be a source of uncertainty in reconstructing past exposures to the Gibb and Luippold cohorts. Exposures to the Gibb cohort in the Baltimore plant from 1950 until 1961 were determined based on periodic collection of samples of airborne dust using high volume sampling pumps and impingers that were held in the breathing zone of the worker for relatively short periods of time (*e.g.*, tens of minutes) (Ex. 31–22–11). The use of high volume sampling with impingers to collect Cr(VI) samples may have underestimated exposure since the accuracy of these devices depended on an air flow low enough to ensure efficient Cr(VI) capture, the absence of agents capable of reducing Cr(VI) to Cr(III), the proper storage of the collected samples, and the ability of short-term collections to accurately represent full-shift worker exposures. Further, impingers would not adequately capture any insoluble forms of Cr(VI) present, although other survey methods indicated minimal levels of insoluble Cr(VI) were produced at the Baltimore facility (Ex. 13–18–14).

In the 1960s, the Baltimore plant expanded its Cr(VI) air monitoring program beyond periodic high volume sampling to include extensive area monitoring in 27 exposure zones around the facility. Multiple short-term samples were collected (*e.g.*, twelve one-hour or eight three-hour samples) on cellulose tape for an entire 24 hour period and analyzed for Cr(VI). Studies have shown that Cr(VI) can be reduced to Cr(III) on cellulose filters under certain circumstances so there is potential for underestimation of Cr(VI) using this collection method (Ex. 7–1, p. 370). Monitoring was conducted prior to 1971, but the results were misplaced and were not accessible to Gibb *et al.* The area monitoring was supplemented by routine full-shift personal monitoring of workers starting in 1977. The 24-hour area sampling supplemented with personal monitoring was continued until plant closure in 1985.

Some of the same uncertainties exist in reconstructing exposures from the Luippold cohort. Exposure monitoring from operations at the Painesville plant in the 1940s and early 1950s was sparse and consisted of industrial hygiene surveys conducted by various groups (Ex. 35–61). The United States Public Health Service (USPHS) conducted two industrial hygiene surveys (1943 and 1951), as did the Metropolitan Life Insurance Company (1945 and 1948). The Ohio Department of Health (ODH) conducted surveys in 1949 and 1950. The most detailed exposure information was available in annual surveys conducted by the Diamond Alkali Company (DAC) from 1955 to 1971. Exponent chose not to consider the ODH data in their analysis since the airborne Cr(VI) concentrations reported in these surveys were considerably lower than values measured at later dates by DAC. Excluding the ODH survey data in the exposure reconstruction process may have led to higher worker exposure estimates and lower predicted lung cancer risks.

There were uncertainties associated with the early Cr(VI) exposure estimates for the Painesville cohort. Like the monitoring in the Baltimore plant, Cr(VI) exposure levels were determined from periodic short-term, high volume sampling with impingers that may have underestimated exposures (Ex. 35–61). Since the Painesville plant employed a ''high-lime'' roasting process to produce soluble Cr(VI) from chromite ore, a significant amount of slightly soluble and insoluble Cr(VI) was formed. It was estimated that up to approximately 20 percent of the airborne Cr(VI) was in the less soluble form in some areas of the plant prior to 1950 (Ex. 35–61). The impingers were unlikely to have captured this less soluble Cr(VI) so some reported Cr(VI) air concentrations may have been underestimated for this reason.

The annual air monitoring program at the Painesville plant was upgraded in 1966 in order to evaluate a full 24 hour period (Ex. 35–61). Unlike the continuous monitoring at the Baltimore plant, twelve area air samples from sites throughout the plant were collected for only 35 minutes every two hours using two in-series midget impingers containing water. The more frequent monitoring using the in-series impinger procedure may be an improvement over previous high-volume sampling and is believed to be less susceptible to Cr(VI) reduction than cellulose filters. While the impinger collection method at the Painesville plant may have reduced one source of potential exposure uncertainty, another source of potential uncertainty was introduced by failure to collect air samples for more than 40 percent of the work period. Also, personal monitoring of workers was not conducted at any time.

Concerns about the accuracy of the Gibb and Luippold exposure data were expressed in comments following the publication of the proposed rule. Several commenters suggested that exposures of workers in both the Gibb and Luippold (2003) cohorts may have been underestimated, resulting in systematic overestimation of risk in the analyses based on these cohorts (Exs. 38–231, pp. 19–20; 38–233, p. 82; 39–74, p. 2; 47–27, p. 15; 47–27–3, p. 1). In particular, the possibility was raised that exposure measurements taken with the RAC sampler commonly used in the 1960s may have resulted in lower reported Cr(VI) levels as a result of reduction of Cr(VI) on the sample strip. Concerns were also raised that situations of exceptionally high exposure may not have been captured by the sampling plans at the Baltimore and Painesville plants and that Cr(VI) concentrations in workers' breathing zones would have been generally higher than concentrations measured in general area samples taken in the two plants (Exs. 38–231, p. 19; 40–12–1, p. 2). One commenter noted that ''the exposure values identified in both the Painesville and Baltimore studies are consistently lower than those reported for a similar time period by alternative sources (Braver *et al.* 1985; PHS 1953)'' (Exs. 38–231, p. 19; 40–12–1, p. 2). It was also suggested that impinger samples used to estimate exposures in the Painesville plant and the impinger and RAC samples used between 1950 and 1985 in the Baltimore plant did not efficiently capture particles smaller than 1 μm in diameter, which were believed to have constituted a substantial fraction of particles generated during the chromite ore roasting process, and thus led to an underestimate of exposures (Ex. 47–27–3, pp. 1–4).

In his written testimony for the public hearing, Dr. Herman Gibb addressed concerns about the type of samples on which the Gibb cohort exposure estimates were based. Dr. Gibb stated, ''[a] comparison of the area and personal samples [collected during 1978–1985] found essentially no difference for approximately two-thirds of the job titles with a sufficient number of samples to make this comparison.'' An adjustment was made for the remaining job titles, in which the area samples were found to underestimate the breathing zone exposure, so that the potential for underestimation of exposures based on general area samples '' * * * was accounted for and corrected * * * '' in the Gibb cohort exposure estimates (Ex. 44–4, pp. 5–6). Dr. Gibb also noted that the publications claimed by commenters to have reported consistently higher levels of exposure than those specified by the authors of the Gibb *et al.* and Luippold *et al.* studies, in fact did not report exposures in sufficient detail to provide a meaningful comparison. In particular, Dr. Gibb said that the Public Health Service (PHS) publication did not report plant-specific exposure levels, and that Braver *et al.* did not report the locations or sampling strategies used (Ex. 44–4, pp. 5–6).

OSHA agrees with Dr. Gibb that the use of RAC general area samples in the Baltimore plant are unlikely to have caused substantial error in risk estimates based on the Gibb cohort. A similar comparison and adjustment between area and personal samples could not be performed for the Luippold *et al.* cohort, for which only area samples were available. The fact that most general area samples were similar to personal breathing zone samples in the Gibb cohort does not support the contention that reduction on the RAC sample strip or small particle capture issues would have caused substantial error in OSHA's risk estimates. Speculation regarding unusually high exposures that may not have been accounted for in sampling at the Baltimore and Painesville plants raises an uncertainty common to many epidemiological studies and quantitative risk analysis, but does not provide evidence that occasional high exposures would have substantially affected the results of this risk assessment.

OSHA received comments from the Small Business Administration's Office of Advocacy and others suggesting that, in addition to water-soluble sodium dichromate, sodium chromate, potassium dichromate, and chromic acid, some members of the Gibb and Luippold cohorts may have been exposed to less soluble compounds such as calcium chromate (Tr. 1825, Exs. 38–7, p. 4; 38–8, p. 12; 40–12–5, p. 5). These less soluble compounds are believed to be more carcinogenic than Cr(VI) compounds that are water-soluble or water-insoluble (*e.g.* lead chromate). The Painesville plant used a high-lime process to roast chromite ore, which is known to form calcium chromate and lesser amounts of other less water-soluble Cr(VI) compounds (Ex. 35–61). The 1953 USPHS survey estimated that approximately 20 percent of the total Cr(VI) in the roasting residue at the Painesville plant consisted of the less water-soluble chromates (Ex. 2–14). The high lime roasting process is no longer used in the production of chromate compounds.

Proctor *et al.* estimated that a portion of the Luippold cohort prior to 1950 were probably exposed to the less water-soluble Cr(VI) compounds due to the use of a high-lime roasting process, but that it would amount to less than 20 percent of their total Cr(VI) exposure (Ex. 35–61). The Painesville plant subsequently reduced and eliminated exposure to Cr(VI) roasting residue through improvements in the production process. A small proportion of workers in the Special Products Division of the Baltimore plant may have been exposed to less water-soluble Cr(VI) compounds during the occasional production of these compounds over the years. However, the high-lime process believed to generate less soluble compounds at the Painesville plant was not used at the Baltimore plant, and the 1953 USPHS survey detected minimal levels of less soluble Cr(VI) at this facility (Braver *et al.* 1985, Ex. 7–17).

OSHA agrees that some workers in the Luippold 2003 cohort (Painesville plant) and perhaps in the Gibb cohort (Baltimore plant) may have been exposed to minor amounts of calcium chromate and other less-soluble Cr(VI) compounds. However, these exposures would have been limited for most workers due to the nature of the production process and controls that were instituted after the early production period at the Painesville plant. The primary operation at the plants in Painesville and Baltimore was the production of the water-soluble sodium dichromate from which other primarily water-soluble chromates such as sodium chromate, potassium dichromate, and chromic acid could be made (Exs. 7–14; 35–61). Therefore, the Gibb and Luippold cohorts were principally exposed to water-soluble Cr(VI). Risk of lung cancer in these cohorts is therefore likely to reflect exposure to sodium chromate and sodium dichromate, rather than calcium chromate.

The results of the recent German post-change cohort showed that excess lung cancer mortality occurred among chromate-exposed workers in plants exclusively using a no-lime production process (Ex. 48–4). Like the Gibb cohort, the German cohort was exposed to average full-shift Cr(VI) exposures well below the previous PEL of 52 μg/m³ but without the possible contribution from the more carcinogenic calcium chromate (Exs. 48–1–2; Ex. 7–91). OSHA believes the elevated lung cancer mortality in these post-change workers are further evidence that occupational exposure to the less carcinogenic water-soluble Cr(VI) present a lung cancer risk.

In their post-hearing brief, the Aerospace Industries Association of America (AIA) stated:

> OSHA's quantitative risk estimates are based on exposure estimates derived from impinger and RAC samplers in the Painesville and Baltimore chromate production plants. It is likely that these devices substantially underestimated airborne levels of Cr(VI), especially considering that particles were typically <1 μm. If exposure in these studies were underestimated, the risk per unit exposure was overestimated, and the risk estimates provided in the proposed rule overstate lung cancer risks (Ex. 47–29–2, p. 4).

AIA supports its statements by citing a study by Spanne *et al.* (Ex. 48–2) that found very low collection efficiencies (*e.g.* <20 percent) of submicron particles (*i.e.* <1 μm) using midget impingers. OSHA does not dispute that liquid impinger devices, primarily used to measure Cr(VI) air levels at the Painesville plant, are less effective at collecting small submicron particles. However, OSHA does not believe AIA has adequately demonstrated that the majority of Cr(VI) particles generated during soluble chromate production are submicron in size. This issue is further discussed in preamble section VI.G.4.a. Briefly, the AIA evidence is principally based on a particle size distribution from two airborne dust samples collected at the Painesville plant by an outdated sampling device under conditions that essentially excludes particles >5 μm (Ex. 47–29–2, Figure 4).

OSHA believes it is more likely that Cr(VI) production workers in the Gibb and Luippold cohorts were exposed to Cr(VI) mass as respirable dust (*i.e.* <10 µm) mostly over 1 µm in size. The Spanne *et al.* study found that the impinger efficiency for particles greater than 2 µm is above 80 percent. Cr(VI) exposure not only occurs during roasting of chromite ore, where the smallest particles are probably generated, but also during the leaching of water-soluble Cr(VI) and packaging sodium dichromate crystals where particle sizes are likely larger. Based on this information, OSHA does not have reason to believe that the impinger device would substantially underestimate Cr(VI) exposures during the chromate production process or lead to a serious overprediction of risk.

The RAC samplers employed at the Baltimore plant collected airborne particles on filter media, not liquid media. AIA provided no data on the submicron particle size efficiency of these devices. For reasons explained earlier in this section, OSHA finds it unlikely that use of the RAC samplers led to substantial error in worker exposure estimates for the Gibb cohort.

In summary, uncertainties associated with the exposure estimates are a primary source of uncertainty in any assessment of risk. However, the cumulative Cr(VI) exposure estimates derived from the Luippold (2003) and Gibb cohorts are much more extensive than usually available for a cancer cohort and are more than adequate as a basis for quantitative risk assessment. OSHA does not believe the potential inaccuracies in the exposure assessment for the Gibb and Luippold (2003) cohorts are large enough to result in serious overprediction or underprediction of risk.

2. Model Uncertainty, Exposure Threshold, and Dose Rate Effects

The models used to fit the observed data may also introduce uncertainty into the quantitative predictions of risk. In the Preamble to the Proposed Rule, OSHA solicited comments on whether the linear relative risk model is the most appropriate approach on which to estimate risk associated with occupational exposure to Cr(VI) (FR 69 at 59307). OSHA expressed particular interest in whether there is convincing scientific evidence of a non-linear exposure-response relationship and, if so, whether there are sufficient data to develop a non-linear model that would provide more reliable risk estimates than the linear approach that was used in the preliminary risk assessment.

OSHA received a variety of comments regarding the uncertainties associated with using the risk model based on the Gibb and Luippold cohorts to predict risk to individuals exposed over a working lifetime to low levels of Cr(VI). OSHA's model assumes that the risk associated with a cumulative exposure resulting from long-term, low-level exposure is similar to the risk associated with the same cumulative exposure from briefer exposures to higher concentrations, and that a linear relative risk model adequately describes the cumulative exposure-response relationship. These assumptions are common in cancer risk assessment, and are based on scientifically accepted models of genotoxic carcinogenesis. However, OSHA received comments from the Small Business Administration's Office of Advocacy and others that questioned the Agency's reliance on these assumptions in the case of Cr(VI) (see *e.g.* Exs. 38–7, p. 2; 38–231, p. 18; 39–74, p. 2; 40–12–1, p. 2; 38–106, p. 10, p. 23; 38–185, p. 4; 38–233, p. 87; 38–265–1, pp. 27–29; 43–2, pp. 2–3). Some comments suggested that a nonlinear or threshold exposure-response model is an appropriate approach to estimate lung cancer risk from Cr(VI) exposures. Evidence cited in support of this approach rely on: (1) The lack of a statistically significant increased lung cancer risk for workers exposed below a cumulative Cr(VI) exposure of 1.0 mg/m^3=yr (*e.g.*, roughly equivalent to 20 µg/m^3 TWA for a 45 year working lifetime) and below ''a highest reported eight hour average'' Cr(VI) concentration of 52 µg/m^3; (2) the lack of observed lung tumors at lower dose levels in rats chronically exposed to Cr(VI) by inhalation and repeated intratracheal installations; and (3) the existence of physiological defense mechanisms within the lung, such as extracellular reduction of Cr(VI) to Cr(III) and repair of DNA damage. These commenters argue that the evidence suggests a sublinear nonlinearity or threshold in exposure-response at exposures in the range of interest to OSHA.

The Small Business Administration's Office of Advocacy and several other commenters stated that OSHA's risk model may overestimate the risk to individuals exposed for a working lifetime at ''low'' concentrations (Exs. 38–7, p. 2; 38–231, p. 18; 39–74, p. 2; 40–12–1, p. 2) or at concentrations as high as 20–23 µg/m^3 (Exs. 38–7, p. 6; 38–106, p. 10, p. 23; 38–185, p. 4; 38–233, p. 87; 38–265–1, pp. 27–29; 43–2, pp. 2–3), due to possible nonlinear features in the exposure-response relationship for Cr(VI). These comments cited various published analyses of the Luippold and Gibb cohorts, including the Luippold *et al.* 2003 publication (Exs. 38–106, p. 10, p. 22; 38–233–4, p. 17), the Proctor *et al.* 2004 publication (Ex. 38–233–4, p. 17), the Crump *et al.* 2003 publication (Exs. 38–106, p. 22; 38–265–1, p. 27), and an analysis conducted by Exponent on behalf of chromium industry representatives (Ex. 31–18–15–1). The following discussion considers each of these analyses, as well as the overall weight of evidence with respect to cancer risk from low exposure to Cr(VI).

a. Linearity of the Relationship Between Lung Cancer Risk and Cumulative Exposure

In the Luippold *et al.* 2003 publication (Ex. 33–10) and the Proctor *et al.* 2004 publication (Ex. 38–216–10), the authors reported observed and expected lung cancer deaths for five categories of cumulative exposure. Lung cancer mortality was significantly elevated in categories above 1.05 mg/m^3-yr Cr(VI) ($p < 0.05$), and was non-significantly elevated in the category spanning 0.20–0.48 mg/m^3-yr (8 observed lung cancer deaths vs. 4.4 expected), with a slight deficit in lung cancer mortality for the first and third categories (3 observed vs. 4.5 expected below 0.2 mg/m3-yr, 4 observed vs. 4.4 expected at 0.48–1.04 mg/m^3-yr) (Ex. 33–10, p. 455). This analysis is cited by commenters who suggest that the lack of a significantly elevated lung cancer risk in the range below 1.05 mg/m^3-yr may reflect the existence of a threshold or other nonlinearity in the exposure-response for Cr(VI), and that OSHA's use of a linear relative risk model in the preliminary risk assessment may not be appropriate (Exs. 38–106, pp. 10–11; 38–233–4, p. 18). OSHA received similar comments citing the Crump *et al.* (2003) publication, in which the authors found a ''consistently significant'' trend of increasing risk with increasing cumulative exposure for categories of exposure above 1 mg/m^3-yr (Ex. 35–58, p. 1157). The Exponent analysis of the Gibb *et al.* cohort was also cited, which found that lung cancer SMRs were not significantly elevated for workers with cumulative exposures below 0.42 mg/m^3-yrs Cr(VI) when Baltimore reference rates and a six-category exposure grouping were used (Ex. 31–18–15–1, Table 6).

Some commenters have interpreted these analyses to indicate uncertainty about the exposure-response relationship at low exposure levels. Others have asserted that ''[c]redible health experts assessing the same data as OSHA have concluded that 23 μg/m³ is a protective workplace standard (Ex. 38–185, p. 4) or that ''[t]he Crump study concluded that 23 μg/m³ would be a standard that is protective of workers health'' (Ex. 47–35–1, p. 5). Contrary to these assertions, it should be noted that the Gibb *et al.*, Luippold *et al.*, and Crump *et al.* publications do not include any statements concluding that 23 μg/m³ or any other exposure level is protective against occupational lung cancer. OSHA has reviewed these analyses to determine whether they provide sufficient evidence to support the use of a nonlinear or threshold-based exposure-response model for the Cr(VI) risk assessment, and whether they support the assertion that a PEL higher than that proposed would protect workers against a significant risk of lung cancer.

In discussing their results, Luippold *et al.* reported that evaluation of a linear dose-response model using a chi-squared test showed no significant departure from linearity and concluded that the data are consistent with a linear dose-response model. They noted that the results were also consistent with threshold or nonlinear effects at low cumulative exposures, as they observed substantial increases in cumulative exposure levels above approximately 1 mg/m³-yrs (Ex. 33–10, p. 456). Ms. Deborah Proctor, lead author of the Proctor *et al.* (2004) publication, confirmed these conclusions at the public hearing, stating her belief that nonlinearities may exist but that the data were also consistent with a linear dose response (Tr. 1845). The authors of the Crump *et al.* 2003 publication (Ex. 35–58), in which trend analyses were used to examine the exposure-response relationship for cumulative exposure, stated that the data were '' * * * neutral with respect to these competing hypotheses'' (Ex. 35–58, pp. 1159–1160). Crump *et al.* concluded that their study of the Luippold cohort '' * * * had limited power to detect increases [in lung cancer risk] at these low exposure levels'' (Ex. 35–58, p. 1147). OSHA agrees with Crump *et al.*'s conclusion that their study could not detect the relatively small increases in risk that would be expected at low exposures. With approximately 3000 person-years of observation time and 4.5 expected lung cancers in each of the three cumulative exposure categories lower than 0.19 mg/m³-yrs Cr(VI) (Ex. 33–10, p. 455), analyses of the Luippold cohort cannot effectively discriminate between alternative risk models for cumulative exposures that a worker would accrue from a 45-year working lifetime of occupational exposure at relatively low exposures (*e.g.*, 0.045–0.225 mg/m³-yrs Cr(VI), corresponding to a working lifetime of exposure at 1–5 μg Cr(VI)/m³).

The Exponent reanalysis of the Gibb cohort found that lung cancer rates associated with exposures around 0.045 mg/m³-yrs Cr(VI) and below were not significantly elevated in some analyses (Ex. 31–18–15–1, Table 6 p. 26). However, OSHA believes that this result is likely due to the limited power of the study to detect small increases in risk, rather than a threshold or nonlinearity in exposure-response. In written testimony, Dr. Gibb explained that ''[l]ack of a statistically elevated lung cancer risk at lower exposures does not imply that a threshold of response exists. As exposure decreases, so does the statistical power of a given sample size to detect a significantly elevated risk'' (Ex. 44–4, p. 6). Exponent's analyses found (non-significant) elevated risks for all exposure groups above approximately 0.1 mg/m³-yrs, equivalent to 45 years of occupational exposure at about 2.25 μg/m³ Cr(VI) (Ex. 31–18–15–1, p. 20, Table 3). Furthermore, Gibb *et al.*'s SMR analysis based on exposure quartiles found statistically significantly elevated lung cancer risks among workers with cumulative exposures well below the equivalent of 45 years at the proposed PEL of 1 μg/m³. As Dr. Gibb commented at the hearing, the proposed PEL '' * * * is within the range of observation [of the studies] * * * In a sense, you don't even need risk models'' to show that workers exposed to cumulative exposures equivalent to a working lifetime of exposure at or above the proposed PEL have excess risk of lung cancer as a result of their occupational exposure to Cr(VI)'' (Tr. 121–122).

Furthermore, Robert Park of NIOSH reminded OSHA that ''[a]nalysts of both the Painesville and the Baltimore cohorts * * * did test for deviation or departure from linearity in the exposure response and found no significant effect. If there was a large threshold, you would expect to see some deviance there'' (Tr. 350–351). Post-hearing comments from NIOSH indicated that further analysis of the Gibb data provided no significant improvement in fit for nonlinear and threshold models compared to the linear relative risk model (Ex. 47–19, p. 7). Based on this evidence and on the previously discussed findings that (1) linear relative risk models fit both the Gibb and Luippold data sets adequately, and (2) the wide variety of nonlinear models tested by various analysts failed to fit the available data better than the linear model, OSHA believes that a linear risk model is appropriate and that there is not convincing evidence to support the use of a threshold or nonlinear exposure-response model, or to conclude that OSHA's risk assessment has seriously overestimated risk at low exposures.

b. The Cumulative Exposure Metric and Dose-Rate Effects on Risk

The Small Business Administration's Office of Advocacy and several other commenters questioned OSHA's reliance in the preliminary risk assessment on models using cumulative exposure to estimate excess risk of lung cancer, suggesting that cumulative exposures attained from exposure to high concentrations of Cr(VI) for relatively short periods of time, as for some individuals in the Gibb and Luippold cohorts, may cause greater excess risk than equivalent cumulative exposures attained from long-term exposure to low concentrations of Cr(VI) (Exs. 38–7, pp. 3–4, 38–215–2, pp. 17–18; 38–231, p. 18; 38–233, p. 82; 38–265–1, p. 27; 39–74, p. 2, 40–12–1, p. 2, 43–2, p. 2, 47–27, p. 14; 47–27–3, p. 1). This assertion implies that OSHA's risk assessment overestimates risk from exposures at or near the proposed PEL due to a threshold or dose-rate effect in exposure intensity. One commenter stated that ''[a]pplication of a linear model estimating lung cancer risk from high-level expsoures . . . to very low-level exposure using the exposure metric of cumulative dose will inevitably overestimate risk estimates in the proposed PEL'' (Ex. 47–27–3, p. 1). Comments on this subject have cited analyses by Proctor *et al.* (2004) (Ex. 38–233–4, p. 17), Crump *et al.* (2003) (Exs. 38–106, p. 22; 38–265–1, p. 27), Exponent (Ex. 31–18–15–1, pp. 31–34) and NIOSH (Ex. 47–19–1, p. 7); a new study by Luippold *et al.* on workers exposed to relatively low concentrations of Cr(VI) (Ex. 47–24–2); and mechanistic and animal studies examining the potential for dose-rate effects in Cr(VI)-related health effects (Exs. 31–18–7; 31–18–8; 11–7).

Of the two featured cohorts in OSHA's preliminary risk assessment, the Gibb cohort is better suited to assess risk from exposure concentrations below the previous PEL of 52 μg Cr(VI)/m³. Contrary to some characterizations of the cohort's exposures as too high to provide useful information about risk under modern workplace conditions (*See e.g.* Exs. 38–106, p. 21; 38–233, p. 82; 38–265–1, p. 28), most members of the Gibb cohort had relatively low exposures, with 42% of the cohort members having a median annual average exposure value below 10 μg/m^3 Cr(VI), 69% below 20 μg/m^3, and 91% below the previous PEL (Ex. 35–295). In addition, Dr. Gibb indicated that exposures in general were lower than suggested by some commenters (Tr. 1856, Ex. 38–215–2, p. 17). For example, about half of the total time that workers were exposed was estimated to be below 14 μg/m^3 Cr(VI) from 1960–1985 (Ex. 47–8, p. 1).

Exponent calculated SMRs for six groups of workers in the Gibb cohort, classified according to the level of their highest average annual exposure estimates. They found that only the group of workers whose highest exposure estimates were above approximately 95 μg/m^3 Cr(VI) had statistically significantly elevated lung cancer risk when Baltimore reference rates were used (Ex. 31–18–15–1, p. 33). Exponent's results are presented in Table VI–8 below, adapted from Table 10 in their report (Ex. 31–18–15–1, p. 33).

Table VI-8

Exponent SMR Analysis of Peak Exposures in Gibb Cohort

Group	Peak Exposure (μg Cr(VI)/m^3)	Observed Cancer Deaths	Person-years of Observation	SMR (95% CI)	
				Maryland	Baltimore
1	0.000 - 3.7	50	36,733	1.18 (0.87 - 1.55)	0.91 (0.67 - 1.20)
2	3.7 - 10.0	21	10,401	1.97 (1.22 - 3.01)	1.51 (0.94 - 2.31)
3	10.0 - 25.0	19	9,800	2.07 (1.24 - 3.23)	1.56 (0.94 - 2.43)
4	25.0 - 54.9	12	6,707	2.06 (1.07 - 3.60)	1.54 (0.80 - 2.69)
5	54.9 - 94.6	7	3,462	2.20 (0.88 - 4.53)	1.66 (0.67 - 3.43)
6	94.6 - 419.3	13	3,664	3.00 (1.60 - 5.13)	2.35 (1.25 - 4.02)

OSHA does not believe that Exponent's analysis of the Gibb data provides convincing evidence of a threshold in exposure-response. While the lower-exposure groups do not have statistically significantly elevated lung cancer risk ($p > 0.05$) when compared with a Baltimore reference population, the SMRs for all groups above 3.7 μg/m^3 are consistently elevated. Moreover, the increased risk approaches statistical significance, especially for those subgroups with higher power (Groups 2 and 3). This can be seen by the lower 95% confidence bound on the SMR for these groups, which is only slightly below 1. The analysis suggests a lack of power to detect excess risk in Groups 2–5, rather than a lack of excess risk at these exposure levels.

Analyses of the Luippold cohort by Crump *et al.* (Ex. 35–58) and Proctor *et al.* (Ex. 38–216–10) used exposure estimates they called "highest average monthly exposure" to explore the effects of exposure intensity on lung cancer risk. They reported that lung cancer risk was elevated only for individuals with exposure estimates higher than the previous PEL of 52 μg/m^3 Cr(VI). Crump *et al.* additionally found "statistically significant evidence of a dose-related increase in the relative risk of lung cancer mortality" only for groups above four times the previous PEL, using a series of Poisson regressions modeling the increase in risk across the first two subgroups and with the successive addition of higher-exposed subgroups (Ex. 35–58, p. 1154).

As with the Gibb data, OSHA does not believe that the subgroup of workers exposed at low levels is large enough to provide convincing evidence of a threshold in exposure-response. In the Crump *et al.* and Proctor *et al.* analyses, the groups for which no statistically significant elevation or dose-related trends in lung cancer risk were observed are quite small by the standards of cancer epidemiology (*e.g.*, the Luippold cohort had only about 100 workers below the previous PEL and about 40 workers within 1–3 times the previous PEL). Crump *et al.* emphasized that "* * * this study had limited power to detect increases [in lung cancer risk] at these low exposure levels" (Ex. 35–58, p. 1147). The authors did not conclude that their results indicate a threshold. They stated that their cancer potency estimates based on a linear relative risk model using the cumulative exposure metric "* * * are comparable to those developed by U.S. regulatory agencies and should be useful for assessing the potential cancer hazard associated with inhaled Cr(VI)" (Ex. 35–58, p. 1147).

OSHA discussed the Exponent, Crump *et al.* and Luippold *et al.* SMR analyses of the Gibb and Luippold cohorts in the preamble to the proposed rule, stating that the lack of a statistically significant result for a subset of the entire cohort should not be construed to imply a threshold (69 FR at 59382). During the hearing, Robert Park of NIOSH expressed agreement with OSHA's preliminary interpretation, adding that:

> [W]e think that any interpretation of threshold in these studies is basically a statistical artifact * * * It is important I think to understand that any true linear or even just monotonic exposure response that doesn't have a threshold will exhibit a threshold by the methods that they used. If you stratify the exposure metric fine enough and look at the lower levels, they will be statistically insignificant in any finite study * * * telling you nothing about whether or not in fact there is a threshold (Tr. 351).

To further explore the effects of highly exposed individuals on OSHA's risk model, The Chrome Coalition suggested that OSHA should base its exposure-response model on a subcohort of workers excluding those who were exposed to "* * * an extraordinary exposure level for some extended period of time* * * ", *e.g.*, estimated exposures greater than the previous PEL for more than one year (Ex. 38–231, p. 21). The Chrome Coalition stated,

> We are not aware of any study that has performed this type of analysis but we believe that it should be a way of better estimating the risk for exposures in the range that OSHA is considering for the PEL (Ex. 38–231, p. 21).

To gauge the potential utility of such an analysis, OSHA examined the subset of the Gibb cohort that was exposed for more than 365 days and had average annual exposure estimates above the previous PEL of 52 μg/m^3 Cr(VI). The Agency found that the subcohort includes only 82 such individuals, of whom 37 were reported as deceased at the end of follow-up and five had died of lung cancer. In a cohort of 2357 workers with 122 lung cancers out of 855 deaths, it is unlikely that exclusion of a group this size would impact the results of a regression analysis significantly, especially as the proportion of mortality attributable to lung cancer is similar in the highly-exposed subgroup and the overall cohort (5/37 0.135, 122/855 ≅ 0.143). The great majority of the Gibb cohort members did not have the 'extraordinary' exposure levels implied by the Chrome Coalition. As discussed previously, most had relatively low exposures averaging less than 20 μg/m^3.

As discussed in their post-hearing comments, NIOSH performed regression analyses designed to detect threshold or dose-rate effects in the exposure-response relationship for the Gibb dataset (Ex. 47–19–1, p. 7). NIOSH reported that ''[t]he best fitting models had no threshold for exposure intensity and the study had sufficient power to rule out thresholds as large as 30 μg/m^3 CrO_3 (15.6 μg/m^3 Cr(VI) * * * '' and that there was no statistically significant departure from dose-rate linearity when powers of annual average exposure values were used to predict lung cancer risk (Ex. 47–19–1, p. 7). This indicates that a threshold of approximately 20 μg/m^3 Cr(VI) suggested in some industry comments is not consistent with the Gibb cohort data. Based on these and other analyses described in their post-hearing comments, NIOSH concluded that:

> [E]xamination of non-linear features of the hexavalent chromium-lung cancer response supports the use of the traditional (lagged) ''cumulative exposure paradigm * * * '': that is, linear exposure-response with no threshold (Ex. 47–19–1, p. 7).

OSHA recognizes that, like most epidemiologic studies, neither the Luippold nor the Gibb cohort provides ideal information with which to identify a threshold or detect nonlinearities in the relationship between Cr(VI) exposure and lung cancer risk, and that it is important to consider other sources of information about the exposure-response relationship at very low levels of Cr(VI) exposure. The Agency agrees with Dr. Gibb's belief that '' * * * arguments for a 'threshold' should not be based on statistical arguments but rather on a biological understanding of the disease process'' (Ex. 44–4, p. 7) and Crump *et al.*'s statement that '' * * * one needs to consider supporting data from mechanistic and animal studies'' in order to determine the appropriateness of assuming that a threshold (or, presumably, other nonlinearity) in exposure-response exists (Ex. 35–58, p. 1159). Experimental and mechanistic evidence and related comments relevant to the issue of threshold and dose-rate effects are reviewed in the following discussion.

c. Animal and Mechanistic Evidence Regarding Nonlinearities in Cr(VI) Exposure-Response

In the NPRM, OSHA analyzed several animal and mechanistic studies and did not find convincing evidence of a threshold concentration in the range of interest (*i.e.* 0.25 to 52 μg/m^3). However, the Agency recognized that evidence of dose rate effects in an animal instillation study and the existence of extracellular reduction, DNA repair, and other molecular pathways within the lung that protect against Cr(VI)-induced respiratory tract carcinogenesis could potentially introduce nonlinearities in Cr(VI) exposure-cancer response. OSHA solicited comment on the scientific evidence for a non-linear exposure-response relationship in the occupational exposure range of interest and whether there was sufficient data to develop a non-linear model that would provide more reliable risk estimates than the linear approach used in the preliminary risk assessment (69 FR at 59307).

Some commenters believed the scientific evidence from animal intratracheal instillation and inhalation of Cr(VI) compounds showed that a linear risk model based on lung cancers observed in the Gibb and Luippold cohorts seriously overpredicts lung cancer risk to workers exposed at the proposed PEL (Exs. 38–216–1; 38–233–4; 38–231). The research cited in support of this presumed non-linear response was the intratracheal instillation study of Steinhoff *et al.* and the inhalation study of Glaser *et al.* (Exs. 11–7; 10–11). For example, Elementis Chromium states that:

> Considering either the Steinhoff or Glaser studies, a calculated risk based on the effect frequency at the highest daily exposure would be considerably greater than that calculated from the next lower daily exposure. We believe that the same effect occurs when humans are exposed to Cr(VI) and consideration of this should be taken when estimating risk at very low exposure levels based on effects at much higher exposure levels (Ex. 38–216–1, p. 4).

Despite the different mode of Cr(VI) administration and dosing schemes, the Steinhoff and Glaser studies both feature dose levels at which there was no observed incidence of lung tumors. The Steinhoff study found no significant lung tumor incidence in rats intratracheally administered highly soluble sodium dichromate at 87 μg Cr(VI)/kg or less regardless of whether the dose was received five times a week or once a week for 30 months. However, rats administered a higher dose of 437 μg Cr(VI)/kg of sodium dichromate or a similar amount of the slightly soluble calcium chromate once a week developed significant increases (about 17 percent incidence) in lung tumors. The study documented a 'dose rate effect' since the same total dose administered more frequently (*i.e.* five times weekly) at a five-fold lower dose level (*i.e.* 87 μg Cr(VI)/kg) did not increase lung tumor incidence in the highly soluble sodium dichromate-treated rats. The Glaser inhalation study reported no lung tumors in rats inhaling 50 μg Cr(VI)/m^3 of sodium dichromate or lower Cr(VI) concentrations for 22 hours/day, 7 days a week. However, the next highest dose level of 100 μg Cr(VI)/m^3 produced a 15 percent lung tumor incidence (*i.e.* 3 of 19 rats). Both studies are more fully described in Section V.B.7.a.

The apparent lack of lung tumors at lower Cr(VI) dose levels is interpreted by the commenters to be evidence of a non-linear exposure-response relationship and, possibly, an exposure threshold below which there is no risk of lung cancer.

In written testimony, Dr. Harvey Clewell of ENVIRON Health Science Institute addressed whether the Steinhoff, Glaser and other animal studies provided evidence of a threshold for Cr(VI) induced lung carcinogenicity (Ex. 44–5). He stated that the argument for the existence of a threshold rests on two faulty premises:

> (1) Failure to detect an increased incidence of tumors from a given exposure indicates there is no carcinogenic activity at that exposure, and
>
> (2) Nonlinearities in dose response imply a threshold below which there is no carcinogenic activity (Ex. 44–5, p. 13).

In terms of the first premise, Dr. Clewell states:

> The ability to detect an effect depends on the power of the study design. A statistically-based No Observed Adverse Effect Level (NOAEL) in a toxicity study does not necessarily mean there is no risk of adverse effect. For example, it has been estimated that a typical animal study can actually be associated with the presence of an effect in as many as 10% to 30% of the animals. Thus the failure to observe a statistically significant increase in tumor incidence at a particular exposure does not rule out the presence of a substantial carcinogenic effect at that exposure (Ex. 44–5, p. 13–14).

Dr. Clewell also addressed the second premise as it applies to the Steinhoff instillation study as follows:

> It has been suggested, for example, that the results of the Steinhoff study suggest that

> dose rate is an important factor in the carcinogenic potency of chrome (VI), and therefore, there must be a threshold. But these data, while they do provide an indication of a dose rate effect * * * they don't provide information about where and whether a threshold or even a non-linearity occurs, and to what extent it does occur at lower concentrations (Tr. 158–159).

OSHA agrees with Dr. Clewell that the absence of observed lung tumor incidence at a given exposure (*i.e.* a NOAEL) in an animal study should not be interpreted as evidence of a threshold effect. This is especially true for clearly genotoxic carcinogens, such as Cr(VI), where it is considered scientifically reasonable to expect some small, but finite, probability that a very few molecules may damage DNA in a single cell and eventally develop into a tumor. For this reason, it is not appropriate to regard the lack of tumors in the Steinhoff or Glaser studies as evidence for an exposure-response threshold.

Exponent, in a technical memorandum prepared for an ad hoc group of steel manufacturers, raises the possibility that the lung tumor responses in the Steinhoff and Glaser studies were the result of damage to lung tissue from excessive levels of Cr(VI). Exponent suggests that lower Cr(VI) exposures that do not cause 'respiratory irritation' are unlikely to lead an excess lung cancer risk (Ex. 38–233–4). Exponent went on to summarize:

> In examining the weight of scientific evidence, for exposure concentrations below the level which causes irritation, lung cancer has not been reported. Not surprisingly, Cr(VI)-induced respiratory irritation is an important characteristic of Cr(VI)-induced carcinogenicity in both humans and animals * * * Based on the information reviewed herein, it appears that the no effect level for non-neoplastic respiratory irritation and lung cancer from occupational exposure to Cr(VI) is approximately 20 µg/m³. Thus establishing a PEL of 1 µg/m³ to protect against an excess lung cancer risk is unnecessarily conservative (Ex. 38–233–4, p. 24).

In support of the above hypothesis, Exponent points out that only the highest Cr(VI) dose level (*i.e.* 437 µg Cr(VI)/kg) of sodium dichromate employed in the Steinhoff study resulted in significant lung tumor incidence. Tracheal instillation of this dose once a week severely damaged the lungs leading to emphysematous lesions and pulmonary fibrosis in the Cr(VI)-exposed rats. Lower Cr(VI) dose levels (*i.e.* 87 µg Cr(VI)/kg or less) of the highly water-soluble sodium dichromate that caused minimal lung damage did not result in significant tumor incidence. However, the study also showed that a relatively low dose (*i.e.* 81 µg Cr(VI)/kg) of slightly soluble calcium chromate repeatedly instilled (*i.e.* five times a week) in the trachea of rats caused significant lung tumor incidence (about 7.5 percent) in the absence of lung tissue damage. This finding is noteworthy because it indicates that tissue damage is not an essential requirement for Cr(VI)-induced respiratory tract carcinogenesis. The same instilled dose of the slightly soluble calcium chromate would be expected to provide a more persistent and greater source of Cr(VI) in proximity to target cells within the lung than would the highly water-soluble sodium dichromate. This suggests that the internal dose of Cr(VI) at the tissue site, rather than degree of damage, may be the critical factor determining lung cancer risk from low-level Cr(VI) exposures.

Exponent applies similar logic to the results of the Glaser inhalation study of sodium dichromate in rats. Exponent states:

> In all experimental groups (*i.e.* 25, 50, and 100 µg Cr(VI)/m³), inflammation effects were observed, but at 100 µg Cr(VI)/m³ [the high dose group with significant lung tumor incidence], effects were more severe, as expected (Ex. 38–233–4, p. 22).

This assessment contrasts with that of the study authors who remarked:

> In this inhalation study, in which male Wistar rats were continuously exposed for 18 months to both water soluble sodium dichromate and slightly soluble chromium oxide mixture aerosols, no clinical signs of irritation were obvious * * * For the whole time of the study no significant effects were found from routine hematology and clinico-chemical examinations in all rats exposed to sodium dichromate aerosol (Ex. 10–11, p. 229).

The rats in the Glaser carcinogenicity study developed a focalized form of lung inflammation only evident from microscopic examination. This mild response should not be considered equivalent to the widespread bronchiolar fibrosis, collapsed/distorted alveolar spaces and severe damage found upon macroscopic examination of rat lungs instilled with the high dose (437 µg Cr(VI)/kg) of sodium dichromate in the Steinhoff study. The non-neoplastic lung pathology (*e.g.* accumulation of pigmentized macrophages) described following inhalation of sodium dichromate at all air concentrations of Cr(VI) in the Glaser study are more in line with the non-neoplastic responses seen in the lungs of rats intratracheally instilled with lower dose levels of sodium dichromate (*i.e.* 87 µg Cr(VI)/kg or less) that did not cause tumor incidence in the Steinhoff study. OSHA finds no evidence that severe pulmonary inflammation occurred following inhalation of 100 µg Cr(VI)/m³ in the Glaser carcinogenicity study or that the lung tumors observed in these rats were the result of 'respiratory irritation'. Dr. Clewell also testified that lung damage or chronic inflammation is not a necessary and essential condition for C(VI) carcinogenesis in the Glaser study:

> I didn't find any evidence that it [lung damage and chronic inflammation] was necessary and essential. In particular, I think the Glaser study was pretty good in demonstrating that there were effects where they saw no evidence of irritation, or any clinical signs of those kinds of processes (Tr. 192).

Subsequent shorter 30-day and 90-day inhalation exposures with sodium dichromate in rats were undertaken by the Glaser group to better understand the non-neoplastic changes of the lung (Ex. 31–18–11). The investigation found a transitory dose-related inflammatory response in the lungs at exposures of 50 µg Cr(VI)/m³ and above following the 30 day inhalation. This initial inflammatory response did not persist during the 90 day exposure study except at the very highest dose levels (*i.e.* 200 and 400 µg Cr(VI)/m³). Significant increases in biomarkers for lung tissue damage (such as albumin and lactate dehydrogenase (LDH) in bronchioalveolar lavage fluid (BALF) as well as bronchioalveolar hyperplasia) also persisted through 90 days at these higher Cr(VI) air levels, especially 400 µg Cr(VI)/m³. The study authors considered the transient 30-day responses to represent adaptive, rather than persistent pathological, responses to Cr(VI) challenge. A dose-related elevation in lung weights due to histiocytosis (*i.e.* accumulation of lung macrophages) was seen in all Cr(VI)-administered rats at both time periods. The macrophage accumulation is also likely to be an adaptive response that reflects lung clearance of inhaled Cr(VI). These study results are more fully described in section V.C.3.

OSHA believes that Cr(VI)-induced carcinogenesis may be influenced not only by the total Cr(VI) dose retained in the respiratory tract but also by the rate at which the dose is administered. Exponent is correct that one possible explanation for the dose rate effect observed in the Steinhoff study may be the widespread, severe damage to the lung caused by the immediate instillation of a high Cr(VI) dose to the respiratory tract repeated weekly for 30 months. It is biologically plausible that the prolonged cell proliferation in response to the tissue injury would enhance tumor development and progression compared to the same total Cr(VI) instilled more frequently at smaller dose levels that do not cause widespread damage to the respiratory tract. This is consistent with the opinion of Dr. Clewell who testified that:

> I would not say that it [respiratory tract irritation, lung damage, or chronic inflammation] is necessary and sufficient, but rather it exacerbates an underlying process. If there is a carcinogenic process, then increased cell proliferation secondary to irritation is going to put mitogenic pressure on the cells, and this will cause more likelihood of a transformation (Tr. 192).

OSHA notes that increased lung tumor incidence was observed in animals instilled with lower dose levels of calcium chromate in the Steinhoff study and after inhalation of sodium dichromate in the Glaser study. These Cr(VI) exposures did not trigger extensive lung damage and OSHA believes it unlikely that the lung tumor response from these treatments was secondary to 'respiratory irritation' as suggested by Exponent. The more thorough investigation by the Glaser group did not find substantive evidence of persistent tissue damage until rats inhaled Cr(VI) at doses two- to four-fold higher than the Cr(VI) dose found to elevate lung tumor incidence in the their animal cancer bioassay.

Exponent goes on to estimate a NOAEL (no observable adverse effect level) for lung histopathology in the Steinhoff study. They chose the lowest dose level (*i.e.* 3.8 μg Cr(VI)/kg) in the study as their NOAEL based on the minimal accumulation of macrophages found in the lungs instilled with this dose of sodium dichromate five times weekly (Ex. 38–233–4, p. 21). Exponent calculates that this lung dose is roughly equivalent to the daily dose inhaled by a worker exposed to 27 μg Cr(VI)/m^3 using standard reference values (*e.g.* 70 kg human inhaling 10 m^3/day over a daily 8 hour work shift). Exponent considers this calculated Cr(VI) air level as a threshold below which no lung cancer risk is expected in exposed workers.

However, Steinhoff *et al.* instilled Cr(VI) compounds directly on the trachea rather than introducing the test compound by inhalation, and was only able to characterize a significant dose rate effect at one cumulative dose level. For these reasons, OSHA considers the data inadequate to reliably determine the human exposures where this potential dose transition might occur and to confidently predict the magnitude of the resulting non-linearity. NIOSH presents a similar view in their post-hearing comments:

> NIOSH disagrees with Dr. Barnhardt's analysis [Ex. 38–216–1] and supports OSHA's view that the Steinhoff *et al.* [1986] rat study found a dose-rate effect in rats under the specified experimental conditions, that this effect may have implications for human exposure and that the data are insufficient to use in a human risk assessment for Cr(VI) * * * The study clearly demonstrates that, within the constraints of the experimental design, a dose rate effect was observed. This may be an important consideration for humans exposed to high levels of Cr(VI). However, quantitative extrapolation of that information to the human exposure scenario is difficult (Ex. 47–19–1, p. 8).

Exponent also relies on a case investigation of the benchmark dose methodology applied to the pulmonary biomarker data measured in the 90-day Glaser study (Ex. 40–10–2–8). In this instance, the benchmark doses represent the 95 percent lower confidence bound on the Cr(VI) air level corresponding a 10 percent increase relative to unexposed controls for a chosen biomarker (*e.g.* BALF total protein, albumin, or LDH). The inhaled animal doses were adjusted to reflect human inhalation and deposition in the respiratory tract as well as continuous environmental exposure (*e.g.* 24 hours/day, 7 days/week) rather than an occupational exposure pattern (*e.g.* 8 hours/day, 5 days/week). The benchmark doses were reported to range from 34 to 140 μg Cr(VI)/m^3.

Exponent concludes that ''these [benchmark] values are akin to a no-observed-adverse-effect level NOAEL in humans to which uncertainty factors are added to calculate an RfC [*i.e.* Reference Concentration below which adverse effects will not occur in most individuals]'' and ''taken as a whole, the studies of Glaser *et al.* suggest that both non-neoplastic tissue damage and carcinogenicity are not observed among rats exposed to Cr(VI) at exposure concentrations below 25 μg/m^3'' (Ex. 38–233–4, p. 22). Since the Exponent premise is that Cr(VI)-induced lung cancer only occurs as a secondary response to histopathological changes in the respiratory tract, the suggested 25 μg Cr(VI)/m^3 is essentially being viewed as a threshold concentration below which lung cancer is presumed not to occur.

In his written testimony, Dr. Clewell indicated that the tumor data from the Glaser cancer bioassay was more appropriately analyzed using linear, no threshold exposure-response model rather than the benchmark uncertainty factor approach that presumes the existence of threshold exposure-response.

> The bioassay of Glaser *et al.* provides an example of a related difficulty of interpreting data from carcinogenicity studies. The tumor outcome appears to be nonlinear (0/18, 0/18, and 3/19 at 0.025, 0.05, and 0.1 mg Cr/m^3). However, although the outcomes are restricted to be whole numbers (of animals), they should not be evaluated as such. Because the nature of cancer as a stochastic process, each observed outcome represents a random draw from a Poisson distribution. Statistical dose-response modeling, such as the multistage model used by OSHA, is necessary to properly interpret the cancer dose-response. In the case of Glaser *et al.* (1986) study, such modeling would produce a maximum likelihood estimate of the risk at the middle dose that was greater than zero. In fact, the estimated risk at the middle dose would be on the order of several percent, not zero. Therefore, suggesting a lack of lung cancer risk at a similar human exposure would not be a health protective position (Ex. 44–5, p. 14).

The U.S. Environmental Protection Agency applied a linearized (no threshold) multistage model to the Glaser data (Ex. 17–101). They reported a maximum likelihood estimate for lifetime lung cancer risk of 6.3 per 1000 from continuous exposure to 1 μg Cr(VI)/m^3. This risk would be somewhat less for an occupational exposure (*e.g.* 8 hours/day, 5 days/week) to the same air level and would be close to the excess lifetime risk predicted by OSHA (*i.e.* 2–9 per 1000).

In summary, OSHA does not believe the animal evidence demonstrates that respiratory irritation is required for Cr(VI)-induced carcinogenesis. Significant elevation in lung tumor incidence was reported in rats that received Cr(VI) by instillation or inhalation at dose levels that caused minimal lung damage. Consequently, OSHA believes it inappropriate to consider a NOAEL (such as 25 μg/m^3) where lung tumors were not observed in a limited number of animals to be a threshold concentration below which there is no risk. Statistical analysis of the animal inhalation data using a standard dose-response model commonly employed for genotoxic carcinogens, such as Cr(VI), is reported to predict risks similar to those estimated by OSHA from the occupational cohorts of chromate production workers. While the rat intratracheal instillation study indicates that a dose rate effect may exist for Cr(VI)-induced carcinogenesis, it can not be reliably determined from the data whether the effect would occur at the occupational exposures of interest (*e.g.* working lifetime exposures at 0.25 to 52 μg Cr(VI)/m^3) without a better quantitative understanding of Cr(VI) dosimetry within the lung. Therefore, OSHA does not believe that the animal data show that cumulative Cr(VI) exposure is an inappropriate metric to estimate lung cancer risk.

Exponent used the clinical findings from chromate production workers in the Gibb and Luippold cohorts to support their contention that 'respiratory irritation' was key to Cr(VI)-induced lung cancer (Ex. 28–233–4, p. 18–19). They noted that over 90 percent of chromate production workers employed at the Painesville plant during the 1930s and 1940s, including some Luippold cohort members, were reported to have damaged nasal septums. Based on this, Exponent concludes:

> Thus, it is possible that the increased incidence of lung cancer in these workers (*i.e.* SMR of 365 from Luippold *et al.* cohort exposed during the 1940s) is at least partially due to respiratory system tissue damage resulting from high Cr(VI) concentrations to which these workers were exposed. These exposures clearly exceed a threshold for both carcinogenic and non-carcinogenic (*i.e.* respiratory irritation) health effects (Ex. 38–233–4, p. 18).

Exponent noted that about 60 percent of the Gibb cohort also suffered ulcerated nasal septum tissue. The mean estimated annual Cr(VI) air level at time of diagnosis was about 25 µg Cr(VI)/m^3. Ulcerated nasal septum was found to be highly correlated with the average annual Cr(VI) exposure of the workers as determined by a proportional hazards model. These findings, again, led Exponent to suggest that:

> It may be reasonable to surmise that the high rates of lung cancer risk observed among the featured cohorts (*i.e.* Gibb and Luippold) was at least partially related to respiratory irritation (Ex. 38–233–4, p. 19).

In its explanations, Exponent assumes that the irritation and damage to nasal septum tissue found in the exposed workers also occurs elsewhere in the respiratory tract. Exponent provided no evidence that Cr(VI) concentrations that damage tissue at the very front of the nose will also damage tissue in the bronchoalveolar regions where lung cancers are found. A national medical survey of U.S. chromate production workers conducted by the U.S. Public Health Service in the early 1950s found greater than half suffered nasal septum perforations (Ex. 7–3). However, there was little evidence of non-cancerous lung disease in the workers. The survey found only two percent of the chromate workers had chronic bronchitis which was only slightly higher than the prevalence in nonchromate workers at the same plants and less than had been reported for ferrous foundry workers. Just over one percent of the chromate production workers in the survey were found to have chest X-ray evidence consistent with pulmonary fibrosis. This led the U.S. Public Health Service to conclude ''on the basis of X-ray data we cannot confirm the presence of pneumoconiosis from chromate exposure'' (Ex. 7–3, p. 80). An earlier report noted fibrotic areas in the autopsied lungs of three Painesville chromate production workers employed during the 1940s who died of lung cancer (Ex. 7–12). The authors attributed the fibrotic lesions to the large amounts of chromite (a Cr(III) compound) ore found in the lungs.

Exponent correctly noted that prevalence of nasal septum ulceration in the Gibb cohort was ''significantly associated with [average annual] Cr(VI) exposure concentrations'' using a proportional hazards model (Ex. 38–233–4, p. 19). However, other related symptomatology, such as nasal irritation and perforation, was not found to be correlated with annual average Cr(VI) air levels. This led the authors to suggest that nasal septum tissue damage was more likely related to short-term, rather than annual, Cr(VI) air levels. Nasal septum ulceration was also not a significant predictor of lung cancer when the confounding effects of smoking and cumulative Cr(VI) exposure were accounted for in the proportional hazards model (Ex. 31–22–11). The authors believed the lack of correlation probably reflected cumulative Cr(VI) as the dominant exposure metric related to the elevated lung cancer risk in the workers, rather than the high, short-term Cr(VI) air levels thought to be responsible for the high rate of nasal septum damage. The modeling results are not consistent with nasal septum damage as a predictor of Cr(VI)-induced lung cancer in chromate production workers. Dr. Herman Gibb confirmed this in oral testimony:

> * * * I was curious to see if [respiratory] irritation might be predictive of lung cancer. We did univariate analyses and found that a number of them were [predictive]. But whenever you looked at, when you put it into the regression model, none of them were. In other words, [respiratory] irritation was not predictive of the lung cancer response (Tr. 144).

OSHA does not believe the evidence indicates that tissue damage in the nasal septum of chromate production workers exposed to Cr(VI) air levels around 20 µg/m^3 is responsible for the observed excess lung cancers. The lung cancers are found in the bronchioalveolar region, far removed from the nasal septum. Careful statistical analysis of the Gibb cohort did not find a significant relationship between clinical symptoms of nasal septum damage (*e.g.* ulceration, persistent bleeding, perforation) and lung cancer mortality. A 1951 U.S. Public Health Service medical survey found a high prevalence of nasal septum damage with few cases of chronic non-neoplastic lung disease (*e.g.* chronic bronchitis, pulmonary fibrosis). This suggests that the nasal septum damage caused by high Cr(VI) air concentrations was not mirrored by damage in lower regions of the respiratory tract where lung cancer takes place. Given these findings, it seems unlikely that the lower Cr(VI) air levels experienced by the Gibb cohort caused pervasive bronchioalveolar tissue damage that would be responsible for the clearly elevated lung cancer incidence in these workers. Therefore, the Agency does not concur with Exponent that there is credible evidence from occupational cohort studies that the high rates of lung cancer are related to tissue damage in the respiratory tract or that occupational exposure to 20 µg Cr(VI)/m^3 represents a 'no effect' level for lung cancer.

Some commenters felt that certain physiological defense mechanisms that protect against the Cr(VI)-induced carcinogenic process introduce a threshold or sublinear dose-response (Exs. 38–233–4; 38–215–2; 38–265). Some physiological defenses are thought to reduce the amount of biologically active chromium (*e.g.* intracellular Cr(V), Cr(III), and reactive oxygen species) able to interact with critical molecular targets within the lung cell. A prime example is the extracellular reduction of permeable Cr(VI) to the relatively impermeable Cr(III) which reduces Cr(VI) uptake into cells. Other defense mechanisms, such as DNA repair and apoptosis, can interfere with carcinogenic transformation and progression. These defense mechanisms are presented by commenters as highly effective at low levels of Cr(VI) but are overwhelmed at high dose exposures and, thus, could ''provide a biological basis for a sublinear dose-response or a threshold below which there is expected to be no increased lung cancer risk (Ex. 38–215–2, p. 29).

One study, cited in support of an exposure-response threshold, determined the amount of highly soluble Cr(VI) reduced to Cr(III) *in vitro* by human bronchioalveolar fluid and pulmonary macrophage fractions over a short period (Ex. 31–18–7). These specific activities were used to estimate an ''overall reducing capacity'' of the lung. As previously discussed, cell membranes are permeable to Cr(VI) but not Cr(III), so only Cr(VI) enters cells to any appreciable extent. The authors interpreted these data to mean that high levels of Cr(VI) would be required to ''overwhelm'' the reduction capacity before significant amounts of Cr(VI) could enter lung cells and damage DNA, thus creating a biological threshold to the exposure—response (Ex. 31–18–8).

There are several problems with this threshold interpretation. The in vitro reducing capacities were determined in the absence of cell uptake. Cr(VI) uptake into lung cells happens concurrently and in parallel with its extracellular reduction, so it cannot be concluded from the study data that a threshold reduction capacity must be exceeded before uptake occurs. The rate of Cr(VI) reduction to Cr(III) is critically dependant on the presence of adequate amounts of reductant, such as ascorbate or GSH (Ex. 35–65). It has not been established that sufficient amounts of these reductants are present throughout the thoracic and alveolar regions of the respiratory tract to create a biological threshold. Moreover, the in vitro activity of Cr(VI) reduction in epithelial lining fluid and alveolar macrophages was shown to be highly variable among individuals (Ex. 31–18–7, p. 533). It is possible that Cr(VI) is not rapidly reduced to Cr(III) in some workers or some areas of the lung. Finally, even if there was an exposure threshold created by extracellular reduction, the study data do not establish the dose range in which the putative threshold would occur.

Other commenters thought extracellular reduction and other physiological defenses were unlikely to produce a biological threshold (Exs. 44–5; 40–18–1). For example, Dr. Clewell remarked:

> Although studies attempted to estimate capacities of Cr(VI) (De Flora *et al.*, 1997) the extracellular reduction and cellular uptake of Cr(VI) are parallel and competing kinetic processes. That is, even at low concentrations where reductive capacity is undiminished, a fraction of Cr(VI) will still be taken up into cells, as determined by the relative rates of reduction and transport. For this reason, reductive capacities should not be construed to imply ''thresholds'' below which Cr(VI) will be completely reduced prior to uptake. Rather, they indicate that there is possibly a ''dose-dependent transition'', *i.e.* a nonlinearity in concentration dependence of the cellular exposure to Cr(VI). Evaluation of the concentration-dependence of the cellular uptake of Cr(VI) would require more data than is currently available on the relative kinetics of dissolution, extracellular reduction, and cellular uptake as well as on the homeostatic response to depletion of reductive resources (*e.g.* reduction of glutathione reductase) (Ex. 44–5, p. 16)

The same logic applies to other 'defense mechanisms' such as DNA repair and apoptosis. Despite the ability of cells to repair DNA damage or to undergo apoptosis (*i.e.* a form of programmed cell death) upon exposure to low levels of Cr(VI), these protections are not absolute. Since a single error in a critical gene may trigger neoplastic transformation and DNA damage increases with intracellular concentration of Cr(VI), it stands to reason that there may be some risk of cancer even at low Cr(VI) levels. If the protective pathways are saturable (*e.g.* protective capacity overwhelmed) then it might be manifested as a dose transition or nonlinearity. However, as explained above, an extensive amount of kinetic modeling data would be needed to credibly predict the dose level at which a potential dose transition occurs. OSHA agrees with Dr. Clewell that ''in the absence of such a biologically based [kinetic] dose-response model it is impossible to determine either the air concentration of Cr(VI) at which the nonlinearity might occur or the extent of the departure from a linear dose-response that would result. Therefore, the assumption of a linear dose-response is justified'' (Ex. 44–5, p.17–18).

In conclusion, OSHA believes that examination of the Gibb and Luippold cohorts, the new U.S. cohorts analyzed in Luippold *et al.* (2005), and the best available animal and mechanistic evidence does not support a departure from the traditional linear, cumulative exposure-based approach to cancer risk assessment for hexavalent chromium. OSHA's conclusion is supported by several commenters (see *e.g.* Tr. 121, 186, Exs. 40–10–2, p. 6; 44–7). For example, NIOSH stated:

> It is not appropriate to employ a threshold dose-response approach to estimate cancer risk from a genotoxic carcinogen such as Cr(VI) [Park *et al.* 2004]. The scientific evidence for a carcinogenicity threshold for Cr(VI) described in the Preamble [to the proposed rule] consists of the absence of an observed effect in epidemiology studies and animal studies at low exposures, and in vitro evidence of intracellular reduction. The epidemiologic and animal studies lack the statistical power to detect a low-dose threshold. In both the NIOSH and OSHA risk assessments, linear no-threshold risk models provided good fit to the observed cancer data. The in vitro extracellular reduction studies which suggested a theoretical basis for a non-linear reseponse to Cr(VI) exposure were conducted under non-physiologic conditions. These results do not demonstrate a threshold of response to Cr(VI) exposure (Ex. 40–10–2, p. 6).

OSHA's position is also supported by Dr. Herman Gibb's testimony at the hearing that a linear, no-threshold model best characterizes the relationship between Cr(VI) exposure and lung cancer risk in the Gibb cohort (Tr. 121). Statements from Ms. Deborah Proctor and Crump *et al.* (who conducted analyses utilizing the Luippold cohort) also indicated that these data are consistent with the traditional linear model (Tr. 1845, Exs. 33–10, p. 456; 35–58, pp. 1159–1160). The significant excess risk observed in the Gibb cohort, which was best suited to address risk from low cumulative or average exposures, contradicts comments to the effect that ''[i]ncreased lung cancers have been demonstrated only at workplace exposures significantly higher than the existing standard * * * '' (Ex. 38–185, p. 4) or that characterized OSHA's risk assessment for the proposed PEL as ''speculative'' (Ex. 47–35–1, p. 4) or ''seriously flawed'' (Ex. 38–106, p. 23). OSHA believes that the clear excess risk among workers with cumulative exposures equivalent to those accrued over a 45-year working lifetime of low-level exposure to Cr(VI), combined with the good fit of linear exposure-response models to the Gibb and Luippold (2003) datasets and the lack of demonstrable nonlinearities or dose-rate effects, constitute strong evidence of risk at low exposures in the range of interest to OSHA.

3. Influence of Smoking, Race, and the Healthy Worker Survivor Effect

A common confounder in estimating lung cancer risk to workers from exposure to a specific agent such as Cr(VI) is the impact of cigarette smoking. First, cigarette smoking is known to cause lung cancer. Ideally, lung cancer risk attributable to smoking among the Cr(VI)-exposed cohorts should be controlled or adjusted for in characterizing exposure-response. Secondly, cigarette smoking may interact with the agent (*i.e.*, Cr(VI)) or its biological target (*i.e.*, susceptible lung cells) in a manner that enhances or even reduces the risk of developing Cr(VI)-induced lung cancer from occupational exposures, yet is not accounted for in the risk model. The Small Business Administration's Office of Advocacy commented that such an interactive effect may have improperly increased OSHA's risk estimates (Ex. 38–7, p. 4).

OSHA believes its risk estimates have adequately accounted for the potential confounding effects of cigarette smoking in the underlying exposure-lung cancer response data, particularly for the Gibb cohort. One of the key issues in this regard is whether or not the reference population utilized to derive the expected number of lung cancers appropriately reflects the smoking behavior of the cohort members. The risk analyses of the Gibb cohort by NIOSH and Environ indicate that cigarette smoking was properly controlled for in the exposure-response modeling. NIOSH applied a smoking-specific correction factor that included a cumulative smoking term for individual cohort members (Ex. 33–13). Environ applied a generic correction factor and used lung cancer mortality rates from Baltimore City as a reference population that was most similar to the cohort members with respect to smoking behavior and other factors that might affect lung cancer rates (Ex. 33–12). Environ also used internally standardized models that did not require use of a reference population and included a smoking-specific (yes/no) variable. All these models predicted very similar estimates of risk over a wide range of Cr(VI) exposures. There was less information about smoking status for the Luippold cohort. However, regression modeling that controlled for smoking indicated that it was not a significant confounding factor when relating Cr(VI) exposure to the lung cancer mortality (Ex. 35–58).

Smoking has been shown to interact in a synergistic manner (*i.e.*, combined effect of two agents are greater than the sum of either agent alone) with some lung carcinogens, most notably asbestos (Ex. 35–114). NIOSH reported a slightly negative but nonsignficant interaction between cumulative Cr(VI) exposure and smoking in a model that had separate linear terms for both variables (Ex. 33–13). This means that, at any age, the smoking and Cr(VI) contributions to the lung cancer risk appeared to be additive, rather than synergistic, given the smoking information in the Gibb cohort along with the cumulative smoking assumptions of the analysis. In their final linear relative risk model, NIOSH included smoking as a multiplicative term in the background rate in order to estimate lifetime lung cancer risks attributable to Cr(VI) independent of smoking. Although this linear relative risk model makes no explicit assumptions with regard to an interaction between smoking and Cr(VI) exposure, the model does assume a multiplicative relationship between the background rate of lung cancer in the reference population and Cr(VI) exposure. Therefore, to the extent that smoking is a predominant influence on the background lung cancer risk, the linear relative risk model implicitly assumes a multiplicative (*e.g.*, greater than additive and synergistic, in most situations) relationship between cumulative Cr(VI) exposure and smoking. Since current lung cancer rates reflect a mixture of smokers and non-smokers, OSHA agrees with the Small Business Administration's Office of Advocacy that the excess lung cancer risks from Cr(VI) exposure predicted by the linear relative risk model may overestimate the risks to non-smokers to some unknown extent. By the same token, the model may underestimate the risk from Cr(VI) exposure to heavy smokers. Because there were so few non-smokers in the study cohorts (approximately 15 percent of the exposed workers and four lung cancer deaths in the Gibb cohort), it was not possible to reliably estimate risk for the nonsmoking subpopulation.

Although OSHA is not aware of any convincing evidence of a specific interaction between cigarette smoking and Cr(VI) exposure, prolonged cigarette smoking does have profound effects on lung structure and function that may indirectly influence lung cancer risk from Cr(VI) exposure (Ex. 33–14). Cigarette smoke is known to cause chronic irritation and inflammation of the respiratory tract. This leads to decreases in airway diameter that could result in an increase in Cr(VI) particulate deposition. It also leads to increased mucous volume and decreased mucous flow, that could result in reduced Cr(VI) particulate clearance. Increased deposition and reduced clearance would mean greater residence time of Cr(VI) particulates in the respiratory tract and a potentially greater probability of developing bronchogenic cancer. Chronic cigarette smoking also leads to lung remodeling and changes in the proliferative state of lung cells that could influence susceptibility to neoplastic transformation. While the above effects are plausible consequences of cigarette smoking on Cr(VI)-induced carcinogenesis, the likelihood and magnitude of their occurrence have not been firmly established and, thus, the impact on risk of lung cancer in exposed workers is uncertain.

Differences in lung cancer incidence with race may also introduce uncertainty in risk estimates. Gibb *et al.* reported differing patterns for the cumulative exposure-lung cancer mortality response between whites and non-whites in their cohort of chromate production workers (Ex. 31–22–11). In the assessment of risk from the Gibb cohort, NIOSH reported a strong interaction between cumulative Cr(VI) exposure and race, such that nonwhites had a higher cumulative exposure coefficient (*i.e.*, higher lung cancer risk) than whites based on a linear relative risk model (Ex. 33–13). If valid, this might explain the slightly lower risk estimates in the predominantly white Luippold cohort. However, Environ found that including race as an explanatory variable in the Cox proportional hazards model C1 did not significantly improve model fit (p=0.15) once cumulative Cr(VI) exposure and smoking status had been considered (Ex. 33–12).

NIOSH suggested that exposure or smoking misclassification might plausibly account for the Cr(VI) exposure-related differences in lung cancer by race seen in the Gibb cohort (Ex. 33–13, p. 15). It is possible that such misclassification might have occurred as a result of systematic differences between whites and non-whites with respect to job-specific Cr(VI) exposures at the Baltimore plant, unrecorded exposure to Cr(VI) or other lung carcinogens when not working at the plant, or in smoking behavior. Unknown differences in biological processes critical to Cr(VI)-induced carcinogenesis could also plausibly account for an exposure-race interaction. However, OSHA is not aware of evidence that convincingly supports any of these possible explanations.

Another source of uncertainty that may impact the risk estimates is the healthy worker survivor effect. Studies have consistently shown that workers with long-term employment status have lower mortality rates than short-term employed workers. This is possibly due to a higher proportion of ill individuals and those with a less healthy lifestyle in the short term group (Ex. 35–60). Similarly, worker populations tend to be healthier than the general population, which includes both employed and unemployed individuals. As a result, exposure-response analyses based on mortality of long-term healthy workers will tend to underestimate the risk to short-term workers and vice versa, even when their cumulative exposure is similar. Also, an increase in disease from occupational exposures in a working population may not be detected when workers are compared to a reference population that includes a greater proportion less healthy individuals.

The healthy worker survivor effect is generally thought to be less of a factor in diseases with a multifactorial causation and long onset, such as cancer, than in diseases with a single cause or short onset. However, there is evidence of a healthy worker effect in several studies of workers exposed to Cr(VI), as discussed further in the next section (''Suitability of Risk Estimates for Cr(VI) Exposures in Other Industries''). In these studies, the healthy worker survivor effect may mask increased lung cancer mortality due to occupational Cr(VI) exposure.

4. Suitability of Risk Estimates for Cr(VI) Exposures in Other Industries

At issue is whether the excess lung cancer risks derived from cohort studies of chromate production workers are representative of the risks for other Cr(VI)-exposed workers (*e.g.*, electroplaters, painters, welders). Typically, OSHA has used epidemiologic studies from one industry to estimate risk for other industries. For example, OSHA relied on a cohort of cadmium smelter workers to estimate the excess lung cancer risk in a wide range of affected industries for its cadmium standard (57 FR at 42102, 9/14/1992). This approach is usually acceptable because exposure to a common agent of concern is the primary determinant of risk and not some other factor unique to the workplace. However, in the case of Cr(VI), workers in different industries are exposed to various Cr(VI) compounds that may differ in carcinogenic potency depending to a large extent on water solubility. The chromate production workers in the Gibb and Luippold cohorts were primarily exposed to certain highly water-soluble chromates. As more fully described in section V.B. of the Cancer Effects section, the scientific evidence indicates that all Cr(VI) compounds are carcinogenic but that the slightly soluble chromates (*e.g.* calcium chromate, strontium chromate, and some zinc chromates) exhibit greater carcinogenicity than the highly water soluble chromates (*e.g.* sodium chromate, sodium dichromate, and chromic acid) or the water insoluble chromates (*e.g.* lead chromates) provided the same dose is delivered and deposited in the respiratory tract of the worker. It is not clear from the available scientific evidence whether the carcinogenic potency of water-insoluble Cr(VI) compounds would be expected to be more or less than highly water-soluble Cr(VI) compounds. Therefore, OSHA finds it prudent to regard both types of Cr(VI) compounds to be of similar carcinogenic potency.

The primary operation at the chromate production plants in Painesville (Luippold cohort) and Baltimore (Gibb cohort) was the production of the highly water-soluble sodium dichromate. Sodium dichromate served as a starting material for the production of other highly water-soluble chromates such as sodium chromate, potassium dichromate, and chromic acid (Exs. 7–14; 35–61). As a result, the Gibb and Luippold cohorts were principally exposed to water-soluble Cr(VI). In the NPRM, OSHA requested comment on whether its risk estimates based on the exposure-response data from these two cohorts of chromate production workers were reasonably representative of the risks expected from equivalent exposures to different Cr(VI) compounds encountered in other industry sectors. Of particular interest was whether the preliminary risk estimates from worker cohorts primarily engaged in the production of the highly water soluble sodium chromate and sodium dichromate would substantially overpredict lung cancer risk for workers with the same level and duration of exposure to Cr(VI) but involving different Cr(VI) compounds or different operations. These operations include chromic acid aerosol in electroplating operations, the less water soluble Cr(VI) particulates encountered during pigment production and painting operations, and Cr(VI) released during welding, as well as exposure in other applications.

OSHA received comments on this issue from representatives of a wide range of industries, including chromate producers, specialty steel manufacturers, construction and electric power companies that engage in stainless steel welding, the military and aerospace industry that use anti-corrosive primers containing Cr(VI), the surface finishing industry, color pigment manufacturers, and the Small Business Administration's Office of Advocacy (Exs. 38–231, 38–233; 38–8; 47–5; 40–12–4; 38–215; 40–12–5; 38–106; 39–43; 38–7). Many industry commenters expressed concerns about the appropriateness of the underlying Gibb and Luippold data sets and the methodology (*e.g.* linear instead of threshold model) used to generate the lung cancer risk estimates. These issues have been addressed in other parts of section VI. The color pigment manufacturers asserted that lead chromate pigments, unlike other Cr(VI) compounds, lacked carcinogenic potential. This issue was addressed in section V.B.9 of the Health Effects section. In summary, OSHA finds lead chromate and other water-insoluble Cr(VI) compounds to be carcinogenic. The Agency further concludes that it is reasonable to regard water insoluble Cr(VI) compounds to be of similar carcinogenic potency to highly soluble Cr(VI) compounds. Based on this conclusion, OSHA no longer believes that its risk projections will underestimate the lung cancer risk for workers exposed to equivalent levels of water-insoluble Cr(VI), as suggested in the NPRM (69 FR at 59384).

Several commenters encouraged OSHA to rely on cohort studies that examined the lung cancer mortality of workers in their particular industry in lieu of the chromate production cohorts. Members of the aircraft industry and their representatives commented that OSHA failed to consider the results from several large cohort studies that showed aerospace workers were not at increased risk of lung cancer (Exs. 38–106; 38–215–2; 44–33; 47–29–2). In addition, Boeing Corporation and the Aeropspace Industries Association (AIA) provided data on the size distribution of Cr(VI) aerosols generated during primer spraying operations which showed most particles to be too large for deposition in the region of the respiratory tract where lung cancer typically occurs (Exs. 38–106–2; 38–215–2; 47–29–2). The Specialty Steel Industry maintained that epidemiological data specific to alloy manufacturing and experience within the their industry show that the lung cancer risk estimated by OSHA is unreasonably high for steel workers exposed to the proposed PEL of 1 µg Cr(VI)/m^3 (Ex. 38–233, p. 82). Several comments argued that there was a lack of scientific evidence for a quantifiable exposure-response relationship between Cr(VI) exposure from stainless steel welding (Exs. 38–8; 38–233–4). The commenters went on to suggest that the OSHA quantitative Cr(VI) exposure-lung cancer response model derived from the chromate production cohorts should not be used to characterize the risk to welders. The suitability of the OSHA risk estimates for these particular industries is further discussed below.

a. *Aerospace Manufacture and Maintenance.* Most of the comments on suitability of OSHA risk estimates were provided by AIA (Exs. 38–215; 47–29–2), Exponent on behalf of AIA (Exs. 38–215–2; 44–33), and the Boeing Corporation (Exs. 38–106; 38–106–1). Cr(VI) is used as an anti-corrosive in primers and other coatings applied to the aluminum alloy structural surfaces of aircraft. The principal exposures to Cr(VI) occur during application of Cr(VI) primers and coatings and mechanical sanding of the painted surfaces during aircraft maintenance. Cr(VI) exposures are usually in the form of the slightly soluble strontium and zinc chromates used in primers and chromic acid found in other treatments and coatings designed to protect metal surfaces.

Cohort Studies of Aerospace Workers. AIA commented that:

> OSHA has all but ignored a substantial body of evidence of studies showing no increased risk of lung cancer in aerospace workers * * *. While epidemiologic studies show a link between lung cancer and chromium VI exposure in other industries [*e.g.* chromate production], that relationship is not established in the aerospace industry (Ex.38–106, p. 16).

Aerospace commenters pointed to several cohort studies from aircraft manufacturing and maintenance sites that did not find significantly elevated lung cancer mortality in workers (Exs. 31–16–3; 31–16–4; 35–213; 35–210). However, OSHA believes that the vast majority of workers in these cohorts were not routinely engaged in jobs involving potential Cr(VI) exposures.

Only two of the above studies (*i.e.,* the Alexander and Boice cohorts) specifically investigated the relationship between Cr(VI) exposures and lung cancer mortality (Exs. 31–16–3; 31–16–4). The Alexander cohort was evaluated as a supplemental data set for quantitative risk assessment in sections VI.B.6 and VI.E.4. Briefly, there were 15 observed lung cancer cases in the Alexander *et al.* study with 19.5 expected (Ex. 31–16–3). There was no evidence of a positive trend between cumulative Cr(VI) exposure and lung cancer incidence. The lack of excess lung cancers was probably, in large part, due to the short follow-up period (median nine years per member) and young age of the cohort (median 42 years at the end of follow-up). Lung cancer generally occurs 20 or more years after initial exposure to a carcinogenic agent and mostly in persons aged 55 years and older. There was no Cr(VI) air monitoring data for a significant portion of the study period and reconstruction of worker exposure was reduced to a limited number of 'summary time-weighted average exposure levels' based on job category (Ex. 31–16–3). These limitations may have caused inaccuracies in the worker exposure estimates that could lead to potential misclassification of exposure, and, thus may also have contributed to the lack of a positive Cr(VI) exposure—lung cancer response.

In the their technical comments on behalf of the AIA, Exponent considered the Boice cohort to be ''the largest, best defined, most completely ascertained, and followed for the longest duration'' of the epidemiological studies examining lung cancer mortality and other health outcomes of aerospace workers (Ex. 38–215–2, p. 10). The Boice cohort (previously described in section V.B.6) consisted of 77,965 aerospace workers employed over a thirty-year period at a large aircraft manufacturing plant in California (Ex. 31–16–4). The average duration of employment was over ten years and thirty percent of the cohort was deceased. Therefore, the Boice cohort was larger, older, and had greater follow-up than the Alexander cohort. Unfortunately, Cr(VI) air measurements were sparse in recent years and entirely absent during early years of plant operation so, unlike the Alexander cohort, quantitative Cr(VI) exposure reconstruction was not attempted. Instead, all jobs were qualitatively categorized by the chemicals involved (*e.g.,* chromates, trichloroethylene, perchloroethylene, etc.) and their frequency of chemical usage (routine, intermittent, or no exposure). Duration of potential chemical exposure, including Cr(VI), was determined for the cohort members based on work history (Ex. 47–19–15). There were 3634 workers in the cohort believed to have routine exposures to Cr(VI), mostly in painting/primer operations or operating process equipment used for plating and corrosion protection. Another 3809 workers were thought to have potential 'intermittent exposure' to chromates. Most workers with potential exposure to Cr(VI) also had potential exposures to the chlorinated solvents tricholoroethylene (TCE) and perchloroethylene (PCE). Because of an inadequate amount of Cr(VI) exposure data, OSHA was unable to use the Boice study for quantitative risk assessment.

The Boice *et al.* study did not find excess lung cancer among the 45,323 aircraft factory workers when compared against the race-, age-, calendar year-, and gender-adjusted rates for the general population of the State of California (SMR=97). This is not a surprising result considering more than 90 percent did not work in jobs that routinely involve Cr(VI) exposure. Factory workers potentially exposed to Cr(VI) also did not have significantly elevated lung cancer mortality (SMR=102; 95% CI: 82–126) relative to the California general population based on 87 observed lung cancer deaths. However, workers engaged in spray painting/priming operations that likely had the highest potential for Cr(VI) exposure did experience some excess lung cancer mortality (SMR=111; 95% CI: 80–151) based on 41 deaths, but the increase was not statistically significant.

As commonly encountered in factory work, there was evidence of a 'healthy worker effect' in this aerospace cohort that became increasingly pronounced in workers with long-term employment. The healthy worker effect (HWE) refers to the lower rate of disease relative to the general population sometimes observed in long-term occupational cohorts. For example, the Boice cohort factory workers employed for 20 years had statistically significant lower rates of death than a standardized California reference population for all causes (SMR=78; 95% CI: 75–81), lung cancer (SMR=70; 95% CI: 61–80), heart disease (SMR=79; 95% CI: 74–83), cerebrovascular disease (SMR=67; 95% CI: 56–78), non-malignant respiratory disease (SMR=65; 95% CI: 57–74), and cirrhosis of the liver (SMR=67; 95% CI: 51–88) among other specific causes (Ex. 31–16–4, Table 5). The study authors note that ''these reductions [in disease mortality] seem in part due to the initial selection into the workforce and the continued employment of healthy people [*i.e.* healthy worker effect] that is often found in occupational studies'' (Ex. 31–16–4, p. 592). If not properly accounted for in mortality analysis, HWE can mask evidence of disease risk. Mr. Robert Park, senior epidemiologist from NIOSH, confirmed this at the public hearing when addressing implications of HWE for Cr(VI) lung cancer risk in the Boice cohort.

> This [Boice cohort] is a population where you would expect to see a very dramatic healthy worker effect * * * so just off the top, I would say any [relative risk] estimates for lung cancer in the Boice population based on SMRs, I would want to adjust upwards by 0.9, for example, if the real SMR ought to be around 0.9 due to the healthy worker effect. So if you do that in their population, they have classified some workers as [routinely] exposed to chromates, about 8 percent of the population. They observe a SMR of 1.02 in that group. If you look at some of the other groupings in that study, for example, assembly has an SMR of 0.92, fabrication, which is basically make all the parts, 0.92, maintenance, 0.79. So a lot of evidence for healthy worker effect in general in that population. So the chromate group actually is at least 10 or 12 percent higher in their lung cancer SMR. Now again, the numbers are small, you'd have to have a very huge study for an SMR of 1.1 or 1.15 to be statistically significant. So it is not. But it is a hint (Tr. 345–347).

OSHA agrees with Mr. Park that the relative risks for lung cancer in the Boice cohort are likely understated due to HWE. This is also illustrated in the study analysis of the lung cancer morality patterns by exposure duration to specific chemicals using internal cohort comparisons. The internal analysis presumably minimize any biases (*e.g.* smoking, HWE) that might exist from comparisons to the general population. The results for workers potentially exposed to Cr(VI), trichloroethylene (TCE), and perchloroethylene (PCE) are presented in Table VI–9.

Table VI-9

Relative Risk (RR) of Lung Cancer in Boice Cohort with Duration of Exposure to Selected Chemicals

Years Exposed	Chromate		Trichloro-ethylene		Perchoro-ethylene	
	RR	95% CI	RR	95% CI	RR	95% CI
0	1.00	p>0.2	1.00	P<0.01	1.00	P=0.02
<1	0.90	0.69-1.16	0.85	0.65-1.13	1.15	0.80-1.66
1-4	1.02	0.78-1.33	0.98	0.74-1.30	1.09	0.80-1.48
≥5	1.08	0.75-1.57	0.64	0.46-0.89	0.71	0.49-1.02

As shown in the table, there was a statistically significant decline in relative risk of lung cancer among factory workers with duration of TCE exposure (p<0.01) and PCE exposure (p=0.02). This mirrors the decline with increasing employment duration seen in comparison with the general California population and strongly suggests the internal cohort analysis failed to adequately adjust for HWE.

The table shows that, despite the downward influence of HWE on lung cancer risk, there was a slight nonsignificant upward trend in excess lung cancer mortality with duration of exposure to Cr(VI). The result is that aircraft workers potentially exposed to chromate for five or more years had 50 to 70 percent greater lung cancer mortality than coworkers with a similar duration of potential exposure to the chlorinated solvents. The relative excess is even more noteworthy given that the subgroups had considerable overlap (*e.g.*, many of the same workers in the PCE and TCE groups were also in the chromate group). This implies that a subset of Cr(VI) workers not exposed to chlorinated solvents, possibly spray painters routinely applying Cr(VI) primers over many years, may be at greater lung cancer risk than other Cr(VI)-exposed members of the cohort.

The AIA and its technical representative, Exponent, objected to OSHA reliance on the non-statistically significant upward trend in excess lung cancers with increasing Cr(VI) exposure duration described above (Exs. 38–215–2; 47–29–2). Exponent stated:

> Statistical tests for trend indicated there is no evidence for a trend of increasing risk of lung cancer with increasing years exposed to chromate (P<0.20). OSHA seems to have 'eye-balled' the estimates and felt confident accepting the slight and non-significant increases among risk estimates with overlapping confidence intervals as evidence of a "slightly positive" trend. However, OSHA's interpretation is an overstatement of the finding and should be corrected in the final rule (Ex. 38–215–2, p. 13).

OSHA does not agree with these comments and believes it has objectively interpreted the trend data in a scientifically legitimate fashion. The fact that an upward trend in lung cancer risk with Cr(VI) exposure duration fails to meet a statistical confidence of 95 percent does not mean the relationship does not exist. For example, a trend with a p-value of 0.2 means random chance will not explain the relationship 80 percent of the time. The positive trend is all the more notable given that it occurs in spite of a significant downward trend in lung cancer mortality with years of employment. In other words, aerospace workers exposed to Cr(VI) experienced a slightly greater lung cancer mortality with increasing number of years exposed even while their co-workers exposed to other chemicals were experiencing a substantially lower lung cancer mortality with increasing years exposed.

In its post-hearing comments, NIOSH calculated the observed excess lung cancer risk to the Boice spray painters expected to have the highest Cr(VI) exposures (SMR=1.11) to be 21 percent higher than the minimally Cr(VI)-exposed assembly workers (SMR=0.92). NIOSH assumed the painters were exposed to 15 µg CrO_3/m^3 (*i.e.,* the arithmetic mean of Cr(VI) air sampling data in the plant between 1978 to 1991) for 10 years (*i.e.,* the approximate average duration of employment) to derive an excess risk per mg CrO_3/m^3 of 1.4 (Ex. 47–19–1). NIOSH noted that this was very close to the excess risk per mg CrO_3/m^3 of 1.44 determined from their risk modeling of the Gibb cohort (Ex. 33–13). In a related calculation, OSHA derived the expected excess risk ratio from its linear relative risk model using a dose coefficient consistent with the Gibb and Luippold data sets. Assuming the Boice spray painters were exposed to 10 µg Cr(VI)/m^3 (90th percentile of plant air sampling data converted from µg CrO^3 to µg Cr(VI)) for 12 years (average employment duration of Boice factory workers), the model predicts a risk ratio 1.20 which is also very close to the observed excess risk ratio of 1.21 calculated from the observed SMR data for spray painters above. These calculations suggest that the excess lung cancer mortality observed in the Boice subcohort of Cr(VI)-exposed aerospace workers is consistent with excess risks predicted from models based on the Gibb and Luippold cohort of chromate production workers.

The other cohort studies of aerospace workers cited by AIA were not informative with regard to the association between Cr(VI) and lung cancer. A cohort study by Garabrandt *et al.* of 14,067 persons employed by an aircraft manufacturing company found significantly reduced excess lung cancer mortality (SMR=80; 95% CI: 68–95) compared to adjusted rates in the U.S. and San Diego County populations (Ex. 35–210). The mean duration of follow-up was only 16 years and the study authors are careful to state that the study can not rule out excess risk for diseases, such as lung cancer, that have long latencies of 20 years or more. The consistently low all-cause and cancer mortalities reported in the study strongly suggest the presence of a healthy worker effect. Another cohort study by Blair *et al.* of 14,457 aircraft maintenance workers at Hill Air Force base in Utah did not find elevated lung cancer mortality (SMR=90; 95% CI: 60–130) when compared to the general population of Utah (Ex. 35–213). However, the study was exclusively designed to investigate cancer incidence of chlorinated solvents (*e.g.* TCE, PCE, methylene chloride) and makes no mention of Cr(VI). This was also the case for a cohort study by Morgan *et al.* of 20,508 aerospace workers employed at a Hughes Aircraft manufacturing plant, which found no excess lung cancer mortality (SMR=0.96; 95% CI: 87–106) compared to the general U.S. population. However, a detailed investigation of jobs at a large aircraft manufacturing facility (*i.e.* facility studied by Boice *et al.*) found that only about 8 percent of employees had potential for routine Cr(VI) exposure (Ex. 47–19–15). If this is representative of the workforce in the other studies cited above, it is doubtful whether a Cr(VI)-related increase in lung cancer from a small proportion of workers would be reflected in the mortality experience of the entire cohort, most of whom would not have been exposed to Cr(VI).

In summary, OSHA does not find convincing evidence from the aerospace cohort studies that the Agency's quantitative risk assessment overstates the lung cancer risk to Cr(VI)-exposed workers. An association between Cr(VI) exposure and lung cancer was never addressed in most cohorts relied upon by the aerospace industry. Job analysis shows that only a minor proportion of all aerospace workers are engaged in workplace activities that routinely lead to Cr(VI) exposure. This could explain the lack of excess lung cancer mortality found in studies characterizing the mortality experience of all aerospace workers. Alexander *et al.* identified a cohort of Cr(VI) exposed workers, made individual worker estimates of cumulative Cr(VI) exposures, and found no exposure-related trend with lung cancer incidence. However, the absence of exposure-response could be the result of a number of study limitations including the young age of the cohort (*e.g.* majority of workers were under 50 years of age, when lung cancer incidence is relatively uncommon), the inadequate follow-up period (*e.g.* majority of workers followed < 10 years), and the potential for exposure misclassification (*e.g.* Cr(VI) exposure levels prior to 1975 were not monitored). Boice *et al.* also identified a subcohort of aerospace workers with potential Cr(VI) exposure but lacked adequate air sampling to investigate a quantitative relationship between Cr(VI) exposure and lung cancer response. There was a significant decline in relative lung cancer risk with length of employment among factory workers as well as those exposed to chlorinated solvents, indicating a strong healthy worker survivor effect among this pool of workers. The healthy worker effect may have masked a significant trend in lung cancer with Cr(VI) exposure duration. Risk projections based on the OSHA linear model were found to be statistically consistent with the relative risk ratios observed in the Boice cohort.

Cr(VI) Particle Size Distribution During Aerospace Operations. Differences in the size of Cr(VI) aerosols generated during chromate production and aerospace operations is another reason representatives of the aircraft industry believe the OSHA risk estimates overstate risk to aerospace workers (Exs. 38–106; 38–106–1; 38–215–2; 39–43; 44–33; 47–29–2). The submitted particle size data indicated that spraying Cr(VI) primers mostly generates large aerosol droplets (*e.g.* > 10 µm) not expected to penetrate beyond the very upper portions of the respiratory tract (*e.g.* nasal passages, larynx). Some aerospace commenters also cited research showing that the few respirable primer particulates that reach the lower regions of the lung contain less Cr(VI) per particle mass than the larger non-respirable particles (Exs. 44–33; 38–106; 39–43). As a result, aerospace commenters contend that a very small proportion of Cr(VI) aerosols generated by aircraft primer operations deposit in the bronchioalveolar regions of the lung where lung cancer occurs. OSHA agrees that the particle size studies submitted to the record sufficiently demonstrate that a relatively small proportion of Cr(VI) reaches the critical regions of the lung as a result of these aircraft spraying operations. However, the Agency believes the reduction in lung cancer risk from this lower Cr(VI) particle burden is likely offset by the greater carcinogenic activity of the slightly soluble strontium and zinc chromates inhaled during spray primer application. Evaluation of the study data provided to the record and the rationale behind the OSHA position are described below.

The Agency reviewed the information provided by Boeing on the particle size of paint aerosols from typical spraying equipment used in aerospace applications. Boeing provided size characterization of paint aerosol from their in-house testing of spray paint equipment (Ex. 38–106–1, p. 8–11). They measured droplet size distributions of non-chromated polyurethane enamels generated by high volume low pressure (HVLP) and electrostatic air spray guns under typical settings. The particle size was measured 10 to 12 inches from the nozzle of the gun using laser diffraction techniques. Boeing found the median volumetric droplet diameter (Dv50) of the paint particles to be in the range of 17 to 32 µm under the test conditions. Less than 0.5 percent of droplets in the spray were 5 µm and smaller (*e.g.* typical of particles that deposit in the bronchioalveolar region). Boeing concluded:

> In typical operations and products, the best aerosol size is a distribution with mass median diameter of about 30–40 microns, and a relatively monodisperse distribution. As a result, the fraction of the spray that is <5 micron is about 1% or less; in overspray perhaps ≈2%. Therefore the deposited dose would be far less than from exposure to an equal concentration of a smaller aerosol size, and estimates of risk based on studies of other industry sectors are not relevant to evaluation of risk in aerospace paint spraying (Ex. 38–106–1, p. 16).

Although Boeing used a non-chromated enamel paint in their studies, they contend that the results would be representative of the particle size distribution for a Cr(VI) primer using the same equipment under similar conditions.

Boeing also submitted recent publications by the UCLA Center for Occupational and Environmental Health measuring the Cr(VI) particle size distribution during spray painting operations at an aerospace manufacturing facility (Ex. 38–106–1). The UCLA group investigated particle size distributions of Cr(VI) primers sprayed from HVLP equipment in a lab bench-scale spray booth and in a field study of spray booths at an aerospace facility (Ex. 38–106–1, attachment 6). The tested primers contained the slightly soluble strontium chromate. The study data are presented in two papers by Sabty-Daily *et al.* The aerosol particles were collected at different locations several meters from the spray gun in the bench-scale paint booth using a cascade impactor. Full shift personal breathing zone samples from workers spraying primer were also collected with a cascade impactor in the field studies. The mass median aerodynamic diameter (MMAD) for Cr(VI) particles in the field study was reported to be 8.5 µm with a geometric standard deviation of 2.2 µm. On average, 62 percent of the Cr(VI) mass was associated with non-respirable particles >10 µm. Taking into account deposition efficiency, it was estimated that less than five percent of the Cr(VI) would potentially deposit in the lower regions of the respiratory tract where lung cancer occurs. The bench scale study gave particle distributions similar to the field studies. It was shown that particle size decreases slightly as gun atomization pressure increases. Particles in the direct spray were generally larger than the overspray. Particle size was shown to decrease with distance to the target surface due to evaporation of solvent.

Both Sabty-Daily articles and the Boeing submission made reference to another study that measured particle size distribution of a HVLP-generated paint aerosol in the breathing zone of the worker (Ex. 48–3). Paint droplets were collected on polycarbonate filters with 0.2 µm pore size. Aerosol size was measured using a microscopic method that minimizes bias from solvent evaporation. The breathing zone MMAD in the overspray was reported to be 15 to 19 µm with a GSD of 1.7 µm. In another study, LaPuma *et al.* investigated the Cr(VI) content of primer particles from an HVLP spray gun using a cascade impactor (Ex. 31–2–2). They reported that smaller particles (*i.e.* <7 µm) contained disproportionately less Cr(VI) per mass of dry paint than larger particles.

Boeing concluded that ''the particle size distribution reported by Sabty-Daily *et al.* (2004a) significantly underestimate the size distribution of paint aerosol'' (Ex. 38–106–1, p. 14). They state that ''in typical [spraying] operations and products the best aerosol size is a distribution with mass median diameter of about 30–45 microns'' (Ex. 38–106–1, p. 16). This particle size is larger than 15 to 20 µm reported in independent breathing zone measurements of spray paint aerosol collected on conventional sampling media (*i.e.* polycarbonate filters) (Carlton and Flynn, 1997).

The Boeing rationale for dismissing the UCLA data was that the cascade impactor had low collection efficiency for larger particles relative to the Boeing laser diffraction method, which Boeing believes is more accurate over the entire size distribution. OSHA notes, however, that Boeing did not characterize aerosol particles in the breathing zone of workers spraying Cr(VI) primer. Their study characterized droplet size from an non-chromated enamel spray directly out of the spray gun prior to contact with the target surface. While collection efficiency accounts for some of the particle size difference, other factors may also have contributed. These factors include the composition of the spray paint, the sampling location, and the degree of solvent evaporation. OSHA considers Cr(VI) primer droplets with an average MMAD of 7 to 20 µm, as measured in breathing zone studies, to best represent the particle size inhaled by a worker during spraying operations, since this range was measured in breathing zone studies. The majority of these droplet particles would not be expected to penetrate regions of the respiratory tract where lung cancers occur.

While aerosol particle size during spray application of Cr(VI) primers has been measured, AIA acknowledged that the particle size distribution during sanding procedures has not been well studied (Exs. 38–106; 47–29–2). However, they believe that most of the particles released as a result of sanding and grinding operations to remove old paint coatings from aircraft are non-respirable (*e.g.* >10 µm). OSHA is not aware of reliable data in the record to support or refute this claim.

The Cr(VI) particle size data from spray primer and sanding applications in aerospace need to be evaluated against Cr(VI) particle size during chromate production to determine its impact on OSHA risk estimates. Boeing observed that the high temperature calcination process that oxidizes chromite ore to sodium chromate would likely lead to a high proportion of respirable fume (Ex. 38–106). During post-hearing comments, AIA provided a figure from the 1953 U.S. Public Health Service survey report that indicated the geometric mean airborne dust particle size in a chromate production plant was 0.3 to 0.4 m in size (Ex. 47–29–2, p. 3). The data came from a thermal precipitator analysis of one-hour dust samples collected from the roasting and leaching areas of the plant (Ex. 7–3). An independent 1950 industrial hygiene survey report of the Painesville plant from the Ohio Department of Health indicates the median size of the in-plant dust was 1.7 microns and the median size of the mist generated during the leaching operations was 3.8 microns (Ex. 7–98). The measurement method used to determine this particle size was not clear from the survey report.

The thermal precipitator used by the U.S. Public Health Service survey is an older sampling device specifically used to characterize particles smaller than 5 µm. The thermal precipitator collection efficiency for particles >5 µm was considered suspect due to gravitational and inertial effects caused by the very low air flow rates (*e.g.* 6 ml/min) necessary to operate the device. The survey figure shows that 95 percent of collected particles were smaller than 1 µm. However, this is probably an inflated percentage given that the thermal precipitator is unable to effectively collect particles outside the fine and ultrafine range (*e.g.* greater than about 5 µm).

In their post-hearing brief, AIA introduced an Exponent microscopic analysis of particles claimed to be landfilled 'roast residue' generated as airborne dust from the Painesville plant 'decades' earlier (Ex. 47–29–2). AIA stated that ''the particle diameters ranged from 0.11 to 9.64 µm and that 82 percent of the particles were less than 2.5 µm (Ex. 47–29–2, p. 3). OSHA was unable to verify the nature of the landfill dust or determine its relevance from the information provided by AIA.

In the same submission, AIA referenced several experimental and animal studies as evidence that small particles less than 2.5 µm in diameter cause greater lung toxicity than larger particles (Ex. 47–29–2). AIA concluded that:

> It is important for OSHA to recognize in the quantitative risk assessment that the particles to which the featured chromate production workers were exposed were fine [particle diameters 0.1–2.5 µm] and ultrafine particles [particle diameters <0.1 µm] and that particles of this size range are known to be associated with greater toxicity than larger particles. Thus, the quantitative cancer risk estimates based on these studies are very conservative and likely overestimate risks for Cr(VI) exposures in other industries, most notably aerospace (Ex. 47–29–2, p. 7).

The above studies showed that fine/ultrafine particles penetrate into the alveolar region of the lung, are slowly cleared from respiratory tract, and can lead to pulmonary inflammation and non-neoplastic respiratory disease. OSHA agrees that fine/ultrafine particles can disrupt pulmonary clearance and cause chronic inflammation if sufficient amounts are inhaled. However, AIA did not provide data that demonstrated the Gibb and Luippold workers were routinely exposed to levels of small particles that would trigger serious lung toxicity.

AIA also referred to a human epidemiological study that reported the excess risk of lung cancer mortality from airborne fine/ultrafine particles (*i.e.* 8 percent increase per 10 µg/m^{3} in particles) to be similar to the excess risk of cardiopulmonary disease (*i.e.* 6 percent increase with each 10 µg/m^{3} in particles). AIA suggested these results were evidence that the excess lung cancer mortality attributed to Cr(VI) in chromate production cohorts were, in large part, due to fine/ultrafine particles. However, the Luippold cohort had an excess mortality from lung cancer (SMR=239) that was 10.6-fold higher than the excess mortality of heart disease (SMR=113) (Ex. 33–10). The Gibb cohort had an excess mortality from lung cancer that was 5.7-fold higher than the excess mortality of arteriosclerotic heart disease (SMR=114) (Ex. 33–11). These mortality patterns are not consistent with the small particle study results above and strongly indicate fine/ultrafine particles are not the primary cause of excess lung cancer among the chromate production workers in the Luippold and Gibb cohorts. Given the information provided, OSHA does not have reason to expect that exposure to fine/ultrafine particles in the Luippold and Gibb cohorts had a substantial quantitative impact on its estimates of lung cancer risk from exposure to Cr(VI).

Based on the evidence presented, OSHA believes the production of sodium chromate and dichromate likely generated a greater proportion of respirable Cr(VI) particles than the aerospace spray priming operations. The roasting operation that oxidizes trivalent chromite ore and soda ash to hexavalent sodium chromate salts would be expected to generate a small particle fume based on information from other high temperature calcination processes (*e.g.* beryllium oxide production). This is supported by a small amount of particle size information from the 1940s and 1950s (Ex. 7–98). However, there are insufficient data to reliably determine the median diameter of Cr(VI) particles or otherwise characterize the particle size distribution generated during sodium chromate production in the breathing zone of the worker. It should also be recognized that significant Cr(VI) exposures occurred during other chromate production operations, such as leaching sodium chromate from the roast, separating sodium dichromate crystals, and drying/bagging the final purified sodium dichromate product. There is no information on particle size for these operations, but it is reasonable to expect greater proportions of larger particles than generated during the roasting process. For these reasons, there is some degree of uncertainty with regard to size distribution of Cr(VI) aerosols inhaled by chromate production workers.

OSHA agrees with the aerospace industry that the reduced proportion of respirable particles from spray primer operations relative to chromate production will tend to lower the lung cancer risk from equivalent Cr(VI) exposures. This is because less Cr(VI) will reach the bronchioalveolar regions of the respiratory tract where lung cancer occurs. However, the chemical form of Cr(VI) must also be considered. Spray primer and painting operations expose workers to the slightly soluble strontium and zinc chromates while chromate production workers are exposed primarily to highly soluble sodium chromate/dichromate.

As explained earlier in section V.B.9 on carcinogenic effects, animal and mechanistic evidence suggest that the slightly soluble strontium and zinc chromates are more carcinogenic than the highly soluble Cr(VI) compounds when equivalent doses are delivered to critical regions of the respiratory tract. Slightly soluble Cr(VI) compounds produced a higher incidence of bronchogenic tumors than highly soluble Cr(VI) compounds (*e.g.* sodium dichromate, chromic acid) when instilled in the respiratory tract of rats at similar dosing and other experimental conditions (Ex. 11–2; 11–7). For example, intrabronchial instillation of strontium chromate produced a 40 to 60-fold greater tumor incidence than instillation of sodium dichromate in one study (Ex. 11–2). Unlike the highly soluble Cr(VI) compounds, the less water soluble Cr(VI) compounds are better able to provide a persistent source of high Cr(VI) concentration within the immediate microenvironment of the lung epithelia facilitating cellular uptake of chromate ion into target cells. The greater carcinogenicity of the slightly soluble Cr(VI) compounds have led to ACGIH TLVs that are from 5-fold (*i.e.* zinc chromates) to 100-fold (*i.e.* strontium chromates) lower than the TLV for highly water soluble Cr(VI) compounds.

For these reasons, the risk reductions achieved from the lower Cr(VI) particle burden that reaches the bronchioalveolar region of the lung may, to a large extent, be offset by the greater carcinogenic activity of the Cr(VI) compounds that are inhaled during aircraft spray painting operations. Since significant lung cancer risk exists at Cr(VI) air levels well below the new PEL (*e.g.* 0.5–2.5 μg/m³) based on chromate production cohorts, the risk would also likely be significant even if the lung cancer risk from similar Cr(VI) exposures in aerospace operations is slightly lower. Therefore, OSHA believes that the risk models based on the Gibb and Luippold data sets will provide reasonable estimates of lung cancer risk for aerospace workers exposed to equivalent levels of Cr(VI). However, based on the lower lung burden expected after considering the particle size distribution evidence submitted to the record, OSHA no longer believes that its risk projections will underestimate lung cancer risk for aerospace workers exposed to strontium or zinc chromates, as suggested in the NPRM (69 FR at 59384).

b. Specialty Steel Industry and Stainless Steel Welding.

Collier Shannon Scott submitted comments to OSHA on behalf of a group of steel and superalloy industry trade associations and companies including the Specialty Steel Industry of North America (SSINA), the Steel Manufacturers Association (SMA), and the American Iron and Steel Institute (AISI) as well as various individual companies. They requested that OSHA ‘‘seriously consider’’ the results of the Arena *et al.* (1998) study of workers employed in the high nickel alloys industry (Tr. 661), as well as studies by Huvinen *et al.* (1996, 2002) and Moulin *et al.* (1990) on stainless steel production workers (Exs. 38–233, p. 85; 47–5, p. 10) and by Danielsen *et al.* (1996) on Norweigen stainless steel welders (Ex. 47–5, p. 10). On behalf of the SSINA, Ms. Joan Fessler testified that the Arena *et al.* study (Ex. 38–233–2), also referred to as the ‘‘Redmond Study’’, found no relationship between Cr(VI) exposure and lung cancer, and in general ‘‘ * * * no strong epidemiological evidence causally associating occupational exposures with excess risk’’ (Tr. 662). Ms. Fessler concluded that the study results ‘‘ * * * stand in stark contrast to the extrapolated estimates of cancer risk OSHA has developed from the chromate worker cohorts to develop the proposed rule’’ (Tr. 662) and ‘‘[show] that there is no significant excess risk of lung cancer for workers in the steel industry’’ (Ex. 40–12–4, p. 2). She cited studies conducted by Huvinen *et al.* as additional evidence that workers in the stainless steel production industry do not have excess risk of lung cancer from Cr(VI) exposure (Tr. 663).

OSHA reviewed the Arena *et al.* (1998) study, which examined mortality in a cohort of 31,165 workers employed at 13 U.S. high nickel alloy plants for at least one year between 1956 and 1967 (Ex. 38–233–2, p. 908). The focus of the study is nickel exposure; it does not report how many of the cohort members were exposed to Cr(VI) or the levels of Cr(VI) exposure to which they may have been exposed. Therefore there does not appear to be any basis for SSINA’s conclusion that ‘‘[t]here was no strong epidemiological evidence causally associating occupational exposures with excess risk’’ in the study and that ‘‘[n]o dose response relationship was demonstrated * * * ’’ (Tr. 662). Ms. Fessler stated, in response to a question by Dr. Lurie of Public Citizen, that there is no information in the study on Cr(VI) exposures with which to assess a dose-response relationship between occupational exposure to Cr(VI) and excess lung cancer risk in the cohort (Tr. 685). Without any information on the proportion of workers that were exposed to Cr(VI) or the levels to which they were exposed, one cannot determine that there is no carcinogenic effect of Cr(VI) exposure, or that the results of the Arena study contradict OSHA’s risk estimates.

To more meaningfully compare the lung cancer risk predicted by OSHA’s risk model and that observed in the

Arena *et al.* study, OSHA estimated Cr(VI) exposures for the cohort members based in part on exposures in the stainless steel industry. High-nickel alloys that contain chromium are roughly comparable to stainless steel in terms of chromium content and the temperatures at which they are melted. This in turn determines the amount of trivalent chromium that converts to hexavalent chromium in the heating process. For example, cast stainless steels with high nickel composition (*e.g.* Cast 18–38, Cast 12–60, Cast 15–65, and Cast 15–35) have chromium content ranging from 10–21% and have melting points between 2350 and 2450 degrees Fahrenheit. Other high-nickel alloys with chromium content, such as Hastelloy alloys C and G, Incoloy, Nimonic, and Inconel, range from 13 to 22% chromium (except Incoloy 804=29.7% Cr) with melting points of 2300–2600 degrees Fahrenheit. Stainless steels, in general, have 12–30% chromium content and melting points between 2350 and 2725 degrees Fahrenheit.

For this analysis OSHA projected that the proportion of workers in each production job category is approximately similar in stainless steel and high-nickel alloy production. For example, OSHA assumed that the percent of alloy production workers who are furnace operators is, as in steel production, about 5%. Assuming that both the Cr(VI) exposures typical of various production jobs and the proportion of workers employed in each job are roughly similar, workers in the Arena cohort producing high-nickel stainless steels and alloys containing chromium are likely to have Cr(VI) exposures comparable to those generally found in stainless steel production. Workers' exposures were estimated using the exposure profile shown in Table III–62 of the Final Economic Analysis section on steel mills (Ex. 49–1).

Not all workers in the Arena *et al.* cohort had Cr(VI) exposures comparable to those in stainless steel facilities. As discussed by Ms. Fessler at the hearing, exposure to "* * * [c]hrome was not uniform in all [industries included in the study] because some of those industries * * * did only high nickel work or nickel mining or whatever specific nickel work there was" (Tr. 683). OSHA assumed that Cr(VI) exposures of workers producing high-nickel alloys without chromium content, such as Duranickel, Permanickel, Hastelloy alloys B, D, and G, and Monel alloys, are similar to those found in carbon steel mills and other non-stainless facilities, which according to comments submitted by Collier Shannon Scott:

> * * * may generate Cr(VI) due to trace levels of chromium in feedstock materials or the inadvertent melting of stainless steel scrap, as well as during various maintenance and welding operations (Ex. 38–233, p. 10).

Exposure levels for Arena cohort workers producing these alloys were estimated using the carbon steel exposure profile shown in Table III–64 of the Final Economic Analysis section on steel mills (Ex. 49–1).

Table VI–10 below shows the risk ratios (ratio of excess plus background cancers to background only cancers) predicted by OSHA's model for workers producing high-nickel alloys with and without chromium content. The percentage of workers with 8-hour TWA exposures in each range shown below are calculated for Ni-Cr alloys and non-Cr alloys using profiles developed for the Final Economic Analysis sections on stainless steel and carbon steel industries, respectively (Ex. 49–1). An average exposure duration of 20 years was assumed. While it was not clear how long workers were exposed on average, the reported length of follow-up in the study indicates that the duration of exposure was probably less than 20 years for most workers. Risk ratios were calculated assuming that workers were followed through age 70. The average age at end of follow-up was not clear from the Arena *et al.* publication. Over half of the original cohort was under 30 as of 1978, and follow-up ended in 1988 (Ex. 38–233–2, p. 908). Follow-up through age 70 may therefore lead OSHA's model to overestimate risk in this population, but would probably not lead to underestimation of risk.

Table VI-10: Relative Risks Predicted for Workers in High Nickel Alloy Production

Range of Personal TWA exposures (µg/m^3)	Midpoint Exposure for Risk Model	Percentage of Workers		Risk Ratio Predicted by OSHA's Model
		Ni-Cr Alloys	Non-Cr Alloys	
Unexposed	0.0	66.1%	66.1%	1.000
below LOD	0.015	4.4%	9.8%	1.0002 - 1.001
LOD - < 0.25	0.133	5.4%	9.1%	1.002 - 1.009
0.25 - < 0.5	0.375	8.8%	4.1%	1.006 - 1.026
0.5 - < 1.0	0.750	4.1%	8.1%	1.012 - 1.051
1.0 - < 5.0	3.0	8.5%	0.3%	1.047 - 1.206
5.0 - < 10.0	7.5	0.3%	1.7%	1.117 - 1.514
10.0 - 20.0	15.0	1.7%	0.7%	1.233 - 2.026
> 20.0	30.0	0.7%	0.0%	1.466 - 3.046
Total - Ni-Cr Alloys	***	***	***	1.013 - 1.056
Total - Non-Cr Alloys	***	***	***	1.005 - 1.023

The Arena *et al.* study reported lung cancer rates among white males (who comprised the majority of the cohort) about 2%–13% higher than background depending on the reference population used. The table above illustrates that with reasonable assumptions about exposures in the Arena cohort, OSHA's risk model predicts excess risks as low as those reported by Arena *et al.* OSHA's model predicts the highest risks (1–6% higher than background) among workers producing alloy mixtures similar to stainless steel in chromium content. Unfortunately, it is not clear from the Arena *et al.* publication how many of the workers were involved in production of chromium-containing alloys. If an even split is assumed between workers producing alloys with and without chromium content in the Arena *et al.* cohort, OSHA's model predicts a lung cancer rate between 0.8% and 3.8% higher than background.

More precise information about the level or duration of cohort members' exposures might increase or decrease OSHA's model predictions somewhat. For example, some workers in the historical alloy industry would have had higher exposures than their modern-day counterparts, so that better exposure information may lead to somewhat higher model predictions. On the other hand, better information on the duration of exposure and workers' age at the end of follow-up would lower the model predictions, because this analysis made assumptions likely to overestimate both. The analysis presented here should be interpreted cautiously in light of the considerable uncertainty about the actual exposures to the Arena cohort members, and the fact that OSHA's model predictions are based on a lifetable using year 2000 U.S. all-cause mortality data (rather than data from the time period during which the cohort was followed). This analysis is not intended to provide a precise estimate of risk from exposure to Cr(VI) in the Arena cohort, but rather to demonstrate that the relatively low excess risk seen in the cohort is reasonably consistent with the excess risk that OSHA's model would predict at low exposures. It illustrates that OSHA's risk model does not predict far higher risk than was observed in this cohort. Rather, the majority of workers in alloy production would be predicted to have relatively low risk of occupational lung cancer based on their relatively low exposure to Cr(VI).

Regarding the Huvinen *et al.* (1996, 2002) studies, the comments submitted by Collier Shannon Scott state that "there was not a significant increase in the incidence of any disease, including lung cancer, as compared to the control population" (Ex. 38–233, p. 85). However, the authors also noted that risk of cancer could not be excluded because the follow-up time was short and the exposed group was young and small (Ex. 38–233–3, p. 747).

In addition to the small size (109 workers) and young age (mean 43.3 years) of the Cr(VI)-exposed group in the Huvinen *et al.* study population, the design of this study limits its relevance to the issue of lung cancer risk among stainless steel workers. The subjects were all employed by the company at the time of the study. Individuals with lung cancer would be expected to leave active employment, and would not have been surveyed in the study. The authors made only a limited attempt to track former workers: Those who met the study criteria of 8 years' employment in a single production department were surveyed by mailed questionnaire (Ex. 38–233–3, p. 743), and no follow-up on nonrespondents was reported. A second study conducted on the original study group five years later was again limited to employed workers, as those who had left the company " * * * could not be contacted" (Ex. 38–233–3, p. 204). Due to the short follow-up period and the restriction to living workers (still employed or survey respondents), these studies are not well suited to identify lung cancer cases.

Post-hearing comments stated that " * * * OSHA has failed to even consider specific epidemiological studies performed on stainless steel production workers and welders that would be far more relevant than the chromate production studies OSHA relied upon for its analysis" (Ex. 47–5, p. 10). In particular, they suggest that OSHA should consider a study by Danielsen *et al.* (1996) on Norweigian boiler welders and a study by Moulin *et al.* (1990) on French stainless steel production workers (Ex. 47–5, p. 10). However, the Moulin *et al.* study (Ex. 35–282), was discussed in the Preamble to the Proposed Rule (69 FR at 59339). OSHA concluded that the association between Cr(VI) and respiratory tract cancer in this and similar studies is difficult to assess because of co-exposures to other potential carcinogens such as asbestos, polycyclic aromatic hydrocarbons, nickel, and the lack of information on smoking (69 FR at 59339).

The Danielsen *et al.* study was not evaluated in the NPRM, but is similar to other studies of welders evaluated by OSHA in which excess risk of lung cancer did not appear to be associated with stainless steel welding. In Danielsen *et al.*, as in most other welding studies, no quantitative information on Cr(VI) exposure was available, there was potential confounding by smoking and asbestos exposure, and there appeared to be an overall healthy worker effect in the study (625 deaths vs. 659 expected). Therefore, OSHA does not believe that Danielsen *et al.* contributes significant information beyond that in the studies that are reviewed in Section V.B.4 of this preamble. OSHA's interpretation and conclusions regarding the general findings of welding cohort studies, discussed below in the context of comments submitted by the Electric Power Research Institute, apply to the results of Danielsen *et al.* as well.

The Electric Power Research Institute (EPRI), Exponent, and others submitted comments to OSHA that questioned whether the Agency's exposure-response model, based on the Gibb and Luippold chromate production industry cohorts, should be used to estimate lung cancer risks to welders exposed to Cr(VI) (Exs. 38–8; 38–233–4; 39–25, pp. 2–3). EPRI stated that:

> OSHA's review of the toxicology, epidemiology, and mechanistic data associated with health effects among welders was thorough and accurate. We concur with the selection of the two focus cohorts (Luippold *et al.* 2003 and Gibb *et al.* 2000) as the best data available upon which to base an estimate of the exposure-response relationship between occupational exposure to Cr(VI) and an increased lung cancer risk"; however * * * it may be questionable whether that relationship should be used for stainless steel welders given that a positive relationship between exposure to Cr(VI) and lung cancer risk was not observed in most studies of welder cohorts (Ex. 38–8, pp. 6–7).

EPRI's concerns, like other comments submitted to OSHA on risk to welders, are based primarily on the results of the Gerin *et al.* (1993) study and on several studies comparing stainless steel and mild steel welders.

As discussed above in Section V., Gerin *et al.* (1993) is the only available study that attempts to relate estimated cumulative Cr(VI) exposure and lung cancer risk among welders. While excess lung cancer risks were found among stainless steel welders, there was no clear relationship observed between the estimated amount of Cr(VI) exposure and lung cancer (Ex. 38–8, p. 8). This led the authors to suggest that the elevated risks might be " * * * related to other exposures such as cigarette smoking, background asbestos exposure at work or other occupational or environmental risks * * * " rather than to Cr(VI) exposure. On the other hand, Gerin *et al.* stated that " * * * the welding fume exposures in these populations may be too low to demonstrate a gradient of risk'', or misclassification of exposure might obscure the dose-response relationship (Ex. 7–120, pp. S25–S26), a point with which EPRI expressed agreement (Ex. 38–8, p. 8).

OSHA agrees with Gerin *et al.* that co-exposures to carcinogens such as nickel, asbestos, and cigarette smoke may have contributed to the elevated lung cancer risks among welders. OSHA also agrees with the authors that exposure misclassification may explain the absence of a clear relationship between Cr(VI) and lung cancer in this study. Gerin *et al.* derived their exposure data primarily from literature on welding fume, as well as from a limited number of industrial hygiene measurements taken in the mid 1970s in eight of the 135 companies participating in the study (Ex. 7–120, p. S24, p. S27). Their exposure estimates took account of the welding process used and the base metal welded by individuals in the cohort, but they apparently had no information on other important items, such as the size of the work piece and weld time, which were identified by EPRI as factors affecting the level of Cr(VI) exposure from welding (Ex. 38–8, p. 5).

EPRI also identified ventilation as a particularly important determinant of exposure (Ex. 38–8, p. 5). Gerin *et al.* did not appear to have individual information on ventilation use for their exposure estimates, relying instead on ''information on the history of welding practice * * * obtained from each company on the basis of an ad hoc questionnaire'' that described for each company the average percent of time that welders used local ventilation, operated in confined or open areas, and worked indoors or outdoors (Ex. 7–120, p. S23). The use of local ventilation, time spent welding in confined areas, and time spent welding outdoors may have varied considerably from worker to worker within any single company. In this case exposure estimates based on company average information would tend to overestimate exposure for some workers and underestimate it for others, thus weakening the appearance of an exposure-response relationship in the cohort.

Gerin *et al.* also stated that the average exposure values they estimated do not account for a number of factors which affect welders' exposure levels, including '' * * * type of activity (*e.g.* maintenance, various types of production), special processes, arcing time, voltage and current characteristics, welder position, use of special electrodes or rods, presence of primer paints and background fumes coming from other activities'' (Ex. 7–120, p. S25). They noted that the resulting difficulty in the construction of individual exposure estimates is exacerbated by aggregation of data across small cohorts from many different companies that may have different exposure conditions (Ex. 7–120, p. S25). According to Gerin *et al.*, exposure misclassification of this sort may have obscured a dose-response relationship in this cohort (Ex. 7–120, p. S25). The authors suggest that their estimates should be checked or corrected '' * * * with data coming from well-documented industrial hygiene studies or industrial hygiene data banks including information on the major relevant factors'' (Ex. 7–120, p. S26). OSHA believes that there is insufficient information to determine why a clear relationship between Cr(VI) exposure and lung cancer is not observed in the Gerin *et al.* study, but agrees with the authors that exposure misclassification and the influence of background exposures may explain this result.

EPRI noted the apparent lack of a relationship between exposure duration and lung cancer risk in the Gerin *et al.* cohort (Ex. 38–8, p. 10). Duration of exposure is expected to show a relationship with cancer risk if duration serves as a reasonable proxy for a measure of exposure (*e.g.* cumulative exposure) that is related to risk. Since cumulative exposure is equal to exposure duration multiplied by average exposure level, duration of exposure may correlate reasonably well with cumulative exposure if average exposure levels are similar across workers, or if workers with longer employment tend to have higher average exposure levels. In a cohort where exposure duration is believed to correlate well with cumulative exposure, the absence of a relationship between exposure duration and disease risk could be interpreted as evidence against a relationship between cumulative exposure and risk.

High variation in average exposures among workers, unrelated to the duration of their employment, would tend to reduce the correlation between exposure duration and cumulative exposure. If, as EPRI states, Cr(VI) exposure depends strongly on process, base metal, and other work conditions that vary from workplace to workplace, then duration of exposure may not correlate well with cumulative exposure across the 135 companies included in the Gerin *et al.* study. The lack of a positive relationship between exposure duration and lung cancer in the Gerin *et al.* cohort may therefore signify that duration of exposure is not a good proxy for the amount of exposure accumulated by workers, and should not be interpreted as evidence against an exposure-response relationship.

In post-hearing comments Mr. Robert Park of NIOSH discussed other issues related to exposure duration in the Gerin *et al.* and other welding cohorts:

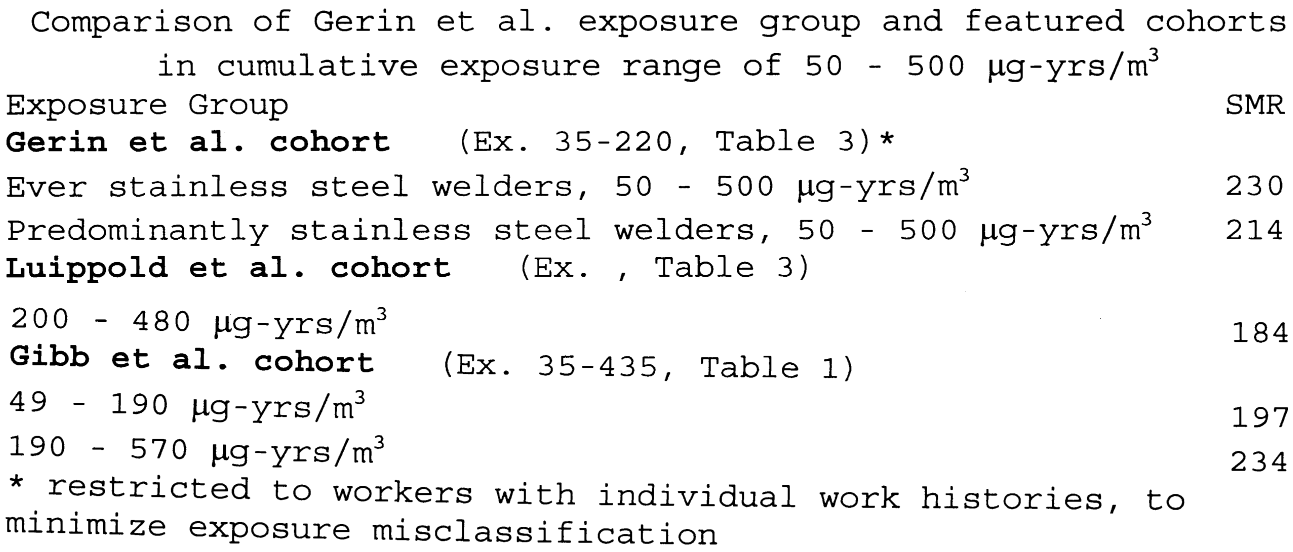
> Several factors may impact the interpretation of [the Gerin *et al.* (1993) and Simonato *et al.* (1991) welder cohort studies] and are consistent with an underlying risk associated with duration * * *. The healthy worker survivor effect is a form of confounding in which workers with long employment durations systematically diverge from the overall worker population on risk factors for mortality. For example, because smoking is a risk factor for disease, disability and death, long duration workers would tend to have a lower smoking prevalence, and hence lower expected rates of diseases that are smoking related, like lung cancer. Not taking this into account among welders might result in long duration welders appearing to have diminished excess risk when, in fact, excess risk continues to increase with time (Ex. 47–19–1, p. 6).

Mr. Park also emphasized the special importance of detailed information for individual workers in multi-employer studies with exposure conditions that vary widely across employers. He notes that high worker turnover in highly exposed jobs '' * * * could result in long duration welding employment appearing to have lower risk than some shorter duration [welding] employment when it does not'' (Ex. 47–19–1, p. 6).

EPRI compared the risk of lung cancer among a subset of workers in the Gerin cohort exposed to high cumulative levels of Cr(VI) to the risk found among chromate production workers in the Gibb *et al.* and Luippold *et al.* studies. ''Focusing on the highest exposure group, SMRs for the cohorts of stainless steel workers studied by Gerin et al (1993) * * * range from 133 to 148 for exposures >1.5 mg-yrs/m^3 * * *. By comparison, the SMR from the Luippold *et al.* (2003) cohort is 365 for cumulative exposures of 1.0 to 2.69 mg-yrs/m^3'', a difference that EPRI argues '' * * * draws into question whether the exposure-specific risk estimates from the chromate production industry can be extrapolated to welders'' (Ex. 38–8, p. 25). It is not clear why EPRI chose to focus on the high exposure group, which had a minimum of 1.5 mg/m^3-years cumulative Cr(VI) exposure, a mean of 2.5 mg/m^3-years, and no defined upper limit. Compared to the other exposure groups described by Gerin *et al.*, this group is likely to have had more heterogenous exposure levels; may be expected to have a stronger healthy worker effect due to the association between high cumulative exposure and long employment history; and is the least comparable to either workers exposed for a working lifetime at the proposed PEL (1 $\mu g/m^3$ * 45 years = 0.045 mg/m^3-years cumulative exposure) or welders in modern-day working conditions, who according to an IARC review cited in EPRI's comments typically have exposure levels less than 10 $\mu g/m^3$ (< 0.45 mg/m^3-years cumulative exposure over 45 years) (Ex. 38–8, p. 4). In addition, the majority of the observation time in the Luippold *et al.* cohort and the vast majority in the Gibb *et al.* cohort is associated with exposure estimates lower than 1.5 mg/m^3-years Cr(VI) (Ex. 33–10, p. 455, Table 3; 25, p. 122, Table VI).

It should be noted that the levels of excess lung cancer risk observed among welders in the Gerin *et al.* cohort and chromate production workers in the Gibb and Luippold cohorts are quite similar at lower cumulative exposure ranges that are more typical of Cr(VI) exposures experienced in the cohorts. For example, the group of welders with estimated cumulative exposures ranging from 50 to 500 μg-yrs/m^3 has an SMR of 230. Chromate production workers from the Gibb and Luippold cohorts with cumulative exposures within this range have comparable SMRs, ranging from 184 to 234, as shown in Table VI–11 below. For reference, 45 years of occupational exposure at approximately 1.1 $\mu g/m^3$ Cr(VI) would result in a cumulative exposure of 50 μg-yrs/m^3; 45 years of occupational exposure at approximately 11.1 $\mu g/m^3$ Cr(VI) would result in a cumulative exposure of 500 μg-yrs/m^3.

Table VI-11



Comparison of Gerin et al. exposure group and featured cohorts in cumulative exposure range of 50 - 500 μg-yrs/m^3

Exposure Group	SMR
Gerin et al. cohort (Ex. 35-220, Table 3)*	
Ever stainless steel welders, 50 - 500 μg-yrs/m^3	230
Predominantly stainless steel welders, 50 - 500 μg-yrs/m^3	214
Luippold et al. cohort (Ex. , Table 3)	
200 - 480 μg-yrs/m^3	184
Gibb et al. cohort (Ex. 35-435, Table 1)	
49 - 190 μg-yrs/m^3	197
190 - 570 μg-yrs/m^3	234

* restricted to workers with individual work histories, to minimize exposure misclassification

OSHA performed an analysis comparing the risks predicted by OSHA's models, based on the Gibb and Luippold data collected on chromate production workers, with the lung cancer deaths reported for the welders in the Gerin *et al.* study. Gerin *et al.* presented observed and expected lung cancer deaths for four categories of cumulative exposure: <50 μg-yrs/m^3, 50–500 μg-yrs/m^3, 500–1500 μg-yrs/m^3, and 1500+ μg-yrs/m^3. The great majority of the Gerin *et al.* data on stainless steel welders (98% of person-years) are in the highest three categories, while the lowest category is extremely small (<300 person-years of observation). OSHA's preferred risk models (based on the Gibb and Luippold cohorts) were used to predict lung cancer risk for each of the three larger exposure categories. The OSHA predictions were derived using the mean values from each exposure range, except for the open-ended highest category, for which Gerin *et al.* reported a mean exposure level of 2500 μg-yrs/m^3 (Ex. 7–120, p. S26). The ratio of predicted to background lung cancer deaths, which approximately characterizes the expected SMRs for these exposure groups, was calculated for each group.

The OSHA model predictions were calculated assuming that workers were first exposed to Cr(VI) at age 29, the average age at the start of employment reported by Gerin *et al.* (Ex. 7–120, p. S26). The SMRs reported by Gerin *et al.* were calculated for welders with at least five years of employment and at least 20 years of follow-up. However, the average duration of employment and follow-up was not evident from the publication. The OSHA model predictions were therefore calculated using a range of reasonable assumptions about the duration of employment over which workers were exposed (5, 10, 15, and 20 years) and the length of follow-up (30, 40, and 50 years).

Table VI–12 below presents the SMRs reported by Gerin *et al.* for stainless steel welders in the three highest exposure categories, together with the ratio of predicted to background lung cancer deaths from OSHA's risk models. It should be noted that the ratio was calculated using year 2000 U.S. lung cancer mortality rates, while the SMRs reported by Gerin *et al.* were calculated using national lung cancer mortality rates for the nine European countries represented in the study (Ex. 7–114).

Table VI-12

Comparison of Gerin et al. SMRs and OSHA risk model predictions

Gerin *et al.* cohort*		**OSHA risk model**	
Cumulative exposure range ($\mu g/m^3$-yrs)	*Ratio of observed to expected lung cancer deaths (SMR) (95% C.I.)*	*Cumulative exposure ($\mu g/m^3$-yrs)*	*Ratio of predicted to background lung cancer deaths (95% C.I.)*
50 - 500	214 – 230 (44 – 589)	275	119 – 194 (111 – 260)
500 - 1500	252 – 258 (69 – 661)	1000	168 – 441 (140 – 677)
> 1500	130 – 133 (36 – 339)	2500	270 – 941 (201 – 1510)

* restricted to workers with individual work histories, to reduce exposure misclassification

Table VI–12 shows that the range of risk ratios predicted by OSHA's model is higher than the ratios reported for the highest exposure group in the Gerin *et al.* cohort, consistent with EPRI's observations (Ex. 38–8, p. 25). However, the risk ratios predicted by OSHA's model are consistent with the Gerin SMRs for the 500–1500 μg-yrs/m^3 cumulative exposure range. For the 50–500 μg-yrs/m^3 cumulative exposure range, the OSHA prediction falls slightly below the lung cancer mortality ratio observed for the Gerin *et al.* cohort. The OSHA predictions for each group overlap with the 95% confidence intervals of the Gerin *et al.* SMRs, suggesting that sampling error may partly account for the discrepancies between the observed and predicted risk ratios in the lowest and highest exposure groups.

As previously discussed, OSHA believes that the lack of a clear exposure-response trend in the Gerin *et al.* study may be partly explained by exposure misclassification. As shown in Table VI–12, the highest exposure group has lower risk than might be expected based on OSHA's preferred risk models, while the lowest exposure group appears to have higher risk than OSHA's models would predict. This overall pattern of generally elevated but non-increasing SMRs across the three larger exposure groups in the Gerin study is consistent with potentially severe exposure misclassification. The higher-than-predicted risks among welders in the lowest exposure group could similarly reflect misclassification. However, it is not possible to determine with certainty that exposure misclassification is the cause of the differences between the risk predicted by OSHA's model and that observed in the Gerin cohort.

Finally, EPRI cites the generally similar relative risks found among stainless steel and mild steel welders as further evidence that exposure to Cr(VI) may not carry the same risk of lung cancer in welding operations as it does in the chromate production industry. EPRI states:

> [I]t is reasonable to expect that if Cr(VI) were a relevant risk factor for welders in the development of lung cancer, and certain types of welding involve Cr(VI) more than other types, then subgroups of welders who are more exposed to Cr(VI) by virtue of the type of welding they do should have higher rates of lung cancer than welders not exposed to Cr(VI) in their welding occupation;

in particular, “* * *stainless steel welders should have a higher risk of lung cancer than welders of mild steel” (Ex. 38–8, p. 13). OSHA believes that EPRI's point would be correct if the subgroups in question are similar in terms of other important risk factors for lung cancer, such as smoking, co-exposures, and overall population health. However, no analysis comparing stainless steel welders with mild steel welders has properly controlled for these factors, and in fact there have been indications that mild steel welders may be at greater risk of lung cancer than stainless steel welders from non-occupational causes. As discussed by EPRI, “[r]esults from cohort studies of stainless steel welders with SMRs much less than 100 support an argument that the healthy worker effect might be more marked among stainless steel workers compared to mild steel welders'; also “* * *stainless steel welders are generally more qualified and paid more than other welders” (Ex. 38–8, p. 16), a socioeconomic factor that suggests possible differences in lung cancer risk due to smoking, community exposures, or occupational exposures from employment other than welding.

Comments submitted by Exponent (Ex. 38–233–4) and EPRI (Ex. 38–8) compare the Cr(VI) compounds found in welding fumes and those found in the chromate production environments of the Gibb and Luippold cohorts. Exponent stated that “[t]he forms of Cr(VI) to which chromate production workers were historically exposed are primarily the soluble potassium and sodium chromates” found in stainless steel welding fumes. Less soluble forms of Cr(VI) are also found in stainless steel welding fumes in limited amounts, as discussed in the 1990 IARC monograph on welding (Ex. 35–242, p. 460), and are believed to have been present in limited amounts at the plants where the Gibb and Luippold workers were employed (Ex. 38–233–4, p. 4). Exponent concludes that, while it is difficult to compare the exposures of welders to chromate production workers, “* * *there is no obvious difference * * * in solubility * * *” that would lead to a significantly lesser risk from Cr(VI) exposure in welding as compared to the Gibb and Luippold cohort exposures (Ex. 38–233–4, p. 3, p. 11). OSHA believes that the similarity in the solubility of Cr(VI) exposures to welders and chromate production workers supports the Agency's use of its risk model to describe Cr(VI)-related risks to welders.

Exponent and others (Exs. 38–8; 39–25) commented on the possibility that the bioavailability of Cr(VI) may nevertheless differ between welders and chromate production workers, stating that “* * * bioavailability of Cr(VI)-containing particles from welding fumes may not be specifically related to solubility of the Cr(VI) chemical species in the fume” (Ex. 38–233–4, p. 11). In this case, Exponent argues,

> delivered doses of Cr(VI) to the lung could be quite dissimilar among welders as compared to chromate production industry workers exposed to the same Cr(VI) chemical species at the same Cr(VI) airborne concentrations (Ex. 38–233–4, p. 11).

However, Exponent provided no data or plausible rationale that would support a Cr(VI) bioavailability difference between chromate production and welding. The low proportion of respirable Cr(VI) particles that apparently limits bioavailability of inhaled Cr(VI) during aircraft spray priming operations described previously is not an issue with welding. High temperature welding generates fumes of small respirable-size Cr(VI) particles able to penetrate the bronchoalveolar region of the lung. OSHA finds no evidence indicating that Cr(VI) from welding is less bioavailable than Cr(VI) from soluble chromate production.

In summary, OSHA agrees with EPRI and other commenters that evidence of an exposure-response relationship is not as strong in studies of Cr(VI)-exposed welders compared to studies of chromate production workers. OSHA believes that the available welding studies are less able to detect an exposure-response relationship, due to the potentially severe exposure misclassification, occupational exposure to other cancer causing agents, and the general lack of information with which to control for any differences in background lung cancer risk between Cr(VI)-exposed and unexposed welders. In contrast, the two featured cohorts had sufficient information on workers' Cr(VI) exposures and potential confounding exposures to support a reliable exposure-response assessment. These are the primary factors that led OSHA to determine (like EPRI and Exponent) that the Luippold and Gibb cohorts are the best data available on which to base a model of exposure-response between Cr(VI) and lung cancer (Exs. 38–8, p. 6; 38–233–4, p. 1). Moreover, EPRI admitted that examination of "* * * the forms of Cr(VI) to which welders are exposed, exposure concentrations, and other considerations such as particle size * * *" identified "* * * no specific basis * * *" for a difference in Cr(VI)-related lung cancer risk among welders and the Gibb and Luippold chromate production cohorts (Ex. 38–8, p. 7). OSHA concludes that it is reasonable and prudent to estimate welders' risk using the exposure-response model developed on the basis of the Gibb *et al.* and Luippold *et al.* datasets.

H. Conclusions

OSHA believes that the best quantitative estimates of excess lifetime lung cancer risks are those derived from the data sets described by Gibb *et al.* and Luippold *et al.* Both data sets show a significant positive trend in lung cancer mortality with increasing cumulative Cr(VI) exposure. The exposure assessments for these two cohorts were reconstructed from air measurements and job histories over three or four decades and were superior to those of other worker cohorts. The linear relative risk model generally provided the best fit among a variety of different models applied to the Gibb *et al.* and Luippold *et al.* data sets. It also provided an adequate fit to three additional data sets (Mancuso, Hayes *et al.*, and Gerin *et al.*). Thus, OSHA believes the linear relative risk model is the most appropriate model to estimate excess lifetime risk from occupational exposure to Cr(VI). Using the Gibb *et al.* and Luippold *et al.* datasets and a linear relative risk model, OSHA concludes that the lifetime lung cancer risk is best expressed by the three-to five-fold range of risk projections bounded by the maximum likelihood estimates from the two featured data sets. This range of projected risks is within the 95 percent confidence intervals from all five data sets.

OSHA does not believe that it is appropriate to employ a threshold dose-response approach to estimate cancer risk from a genotoxic carcinogen, such as Cr(VI). Federal agencies, including OSHA, assume an exposure threshold for cancer risk assessments to genotoxic agents only when there is convincing evidence that such a threshold exists (see *e.g.* EPA, Guidelines for Carcinogen Risk Assessment, March 2005, pp. 3–21). In addition, OSHA does not consider absence of a statistically significant effect in an epidemiologic or animal study that lacks power to detect such effects to be convincing evidence of a threshold or other non-linearity. OSHA also does not consider theoretical reduction capacities determined in vitro with preparations that do not fully represent physiological conditions within the respiratory tract to be convincing evidence of a threshold. While physiological defense mechanisms (*e.g.* extracellular reduction, DNA repair, apoptosis) can potentially introduce dose transitions, there is no evidence of a significantly non-linear Cr(VI) dose-lung cancer response in the exposures of interest to OSHA. Finally, as previously discussed, linear no-threshold risk models adequately fit the existing exposure-response data.

The slightly soluble Cr(VI) compounds produced a higher incidence of respiratory tract tumors than highly water soluble or highly water insoluble Cr(VI) compounds in animal studies that tested Cr(VI) compounds under similar experimental conditions. This likely reflects the greater tendency for chromates of intermediate water solubility to provide a persistent high local concentration of solubilized Cr(VI) in close proximity to the target cell. Highly soluble chromates rapidly dissolve and diffuse in the aqueous fluid lining the epithelia of the lung and are more quickly cleared from the respiratory tract. Thus, these chromates are less able to achieve the higher and more persistent local concentrations within close proximity of the lung cell surface than the slightly water soluble chromates. Water insoluble Cr(VI) particulates are also able to come in close contact with the lung cell surface but do not release readily absorbed chromate ions into the biological environment as rapidly. OSHA concludes that slightly soluble Cr(VI) compounds are likely to exhibit a greater degree of carcinogenicity than highly water soluble or water insoluble Cr(VI) when the same dose is delivered to critical target cells in the respiratory tract of the exposed worker. OSHA also believes it reasonable to regard water insoluble Cr(VI) to be of similar carcinogenic potency to highly water soluble Cr(VI) compounds in the absence of convincing scientific evidence to indicate otherwise.

The Gibb and Luippold cohorts were predominantly exposed to highly water-soluble chromates, particularly sodium chromate and dichromate. After evaluating lung cancer rates in other occupational cohort studies with respect to the forms of Cr(VI) in the workplace, reliability in the Cr(VI) exposure data, and the presence of potentially confounding influences (*e.g.* smoking) and bias (*e.g.* healthy worker survivor bias) as well as information on solubility, particle size, cell uptake, and other factors influencing delivery of Cr(VI) to lung cells, OSHA finds the risks estimated from the Gibb and Luippold cohorts adequately represent risks to workers exposed to equivalent levels of Cr(VI) compounds in other industries.

As with any risk assessment, there is some degree of uncertainty in the projection of risks that results from the data, assumptions, and methodology used in the analysis. The exposure estimates in the Gibb *et al.* and Luippold *et al.* data sets relied, to some extent, on a paucity of air measurements using less desirable sampling techniques to reconstruct Cr(VI) exposures, particularly in the 1940s and 1950s. Additional uncertainty is introduced when extrapolating from the cohort exposures, which usually involved exposures to higher Cr(VI) levels for shorter periods of time to an equivalent cumulative exposure involving a lower level of exposure for a working lifetime. The study cohorts consisted mostly of smokers, but detailed information on their smoking behavior was unavailable. While the risk assessments make some adjustments for the confounding effects of smoking, it is unknown whether the assessments fully account for any interactive effects that smoking and Cr(VI) exposure may have on carcinogenic action. In any case, OSHA does not have reason to believe the above uncertainties would introduce errors that would result in serious overprediction or underprediction of risk.

OSHA's estimate of lung cancer risk from a 45 year occupational exposure to Cr(VI) at the previous PEL of 52 $\mu g/m^3$ is 101 to 351 excess deaths per 1000 workers. This range, which is defined by maximum likelihood estimates based on the Gibb and Luippold epidemiological cohorts, is OSHA's best estimate of excess risk. It does not account for statistical uncertainty, or for other potential sources of uncertainty or bias. The wider range of 62 to 493 excess deaths per 1000 represents the statistical uncertainty associated with OSHA's excess risk estimate at the previous PEL, based on lowest and highest 95% confidence bounds on the maximum likelihood estimates for the two featured data sets. The excess lung cancer risks at alternative 8 hour TWA PELs that were under consideration by the Agency were previously shown in Table VI–7, together with the uncertainty bounds for the primary and supplemental studies at these exposure concentrations. The 45-year exposure estimates satisfy the Agency's statutory obligation to consider the risk of material impairment for an employee with regular exposure to the hazardous agent for the period of his working life (29 U.S.C. 651 *et seq.*). Occupational risks from Cr(VI) exposure to less than a full working lifetime are considered in Section VII on the Significance of Risk and in Section VIII on the Benefits Analysis.

VII. Significance of Risk

In promulgating health standards, OSHA uses the best available information to evaluate the risk associated with occupational exposures, to determine whether this risk is severe enough to warrant regulatory action, and to determine whether a new or revised rule will substantially reduce this risk. OSHA makes these findings, referred to as the ''significant risk determination'', based on the requirements of the OSH Act and the Supreme Court's interpretation of the Act in the ''benzene'' decision of 1980 (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607). The OSH Act directs the Secretary of Labor to:

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard * * * for the period of his working life [6(b)(5)].

OSHA's authority to promulgate regulations to protect workers is limited by the requirement that standards be ''reasonably necessary and appropriate to provide safe or healthful employment'' [3(8)].

In the benzene decision, the Supreme Court's interpretation of Section 3(8) further defined OSHA's regulatory authority. The Court stated:

> By empowering the Secretary to promulgate standards that are ''reasonably necessary or appropriate to provide safe or healthful employment and places of employment,'' the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe (*IUD* v. *API* 448 U.S. at 642).

''But 'safe' is not the equivalent of 'risk-free' '', the Court maintained. ''[T]he Secretary is required to make a threshold finding that a place of employment is unsafe-in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' (*IUD* v. *API*, 448 U.S. at 642). It has been Agency practice in regulating health hazards to establish this finding by estimating risk to workers using quantitative risk assessment, and determining the significance of this risk based on judicial guidance, the language of the OSH Act, and Agency policy considerations.

The Agency has considerable latitude in defining significant risk and in determining the significance of any particular risk. The Court did not stipulate a means to distinguish significant from insignificant risks, but rather instructed OSHA to develop a reasonable approach to the significant risk determination. The Court stated that ''it is the Agency's responsibility to determine in the first instance what it considers to be a 'significant' risk'', and it did not express ''any opinion on the* * *difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate'' (448 U.S. at 659). The Court also stated that, while OSHA's significant risk determination must be supported by substantial evidence, the Agency ''is not required to support the finding that a significant risk exists with anything approaching scientific certainty'' (448 U.S. at 656). Furthermore,

> A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and] * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection [so long as such assumptions are based on] a body of reputable scientific thought (448 U.S. at 655, 656).

To make the significance of risk determination for a new or proposed standard, OSHA uses the best available scientific evidence to identify material health impairments associated with potentially hazardous occupational exposures, and, when possible, to provide a quantitative assessment of exposed workers' risk of these impairments. OSHA has reviewed extensive epidemiological and experimental research pertaining to adverse health effects of occupational Cr(VI) exposure, including lung cancer, and has established quantitative estimates of the excess lung cancer risk associated with previously allowable Cr(VI) exposure concentrations and the expected impact of the new PEL. OSHA has determined that long-term exposure at the previous PEL would pose a significant risk to workers' health, and that adoption of the new PEL and other provisions of the final rule will substantially reduce this risk.

A. Material Impairment of Health

As discussed in Section V of this preamble, there is convincing evidence that exposure to Cr(VI) may cause a variety of adverse health effects, including lung cancer, nasal tissue damage, asthma, and dermatitis. OSHA considers these conditions to be material impairments of health, as they are marked by significant discomfort and long-lasting adverse effects, can have adverse occupational and social consequences, and may in some cases have permanent or potentially life-threatening consequences. Based on this finding and on the scientific evidence linking occupational Cr(VI) to each of these effects, OSHA concludes that exposure to Cr(VI) causes ''material impairment of health or functional capacity'' within the meaning of the OSH Act.

1. Lung Cancer

OSHA considers lung cancer, an irreversible and frequently fatal disease, to be a clear material impairment of health. OSHA's finding that inhaled Cr(VI) causes lung cancer is based on the best available epidemiological data, reflects substantial evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations, including NIOSH, EPA, ACGIH, NTP, and IARC (Exs. 35–117; 35–52; 35–158; 17–9–D; 18–3, p. 213). The Agency's primary evidence comes from two epidemiological studies that show significantly increased incidence of lung cancer among workers in the chromate production industry (Exs. 25; 33–10). The high quality of the data collected in these studies and the analyses performed on them has been confirmed by OSHA and by independent peer review. Supporting evidence of Cr(VI) carcinogenicity comes from occupational cohort studies in chromate production, chromate pigment production, and chromium plating, and by cell culture research into the processes by which Cr(VI) disrupts normal gene expression and replication. Studies demonstrating uptake, metabolism, and genotoxicity of a variety of soluble and insoluble Cr(VI) compounds support the Agency's position that all Cr(VI) compounds should be regulated as occupational carcinogens (Exs. 35–148; 35–68; 35–67; 35–66; 12–5; 35–149; 35–134).

2. Non-Cancer Impairments

While OSHA has relied primarily on the association between Cr(VI) inhalation and lung cancer to demonstrate the necessity of the standard, the Agency has also determined that several other material health impairments can result from exposure to airborne Cr(VI). As shown in several cross-sectional and cohort studies, inhalation of Cr(VI) can cause ulceration of the nasal passages and perforation of the nasal septum (Exs. 35–1; 7–3; 9–126; 35–10; 9–18; 3–84; 7–50; 31–22–12). Nasal tissue ulcerations are often accompanied by swelling and bleeding, heal slowly, and in some cases may progress to a permanent perforation of the nasal septum that can only be repaired surgically. Inhalation of Cr(VI) may also lead to asthma, a potentially life-threatening condition in which workers become allergic to Cr(VI) compounds and experience symptoms such as coughing, wheezing, and difficulty in breathing upon exposure to small amounts of airborne Cr(VI). Several case reports have documented asthma from Cr(VI) exposure in the workplace, supporting Cr(VI) as the sensitizing agent by bronchial challenge (Exs. 35–7; 35–12; 35–16; 35–21).

During the comment period, NIOSH requested that OSHA consider allergic contact dermatitis (ACD) as a material impairment of health due to occupational exposure to Cr(VI). NIOSH reasoned:

> Dermal exposure to Cr(VI) through skin contact * * * may lead to sensitization or allergic contact dermatitis. This condition, while not life-threatening, is debilitating and marked by significant discomfort and long-lasting adverse effects; it can have adverse occupational and social consequences and should be a material impairment to the health of affected workers * * * Including allergic contact dermatitis in OSHA's determination of material impairment of health draws attention to the fact that Cr(VI) is both a dermal exposure hazard and an inhalation hazard, and alerts employers that they should seek to minimize exposure to both routes (Ex. 40–10–2, p. 3)

OSHA fully agrees with the NIOSH comment. There is strong evidence that unprotected skin contact with Cr(VI)-containing materials and solutions can cause ACD as well as irritant dermatitis and skin ulceration (see section V.D). ACD is a delayed hypersensitivity response. The worker initially becomes sensitized to Cr(VI) following dermal exposure. Once a worker becomes sensitized, brief exposures to small amounts of Cr(VI) can trigger symptoms such as redness, swelling, itching, and scaling. ACD is characterized by the initial appearance of small raised papules that can later develop into blisters and dry thickened, cracked skin. The allergic condition is persistent, causing some workers to leave their jobs (Ex. 35–320). Symptoms of ACD frequently continue long after occupational exposure to Cr(VI) ends, since sensitized individuals can react to contact with Cr(VI) in consumer products and other non-occupational sources.

Skin exposure to Cr(VI) compounds can also cause a non-allergic form of dermatitis. This skin impairment results from direct contact with Cr(VI) doses that damage or irritate the skin, but do not involve immune sensitization. This form of dermatitis can range from mild redness to severe burns and ulcers, known as ‘‘chrome holes'', that penetrate deep into tissues. Once the worker is removed from exposure, the skin ulcers heal slowly, often with scarring.

B. Risk Assessment

When possible, epidemiological or experimental data and statistical methods are used to characterize the risk of disease that workers may experience under the currently allowable exposure conditions, as well as the expected reduction in risk that would occur with implementation of the new PEL. The Agency finds that the available epidemiological data are sufficient to support quantitative risk assessment for lung cancer among Cr(VI)-exposed workers. Using the best available studies, OSHA has identified a range of expected risk from regular occupational exposure at the previous PEL (101–351 excess lung cancer deaths per 1000 workers) and at the new PEL of 5 μg/m^3 (10–45 per 1000 workers), assuming a working lifetime of 45 years' exposure in each case. These values represent the best estimates of multiple analysts working with data from two extensively studied worker populations, and are highly consistent across analyses using a variety of modeling techniques and assumptions. While some attempts have been made to assess the relationship between Cr(VI) exposure level and noncancer adverse health effects, the Agency does not believe that a reliable quantitative risk assessment can be performed for noncancer effects at this time, and has therefore characterized noncancer risk qualitatively.

For estimates of lung cancer risk from Cr(VI) exposure, OSHA has relied upon data from two cohorts of chromate production workers. The Gibb cohort, which originates from a chromate production facility in Baltimore, Maryland, includes 2357 workers who began work between 1950 and 1974 and were followed up through 1992 (Ex. 33–11). The extensive exposure documentation available for this cohort, the high statistical power afforded by the large cohort size, and the availability of information on individual workers' race and smoking status provide a strong basis for risk analysis. The Luippold cohort, from a facility in Painesville, Ohio, includes 482 workers who began work between 1940 and 1972, worked for at least one year at the plant, and were followed up through 1997 (Ex. 33–10). This cohort also provides a strong basis for risk analysis, in that it has high-quality documentation of worker Cr(VI) exposure and mortality, a long period of follow-up, and a large proportion of relatively long-term employees (55% were employed for longer than 5 years).

1. Lung Cancer Risk Based on the Gibb Cohort

Risk assessments were performed on the Gibb cohort data by Environ International Corporation (Ex. 33–12), under contract with OSHA; Park *et al.*, as part of an ongoing effort by NIOSH (Ex. 33–13); and Exponent on behalf of the Chrome Coalition (Ex. 31–18–15–1). A variety of statistical models were considered, allowing OSHA to identify the most appropriate models and assess the resulting risk estimates' sensitivity to alternate modeling approaches. Models were tried with additive and relative risk assumptions; various exposure groupings and lag times; linear and nonlinear exposure-response functions; external and internal standardization; reference lung cancer rates from city-, state-, and national-level data; inclusion and exclusion of short-term workers; and a variety of ways to control for the effects of smoking. OSHA's preferred approach, a relative risk model using Baltimore lung cancer reference rates, and NIOSH's preferred approach, a relative risk model using detailed smoking information and U.S. lung cancer reference rates, are among several models that use reasonable assumptions and provide good fits to the data. As discussed in section VI, the Environ, Park *et al.*, and linear Exponent models yield similar predictions of excess risk from exposure at the previous PEL and the new PEL (see Tables VI–2 and VI–3). OSHA's preferred models (from the Gibb data set) predict about 300–350 excess lung cancers per 1000 workers exposed for a working lifetime of 45 years at the previous PEL and about 35–45 excess lung cancers per 1000 workers at the new PEL of 5 $\mu g/m^3$.

Environ and Crump *et al.* performed risk assessments on the Luippold cohort, exploring additive and relative risk models, linear and quadratic exposure-response functions, and several exposure groupings (Exs. 35–59; 35–58). Additive and relative risk models by both analyst groups fit the data adequately with linear exposure-response. All linear models predicted similar excess risks, from which OSHA has selected preferred estimates based on the Crump *et al.* analysis of about 100 excess lung cancer deaths per 1000 workers exposed for 45 years at the previous PEL, and ten excess lung cancer deaths per 1000 workers at the new PEL.

2. Lung Cancer Risk Based on the Luippold Cohort

The risk assessments performed on the Luippold cohort yield somewhat lower estimates of lung cancer risk than those performed on the Gibb cohort. This discrepancy is probably not due to statistical error in the risk estimates, as the confidence intervals for the estimates do not overlap. The risk estimates based on the Gibb and Luippold cohorts are nonetheless reasonably close. OSHA believes that both cohorts support reasonable estimates of lung cancer risk, and based on their results has selected a representative range of 101–351 per 1000 for 45 years' occupational exposure at the previous PEL and 10–45 per 1000 for 45 years' occupational exposure at the new PEL for the significant risk determination. OSHA's confidence in these risk estimates is further strengthened by the results of the independent peer review to which the risk assessment was submitted, which supported the Agency's approach and results. OSHA also received several comments in support of its risk estimates (Exs. 44–7, 38–222; 39–73–1). A full analysis of major comments on the results of OSHA's quantitative risk assessment can be found in section VI.F.

3. Risk of Non-Cancer Impairments

Although nasal damage and asthma may be associated with occupational exposure to airborne Cr(VI), OSHA has determined that there are insufficient data to support a formal quantitative risk assessment for these effects. Available occupational studies of Cr(VI)-induced nasal damage are either of cross-sectional study design, do not provide adequate data on short-term airborne Cr(VI) exposure over an entire employment period, or do not account for possible contribution from hand-to-nose transfer of Cr(VI) (Exs. 31–22–12; 9–126; 35–10; 9–18). Occupational asthma caused by Cr(VI) has been documented in clinical case reports but asthma occurrence has not been linked to specific Cr(VI) exposures in a well-conducted epidemiological investigation. The Agency has nonetheless made careful use of the best available scientific information in its evaluation of noncancer health risks from occupational Cr(VI) exposure. In lieu of a quantitative analysis linking the risk of noncancer health effects, such as damage to nasal tissue, with specific occupational exposure conditions, the Agency has qualitatively considered information on the extent of these effects and occupational factors affecting risk, as discussed below.

Damage to the nasal mucosa and septum can occur from inhalation of airborne Cr(VI) or transfer of Cr(VI) on workers' hands to the interior of the nose. Epidemiological studies have found varying, but substantial, prevalence of nasal damage among workers exposed to high concentrations of airborne Cr(VI). In the cohort of 2357 chromate production workers studied by Gibb *et al.*, over 60% experienced nasal tissue ulceration at some point during their employment, with half of these workers' first ulcerations occurring within 22 days from the date they were hired (Ex. 31–22–12). The authors found a statistically significant relationship between nasal ulceration and workers' contemporaneous exposures, with about half of the workers who developed ulcerations first diagnosed while employed in a job with average exposure concentrations greater than 20 $\mu g/m^3$. Nasal septum perforations were reported among 17% of the Gibb cohort workers, and developed over relatively long periods of exposure (median time 172 days from hire date to diagnosis).

A high prevalence of nasal damage was also found in a study of Swedish chrome platers (Ex. 9–126). Platers exposed to average 8-hour Cr(VI) concentrations above 2 $\mu g/m^3$ with short-term excursions above 20 $\mu g/m^3$ from work near the chrome bath had a nearly 50 percent prevalence (*i.e.* 11 out of 24 workers) of nasal ulcerations and septum perforations. These data, along with that from the Gibb cohort, suggest a substantial and clearly significant risk of nasal tissue damage from regular short-term exposures above 20 $\mu g/m^3$. More than half of the platers (*i.e.* 8 of 12 subjects) with short-term excursions to somewhat lower Cr(VI) concentrations between 2.5 and 11 $\mu g/m^3$ had atrophied nasal mucosa (*i.e.* cellular deterioration of the nasal passages) but not ulcerations or perforations. This high occurrence of nasal atrophy was substantially greater than found among the workers with mean Cr(VI) levels less than 2 $\mu g/m^3$ (4 out of 19 subjects) and short-term Cr(VI) exposures less than 1 $\mu g/m^3$ (1 of 10 subjects) or among the office workers not exposed to Cr(VI) (0 of 19 subjects). This result is consistent with a concentration-dependant gradation in response from relatively mild nasal tissue atrophy to the more serious nasal tissue ulceration with short-term exposures to Cr(VI) levels above about 10 $\mu g/m^3$. For this reason, OSHA believes short-term Cr(VI) exposures regularly exceeding about 10 $\mu g/m^3$ may still result in a considerable risk of nasal impairment. However, the available data do not allow a precise quantitative estimation of this risk.

While dermal exposure to Cr(VI) can cause material impairment to the skin, a credible quantitative assessment of the risk is not possible because few occupational studies have measured the amounts of Cr(VI) that contact the skin during job activities; studies rarely distinguish dermatitis due to Cr(VI) from other occupational and non-occupational sources of dermatitis; and immune hypersensitivity responses, such as ACD, have an exceedingly complex dose-response.

C. Significance of Risk and Risk Reduction

The Supreme Court's benzene decision of 1980 states that ''before he can promulgate any permanent health or safety standard, the Secretary [of Labor] is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' (*IUD* v. *API*, 448 U.S. at 642). The Court broadly describes the range of risks OSHA might determine to be significant:

> It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*IUD* v. *API*, 448 U.S. at 655).

The Court further stated, ''The requirement that a ''significant'' risk be identified is not a mathematical straitjacket * * *. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as ''unsafe''' and proceed to promulgate a regulation (*IUD* v. *API*, 448 U.S. at 655).

Table VII–1 presents the estimated excess risk of lung cancer associated with various levels of Cr(VI) exposure allowed under the current rule, based on OSHA's risk assessment and assuming either 20 years' or 45 years' occupational exposure to Cr(VI) as indicated. The purpose of the OSH Act, as stated in Section 6(b), is to ensure ''that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard * * * for the period of his working life.'' 29 U.S.C. 655(b)(5). Taking a 45-year working life from age 20 to age 65, as OSHA has always done in significant risk determinations for previous standards, the Agency finds an excess lung cancer risk of approximately 100 to 350 per 1000 workers exposed at the previous PEL of 52 $\mu g/m^3$ Cr(VI). This risk is clearly significant, falling well above the level of risk the Supreme Court indicated a reasonable person might consider acceptable. Even assuming only a 20-year working life, the excess risk of about 50 to 200 per 1000 workers is still clearly significant. The new PEL of 5 $\mu g/m^3$ Cr(VI) is expected to reduce these risks substantially, to below 50 excess lung cancers per 1000 workers. However, even at the new PEL, the risk posed to workers with a lifetime of regular exposure is still clearly significant.

Table VII-1: Expected Excess Lung Cancer Deaths per 1000 Workers

	Cr(VI) Concentration, ug/m³	*20-year Exposure*	*45-year Exposure*
Previous PEL:	52	43 - 198	101 - 351
	20	17 - 83	41 - 164
	10	9 - 43	21 - 86
New PEL:	5.0	4.3 - 22	10 - 45
	1.0	0.85 - 4.4	2.1 - 9.1
	0.5	0.43 - 2.2	1.1 - 4.6
	0.25	0.21 - 1.1	0.53 - 2.3

Workers exposed to concentrations of Cr(VI) lower than the new PEL and for shorter periods of time may also have significant excess cancer risk. The Agency's risk estimates are roughly proportional to duration for any given exposure concentration. The estimated risk to workers exposed at any fixed concentration for 10 years is about one-half the risk to workers exposed for 20 years; the risk for five years' exposure is about one-fourth the risk for 20 years. For example, about 11 to 55 out of 1000 workers exposed at the previous PEL for five years are expected to develop lung cancer as a result of their exposure. Those exposed to 10 $\mu g/m^3$ Cr(VI) for 5 years have an estimated excess risk of about 2–12 lung cancer deaths per 1000 workers. It is thus not only workers exposed for many years at high levels who have significant cancer risk under the old standard; even workers exposed for shorter periods at levels below the previous PEL are at substantial risk, and will benefit from implementation of the new PEL.

To further demonstrate significant risk, OSHA compares the risk from currently permissible Cr(VI) exposures to risks found across a broad variety of occupations. The Agency has used similar occupational risk comparisons in the significant risk determination for substance-specific standards promulgated since the benzene decision. This approach is supported by evidence in the legislative record that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not ''to establish a utopia free from any hazards''(116 Cong. Rec. 37614 (1970), Leg. Hist 480), or to address risks comparable to those that exist in virtually any occupation or workplace. It is also consistent with Section 6(g) of the OSH Act, which states:

> In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments.

Fatal injury rates for most U.S. industries and occupations may be obtained from data collected by the Bureau of Labor Statistics. Table VII–2 shows average annual fatality rates per 1000 employees for several industries between 1992 and 2001, as well as projected fatalities per 1000 employees for periods of 20 and 45 years based on these annual rates (Ex. 35–305). While it is difficult to compare aggregate fatality rates meaningfully to the risks estimated in the quantitative risk assessment for Cr(VI), which target one specific hazard (inhalation exposure to Cr(VI)) and health outcome (lung cancer), these rates provide a useful frame of reference for considering risk from Cr(VI) inhalation. Regular exposures at high levels, including the previous PEL of 52 $\mu g/m^3$ Cr(VI), are expected to cause substantially more deaths per 1000 workers from lung cancer than result from occupational injuries in most private industry. At the new PEL of 5 $\mu g/m^3$ Cr(VI) the Agency's estimated range of excess lung cancer mortality overlaps the fatality risk for mining and approaches that for construction, but still clearly exceeds the risk in lower-risk industries such as manufacturing.

Table VII-2: Fatal Injuries per 1000 Employees, by Industry

	over 1 year	*over 20 years*	*over 45 years*
All Private Industry:	0.06	1.1	2.5
Coal Mining:	0.41	8.3	18.6
Mining (General):	0.27	5.5	12.3
Construction:	0.19	3.9	8.7
Manufacturing:	0.04	0.8	1.8
Wholesale Trade:	0.04	0.8	1.7
Retail Trade:	0.03	0.6	1.4
Finance, Insurance, and Real Estate:	0.02	0.3	0.7
Health Services:	0.01	0.2	0.4

Because there is little available information on the incidence of occupational cancer, risk from Cr(VI) exposure cannot be compared with overall risk from other workplace carcinogens. However, OSHA's previous risk assessments provide estimates of risk from exposure to certain carcinogens. These risk assessments, like the current assessment for Cr(VI), were based on animal or human data of reasonable or high quality and used the best information then available. Table VII–3 shows the Agency's best estimates of cancer risk from 45 years' occupational exposure to several carcinogens, as published in the preambles to final rules promulgated since the benzene decision in 1980.

Table VII-3: Selected OSHA Risk Estimates (Excess Cancers per 1000 Workers)

Standard	*Risk at prior PEL*	*Risk at new PEL*	*Federal Register date*
Ethylene Oxide	63 - 109 per 1000	1.2 - 2.3 per 1000	June 22, 1984
Asbestos	64 per 1000	6.7 per 1000	June 20, 1986
Benzene	95 per 1000	10 per 1000	September 11, 1987
Formaldehyde	0.43 – 18.9 per 1000*	.0056 – 2.64 per 1000*	December 4, 1987
Methylenedianiline	6 - 30 per 1000**	0.8 per 1000	August 10, 1992
Cadmium	58 - 157 per 1000	3 - 15 per 1000	September 14, 1992
1,3-Butadiene	11.2 - 59.4 per 1000	1.3 - 8.1 per 1000	November 4, 1996
Methylene Chloride	126 per 1000	3.6 per 1000	January 10, 1997
Chromium VI	101 - 351 per 1000	10 - 45 per 1000	2006

*** range is based on maximum likelihood estimate (0.43, .0056) and upper 95% confidence limit (18.9, 2.64)**

**** no prior standard; reported risk is based on estimated exposures at the time of the rulemaking**

The Cr(VI) risk estimate at the previous PEL is higher than many risks the Agency has found to be significant in previous rules (Table VII–3, ''Risk at Previous PEL''). The estimated risk from lifetime occupational exposure to Cr(VI) at the new PEL is 10–45 excess lung cancer deaths per 1000 workers, a range which overlaps the estimated risks from exposure at the current PELs for benzene and cadmium (Table VII–3, ''Risk at new PEL'').

Based on the results of the quantitative risk assessment, the Supreme Court's guidance on acceptable risk, comparison with rates of occupational fatality in various industries, and comparison with cancer risk estimates developed in previous rules, OSHA finds that the risk of lung cancer posed to workers under the previous permissible level of occupational Cr(VI) exposure is significant. The new PEL of 5 is expected to reduce risks to workers in Cr(VI)-exposed occupations substantially (by about 8- to 10-fold). OSHA additionally finds that nasal tissue ulceration and septum perforation can occur under exposure conditions allowed by the previous PEL leading to an additional health risk beyond the significant lung cancer risk present. The reduction of the Cr(VI) PEL from 52 $\mu g/m^3$ to 5 $\mu g/m^3$ is expected to substantially reduce workers' risk of nasal tissue damage. With regard to dermal effects from Cr(VI) exposure, OSHA believes that provision of appropriate protective clothing and adherence to prescribed hygiene practices will serve to protect workers from the risk of Cr(VI)-induced skin impairment.

VIII. Summary of the Final Economic and Regulatory Flexibility Analysis

A. Introduction

OSHA's Final Economic and Regulatory Flexibility Analysis (FEA) addresses issues related to the costs, benefits, technological and economic feasibility, and economic impacts (including small business impacts) of the Agency's Occupational Exposure to Hexavalent Chromium rule. The full Final Economic and Regulatory Flexibility Analysis has been placed in the docket as Ex. 49. The analysis also evaluates alternatives that were considered by the agency before adopting the final rule. This rule is an economically significant rule under Section 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order. The purpose of this Final Economic and Regulatory Flexibility Analysis is to:

- Identify the establishments and industries potentially affected by the final rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits of the rule in terms of the reduction in lung cancer and dermatoses employers will achieve by coming into compliance with the standard;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the final standard;
- Assess the economic feasibility of the rule for affected industries; and
- Evaluate the principal regulatory alternatives to the final rule that OSHA has considered.

The full Final Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Industrial Profile
Chapter III. Technological Feasibility
Chapter IV. Costs of Compliance
Chapter V. Economic Impacts
Chapter VI. Benefits and Net Benefits
Chapter VII. Final Regulatory Flexibility Analysis
Chapter VIII. Environmental Impacts
Chapter IX. Assessing the Need for Regulation.

These chapters are summarized in sections B to H of this Preamble summary.

B. Introduction and Industrial Profile (Chapters I and II)

The final standard for occupational exposure to hexavalent chromium was developed by OSHA in response to evidence that occupational exposure to Cr(VI) poses a significant risk of lung cancer, nasal septum ulcerations and perforations, and dermatoses. Exposure to Cr(VI) may also lead to asthma. To protect exposed workers from these effects, OSHA has set a Permissible Exposure Limit (PEL) of 5 $\mu g/m^3$ measured as an 8-hour time weighted average. OSHA also examined alternative PELs ranging from 20 $\mu g/m^3$ to 0.25 $\mu g/m^3$ measured as 8-hour time weighted averages.

OSHA's final standards for occupational exposure to Cr(VI) are similar in format and content to other OSHA health standards promulgated under Section 6(b)(5) of the Act. In addition to setting PELs, the final rule requires employers to:

- Monitor the exposure of employees (though allowing a performance-oriented approach to monitoring);
- Establish regulated areas when exposures may reasonably be expected to exceed the PEL (except in shipyards and construction);
- Implement engineering and work practice controls to reduce employee exposures to Cr(VI);
- Provide respiratory protection to supplement engineering and work practice controls where those controls are not feasible, where such controls are insufficient to meet the PEL, or in emergencies;
- Provide other protective clothing and equipment as necessary for dermal protection;
- Make industrial hygiene facilities (hand washing stations) available in some situations;
- Provide medical surveillance when employees are exposed above the action level for 30 days or more;
- Train workers about the hazards of Cr(VI) (including elements already required by OSHA's Hazard Communication Standard); and
- Keep records related to the standard.

The contents of the standards, and the reasons for issuing separate standards for general industry, construction and shipyard employment, are more fully discussed in the Summary and Explanation section of this Preamble.

Chapter II of the full FEA describes the uses of Cr(VI) and the industries in which such uses occur. Employee exposures are defined in terms of ''application groups,'' i.e., groups of firms where employees are exposed to Cr(VI) when performing a particular function. This methodology is appropriate to exposure to Cr(VI) where a widely used chemical like chromium may lead to exposures in many kinds of firms in many industries but the processes used, exposures generated, and controls needed to achieve compliance may be the same. For example, because a given type of welding produces Cr(VI) exposures that are essentially the same regardless of whether the welding occurs in a ship, on a construction site, as part of a manufacturing process, or as part of a repair process, it is appropriate to analyze such processes as a group. However, OSHA's analyses of costs and economic feasibility reflect the fact that baseline controls, ease of implementing ancillary provisions, and the economic situation of the employer may differ within different industries in an application group.

The most common sources of occupational exposure to Cr(VI), in addition to the production and use of chromium metal and chromium metal alloys, are chromium electroplating; welding of metals containing chromium, particularly stainless steel or other high-chromium steels, or with chromium coatings; and the production and use of Cr(VI)-containing compounds, particularly Cr(VI) pigments, but also Cr(VI) catalysts, chromic acid, and the production of chromium-containing pesticides.

Some industries are seeing a sharp decline in chromium use. However, many of the industries that are seeing a sharp decline have either a small number of employees or have low exposure levels (e.g., wood working, printing ink manufacturers, and printing). In the case of lead chromate in pigment production, OSHA's sources indicate that there is no longer domestic output containing lead chromates. Therefore, this trend has been recognized in the FEA. Painting activities in general industry primarily involve the application of strontium chromate coatings to aerospace parts; these exposures are likely to continue into the foreseeable future. Similarly, removal of lead chromate paints in construction and maritime is likely to present occupational risks for many years.

In application groups where exposures are particularly significant, both in terms of workforce size and exposure levels—notably in electroplating and welding—OSHA anticipates very little decline in exposures to hexavalent chromium due to the low potential for substitution in the foreseeable future.

OSHA has made a number of changes to the industrial profile of the application groups as a result of comments on the proposed rule. Among the most important are:

- Additions to the electroplating application group to include such processes as chrome conversion, which were not considered at the time of the proposal;
- Additions to the painting application group to cover downstream users, particularly automobile repair shops and construction traffic painting;
- Additions to glass manufacturing to cover fiberglass, flat glass, and container glass industries;
- Addition of the forging industry;
- Addition of the ready mixed concrete industry;

- Additions to the welding application group to include welding on low-chromium steel and increase the estimated number of exposed workers in the maritime sector; and
- More careful division of the many different industries in which electroplating, welding and painting may appear as applications.

Table VIII–1 shows the application groups analyzed in OSHA's FEA, as well as the industries in each application group, and for each provides the number of establishments affected, the number of employees working in those establishments, the number of entities (firms or governments) fitting SBA's small business criteria for the industry, and the number of employees in those firms. (The table shows data for both establishments and entities—defined as firms or governments. An entity may own more than one establishment.) The table also shows the revenues of affected establishment and entities, updated to reflect 2002 data. (This table provides the latest available data at the time this analysis was produced.) As shown in the table, there are a total of 52,000 establishments affected by the final standard.

Various types of welding applications account for the greatest number of establishments and number of employees affected by the final standard.

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Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Entities^{BB}		Affected Establishments^{BB}			
Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)^{A}	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
1 Electroplating - General Industry	All General Industry^{B}	All General Industry	500 employees	5,284	5,399	3,820	2,030	5,582	5,850
	237	Heavy construction (234)	$28.5 million	3	3	1	2	3	3
	238	Special trade contractors (235)	$12 million	5	5	3	2	5	5
	313	Textile mills	500 employees	6	7	3	4	6	7
	314	Textile product mills	500 employees	14	15	10	5	14	15
	315	Apparel mfg	500 employees	3	3	1	2	3	3
	316	Leather & allied product mfg	500 employees	8	8	3	6	9	9
	321	Wood product mfg	500 employees	27	28	19	11	29	30
	322	Paper mfg	500 employees	42	45	22	42	48	64
	323	Printing & related support activities	500 employees	72	73	56	21	75	77
	324	Petroleum & coal products mfg	500 employees	6	7	5	4	7	9
	325	Chemical mfg	500 employees	40	42	28	25	43	53
	326	Plastics & rubber products mfg	500 employees	35	37	19	26	39	45
	327	Nonmetallic mineral product mfg	500 employees	2	3	1	2	2	3
	331^{C}	Primary metal mfg	500 employees	18	19	11	11	19	22
	332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	500 employees	2,598	2,630	1,948	879	2,771	2,827
	Other 332^{D}	Fabricated Metal Product Manufacturing	500 employees	1,027	1,042	738	372	1,076	1,110
	333^{E}	Machinery Manufacturing	500 employees	422	435	287	181	441	468
	334	Computer & electronic product mfg	500 employees	217	228	134	116	226	250
	335	Electrical equipment, appliance, & component mfg	500 employees	69	73	39	45	73	84
	336 (except 33661)^{F}	Transportation Equipment Manufacturing	1,000 employees	214	226	108	164	224	272
	339	Miscellaneous Manufacturing	500 employees	366	371	298	85	374	383
	423	Wholesale trade, durable goods (421)	100 employees	0	1	5	0	0	5
	441	Motor vehicle & parts dealers	$6 million	2	2	2	0	2	2
	442	Furniture & home furnishings stores	$6 million	1	1	1	0	1	1
	443	Electronics & appliance stores	$7.50 million	1	1	1	0	1	1
	444	Building material & garden equipment & supplies dealers	$6 million	2	2	2	0	2	2
	446	Health & personal care stores	$6 million	1	1	1	0	1	1
	453	Miscellaneous store retailers	$6 million	2	2	2	0	2	2
	454	Nonstore retailers	$6 million	1	1	1	0	1	1
	511	Publishing industries	500 employees	11	12	7	10	13	17
	512	Motion picture & sound recording industries	$6 million	7	8	6	3	8	9
	519	Information services & data processing services (514)	$6 million	0	1	1	0	0	1
	522	Credit intermediation & related activities	$6 million	7	8	6	2	7	8
	532	Rental & leasing services	$6 million	2	3	2	1	2	3
	541	Professional, scientific, & technical services	$6 million	28	29	27	3	29	30
	561	Administrative & support services	$6 million	12	13	11	3	13	14
	562	Waste management & remediation services	$10.5 million	3	4	2	2	3	4
	711	Performing arts, spectator sports, & related industries	$6 million	1	1	1	0	1	1
	812	Personal & laundry services	$6 million	9	9	8	1	9	9
Total Electroplating				5,284	5,399	3,820	2,030	5,582	5,850

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
1	Electroplating - General Industry	All General Industry[B]	All General Industry	62,697	66,857	$51,456,897,289	$15,327,796,671	$73,703,107,293	$9,738,247	$4,012,512	$13,651,252
		237	Heavy construction (234)	6	6	$36,861,189	$1,105,508	$36,861,189	$12,287,063	$1,105,508	$12,287,063
		238	Special trade contractors (235)	54	54	$13,532,915	$1,314,463	$13,532,915	$2,706,583	$438,154	$2,706,583
		313	Textile mills	81	95	$32,610,167	$1,169,688	$43,090,327	$5,435,028	$389,896	$6,155,761
		314	Textile product mills	19	20	$66,732,450	$7,663,020	$81,499,808	$4,766,604	$766,302	$5,433,321
		315	Apparel mfg	18	18	$32,969,030	$1,041,838	$32,969,030	$10,989,677	$1,041,838	$10,989,677
		316	Leather & allied product mfg	30	30	$124,966,875	$2,920,839	$124,966,875	$15,620,859	$973,613	$15,620,859
		321	Wood product mfg	60	62	$154,224,250	$20,043,706	$167,642,304	$5,712,009	$1,054,932	$5,987,225
		322	Paper mfg	1,332	1,776	$1,133,840,705	$50,865,731	$1,800,286,843	$26,996,207	$2,312,079	$40,006,374
		323	Printing & related support activities	377	387	$213,850,692	$36,946,323	$232,472,204	$2,970,148	$659,756	$3,184,551
		324	Petroleum & coal products mfg	93	120	$995,627,241	$190,557,087	$1,800,697,395	$165,937,873	$38,111,417	$257,242,485
		325	Chemical mfg	335	413	$1,461,395,879	$128,038,151	$2,350,301,031	$36,534,897	$4,572,791	$55,959,548
		326	Plastics & rubber products mfg	389	449	$322,684,612	$19,062,639	$413,771,203	$9,219,560	$1,003,297	$11,183,005
		327	Nonmetallic mineral product mfg	7	10	$10,976,726	$1,179,027	$20,774,425	$5,488,363	$1,179,027	$6,924,808
		331[C]	Primary metal mfg	19	22	$354,993,904	$18,504,671	$481,177,367	$19,721,884	$1,682,243	$25,325,125
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	29,834	30,437	$2,282,817,042	$485,520,234	$2,296,774,503	$878,682	$249,240	$873,298
		Other 332[D]	Fabricated Metal Product Manufacturing	8,425	8,691	$4,563,825,718	$707,722,840	$4,951,717,723	$4,443,842	$958,974	$4,752,128
		333[E]	Machinery Manufacturing	5,490	5,826	$4,440,193,595	$462,818,241	$5,137,525,638	$10,521,786	$1,612,607	$11,810,404
		334	Computer & electronic product mfg	5,332	5,898	$7,063,801,532	$322,969,784	$8,822,279,379	$32,552,081	$2,410,222	$38,694,208
		335	Electrical equipment, appliance, & component mfg	1,053	1,212	$2,711,183,335	$116,438,229	$3,550,659,693	$39,292,512	$2,985,596	$48,639,174
		336 (except 33661)[F]	Transportation Equipment Manufacturing	6,531	7,930	$17,497,397,037	$350,890,260	$24,592,503,290	$81,763,538	$3,248,984	$108,816,386
		339	Miscellaneous Manufacturing	2,678	2,742	$2,209,830,532	$365,607,935	$2,428,225,313	$6,037,788	$1,226,872	$6,545,082
		423	Wholesale trade, durable goods (421)	0	12	$0	$7,789,912	$7,789,912	NA	$1,557,982	$7,789,912
		441	Motor vehicle & parts dealers	6	6	$3,652,238	$3,652,238	$3,652,238	$1,826,119	$1,826,119	$1,826,119
		442	Furniture & home furnishings stores	4	4	$647,301	$647,301	$647,301	$647,301	$647,301	$647,301
		443	Electronics & appliance stores	3	3	$857,482	$857,482	$857,482	$857,482	$857,482	$857,482
		444	Building material & garden equipment & supplies dealers	6	6	$1,547,548	$1,547,548	$1,547,548	$773,774	$773,774	$773,774
		446	Health & personal care stores	5	5	$973,952	$973,952	$973,952	$973,952	$973,952	$973,952
		453	Miscellaneous store retailers	6	6	$1,200,604	$1,200,604	$1,200,604	$600,302	$600,302	$600,302
		454	Nonstore retailers	3	3	$706,333	$706,333	$706,333	$706,333	$706,333	$706,333
		511	Publishing industries	291	380	$104,695,551	$6,750,612	$169,992,176	$9,517,777	$964,373	$14,166,015
		512	Motion picture & sound recording industries	99	111	$32,687,285	$5,274,515	$46,393,670	$4,669,612	$879,086	$5,799,209
		519	Information services & data processing services (514)	0	1	$0	$137,552	$137,552	NA	$137,552	$137,552
		522	Credit intermediation & related activities	15	17	$14,440,128	$7,983,657	$20,896,599	$2,062,875	$1,330,610	$2,612,075
		532	Rental & leasing services	3	4	$1,299,324	$1,299,324	$3,673,519	$649,662	$649,662	$1,224,506
		541	Professional, scientific, & technical services	43	44	$17,340,327	$8,422,977	$21,799,002	$619,297	$311,962	$751,690
		561	Administrative & support services	33	36	$7,886,351	$1,475,905	$11,091,574	$657,196	$134,173	$853,198
		562	Waste management & remediation services	7	9	$8,620,657	$1,473,642	$15,767,673	$2,873,552	$736,821	$3,941,918
		711	Performing arts, spectator sports, & related industries	1	1	$82,883	$82,883	$82,883	$82,883	$82,883	$82,883
		812	Personal & laundry services	11	11	$2,219,893	$1,441,813	$2,219,893	$246,655	$180,227	$246,655
	Total Electroplating			62,697	66,857	$45,923,173,283	$3,344,098,464	$59,689,158,366	$8,690,987	$875,418	$11,055,595

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Entities^{BB}		Affected Establishments^{BB}			
Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)^{A}	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
2A Welding - General Industry (stainless steel)	All General Industry^{H}	All General Industry		14,566	15,016	9,205	8,153	15,274	17,358
	113	Forestry and Logging	$6 million	5	6	4	2	5	6
	221	Utilities	500 employees	91	94	88	37	96	125
	311^{C}	Food Manufacturing	500 employees	12	13	7	9	13	16
	312	Beverage and Tobacco Product Manufacturing	500 employees	2	2	1	1	2	2
	313	Textile mills	500 employees	9	10	3	10	10	13
	314	Textile product mills	500 employees	67	68	48	24	69	72
	315	Apparel mfg	500 employees	18	18	2	18	20	20
	316	Leather & allied product mfg	500 employees	5	5	0	5	6	5
	321	Wood product mfg	500 employees	61	62	50	15	63	65
	322	Paper mfg	500 employees	187	199	91	196	214	288
	323	Printing & related support activities	500 employees	56	57	17	50	63	67
	324	Petroleum & coal products mfg	500 employees	7	8	6	3	8	10
	325	Chemical mfg	500 employees	90	94	37	112	104	149
	326	Plastics & rubber products mfg	500 employees	88	90	21	106	104	127
	327	Nonmetallic mineral product mfg	500 employees	24	25	9	38	34	47
	332	Fabricated Metal Product Manufacturing	500 employees	3,975	4,017	2,164	2,337	4,286	4,501
	333	Machinery Manufacturing	500 employees	1,749	1,797	1,079	897	1,844	1,976
	334	Computer & electronic product mfg	500 employees	915	952	489	597	960	1,086
	335	Electrical equipment, appliance, & component mfg	500 employees	187	191	44	211	206	255
	336 (except 33661)	Transportation Equipment Manufacturing	1,000 employees	745	764	223	810	796	1,033
	337	Furniture & Related Product Manufacturing	500 employees	561	565	370	233	582	603
	339	Miscellaneous Manufacturing	500 employees	899	906	440	573	955	1,013
	423	Wholesale trade, durable goods (421)	100 employees	374	378	368	37	391	405
	424	Merchant Wholesalers, nondurable goods (422)	100 employees	7	8	2	12	10	14
	441	Motor vehicle & parts dealers	$6 million	220	221	176	114	273	290
	442	Furniture & home furnishings stores	$6 million	100	101	97	27	111	124
	443	Electronics & appliance stores	$7.50 million	60	61	60	17	65	77
	444	Building material & garden equipment & supplies dealers	$6 million	181	182	163	72	204	235
	445	Food and Beverage Stores	$6 million	10	11	9	2	10	11
	446	Health & personal care stores	$6 million	119	120	117	63	129	180
	447	Gasoline Stations	$7.5 million	6	7	6	2	7	8
	448	Clothing and Clothing Accessory Stores	$7.5 million	5	6	5	1	5	6
	451	Sporting Good, Hobby, Book and Music Stores	$6 million	8	9	8	2	9	10
	452	General Merchandise Stores	$23 million	1	2	1	4	1	5
	453	Miscellaneous store retailers	$6 million	188	189	183	48	208	231
	454	Nonstore retailers	$6 million	68	69	60	26	75	86
	481	Air Transportation	1,500 employees	1	2	0	2	1	2
	483	Water Transportation	500 employees	1	1	0	3	2	3
	484	Truck Transportation	$21.5 million	32	33	18	33	41	51
	485	Transit and Ground Passenger Transportation	$6 million	1	2	0	1	1	1

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
				Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
2A	Welding - General Industry (stainless steel)	All General Industry[H]	All General Industry	39,471	45,326	$87,511,907,381	$6,804,597,966	$97,668,286,331	$6,007,957	$739,228	$6,504,281
		113	Forestry and Logging	6	7	$6,886,523	$2,399,377	$9,356,786	$1,377,305	$599,844	$1,559,464
		221	Utilities	1,039	1,356	$711,902,470	$303,007,421	$2,005,609,190	$7,823,104	$3,437,806	$21,336,268
		311[C]	Food Manufacturing	96	122	$219,759,576	$10,468,330	$326,427,261	$18,313,298	$1,402,737	$25,109,789
		312	Beverage and Tobacco Product Manufacturing	12	12	$169,377,027	$4,012,897	$230,068,104	$84,688,514	$6,093,071	$115,034,052
		313	Textile mills	27	35	$74,530,806	$1,242,684	$102,782,542	$8,281,201	$389,896	$10,278,254
		314	Textile product mills	10	11	$346,897,006	$37,111,607	$388,976,686	$5,177,567	$766,302	$5,720,245
		315	Apparel mfg	26	26	$289,428,407	$2,083,675	$296,143,334	$16,079,356	$1,041,838	$16,452,407
		316	Leather & allied product mfg	11	10	$101,705,030	$0	$110,305,614	$20,341,006	$0	$22,061,123
		321	Wood product mfg	88	91	$227,181,301	$52,746,594	$257,424,388	$3,724,284	$1,054,932	$4,152,006
		322	Paper mfg	734	987	$5,333,703,845	$210,859,936	$8,390,782,758	$28,522,480	$2,312,079	$42,164,737
		323	Printing & related support activities	69	73	$439,510,634	$11,215,848	$478,639,087	$7,848,404	$659,756	$8,397,177
		324	Petroleum & coal products mfg	178	216	$1,033,738,658	$236,706,202	$1,640,901,514	$147,676,951	$38,111,417	$205,112,689
		325	Chemical mfg	547	784	$6,124,857,791	$169,329,905	$10,125,724,512	$68,053,975	$4,572,791	$107,720,474
		326	Plastics & rubber products mfg	308	377	$1,281,100,418	$21,069,233	$1,635,534,135	$14,557,959	$1,003,297	$18,172,602
		327	Nonmetallic mineral product mfg	40	55	$255,553,718	$10,611,245	$378,483,192	$10,648,072	$1,179,027	$15,139,328
		332	Fabricated Metal Product Manufacturing	7,082	7,437	$26,901,235,463	$2,122,071,019	$29,390,625,465	$6,767,606	$980,705	$7,316,561
		333	Machinery Manufacturing	4,983	5,340	$21,521,958,785	$1,740,687,254	$24,897,433,003	$12,305,294	$1,612,607	$13,854,999
		334	Computer & electronic product mfg	4,162	4,709	$35,759,586,131	$1,178,611,803	$44,940,507,682	$39,081,515	$2,410,222	$47,206,416
		335	Electrical equipment, appliance, & component mfg	879	1,089	$12,494,563,479	$131,366,207	$16,250,853,864	$66,815,847	$2,985,596	$85,083,005
		336 (except 33661)	Transportation Equipment Manufacturing	6,796	8,816	$82,576,680,965	$700,387,372	$116,386,566,187	$110,841,183	$3,140,751	$152,338,437
		337	Furniture & Related Product Manufacturing	1,296	1,343	$2,393,328,162	$193,006,181	$2,599,932,010	$4,266,182	$521,576	$4,601,650
		339	Miscellaneous Manufacturing	2,503	2,655	$13,036,858,497	$539,823,797	$14,445,497,799	$14,501,511	$1,226,872	$15,944,258
		423	Wholesale trade, durable goods (421)	355	368	$801,764,141	$482,726,253	$884,252,223	$2,143,754	$1,311,756	$2,339,292
		424	Merchant Wholesalers, nondurable goods (422)	1	2	$179,219,444	$4,397,011	$264,947,120	$25,602,778	$2,198,505	$33,118,390
		441	Motor vehicle & parts dealers	177	188	$1,589,150,769	$321,396,920	$1,777,817,446	$7,223,413	$1,826,119	$8,044,423
		442	Furniture & home furnishings stores	88	98	$105,473,838	$62,788,217	$133,289,363	$1,054,738	$647,301	$1,319,697
		443	Electronics & appliance stores	52	61	$76,573,336	$51,448,935	$115,268,384	$1,276,222	$857,482	$1,889,646
		444	Building material & garden equipment & supplies dealers	152	175	$309,122,426	$126,125,154	$430,090,019	$1,707,859	$773,774	$2,363,132
		445	Food and Beverage Stores	12	13	$14,272,941	$5,525,323	$24,116,746	$1,427,294	$640,255	$2,192,431
		446	Health & personal care stores	85	119	$170,204,687	$113,952,427	$349,945,484	$1,430,291	$973,952	$2,916,212
		447	Gasoline Stations	8	9	$6,390,144	$4,713,651	$7,723,610	$1,065,024	$785,609	$1,103,373
		448	Clothing and Clothing Accessory Stores	5	6	$1,966,617	$1,966,617	$3,316,864	$393,323	$393,323	$552,811
		451	Sporting Good, Hobby, Book and Music Stores	35	39	$6,169,002	$3,929,087	$8,516,688	$771,125	$485,283	$946,299
		452	General Merchandise Stores	0	1	$811,413	$811,413	$73,335,702	$811,413	$811,413	$36,667,851
		453	Miscellaneous store retailers	169	187	$177,718,492	$109,855,292	$225,261,991	$945,311	$600,302	$1,191,862
		454	Nonstore retailers	54	62	$149,611,401	$42,379,981	$215,276,968	$2,200,168	$706,333	$3,119,956
		481	Air Transportation	2	3	$0	$0	$67,287,597	$0	$0	$33,643,799
		483	Water Transportation	3	5	$45,630,582	$0	$68,445,873	$45,630,582	$0	$68,445,873
		484	Truck Transportation	47	59	$146,303,328	$7,842,895	$206,431,155	$4,571,979	$435,716	$6,255,490
		485	Transit and Ground Passenger Transportation	1	1	$0	$0	$3,038,336	$0	$0	$1,519,168

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

					Affected Entities^{BB}		Affected Establishments^{BB}			
	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)^{A}	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
		486	Pipeline Transportation	1,500 employees	6	9	6	4	6	10
		487	Scenic and Sightseeing Transportation	$6 million	3	3	1	2	3	3
		488	Support Activities for Transportation	$6 million	78	79	47	99	105	146
		492	Couriers and Messengers	1,500 employees	4	5	2	11	5	13
		493	Warehousing and Storage	$21.5 million	2	3	1	4	3	5
		511	Publishing industries	500 employees	27	28	20	20	31	40
		512	Motion picture & sound recording industries	$6 million	22	23	18	14	25	32
		519	Information services & data processing services (514)	$6 million	19	20	15	14	22	29
		522	Credit intermediation & related activities	$6 million	28	29	24	57	42	81
		531	Real Estate	$6 million	43	44	40	16	52	56
		532	Rental & leasing services	$6 million	58	59	54	54	72	108
		541	Professional, scientific, & technical services	$6 million	417	418	311	250	487	561
		561	Administrative & support services	$6 million	1,774	1,794	1,568	518	1,874	2,086
		562	Waste management & remediation services	$10.5 million	105	106	90	44	116	133
		611	Educational Services	$6 million	24	25	14	15	26	29
		621	Ambulatory Health Care Services	$8.5 million	23	24	11	33	35	44
		622	Hospitals	$29 million	1	2	0	2	1	2
		623	Nursing and Residential Care Facilities	$6 million	2	2	1	2	3	3
		624	Social Assistance	$6 million	1	1	1	1	2	2
		711	Performing arts, spectator sports, & related industries	$6 million	17	17	10	8	18	18
		713	Amusement, Gambling, and Recreational Industries	$6 million	85	86	65	30	90	95
		722	Food Services and Drinking Places	$6 million	14	15	10	11	18	21
		811	Repair and Maintenance	$6 million	239	240	202	103	282	305
		812	Personal & laundry services	$6 million	85	86	78	38	103	116
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$6 million	21	21	18	4	22	22
2B	Welding - Maritime Industry (stainless steel)	336611^{I}	Ship Building and Repairing	1,000 employees	261	279	111	196	276	307
2C	Welding - Construction Industry (stainless steel)	233^{S}, 234^{T},235^{U}	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$28.5 million^{J}	2,394	2,419	2,220	277	2,410	2,497
2D	Welding - Government (stainless steel)	999200	State	50,000 population	0	26	0	26	0	26
		999300	Local	50,000 population	231	815	0	815	231	815
	Total Welding (stainless steel)				17,119	18,023	0 11,405	9,417	18,343	20,821
2A1	Welding - General Industry (carbon steel)	All General Industry^{H}	All General Industry		14,566	15,016	11,099	10,903	15,274	22,002
		113	Forestry and Logging	6 million	6	7	5	2	7	7
		221	Utilities	500 employees	111	114	107	45	117	152
		311	Food Manufacturing	500 employees	15	16	9	11	16	20
		312	Beverage and Tobacco Product Manufacturing	500 employees	2	2	1	2	2	2
		313	Textile mills	500 employees	11	12	4	12	13	16
		314	Textile product mills	500 employees	82	83	59	29	85	88
		315	Apparel mfg	500 employees	22	22	2	22	24	25
		316	Leather & allied product mfg	500 employees	6	6	0	7	7	7

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
		486	Pipeline Transportation	18	31	$1,903,648	$1,903,648	$7,830,077	$317,275	$317,275	$870,009
		487	Scenic and Sightseeing Transportation	3	2	$9,254,377	$161,092	$9,431,378	$3,084,792	$268,756	$3,143,793
		488	Support Activities for Transportation	74	103	$356,490,924	$27,937,412	$581,536,105	$4,570,396	$594,413	$7,361,217
		492	Couriers and Messengers	12	29	$33,159,835	$783,885	$114,604,560	$8,289,959	$391,942	$22,920,912
		493	Warehousing and Storage	3	6	$8,482,865	$544,880	$16,420,850	$4,241,432	$544,880	$5,473,617
		511	Publishing industries	74	95	$198,853,184	$19,287,463	$340,105,130	$7,364,933	$964,373	$12,146,612
		512	Motion picture & sound recording industries	23	29	$111,768,241	$15,823,546	$206,324,342	$5,080,375	$879,086	$8,970,624
		519	Information services & data processing services (514)	17	23	$14,754,820	$2,063,276	$27,630,991	$776,569	$137,552	$1,381,550
		522	Credit intermediation & related activities	81	155	$153,276,964	$31,614,885	$400,276,586	$5,474,177	$1,330,610	$13,802,641
		531	Real Estate	67	72	$34,484,777	$10,226,543	$39,975,251	$801,972	$255,664	$908,528
		532	Rental & leasing services	87	131	$81,266,329	$35,081,742	$162,780,437	$1,401,144	$649,662	$2,758,990
		541	Professional, scientific, & technical services	702	808	$890,040,431	$97,020,222	$1,210,427,501	$2,134,390	$311,962	$2,895,760
		561	Administrative & support services	2,052	2,285	$1,212,679,105	$210,383,540	$1,872,143,260	$683,585	$134,173	$1,043,558
		562	Waste management & remediation services	3,196	3,677	$258,546,477	$66,215,253	$377,524,458	$2,462,347	$736,821	$3,561,551
		611	Educational Services	118	130	$12,557,956	$611,069	$15,136,125	$523,248	$43,194	$605,445
		621	Ambulatory Health Care Services	37	46	$32,670,695	$1,931,679	$43,790,509	$1,420,465	$175,607	$1,824,605
		622	Hospitals	6	12	$10,622,191	$4,342	$21,248,724	$10,622,191	$52,347	$10,624,362
		623	Nursing and Residential Care Facilities	6	6	$741,319	$35,341	$741,319	$370,660	$35,341	$370,660
		624	Social Assistance	4	4	$560,708	$90,370	$565,406	$560,708	$86,175	$565,406
		711	Performing arts, spectator sports, & related industries	12	12	$63,689,530	$2,108,223	$66,536,972	$3,746,443	$210,822	$3,913,940
		713	Amusement, Gambling, and Recreational Industries	96	101	$67,867,426	$10,303,330	$78,529,080	$798,440	$158,513	$913,129
		722	Food Services and Drinking Places	31	35	$10,771,664	$1,792,835	$13,836,396	$769,405	$179,284	$922,426
		811	Repair and Maintenance	364	394	$165,386,805	$50,469,484	$195,404,884	$691,995	$249,849	$814,187
		812	Personal & laundry services	154	173	$34,107,516	$14,057,679	$43,486,337	$401,265	$180,227	$505,655
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	23	23	$1,092,786	$338,767	$1,127,772	$52,037	$18,820	$53,703
2B	Welding - Maritime Industry (stainless steel)	336611[I]	Ship Building and Repairing	18,907	21,031	$6,463,579,033	$101,920,988	$7,570,453,408	$24,764,671	$918,207	$27,134,242
2C	Welding - Construction Industry (stainless steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	53,837	60,450	$3,836,250,131	$1,474,412,753	$4,282,427,802	$1,602,444	$664,150	$1,770,330
2D	Welding - Government (stainless steel)	999200	State	0	128	$0	N/A	$336,858,834,000	N/A	N/A	$12,956,109,000
		999300	Local	231	815	$847,770,000	N/A	$64,736,832,720	$3,670,000	N/A	$79,431,697
	Total Welding (stainless steel)			112,371	127,750	$229,993,356,992	$11,195,802,005	$699,442,899,062	$13,434,976	$981,671	$38,808,350
2A1	Welding - General Industry (carbon steel)	All General Industry[H]	All General Industry	52,734	60,556	$87,511,907,381	$8,204,696,667	$129,716,630,219	$6,007,957	$739,228	$8,638,561
		113	Forestry and Logging	9	9	$11,973,513	$2,920,641	$11,389,548	$1,995,586	$599,844	$1,627,078
		221	Utilities	1,390	1,812	$868,957,084	$368,835,783	$2,441,327,786	$7,828,442	$3,437,806	$21,415,156
		311	Food Manufacturing	130	163	$257,555,120	$12,742,575	$397,343,583	$17,170,341	$1,402,737	$24,833,974
		312	Beverage and Tobacco Product Manufacturing	13	16	$169,377,027	$4,884,698	$280,050,400	$84,688,514	$6,093,071	$140,025,200
		313	Textile mills	39	47	$95,881,022	$1,512,657	$125,112,049	$8,716,457	$389,896	$10,426,004
		314	Textile product mills	14	14	$429,163,116	$45,174,103	$473,481,871	$5,233,697	$766,302	$5,704,601
		315	Apparel mfg	34	35	$353,282,792	$2,536,353	$360,480,473	$16,058,309	$1,041,838	$16,385,476
		316	Leather & allied product mfg	14	13	$122,046,036	$0	$134,269,509	$20,341,006	$0	$22,378,252

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Entities[BB]		Affected Establishments[BB]			
Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
	321	Wood product mfg	500 employees	74	75	61	19	77	79
	322	Paper mfg	500 employees	227	242	111	239	260	350
	323	Printing & related support activities	500 employees	69	70	21	61	77	82
	324	Petroleum & coal products mfg	500 employees	8	9	8	4	9	12
	325	Chemical mfg	500 employees	109	113	45	136	126	181
	326	Plastics & rubber products mfg	500 employees	107	109	26	129	126	155
	327	Nonmetallic mineral product mfg	500 employees	29	30	11	46	41	57
	332	Fabricated Metal Product Manufacturing	500 employees	4,839	4,890	2,634	2,845	5,217	5,479
	333	Machinery Manufacturing	500 employees	2,129	2,187	1,314	1,091	2,245	2,405
	334	Computer & electronic product mfg	500 employees	1,114	1,160	595	727	1,168	1,322
	335	Electrical equipment, appliance, & component mfg	500 employees	227	232	54	257	250	311
	336 (except 33661)	Transportation Equipment Manufacturing	1,000 employees	906	929	271	986	968	1,257
	337	Furniture & Related Product Manufacturing	500 employees	683	688	450	284	708	734
	339	Miscellaneous Manufacturing	500 employees	1,094	1,103	536	698	1,163	1,233
	423	Wholesale trade, durable goods (421)	100 employees	455	460	448	45	476	493
	424	Merchant Wholesalers, nondurable goods (422)	100 employees	8	9	2	15	12	17
	441	Motor vehicle & parts dealers	6 million	268	269	214	139	332	353
	442	Furniture & home furnishings stores	6 million	122	123	118	33	136	151
	443	Electronics & appliance stores	7.5 million	74	75	73	20	79	93
	444	Building material & garden equipment & supplies dealers	6 million	219	220	198	88	247	286
	445	Food and Beverage Stores	6 million	11	12	11	3	12	13
	446	Health & personal care stores	6 million	144	145	142	76	156	219
	447	Gasoline Stations	7.5 million	7	8	7	2	8	9
	448	Clothing and Clothing Accessory Stores	7.5 million	6	7	6	1	6	7
	451	Sporting Good, Hobby, Book and Music Stores	6 million	10	11	10	2	11	12
	452	General Merchandise Stores	23 million	1	2	1	5	1	7
	453	Miscellaneous store retailers	6 million	229	230	223	58	253	281
	454	Nonstore retailers	6 million	83	84	73	31	92	104
	481	Air Transportation	1,500 employees	1	2	0	2	1	2
	483	Water Transportation	500 employees	2	2	0	4	3	4
	484	Truck Transportation	21.5 million	40	41	22	40	50	62
	485	Transit and Ground Passenger Transportation	6 million	2	3	0	1	1	1
	486	Pipeline Transportation	1,500 employees	7	11	7	5	7	13
	487	Scenic and Sightseeing Transportation	6 million	3	3	1	3	3	3
	488	Support Activities for Transportation	6 million	95	96	57	121	128	178
	492	Couriers and Messengers	1,500 employees	4	5	2	13	5	15
	493	Warehousing and Storage	21.5 million	3	4	1	5	4	6
	511	Publishing industries	500 employees	33	34	24	24	38	48
	512	Motion picture & sound recording industries	6 million	27	28	22	17	31	39
	519	Information services & data processing services (514)	6 million	23	24	18	17	26	35
	522	Credit intermediation & related activities	6 million	33	34	29	70	51	98
	531	Real Estate	6 million	53	54	49	19	63	68

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

			Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
	321	Wood product mfg	118	122	$279,039,715	$64,205,791	$313,349,836	$3,770,807	$1,054,932	$4,177,998
	322	Paper mfg	979	1,318	$6,462,920,392	$256,669,257	$10,213,680,312	$28,471,015	$2,312,079	$42,205,291
	323	Printing & related support activities	92	98	$535,257,220	$13,652,491	$582,623,429	$7,757,351	$659,756	$8,323,192
	324	Petroleum & coal products mfg	220	289	$1,071,850,075	$288,130,625	$1,997,387,368	$133,981,259	$38,111,417	$221,931,930
	325	Chemical mfg	727	1,047	$7,405,907,333	$206,116,827	$12,325,538,162	$67,944,104	$4,572,791	$109,075,559
	326	Plastics & rubber products mfg	409	503	$1,544,195,579	$25,646,524	$1,990,853,926	$14,431,734	$1,003,297	$18,264,715
	327	Nonmetallic mineral product mfg	53	73	$306,900,266	$12,916,538	$460,708,666	$10,582,768	$1,179,027	$15,356,956
	332	Fabricated Metal Product Manufacturing	9,461	9,936	$32,740,706,609	$2,583,090,947	$35,775,738,847	$6,766,007	$980,705	$7,316,102
	333	Machinery Manufacturing	6,658	7,134	$26,212,436,668	$2,118,851,560	$30,306,400,323	$12,312,089	$1,612,607	$13,857,522
	334	Computer & electronic product mfg	5,557	6,291	$43,488,600,542	$1,434,665,217	$54,703,832,975	$39,038,241	$2,410,222	$47,158,477
	335	Electrical equipment, appliance, & component mfg	1,171	1,455	$15,192,494,979	$159,905,515	$19,781,351,866	$66,927,291	$2,985,596	$85,264,448
	336 (except 33661)	Transportation Equipment Manufacturing	9,071	11,778	$100,445,867,018	$852,546,528	$141,671,547,691	$110,867,403	$3,140,751	$152,498,975
	337	Furniture & Related Product Manufacturing	1,730	1,794	$2,910,358,769	$234,936,773	$3,164,767,239	$4,261,140	$521,576	$4,599,952
	339	Miscellaneous Manufacturing	3,345	3,547	$15,895,479,171	$657,100,516	$17,583,782,196	$14,529,688	$1,226,872	$15,941,779
	423	Wholesale trade, durable goods (421)	475	491	$980,665,827	$587,598,532	$1,076,356,019	$2,155,310	$1,311,756	$2,339,904
	424	Merchant Wholesalers, nondurable goods (422)	2	2	$222,925,052	$5,352,262	$322,506,882	$27,865,631	$2,198,505	$35,834,098
	441	Motor vehicle & parts dealers	236	251	$1,925,922,049	$391,220,401	$2,164,048,286	$7,186,276	$1,826,119	$8,044,789
	442	Furniture & home furnishings stores	118	131	$129,567,757	$76,428,957	$162,246,477	$1,062,031	$647,301	$1,319,077
	443	Electronics & appliance stores	69	81	$91,554,801	$62,626,216	$140,310,440	$1,237,227	$857,482	$1,870,806
	444	Building material & garden equipment & supplies dealers	202	234	$373,336,817	$153,525,844	$523,527,076	$1,704,734	$773,774	$2,379,669
	445	Food and Beverage Stores	16	17	$23,423,843	$6,725,699	$29,356,109	$2,129,440	$640,255	$2,446,342
	446	Health & personal care stores	113	158	$204,857,307	$138,708,592	$425,971,140	$1,422,620	$973,952	$2,937,732
	447	Gasoline Stations	10	12	$7,175,753	$5,737,692	$9,401,564	$1,025,108	$785,609	$1,175,195
	448	Clothing and Clothing Accessory Stores	7	8	$2,359,940	$2,393,864	$4,037,453	$393,323	$393,323	$576,779
	451	Sporting Good, Hobby, Book and Music Stores	46	52	$7,139,568	$4,782,682	$10,366,938	$713,957	$485,283	$942,449
	452	General Merchandise Stores	0	2	$811,413	$987,693	$89,267,883	$811,413	$811,413	$44,633,942
	453	Miscellaneous store retailers	226	250	$215,667,740	$133,721,354	$274,200,158	$941,781	$600,302	$1,192,175
	454	Nonstore retailers	73	82	$185,778,169	$51,587,032	$262,045,889	$2,238,291	$706,333	$3,119,594
	481	Air Transportation	2	4	$0	$0	$81,905,827	$0	$0	$40,952,914
	483	Water Transportation	5	6	$68,445,873	$0	$83,315,739	$34,222,937	$0	$41,657,870
	484	Truck Transportation	63	79	$178,146,287	$9,546,763	$251,278,324	$4,453,657	$435,716	$6,128,740
	485	Transit and Ground Passenger Transportation	1	1	$0	$0	$3,698,415	$0	$0	$1,232,805
	486	Pipeline Transportation	23	41	$2,220,922	$2,317,215	$9,531,161	$317,275	$317,275	$866,469
	487	Scenic and Sightseeing Transportation	3	3	$9,254,377	$196,090	$11,480,345	$3,084,792	$268,756	$3,826,782
	488	Support Activities for Transportation	99	138	$434,959,173	$34,006,814	$707,874,824	$4,578,518	$594,413	$7,373,696
	492	Couriers and Messengers	13	39	$33,159,835	$954,183	$139,502,401	$8,289,959	$391,942	$27,900,480
	493	Warehousing and Storage	5	8	$12,451,857	$663,255	$19,988,280	$4,150,619	$544,880	$4,997,070
	511	Publishing industries	100	127	$251,683,146	$23,477,665	$413,992,969	$7,626,762	$964,373	$12,176,264
	512	Motion picture & sound recording industries	31	39	$142,697,354	$19,261,211	$251,148,305	$5,285,087	$879,086	$8,969,582
	519	Information services & data processing services (514)	22	30	$16,980,553	$2,511,522	$33,633,824	$738,285	$137,552	$1,401,409
	522	Credit intermediation & related activities	107	207	$190,881,756	$38,483,218	$487,236,675	$5,784,296	$1,330,610	$14,330,490
	531	Real Estate	89	96	$40,557,118	$12,448,259	$48,659,874	$765,229	$255,664	$901,109

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

					Affected Entities[BB]		Affected Establishments[BB]			
	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
		532	Rental & leasing services	6 million	71	72	66	65	88	131
		541	Professional, scientific, & technical services	6 million	507	508	379	304	592	683
		561	Administrative & support services	6 million	2,160	2,184	1,909	631	2,281	2,540
		562	Waste management & remediation services	10.5 million	128	129	109	53	142	162
		611	Educational Services	6 million	29	30	17	18	32	35
		621	Ambulatory Health Care Services	8.5 million	28	29	13	40	43	53
		622	Hospitals	29 million	1	2	0	2	1	3
		623	Nursing and Residential Care Facilities	6 million	2	2	1	2	3	4
		624	Social Assistance	6 million	1	1	1	1	2	2
		711	Performing arts, spectator sports, & related industries	6 million	20	20	12	10	22	22
		713	Amusement, Gambling, and Recreastional Industries	6 million	103	104	79	36	110	115
		722	Food Services and Drinking Places	6 million	17	18	12	13	22	25
		811	Repair and Maintenance	6 million	291	292	246	125	344	371
		812	Personal & laundry services	6 million	103	104	95	46	125	141
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	6 million	26	26	22	5	27	27
2B1	Welding - Maritime Industry (carbon steel)	336611[I]	Ship Building and Repairing	1,000 employees	261	279	240	423	276	663
2C1	Welding - Construction Industry (carbon steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	28.5 million[J]	2,394	2,419	3,143	416	2,410	3,559
2D1	Welding - Government (carbon steel)	999200	State	50,000 population						
		999300	Local	50,000 population						
	Total Welding (carbon steel)				19,975	20,314	14,482	11,742	17,960	26,224
3A	Painting - General Industry	All General Industry[G]	All General Industry		2,071	2,089	1,686	511	2,163	2,197
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees	102	106	20	110	120	130
		3361[K]	Motor vehicle mfg	1,000 employees	19	21	9	16	19	25
		3362	Motor vehicle body & trailer mfg	1,000 employees	68	71	62	8	69	70
		336411	Aircraft mfg	1,500 employees	14	16	6	11	14	17
		336414	Guided missile & space vehicle mfg	1,000 employees	2	4	0	3	3	3
		336415	Guided missile & space vehicle propulsion unit & parts mfg	1,000 employees	2	2	1	1	2	2
		336419	Other guided missile & space vehicle parts & auxiliary equip mfg	1,000 employees	2	3	2	0	2	2
		336992	Military armored vehicle, tank, & tank component mfg	1,000 employees	1	1	1	0	1	1
		44111	New car dealers	$24.50 million	400	402	162	291	446	453
		44112	Used car dealers	$19.50 million	459	459	454	14	466	468
		811121	Automotive body, paint, & interior repair & maintenance	$6 million	1,002	1,004	969	55	1,021	1,024
3B	Painting - Maritime Industry	336611	Ship building & repairing	1,000 employees[L]	320	335	222	128	326	350
		336612	Boat building	500 employees	493	501	333	193	510	526

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Employees^{BB}		Revenues ($)^{CC}			Revenues per Entity or Establishment ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
		532	Rental & leasing services	117	175	$98,559,054	$42,703,250	$198,144,487	$1,388,156	$649,662	$2,752,007
		541	Professional, scientific, & technical services	936	1,079	$1,080,371,541	$118,097,865	$1,473,392,875	$2,130,910	$311,962	$2,900,380
		561	Administrative & support services	2,741	3,052	$1,476,118,971	$256,089,364	$2,278,866,383	$683,388	$134,173	$1,043,437
		562	Waste management & remediation services	4,295	4,912	$316,164,987	$80,600,517	$459,541,647	$2,470,039	$736,821	$3,562,338
		611	Educational Services	159	174	$15,675,848	$743,824	$18,424,448	$540,546	$43,194	$614,148
		621	Ambulatory Health Care Services	50	61	$40,706,663	$2,351,336	$53,303,997	$1,453,809	$175,607	$1,838,069
		622	Hospitals	6	16	$10,622,191	$5,285	$25,865,010	$10,622,191	$52,347	$12,932,505
		623	Nursing and Residential Care Facilities	6	8	$741,319	$43,019	$902,371	$370,660	$35,341	$451,186
		624	Social Assistance	5	6	$560,708	$110,003	$688,240	$560,708	$86,175	$688,240
		711	Performing arts, spectator sports, & related industries	16	17	$79,506,501	$2,566,234	$80,992,130	$3,975,325	$210,822	$4,049,606
		713	Amusement, Gambling, and Recreastional Industries	129	135	$83,901,988	$12,541,729	$95,589,522	$814,582	$158,513	$919,130
		722	Food Services and Drinking Places	41	47	$13,374,938	$2,182,329	$16,842,353	$786,761	$179,284	$935,686
		811	Repair and Maintenance	487	526	$201,715,602	$61,433,980	$237,856,596	$693,181	$249,849	$814,577
		812	Personal & laundry services	205	231	$41,659,619	$17,111,710	$52,933,744	$404,462	$180,227	$508,978
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	30	30	$1,356,572	$412,364	$1,372,781	$52,176	$18,820	$52,799
2B1	Welding - Maritime Industry (carbon steel)	336611^{I}	Ship Building and Repairing	259	623	$6,463,579,033	$220,369,703	$16,338,682,017	$24,764,671	$918,207	$58,561,584
2C1	Welding - Construction Industry (carbon steel)	233^{S}, 234^{T},235^{U}	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	54,475	80,447	$3,836,250,131	$2,087,423,100	$6,304,514,294	$1,602,444	$664,150	$2,606,248
2D1	Welding - Government (carbon steel)	999200	State								
		999300	Local								
	Total Welding (carbon steel)			107,351	141,626	$276,313,740,002	$21,463,651,807	$370,769,820,227	$13,832,978	$1,482,092	$18,251,936
3A	Painting - General Industry	All General Industry^{G}	All General Industry	36,569	37,539	$42,673,605,403	$1,708,029,958	$58,390,181,330	$20,605,314	$1,013,066	$27,951,260
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	1,440	1,560	$458,550,398	$11,219,551	$503,283,483	$4,495,592	$560,978	$4,747,957
		3361^{K}	Motor vehicle mfg	1,061	1,417	$19,094,740,748	$68,241,187	$31,167,653,129	$1,004,986,355	$7,565,616	$1,484,173,959
		3362	Motor vehicle body & trailer mfg	3,854	3,929	$362,508,890	$121,747,774	$401,277,973	$5,331,013	$1,956,533	$5,651,802
		336411	Aircraft mfg	782	976	$7,013,921,668	$15,627,491	$10,068,017,924	$500,994,405	$2,608,704	$629,251,120
		336414	Guided missile & space vehicle mfg	168	191	$4,485,766,686	$1,101,536	$4,723,275,047	$2,242,883,343	$4,302,791	$1,180,818,762
		336415	Guided missile & space vehicle propulsion unit & parts mfg	112	91	$240,813,679	$1,679,251	$245,838,181	$120,406,840	$2,811,191	$122,919,091
		336419	Other guided missile & space vehicle parts & auxiliary equip mfg	112	136	$4,407,908	$4,325,712	$29,659,724	$2,203,954	$2,203,954	$9,886,575
		336992	Military armored vehicle, tank, & tank component mfg	56	75	$2,757,538	$2,611,992	$35,542,489	$2,757,538	$2,757,538	$35,542,489
		44111	New car dealers	6,688	6,793	$9,877,036,996	$588,446,707	$10,076,295,124	$24,692,592	$3,632,387	$25,065,411
		44112	Used car dealers	6,988	7,018	$683,921,155	$544,775,932	$688,720,943	$1,490,024	$1,199,947	$1,500,481
		811121	Automotive body, paint, & interior repair & maintenance	15,310	15,355	$449,179,737	$348,252,825	$450,617,313	$448,283	$359,394	$448,822
3B	Painting - Maritime Industry	336611	Ship building & repairing	1,174	1,260	$5,542,807,975	$195,127,165	$6,776,888,162	$17,321,275	$878,951	$20,229,517
		336612	Boat building	1,836	1,894	$4,982,262,975	$354,867,690	$5,400,558,594	$10,106,010	$1,065,669	$10,779,558

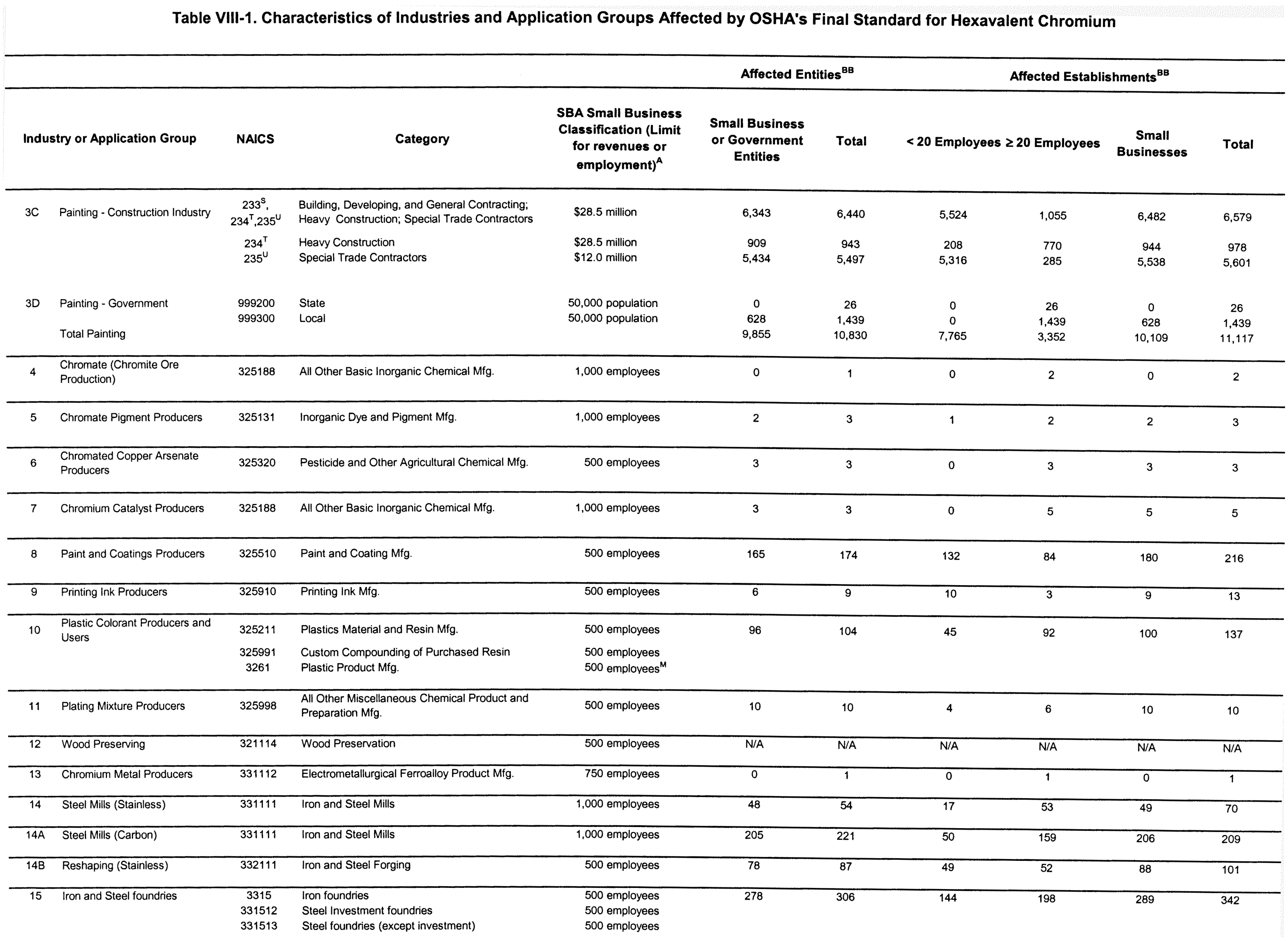

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

					Affected Entities^{BB}		Affected Establishments^{BB}			
	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)^{A}	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
3C	Painting - Construction Industry	233^{S}, 234^{T},235^{U}	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$28.5 million	6,343	6,440	5,524	1,055	6,482	6,579
		234^{T}	Heavy Construction	$28.5 million	909	943	208	770	944	978
		235^{U}	Special Trade Contractors	$12.0 million	5,434	5,497	5,316	285	5,538	5,601
3D	Painting - Government	999200	State	50,000 population	0	26	0	26	0	26
		999300	Local	50,000 population	628	1,439	0	1,439	628	1,439
	Total Painting				9,855	10,830	7,765	3,352	10,109	11,117
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	1,000 employees	0	1	0	2	0	2
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	1,000 employees	2	3	1	2	2	3
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	500 employees	3	3	0	3	3	3
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	1,000 employees	3	3	0	5	5	5
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	500 employees	165	174	132	84	180	216
9	Printing Ink Producers	325910	Printing Ink Mfg.	500 employees	6	9	10	3	9	13
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	500 employees	96	104	45	92	100	137
		325991	Custom Compounding of Purchased Resin	500 employees						
		3261	Plastic Product Mfg.	500 employees^{M}						
11	Plating Mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	500 employees	10	10	4	6	10	10
12	Wood Preserving	321114	Wood Preservation	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	750 employees	0	1	0	1	0	1
14	Steel Mills (Stainless)	331111	Iron and Steel Mills	1,000 employees	48	54	17	53	49	70
14A	Steel Mills (Carbon)	331111	Iron and Steel Mills	1,000 employees	205	221	50	159	206	209
14B	Reshaping (Stainless)	332111	Iron and Steel Forging	500 employees	78	87	49	52	88	101
15	Iron and Steel foundries	3315	Iron foundries	500 employees	278	306	144	198	289	342
		331512	Steel Investment foundries	500 employees						
		331513	Steel foundries (except investment)	500 employees						

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	Industry or Application Group	NAICS	Category	Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
				Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
3C	Painting - Construction Industry	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	32,915	33,408	$22,221,976,765	$5,116,853,453	$23,916,707,178	$3,503,386	$926,295	$3,713,774
		234[T]	Heavy Construction	4,794	4,966	$7,825,578,202	$121,421,527	$8,171,150,337	$8,608,997	$583,757	$8,665,059
		235[U]	Special Trade Contractors	28,122	28,442	$1,907,472,692	$1,222,717,518	$2,098,147,009	$351,026	$230,007	$381,689
3D	Painting - Government	999200	State	0	1,535	$0	N/A	$336,858,834,000	N/A	N/A	$12,956,109,000
		999300	Local	1,878	6,613	$2,304,760,000	N/A	$91,027,413,880	$3,670,000	N/A	$63,257,411
	Total Painting			74,372	82,249	$65,236,487,247	$3,602,163,858	$508,723,173,311	$6,619,633	$463,897	$46,973,516
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	0	150	$0	$0	$114,000,000	N/A	N/A	$114,000,000
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	50	52	$140,969,299	$1,988,410	$142,957,709	$70,484,649	$1,988,410	$47,652,570
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	27	27	$345,794,332	$0	$345,794,332	$115,264,777	N/A	$115,264,777
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	313	313	$227,176,835	$0	$227,176,835	$75,725,612	N/A	$75,725,612
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	1,779	2,569	$2,664,296,816	$419,867,883	$3,716,487,140	$16,147,253	$3,180,817	$21,359,121
9	Printing Ink Producers	325910	Printing Ink Mfg.	77	112	$67,338,538	$36,789,238	$99,168,346	$11,223,090	$3,678,924	$11,018,705
10	Plastic Colorant Producers and Users	325211 325991 3261	Plastics Material and Resin Mfg. Custom Compounding of Purchased Resin Plastic Product Mfg.	303	492	$915,429,632	$50,552,985	$1,450,120,652	$9,535,725	$1,123,400	$13,943,468
11	Plating Mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	49	118	$223,120,857	$17,540,363	$655,524,599	$22,312,086	$4,385,091	$65,552,460
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	0	63	$0	$0	$37,114,939	N/A	N/A	$37,114,939
14	Steel Mills (Stainless)	331111	Iron and Steel Mills	6,493	9,276	$5,524,744,428	$24,043,629	$9,134,579,327	$115,098,842	$1,414,331	$169,158,876
14A	Steel Mills (Carbon)	331111	Iron and Steel Mills	28,945	29,367	$26,886,632,951	$70,716,555	$27,402,323,650	$131,154,307	$1,414,331	$123,992,415
14B	Reshaping (Stainless)	332111	Iron and Steel Forging	938	1,076	$494,327,769	$41,014,150	$645,432,309	$6,337,536	$837,023	$7,418,762
15	Iron and Steel foundries	3315 331512 331513	Iron foundries Steel Investment foundries Steel foundries (except investment)	23,461	30,222	$1,862,053,224	$52,084,042	$2,443,630,547	$6,698,033	$361,695	$7,985,721

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

					Affected Entities[BB]		Affected Establishments[BB]			
	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	1,000 employees	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	1,000 employees	3	3	1	3	4	4
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	1,000 employees	2	3	5	0	2	5
19	Chemical Distributors	42269[V]	Other Chemical and Allied Products	100 employees	1,228	1,258	1,577	209	1,568	1,786
20	Textile Dyeing	313	Textile Mills	500 employees[N]	992	1,026	759	374	1,030	1,133
		314	Textile Product Mills	500 employees[O]						
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	750 employees	22	23	19	6	22	25
		3272129	Other Pressed and Blown Glass and Glassware Mfg.	750 employees						
21A	Fiber, Flat, and Container Glass	327993	Mineral Wool Manufacturing	750 employees	19	45	5	86	19	91
		327211	Flat Glass Manufacturing	750 employees						
		327212	Other Pressed and Blown Glass Mfg.	750 employees						
		327213	Glass Container Manufacturing	750 employees						
22	Printing	32311	Printing Ink Mfg.	500 employees	490	495	400	100	493	500
		323113	Commercial Screen Printing\	500 employees						
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	500 employees[P]	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	1,000 employees	33	71	0	163	44	163
		325120	Industrial Gas Mfg., Including Hydrogen and Ammonia Gas	1,000 employees						
		325211	Plastics Materials, Synthetic Resins, and Nonvulcanizable Elastomers, Including Polyethylene	750 employees						
		325199	Industrial Inorganic Chemicals, Not Otherwise Classified, Including Butadiene and Methanol	1,000 employees						
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	$6 million	5	11	4	21	6	25
	Total Chromium Catalyst Users				38	82	4	184	50	188
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	750 employees	1	6	0	6	1	6
26A	Wood Working -General Industry	321	General Industry	500 employees	203	219	100	187	236	287
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	1,000 employees[Q]	48	64	37	42	52	79

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

				Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	104	104	$213,463,839	$1,959,383	$213,463,839	$71,154,613	$1,959,383	$71,154,613
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	4	11	$4,703,241	$11,758,103	$11,758,103	$2,351,621	$2,351,621	$3,919,368
19	Chemical Distributors	42269[V]	Other Chemical and Allied Products	2,917	3,572	$5,001,323,425	$2,283,847,465	$6,109,221,001	$4,072,739	$1,448,223	$4,856,297
20	Textile Dyeing	313 314	Textile Mills Textile Product Mills	19,798	25,341	$3,887,392,814	$329,198,101	$4,959,484,396	$3,918,743	$433,726	$4,833,805
21	Colored Glass Producers	3272123 3272129	Other Pressed and Blown Glass and Glassware Mfg. Other Pressed and Blown Glass and Glassware Mfg.	154	295	$137,970,586	$12,517,183	$263,423,990	$6,271,390	$658,799	$11,453,217
21A	Fiber, Flat, and Container Glass	327993 327211 327212 327213	Mineral Wool Manufacturing Flat Glass Manufacturing Other Pressed and Blown Glass Mfg. Glass Container Manufacturing	1,063	5,089	$798,998,481	$9,266,899	$4,860,475,189	$42,052,552	$1,853,380	$108,010,560
22	Printing	32311 323113	Printing Ink Mfg. Commercial Screen Printing\	6,289	6,600	$798,951,071	$205,371,939	$837,385,303	$1,630,512	$513,430	$1,691,687
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110 325120 325211 325199	Petrochemical Mfg., Including Styrene Industrial Gas Mfg., Including Hydrogen and Ammonia Gas Plastics Materials, Synthetic Resins, and Nonvulcanizable Elastomers, Including Polyethylene Industrial Inorganic Chemicals, Not Otherwise Classified, Including Butadiene and Methanol	65	243	$4,429,054,507	N/A	$16,407,633,744	$134,213,773	N/A	$231,093,433
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	121	707	$11,284,171	$5,597,660	$65,306,031	$2,256,834	$1,399,415	$5,936,912
	Total Chromium Catalyst Users			186	950	$4,440,338,679	$5,597,660	$16,472,939,775	$116,851,018	$1,399,415	$200,889,509
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	15	90	$10,214,017	N/A	$61,284,104	$10,214,017	N/A	$10,214,017
26A	Wood Working -General Industry	321	General Industry	320	388	$1,380,484,802	$114,093,788	$1,731,495,032	$6,800,418	$1,140,938	$7,906,370
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	261	319	$1,386,462,574	$33,973,663	$1,634,373,467	$28,884,637	$918,207	$25,537,085

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

					Affected Entities^{BB}		Affected Establishments^{BB}			
	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)^{A}	Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
26C	Wood Working - Construction Industry	2332^{W}, 2333^{X}, 2349^{Y}, 23551^{Z}	Construction	$28.5 million^{R}	7,217	7,285	5,960	1,489	7,304	7,449
26D	Wood Working - Government	999200	State	50,000 population	0	26	0	26	0	26
		999300	Local	50,000 population	27	94	0	94	27	94
	Total Wood Working				7,495	7,688	6,097	1,838	7,619	7,935
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$10.5 million	67	97	66	55	70	121
27A	Solid Waste Incineration - Government	999300	Local	50,000 population	0	33	0	33	0	33
	Total Incineration				67	130	66	88	70	154
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	750 employees	N/A	N/A	N/A	N/A	N/A	N/A
30	Superalloy Producers and Users	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	750 employees	1	11	0	18	1	18
		331528	Other Nonferrous Foundries	500 employees						
31B	Construction - Refractory Brick Restoration and Maintenance	235^{U}	Special Trade Contractors	$12.0 million	180	180	166	18	182	184
31C	Construction - Hazardous Waste Site Work	2333^{X}	Nonresidential Building Construction	$28.5 million	201	201	161	49	204	210
31CG	Hazardous Waste Site Work - Government	999200	State	50,000 population	0	1	0	1	0	1
		999300	Local	50,000 population	64	226	0	226	64	226
31D	Construction - Industrial Rehabilitation and Maintenance	23493^{AA}	Industrial Nonbuilding Structure Construction	$28.5 million	231	231	221	62	240	283
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	50,000 population	0	18	0	18	0	18
		999300	Local	50,000 population	24	83	0	83	24	83
	Total Construction				700	940	548	457	714	1,005
32A	Ready-Mixed Concrete	327320	Ready Mixed Concrete Manufacturing	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
	Total Industry				42,321	44,232	31,628	20,363	44,036	51,991

Note: Total affected entities, establishments, revenue, and profit were estimated by adding entities (establishments, etc.) from each industry segment calculated by the following method:

General Industry = Welding--General Industry entities + 1/2 (remaining General Industry entities)
Maritime = Painting--Maritime entities + 1/2 (remaining Maritime entities)
Construction = Woodworking--Construction entities + 1/2 (remaining Construction entities)
Government = Painting--Government entities

Table VIII-1. Characteristics of Industries and Application Groups Affected by OSHA's Final Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	Affected Employees[BB]		Revenues ($)[CC]			Revenues per Entity or Establishment ($)		
				Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
26C	Wood Working - Construction Industry	2332[W], 2333[X], 2349[Y], 23551[Z]	Construction	12,947	13,952	$28,454,882,468	$5,519,795,980	$30,681,541,267	$3,942,758	$926,140	$4,211,605
26D	Wood Working - Government	999200	State	0	27	$0	N/A	$336,858,834,000	N/A	N/A	$12,956,109,000
		999300	Local	27	94	$99,090,000	N/A	$7,428,828,360	$3,670,000	N/A	$79,030,089
	Total Wood Working			13,555	14,780	$31,320,919,844	$5,667,863,431	$378,335,072,127	$4,178,909	N/A	$49,211,118
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	682	2,285	$244,931,875	$107,137,116	$1,228,073,485	$3,655,700	$1,623,290	$12,660,551
27A	Solid Waste Incineration - Government	999300	Local	0	106	$0	N/A	$3,610,169,640	N/A	N/A	$109,399,080
	Total Incineration			682	2,391	$244,931,875	$107,137,116	$4,838,243,125	$3,655,700		$37,217,255
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
30	Superalloy Producers and Users	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	121	2,164	$20,351,647	N/A	$366,329,641	$20,351,647	N/A	$33,302,695
		331528	Other Nonferrous Foundries								
31B	Construction - Refractory Brick Restoration and Maintenance	235[U]	Special Trade Contractors	1,029	1,040	$161,751,294	$73,278,258	$172,810,424	$898,618	$441,435	$960,058
31C	Construction - Hazardous Waste Site Work	2333[X]	Nonresidential Building Construction	1,111	1,213	$928,919,198	$196,411,140	$1,013,517,325	$4,621,489	$1,219,945	$5,042,375
31CG	Hazardous Waste Site Work - Government	999200	State	0	2	$0	N/A	$12,956,109,000	N/A	N/A	$12,956,109,000
		999300	Local	192	677	$234,880,000	N/A	$17,957,530,960	$3,670,000	N/A	$79,458,102
31D	Construction - Industrial Rehabilitation and Maintenance	23493[AA]	Industrial Nonbuilding Structure Construction	1,139	1,684	$3,881,841,378	$690,150,104	$5,738,920,384	$16,804,508	$3,122,851	$24,843,811
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	0	18	$0	N/A	$233,209,962,000	N/A	N/A	$12,956,109,000
		999300	Local	24	83	$88,080,000	N/A	$6,542,625,720	$3,670,000	N/A	$78,826,816
	Total Construction			3,495	4,714	$5,295,471,871	$959,839,503	$277,591,475,813	$7,564,960	$1,751,532	$295,310,081
32A	Ready-Mixed Concrete	327320	Ready Mixed Concrete Manufacturing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total Industry			467,608	558,420	$269,586,773,181	$40,219,731,592.34	$767,562,532,462	$6,370,047	$1,271,650	$17,353,105

Note: Total affected entities, establishments, revenue, and profit were estimated by adding entities (establishments, etc.) from each industry segment calculated by the following method:

General Industry = Welding--General Industry entities + 1/2 (remaining General Industry entities)
Maritime = Painting--Maritime entities + 1/2 (remaining Maritime entities)
Construction = Woodworking--Construction entities + 1/2 (remaining Construction entities)
Government = Painting--Government entities

Footnotes to Table VIII-1

[A] SBA size standards taken from 13 CFR Ch.1 § 121.201. January 1, 2003

[B] Includes industries in NAICS 31-33, NAICS 42, NAICS 51.

[C] Except 311221 "Wet Corn Milling", 311312 "Cane Sugar Refining", 311313 "Beet Sugar Manufacturing", and 311821 Cookie and Cracker Manufacturing, which have an SBA size standard of 750 employees, and also 311223 "Other Oilseed Processing", 311225 "Fats and Oils Refining and Blending", 311230 "Breakfast Cereal Manufacturing", 311422 "Special Canning", which have an SBA size standard of 1,000 employees.

[D] Except 332811 "Metal Heat Treating," 332991 "Ball and Roller Bearing Manufacturing," and 332998 "Enameled Iron and Metal Sanitary Ware Manufacturing," all of which have an SBA size standard of 750 employees; 332431 "Metal Can Manufacturing," 332992 "Small Arms Ammunition Manufacturing," and 332994 "Small Arms Manufacturing," all of which have an SBA size standard of 1,000 employees; and 332993 "Ammunition (except Small Arms) Manufacturing," the SBA size standard for which is 1,500 employees.

[E] Except 333120 "Construction Machinery Manufacturing," 333415 "Air-Conditioning and Warm Air Heating Equipment," and 333924 Industrial Truck, Tractor, Trailer," all of which have an SBA size standard of 750 employees; and except 333313 Office Machinery Manufacturing," 333611 "Turbine and Turbine Generator Set Unit Manufacturing," and 333618 "Other Engine Equipment Manufacturing," all of which have an SBA size standard of 1,000 employees.

[F] Except for 336212 "Truck Trailer Manufacturing," 336214 "Travel Trailer and Camper Manufacturing," 336311 "Carburetor, Piston, Piston Ring and Valve Manufacturing," 336321 "Vehicular Lighting Equipment Manufacturing," 336360 "Motor Vehicle Seating and Interior Trim Manufacturing," 336370 "Motor Vehicle Metal Stamping," 336991 Motorcycle, Bicycle and Parts Manufacturing," and 336999 "All Other Transportation Equipment Manufacturing," all of which have an SBA size standard of 500 employees; 336312 "Gasoline Engine and Engine Parts Manufacturing," 336322 "Other Motor Vehicle Electrical and Electronic Equipment Manufacturing," 336330 "Motor Vehicle Steering and Suspension Components Manufacturing (except Spring)," 336340 "Motor Vehicle Brake System Manufacturing," 336350 "Motor Vehicle Transmission and Power Train Parts Manufacturing," 336391 Motor Vehicle Air-Conditioning Manufacturing," 336399 "All Other Motor Vehicle Parts Manufacturing, all of which have an SBA size standard of 750 employees; and 336411 "Aircraft Manufacturing," which has an SBA size standard of 1,500 employees.

[G] Includes industries in NAICS 332, NAICS 336, NAICS 441, and NAICS 811.

[H] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[I] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[J] Except 2331 "Land Subdivision and Land Development," which has an SBA size standard of $6.0 million.

[K] Except 336411 "Aircraft Manufacturing"

[L] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[M] All of NAICS CODE 3261 have an SBA size standard of 500 employees except 326192 "Resilient Floor Covering Mfg.", the size standard for which is 750 employees.

[N] All of NAICS CODE 313 have an SBA size standard of 500 employees except 313210 "Broad Woven Fabric Mills", 313320 "Broad Woven Finishing Mills", and 313320 "Fabric Coating Mills" all of which have a size standard of 1,000 employees.

[O] All of NAICS CODE 314 have an SBA size standard of 500 employees except 314992 "Tire Cord and Tire Fabric Mill", the size standard for which is 1,000 employees.

[P] All of NAICS CODE 3161 have an SBA size standard of 500 employees except 316211 "Rubber and Plastics Footwear Mfg.", the size standard for which is 1,000 employees.

[Q] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[R] Except 23551 which has an SBA size standard of $12 million.

[S] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[T] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[U] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[V] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[W] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[X] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[Y] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[Z] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[AA] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[BB] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industry profiles in Chapter II for the complete list of references.

[CC] Industry revenues were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2002*** (IRS, 2005). Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

BILLING CODE 4510–26–C

Table VIII–2 shows the current exposures to Cr(VI) by application group. The exposure data relied on by OSHA in developing the exposure profile and evaluating technological feasibility were compiled in a database of exposures taken from OSHA compliance officers, site visits by OSHA contractors and the National Institute for Occupational Safety and Health (NIOSH), the U.S. Navy, published literature, commenters on the proposed rule and other interested parties.

It is also important to note that Table VIII–2 and OSHA's cost and feasibility analyses reflect the full range of exposures occurring in each application group, not the median exposures. Some commenters (e.g., Ex. 47–27–1) misunderstood this and believed OSHA determined that only employers with median exposures above the PEL would incur costs for engineering and work practice controls. OSHA did not use exposure medians to assign compliance costs in this rulemaking. OSHA made limited use of exposure medians for only a few purposes. The first was in the analysis of baseline controls, described in the technological feasibility discussion below. Where both exposure data and information on the controls in place were available, OSHA used the median exposure level experienced in the presence of a specific type of control to assign an effectiveness level to the control. Second, to determine whether to assume baseline controls were already in place in cases where OSHA only had exposure data available, it compared median exposure levels to the median exposure levels previously assigned to baseline controls.

BILLING CODE 4510–26–P

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

			Number of Exposed Workers (μg/m^3)								
Industry Sector		Job Category	Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
1	Electroplating	Hard Chrome	2,590	0	200	424	139	1,261	496	69	0
		Decorative Chrome	1,850	0	529	881	0	88	44	132	176
		Job Shop Chrome Plater	3,330	0	833	740	185	370	570	355	278
		Captive Shop Chrome Plater	2,683	0	278	1,018	370	370	370	93	185
		Job Shop Plater	13,600	0	3,365	6,083	416	1,409	924	671	732
		Captive Shop Plater	7,494	0	1,165	3,975	457	1,005	594	183	114
		Anodizer	1,943	0	795	795	88	0	177	0	88
		Operator	5,181	0	954	1,751	373	842	636	342	282
		Helper/Other	6,939	0	990	3,975	0	688	765	347	173
		Conversion Coater	21,247	0	12,301	7,828	0	1,118	0	0	0
	Subtotal Electroplating		**66,857**	**0**	**21,409**	**27,471**	**2,028**	**7,152**	**4,577**	**2,191**	**2,029**
2A	Welding	SMAW	20,391	4,690	0	0	0	3,670	2,447	6,525	3,059
	(General	GMAW	14,954	6,878	449	0	3,589	2,392	150	1,047	449
	Industry)	TIG	4,531	3,579	0	0	952	0	0	0	0
	(stainless steel/	SAW	1,812	1,812	0	0	0	0	0	0	0
	high-chromium alloy)	Plasma Cutting	467	204	0	0	0	45	23	0	195
		Plasma Welding	453	390	0	0	0	0	63	0	0
		Resistance Welding	2,718	2,718	0	0	0	0	0	0	0
	Subtotal Welding -- General Industry (stainless steel)		**45,326**	**20,271**	**449**	**0**	**4,541**	**6,107**	**2,683**	**7,572**	**3,703**
2B	Welding	SMAW	1,893	555	212	138	250	305	129	157	148
	(Maritime	GMAW	2,734	1,113	432	243	405	487	55	0	0
	Industry)	TIG	631	423	158	25	19	6	0	0	0
	(stainless steel/	FCAW	12,619	5,605	1,251	1,869	1,717	1,088	153	153	784
	high-chromium alloy)	Plasma Cutting	421	58	58	0	29	160	72	0	43
		Plasma Welding	168	0	113	55	0	0	0	0	0
		Oxy-fuel Cutting	420	106	161	76	26	26	13	13	0
		Air Carbon Arc Cutting/Gouging	167	51	15	37	7	0	22	29	7
		Electron Torch Cutting	42	42	0	0	0	0	0	0	0
		Thermal Spray Tungsten Carbide	42	0	42	0	0	0	0	0	0
		SAW	1,682	1,682	0	0	0	0	0	0	0
		Grinding	210	84	126	0	0	0	0	0	0
	Subtotal Welding -- Maritime (stainless steel)		**21,029**	**9,718**	**2,567**	**2,444**	**2,452**	**2,071**	**443**	**351**	**981**
2C	Welding	SMAW	45,338	13,284	5,078	3,310	5,985	7,299	3,083	3,763	3,536
	(Construction	Plasma Cutting	604	83	83	0	42	229	104	0	62
	Industry)	GMAW	9,067	3,690	1,433	807	1,342	1,614	181	0	0
	(stainless steel/	Brazing	4,534	0	0	0	0	0	0	4,534	0
	high-chromium alloy)	Metallizing	906	0	0	0	0	0	154	0	752
	Subtotal Welding -- Construction (stainless steel)		**60,449**	**17,058**	**6,594**	**4,117**	**7,368**	**9,143**	**3,522**	**8,297**	**4,351**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

Industry Sector		Job Category	Number of Exposed Workers ($\mu g/m^3$)								
			Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
2D	Welding	SMAW	707	207	79	52	93	114	48	59	55
	(Government)	Plasma Cutting	9	1	1	0	1	3	2	0	1
	(stainless steel/	GMAW	141	57	22	13	21	25	3	0	0
	high-chromium alloy)	Brazing	72	0	0	0	0	0	0	72	0
		Metallizing	14	0	0	0	0	0	2	0	12
	Subtotal Welding -- Government (stainless steel)		**943**	**266**	**103**	**64**	**115**	**142**	**55**	**131**	**68**
2A1	Welding	SMAW	17,360	0	0	8,680	8,680	0	0	0	0
	(General	GMAW	12,732	0	0	6,366	6,366	0	0	0	0
	Industry)	TIG	3,472	3,472	0	0	0	0	0	0	0
	(carbon steel)	SAW	1,543	1,543	0	0	0	0	0	0	0
		Plasma Cutting	386	0	0	193	193	0	0	0	0
		Plasma Welding	386	386	0	0	0	0	0	0	0
		Resistance Welding	2,315	2,315	0	0	0	0	0	0	0
		FCAW	385	0	0	154	231	0	0	0	0
		Confined Space	22,021	0	1,233	1,233	8,544	7,333	3,678	0	0
	Subtotal Welding -- General Industry (carbon steel)		**60,600**	**7,716**	**1,233**	**16,626**	**24,014**	**7,333**	**3,678**	**0**	**0**
2B1	Welding	SMAW	20	0	0	10	10	0	0	0	0
	(Maritime	GMAW	28	0	0	14	14	0	0	0	0
	Industry)	TIG	7	7	0	0	0	0	0	0	0
	(carbon steel)	FCAW	130	0	0	52	78	0	0	0	0
		Plasma Cutting	4	0	0	2	2	0	0	0	0
		Plasma Welding	2	2	0	0	0	0	0	0	0
		Oxy-fuel Cutting	4	0	0	2	2	0	0	0	0
		Air Carbon Arc Cutting/Gouging	2	0	0	1	1	0	0	0	0
		Electron Torch Cutting	0	0	0	0	0	0	0	0	0
		Thermal Spray Tungsten Carbide	0	0	0	0	0	0	0	0	0
		SAW	18	18	0	0	0	0	0	0	0
		Grinding	2	2	0	0	0	0	0	0	0
		Confined Space	412	0	23	23	160	137	69	0	0
	Subtotal Welding -- Maritime (carbon steel)		**629**	**29**	**23**	**104**	**267**	**137**	**69**	**0**	**0**
2C1	Welding	SMAW	42,720	0	0	21,360	21,360	0	0	0	0
	(Construction	Plasma Cutting	0	0	0	0	0	0	0	0	0
	Industry)	GMAW	8,750	0	0	4,375	4,375	0	0	0	0
	(carbon steel)	Brazing	0	0	0	0	0	0	0	0	0
		Metallizing	0	0	0	0	0	0	0	0	0
		Confined Space	28,934	0	1,619	1,619	11,228	9,636	4,832	0	0
	Subtotal Welding -- Construction (carbon steel)		**80,404**	**0**	**1,619**	**27,354**	**36,963**	**9,636**	**4,832**	**0**	**0**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

			Number of Exposed Workers (μg/m^3)								
Industry Sector		Job Category	Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
3A	Painting	Spray Painter (Aerospace)	3,921	274	657	247	298	874	321	490	760
		Assembler (Aerospace)	2,895	955	492	608	492	116	116	0	116
		Operator (Coil Coating)	1,171	772	129	0	176	94	0	0	0
		Maintenance (Coil Coating)	390	390	0	0	0	0	0	0	0
3A1	Painting	Spray Painter (Auto Body Repair)	4,346	0	217	2,173	0	217	435	869	435
		Sander (Auto Body Repair)	24,820	0	8,191	12,410	0	0	2,730	1,489	0
	Subtotal Painting -- General Industry		**37,543**	**2,391**	**9,686**	**15,438**	**966**	**1,301**	**3,602**	**2,848**	**1,311**
3B	Painting	Spray Painter	135	24	16	0	8	47	16	8	16
	(Maritime	Abrasive Blaster	1,510	121	91	151	106	559	106	106	272
	Industry)	Grinder/Sander	1,510	393	242	151	181	393	151	0	0
	Subtotal Painting -- Maritime		**3,155**	**538**	**348**	**302**	**295**	**998**	**273**	**114**	**288**
3C	Painting	Spray painter	16,304	4,891	4,402	1,141	1,956	1,630	1,141	326	815
	(Construction)	Laborer	16,304	1,793	3,587	0	7,337	3,587	0	0	0
		Traffic painter	800	0	100	600	0	0	100	0	0
	Subtotal Painting -- Construction		**33,408**	**6,684**	**8,089**	**1,741**	**9,293**	**5,217**	**1,241**	**326**	**815**
3D	Painting	Spray painter	4,074	1,222	1,100	285	489	407	285	81	204
	(Government)	Laborer	4,074	448	896	0	1,833	896	0	0	0
	Subtotal Painting -- Government		**8,147**	**1,670**	**1,996**	**285**	**2,322**	**1,304**	**285**	**81**	**204**
4	Chromate	Process Operators	65	1	39	11	13	1	0	0	0
	(Chromite Ore)	Packaging Workers	21	0	7	0	5	9	0	0	0
	Production	Maintenance workers	42	0	32	2	6	2	0	0	0
		Other Exposed Workers	22	0	11	11	0	0	0	0	0
	Subtotal Chromate Production		**150**	**1**	**89**	**24**	**24**	**12**	**0**	**0**	**0**
5	Chromate	Strike Tank Operator	6	0	0	0	0	4	0	1	1
	Pigment	Drying/Blending/Packaging Operator	6	0	0	0	0	2	0	1	3
	Producers	Maintenance Worker	6	0	0	0	1	0	0	1	4
		Laborer	6	0	0	0	0	3	0	0	3
		Laboratory Technician	9	0	0	0	0	5	2	0	2
		Wastewater Treatment Operator	6	0	0	0	0	0	2	2	2
		Manager/Supervisor	7	0	0	0	0	2	1	1	3
		Proprietary Process Operator	3	0	0	0	0	0	0	0	3
		Dispersion Operator	3	0	0	0	0	0	0	0	3
	Subtotal Chromate Pigment Producers		**52**	**0**	**0**	**0**	**1**	**16**	**5**	**6**	**24**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

Industry Sector		Job Category	Number of Exposed Workers (µg/m³)								
			Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
6	Chromated Copper Arsenate (CCA) Producers	Production Operator	15	0	0	0	5	5	5	0	0
		Production Supervisor	6	0	6	0	0	0	0	0	0
		CCA Truck Loader	3	0	3	0	0	0	0	0	0
		Warehouse Operator	3	0	3	0	0	0	0	0	0
	Subtotal CCA Producers		**27**	**0**	**12**	**0**	**5**	**5**	**5**	**0**	**0**
7	Chromium Catalyst Producers	Wet Process Operator	34	0	0	0	1	19	2	2	10
		Dry Process Operator	35	0	0	0	2	5	0	20	8
		Screening Operator	16	0	2	4	8	0	2	0	0
		Quality Control Inspector	15	0	15	0	0	0	0	0	0
		Dry Mix Operator	52	0	52	0	0	0	0	0	0
		Process Control Operator	12	0	12	0	0	0	0	0	0
		Control Room Operator	3	0	0	3	0	0	0	0	0
		Forming Operator	9	0	0	0	0	9	0	0	0
		Team Leader	6	0	0	6	0	0	0	0	0
		Lead Person	4	0	0	0	0	1	1	2	0
		Floor Person	31	0	0	4	5	18	2	1	1
		Warehouse Operator	24	0	16	8	0	0	0	0	0
		Maintenance Person	60	0	30	0	15	15	0	0	0
		Solid Waste Handler	12	0	0	0	0	4	4	4	0
	Subtotal Chromium Catalyst Producers		**313**	**0**	**127**	**25**	**31**	**71**	**11**	**29**	**19**
8	Paint and Coatings Producers	Batchmaker	1,201	400	75	38	38	150	0	21	479
		Packager	600	0	600	0	0	0	0	0	0
		Shipping/receiving Technician	384	0	384	0	0	0	0	0	0
		Laboratory Chemist Technician	384	0	384	0	0	0	0	0	0
	Subtotal Paint and Coating Producers		**2,569**	**400**	**1,443**	**38**	**38**	**150**	**0**	**21**	**479**
9	Printing Ink Producers	Batch Weigher	68	4	0	0	17	47	0	0	0
		Mill Operator	16	4	4	0	0	8	0	0	0
		Utility Worker	12	6	0	0	0	6	0	0	0
		Maintenance Worker	3	0	0	3	0	0	0	0	0
		Production Supervisor	13	13	0	0	0	0	0	0	0
	Subtotal Printing Ink Producers		**112**	**27**	**4**	**3**	**17**	**61**	**0**	**0**	**0**
10	Plastic Colorant Producers and Users	Dry Color Handler	348	0	0	0	0	232	35	58	23
		Wet Mill Operator	30	0	15	15	0	0	0	0	0
		Dry Color Blender/packager	40	0	0	0	0	18	1	6	15
		Production Supervisor	74	37	0	0	0	0	0	0	37
	Subtotal Plastic Colorant Producers and Users		**492**	**37**	**15**	**15**	**0**	**250**	**36**	**64**	**75**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

			Number of Exposed Workers ($\mu g/m^3$)								
Industry Sector		Job Category	Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
11	Plating Mixture Producers	Blender/Mixer Operator-Dry Chrome Process	22	0	0	0	0	22	0	0	0
		Blender/Mixer Operator-Liquid Chrome Process	80	0	0	80	0	0	0	0	0
		Laboratory Chemist	16	0	16	0	0	0	0	0	0
	Subtotal Plating Mixture Producers		**118**	**0**	**16**	**80**	**0**	**22**	**0**	**0**	**0**
12	Wood Preserving	Not Applicable	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	Leach Operator	8	0	0	8	0	0	0	0	0
		Ager Operator	4	0	0	0	0	4	0	0	0
		Lower-cell-room Operator	4	0	0	0	4	0	0	0	0
		Cell Assembler	4	0	0	0	0	4	0	0	0
		Cell Operator	4	0	0	0	4	0	0	0	0
		Plate Hooker	5	0	0	0	0	0	5	0	0
		Plater Stripper	9	0	0	0	9	0	0	0	0
		Mill Operator	4	2	2	0	0	0	0	0	0
		Blender Operator	1	0	1	0	0	0	0	0	0
		Briquetting Operator	1	0	1	0	0	0	0	0	0
		Furnace Loader	3	3	0	0	0	0	0	0	0
		Furnace Operator	3	3	0	0	0	0	0	0	0
		VG Picker	3	0	3	0	0	0	0	0	0
		Brick Layer	3	3	0	0	0	0	0	0	0
		Shipper	3	3	0	0	0	0	0	0	0
		Bagger	4	2	1	1	0	0	0	0	0
	Subtotal Chromium Metal Producers		**63**	**16**	**8**	**9**	**17**	**8**	**5**	**0**	**0**
14	Steel Mills (stainless)	Raw Material Handler	412	0	0	206	206	0	0	0	0
		Furnace Operator	1,260	0	832	214	214	0	0	0	0
		Furnace Helper/Laborer	1,563	391	0	203	297	672	0	0	0
		Crane Operator	1,014	0	254	0	121	639	0	0	0
		Continuous Casting Operator	466	0	233	233	0	0	0	0	0
		Rolling-Mill Operator	1,808	868	108	542	145	145	0	0	0
		Welder	1,219	0	49	0	158	317	49	463	183
		Steel Conditioning Operator	1,534	0	0	1023	0	511	0	0	0
	Subtotal Steel Mills (stainless)		**9,276**	**1,259**	**1,476**	**2,421**	**1,141**	**2,284**	**49**	**463**	**183**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

Industry Sector		Job Category	Number of Exposed Workers ($\mu g/m^3$)								
			Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
14A	Steel Mills	Raw Material Handler	1,302	0	651	651	0	0	0	0	0
	(carbon)	Furnace Operator	3,991	2635	678	678	0	0	0	0	0
		Furnace Helper/Laborer	4,945	1236	643	940	2126	0	0	0	0
		Crane Operator	3,210	803	0	385	2022	0	0	0	0
		Continuous Casting Operator	1,476	738	738	0	0	0	0	0	0
		Rolling-Mill Operator	5,726	3092	1718	458	458	0	0	0	0
		Welder	3,860	0	154	502	1004	154	1467	579	0
		Steel Conditioning Operator	4,858	0	3255	0	1603	0	0	0	0
	Subtotal Steel Mills (carbon)		**29,368**	**8,504**	**7,837**	**3,614**	**7,213**	**154**	**1,467**	**579**	**0**
14B	Reshaping	Raw Material Handler	70	0	0	35	35	0	0	0	0
	(stainless)	Laborer	266	128	16	80	21	21	0	0	0
		Crane Operator	172	0	43	0	21	108	0	0	0
		Rolling-Mill/Forging Operator	307	147	18	92	25	25	0	0	0
		Steel Conditioning Operator	261	0	0	175	0	86	0	0	0
	Subtotal Reshaping		**1,076**	**275**	**77**	**382**	**102**	**240**	**0**	**0**	**0**
15	Iron and Steel	Molders	12,024	2,669	4,016	1,335	2,669	1,335	0	0	0
	Foundries	Furnace Operator	1,728	0	1,083	359	143	143	0	0	0
		Crane Operator	1,530	0	0	383	256	891	0	0	0
		Pourers	1,584	0	1,584	0	0	0	0	0	0
		Shake-out and Abrasive Blasting Operators	396	0	0	0	0	396	0	0	0
		Torch Cutter/Gouger	792	0	0	99	198	0	198	99	198
		Welder	1,782	0	0	223	445	0	445	223	446
		Grinder Operator	6,480	648	3,888	648	0	1,296	0	0	0
		Laborer	3,906	867	1,304	434	867	434	0	0	0
	Subtotal Iron and Steel Foundries		**30,222**	**4,184**	**11,875**	**3,481**	**4,578**	**4,495**	**643**	**322**	**644**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

			Number of Exposed Workers (μg/m³)								
Industry Sector		Job Category	Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
16	Chromium Dioxide Producers	Not Applicable	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	Color Maker	16	0	0	0	0	11	0	1	4
		Drying/Blending/Packaging Operator	30	0	0	0	0	9	0	3	18
		Maintenance Worker	10	0	0	0	0	2	0	2	6
		Laborer	20	0	0	0	0	10	0	0	10
		Laboratory Technician	9	0	0	0	0	5	2	0	2
		Wastewater Treatment Operator	9	0	0	0	0	0	3	3	3
		Manager/Supervisor	10	0	0	0	0	3	1	1	5
	Sub Total Chromium Dye Producers		**104**	**0**	**0**	**0**	**0**	**40**	**6**	**10**	**48**
18	Chromium Sulfate Producers	Reactor Operators	6	0	3	0	0	3	0	0	0
		Railcar Operators	5	0	5	0	0	0	0	0	0
	Subtotal Chromium Sulfate Producers		**11**	**0**	**8**	**0**	**0**	**3**	**0**	**0**	**0**
19	Chemical Distributors	Shipping	3,572	3,572	0	0	0	0	0	0	0
20	Textile Dyeing	Blender	7,926	3,963	0	3,963	0	0	0	0	0
		Dyer	16,125	13,384	2,741	0	0	0	0	0	0
		Maintenance Worker	1,290	645	645	0	0	0	0	0	0
	Subtotal Textile Dyeing		**25,341**	**17,992**	**3,386**	**3,963**	**0**	**0**	**0**	**0**	**0**
21	Colored Glass Producers	Lab Assistant	7	3	2	0	0	2	0	0	0
		Batch Mixer	43	43	0	0	0	0	0	0	0
		Furnace Worker	245	245	0	0	0	0	0	0	0
	Subtotal Colored Glass Producers		**295**	**291**	**2**	**0**	**0**	**2**	**0**	**0**	**0**
21A	Fiber and Other Glass Producers	Batch Operator	468	70	250	37	0	37	37	37	0
		Furnace Operator	1,620	373	989	81	0	113	32	32	0
		EP/Baghouse Operator	72	36	36	0	0	0	0	0	0
		Forehearth Operator	648	110	428	0	0	110	0	0	0
		Hot End Repair/Maintenance	2,281	0	1665	0	0	456	0	0	160
	Subtotal Fiber and Other Glass Producers		**5,089**	**589**	**3,368**	**118**	**0**	**716**	**69**	**69**	**160**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

Industry Sector		Job Category	Number of Exposed Workers (µg/m^3)								
			Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
22	Printing	Printer	5,700	5,700	0	0	0	0	0	0	0
		Mixer	200	200	0	0	0	0	0	0	0
		Shipper	700	700	0	0	0	0	0	0	0
	Subtotal Printing		**6,600**	**6,600**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
23	Leather Tanning	Not Applicable	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	Process Operators, Phillips Polyethylene Plants	112	38	28	11	15	10	10	0	0
		Process Operators, all Catalyst Plants except Phillips Polyethylene Plants	131	0	22	43	22	22	22	0	0
		Field Technician	707	0	119	231	119	119	119	0	0
	Subtotal Chromium Catalyst Users		**950**	**38**	**169**	**285**	**156**	**151**	**151**	**0**	**0**
25	Refractory Brick Producers	Cleaner	6	0	6	0	0	0	0	0	0
		Crusher Operator	12	0	12	0	0	0	0	0	0
		Pressman	12	0	12	0	0	0	0	0	0
		Batchman	18	3	9	3	3	0	0	0	0
		Mold Filler	6	0	6	0	0	0	0	0	0
		Brick Loader	18	0	9	0	9	0	0	0	0
		Grinder Operator	6	6	0	0	0	0	0	0	0
		Saw Operator	6	6	0	0	0	0	0	0	0
		Engineering Intern	6	6	0	0	0	0	0	0	0
	Subtotal Refractory Brick Producers		**90**	**21**	**54**	**3**	**12**	**0**	**0**	**0**	**0**
26	Woodworking	Construction	13,952	4,651	0	4,651	0	3,100	0	1,550	0
		Maritime	319	239	80	0	0	0	0	0	0
		General Industry	388	334	0	0	0	0	0	54	0
		Government	121	40	0	40	0	27	0	14	0
	Subtotal Woodworking		**14,780**	**5,264**	**80**	**4,691**	**0**	**3,127**	**0**	**1,618**	**0**
27	Solid Waste Incineration	Laborer	741	296	0	149	296	0	0	0	0
		Shredder/Heavy Equipment Operator	451	451	0	0	0	0	0	0	0
		Maintenance Mechanic/ Maintenance Helper	451	225	0	113	113	0	0	0	0
		Boiler Operator/Assistant Operator	290	217	0	0	73	0	0	0	0
		Maintenance Electrician	224	112	0	112	0	0	0	0	0
		Truck Operator (ash hauling)	128	64	0	64	0	0	0	0	0
	Subtotal Solid Waste Incineration		**2,285**	**1,365**	**0**	**438**	**482**	**0**	**0**	**0**	**0**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

Industry Sector		Job Category	Number of Exposed Workers (µg/m^3) Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
27A	Solid Waste	Laborer	34	14	0	6	14	0	0	0	0
	Incineration	Shredder/Heavy Equipment Operator	21	21	0	0	0	0	0	0	0
			0								
	(government)	Maintenance Mechanic/ Maintenance Helper	21	11	0	5	5	0	0	0	0
		Boiler Operator/Assistant Operator	14	10	0	0	4	0	0	0	0
		Maintenance Electrician	10	5	0	5	0	0	0	0	0
		Truck Operator (ash hauling)	6	3	0	3	0	0	0	0	0
	Subtotal Solid Waste Incineration -- Government		**106**	**64**	**0**	**19**	**23**	**0**	**0**	**0**	**0**
28	Oil and Gas Well Drilling	Not Applicable	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	Millers	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
30	Superalloy	Melt Specialist	72	72	0	0	0	0	0	0	0
	Producers	Reclaim Weigh Operator	72	0	0	72	0	0	0	0	0
	and Users	EAF Operator	48	0	48	0	0	0	0	0	0
		VIM/AIM Furnace Operator	168	84	56	28	0	0	0	0	0
		Crane Operator	143	0	36	0	17	90	0	0	0
		Refining Unit Operator	236	236	0	0	0	0	0	0	0
		Floor Person	800	400	400	0	0	0	0	0	0
		Welder	40	30	0	0	0	0	0	10	0
		Inert Screener	8	8	0	0	0	0	0	0	0
		Laboratory Technician	144	86	58	0	0	0	0	0	0
		Machine Operator	288	262	26	0	0	0	0	0	0
		Maintenance Worker	144	144	0	0	0	0	0	0	0
	Subtotal Superalloy Producers		**2,163**	**1,322**	**624**	**100**	**17**	**90**	**0**	**10**	**0**
31	Construction	Refractory Brick Repairer	1,040	156	104	0	156	520	52	52	0
		Hazardous Waste Site Worker	1,213	910	230	73	0	0	0	0	0
		Industrial Rehabilitation	1,684	1,684	0	0	0	0	0	0	0
	Subtotal Construction -- Other Operations		**3,937**	**2,750**	**334**	**73**	**156**	**520**	**52**	**52**	**0**

Table VIII-2. Exposure Profile for Job Categories of Affected Workers in Each Industry Sector

			Number of Exposed Workers ($\mu g/m^3$)								
Industry Sector		Job Category	Total	Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
31	Construction	Hazardous Waste Site Worker	679	509	129	41	0	0	0	0	0
	(government)	Industrial Rehabilitation	101	101	0	0	0	0	0	0	0
	Subtotal Construction -- Other Operations -- Government		**780**	**610**	**129**	**41**	**0**	**0**	**0**	**0**	**0**
32A	Ready-Mixed Concrete	Truck Driver	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
32	Precast Concrete Products Producer	Mixer	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total		**558,431**	**121,522**	**85,249**	**115,769**	**104,638**	**62,957**	**27,759**	**25,154**	**15,382**

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, 2006.

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In all sectors OSHA has used the best available information to determine baseline exposures and technological feasibility. Throughout the rulemaking process OSHA requested industry-specific information. These requests included site visits, discussions with industry experts and trade associations, the 2002 Request for Information (RFI), and the SBREFA process. These requests continued through the proposal and the public hearing process where OSHA continued to request information. OSHA reviewed all the data submitted to the record and where appropriate updated the exposure profile. For exposure information to be useful in the profile, only individual personal exposures representing a full shift were used.

As noted earlier, OSHA used a variety of sources to obtain information about exposures in each application group. These sources include: NIOSH Health Hazard Evaluations (HHEs), OSHA's Integrated Management Information System (IMIS) exposure data, data from other government agencies, published literature, OSHA/NIOSH site visits, discussions with industry experts and trade associations, and data submitted to the OSHA record. In some instances OSHA's contractor had difficulty obtaining permission to perform site visits in a specific application group. For instance, OSHA's contractor could obtain permission to conduct a site visit only at a steel mill that used the teeming and primary rolling method—in contrast to continuous casting, now used in approximately 95 percent of steel mills. In these few cases, OSHA acknowledged these potential problems and OSHA (or its contractor) discussed its concerns with industry experts and used their professional judgment to determine technological feasibility.

In response to the exposure data submitted to the record OSHA has made the following major changes to the exposure profile:

- Electroplating—Revised the exposure distribution for hard chrome electroplating to use only the more-detailed exposure data from site visits and other NIOSH reports.
- Welding—In construction, OSHA used exposure data from the maritime sector for analogous operations to supplement the exposure profile. Added additional exposure data to the profile as provided to the record.
- Painting—Revised the exposure profile to reflect the additional aerospace exposure data submitted to the record.
- Steel Mills—Revised the exposure profile to reflect additional exposure data supplied to the record; welders were added directly to this application group.
- Chromium Catalyst Users—Revised the exposure profile based on additional exposure data from a NIOSH HHE.
- Wood working—Added information from the record.
- Construction—Revised the exposure profile to reflect the additional exposure information submitted to the record.

Detailed information on the changes made in the exposure profile for each application group can be found in Chapter III of the Final Economic Analysis.

OSHA's analysis of technological feasibility examined employee exposures at the operation or task level to the extent that such data were available. There are approximately 558,000 workers exposed to Cr(VI), of which 352,000 are exposed above 0.25 micrograms per cubic meter and 68,000 above the PEL of 5 micrograms per cubic meter.

C. Technological Feasibility

In Chapter III of OSHA's FEA, OSHA assesses the current exposures and the technological feasibility of the final standard in all affected industry sectors. The analysis presented in this chapter is organized by application group and analyzes employee exposures at the operation or task level to the extent that such data are available. Accordingly, OSHA collected exposure data at the operation or task level to identify the Cr(VI)-exposed workers or job operations that need to improve their process controls to achieve exposures at or below the PEL. In the few instances where there were insufficient exposure data, OSHA used analogous operations to characterize these operations.

In general, OSHA considered the following kinds of controls that could reduce employee exposures to Cr(VI): local exhaust ventilation (LEV), which could include maintenance or upgrade of the current local exhaust ventilation or installation of additional LEV; process enclosures that would isolate the worker from the exposure; process modifications that would reduce the generation of Cr(VI) dust or fume in the work place; improved general dilution ventilation including assuring that adequate make-up air is supplied to the work place; improved housekeeping; improved work practices; and the supplemental use of respiratory protection if engineering and work practice controls were not sufficient to meet the PEL.

The technologies used in this analysis are commonly known, readily available and are currently used to some extent in the affected industries and processes. OSHA's assessment of feasible controls and the exposure levels they can achieve is based on information collected by Shaw Environmental, Inc. (Ex. 50), a consultant to OSHA, on the current exposure levels associated with existing controls, on the availability of additional controls needed to reduce employee exposures, and on other evidence presented in the docket.

Through the above analysis, OSHA finds that a PEL of 5 $\mu g/m^3$ is technologically feasible for most operations in all affected industries through the use of engineering and work practice controls. As discussed further below, the final rule requires that when painting of aircraft or large aircraft parts is performed in the aerospace industry, the employer is only required to use engineering and work practice controls to reduce employee exposures to Cr(VI) to or below 25 $\mu g/m^3$. The employer must then use respiratory protection to achieve the PEL. Apart from this limited exception, all other industries can achieve the PEL with only minimal reliance on respiratory protection. Table VIII–3 shows OSHA's estimate of respirator use by industry for each of the PELs that OSHA considered. At the final PEL of 5 $\mu g/m^3$, only 3.5 percent of exposed employees will be required to use respirators.

In only three sectors will respirator use be required for more than 5 percent of exposed employees. In two of these sectors, chromate pigment producers and chromium dye producers, use of respirators will be intermittent. The third sector, stainless steel welding, presents technological challenges in certain environments such as confined spaces. OSHA has concluded that, with a few limited exceptions which are discussed below, employers will be able to reduce exposures to the PEL through the use of engineering and work practice controls.

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Table VIII-3. Estimated Number of Hexavalent Chromium-Exposed Workers Requiring Respirators after Application of Engineering and Work Practice Controls (by Industry and Alternative PEL)

Industry	Total No. of Exposed Employees	Number of Employees Requiring Respirators and Percentage of All Exposed Employees					
		0.25	0.5	1	5	10	20
		PEL (µg/m^3)					
Electroplating	66,859	10,171	5,701	964	0	0	0
		15.2%	8.5%	1.4%	0.0%	0.0%	0.0%
Welding - General Industry (stainless steel)	45,326	23,328	17,627	12,360	7,230	1,862	189
Welding –Maritime (stainless steel)	21,029	5,735	2,220	1,547	940	787	23
Welding – Construction (stainless steel)	60,450	28,756	20,721	14,377	5,875	2,261	840
Welding – Government (stainless steel)	942	407	302	224	93	36	13
Welding Stainless Steel Grand Total	*127,746*	*58,225*	*41,982*	*28,509*	*14,353*	*5,009*	*1,066*
		45.6%	*32.9%*	*22.3%*	*11.2%*	*3.9%*	*0.8%*
Welding - General Industry (carbon steel)	60,600	32,784	13,147	5,511	920	0	0
Welding – Maritime (carbon steel)	629	468	246	103	17	0	0
Welding - Construction (carbon steel)	80,404	32,784	17,275	7,241	1,208	0	0
Welding Carbon Steel Grand Total	*141,633*	*72,273*	*30,668*	*12,856*	*2,145*	*0*	*0*
		51.0%	*21.7%*	*9.1%*	*1.5%*	*0.0%*	*0.0%*
Painting - General Industry	37,543	11,037	10,802	1,350	810	704	432
Painting – Construction	33,408	17,120	15,978	5,543	1,460	326	815
Painting – Maritime	3,155	1,839	1,518	1,518	321	321	321
Painting – Government	8,147	4,278	3,993	1,385	366	81	203
Grand Total Painting	*82,253*	*34,274*	*32,291*	*9,796*	*2,957*	*1,432*	*1,771*
		41.7%	*39.3%*	*11.9%*	*3.6%*	*1.7%*	*2.2%*
Producers of Chromates	150	75	**21**	**21**	0	0	0
		50.0%	14.0%	14.0%	0.0%	0.0%	0.0%
Chromate Pigment Producers	52	39	**18**	**18**	**6**	**6**	**6**
		75.0%	**34.6%**	**34.6%**	**11.5%**	**11.5%**	**11.5%**
Chromated Copper Arsenate Producers	27	6	0	0	0	0	0
		22.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Catalyst Producers	313	125	85	**85**	0	0	0
		39.9%	27.2%	**27.2%**	0.00%	0.00%	0.00%
Paint and Coatings Producers	2,569	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table VIII-3, contd. Estimated Number of Hexavalent Chromium-Exposed Workers Requiring Respirators after Application of Engineering and Work Practice Controls (by Industry and Alternative PEL)

Printing Ink Producers	112	85	**85**	**0**	0	0	0
		75.9%	**75.9%**	**0.00%**	0.00%	0.00%	0.00%
Plastic Colorant Producers and Users	492	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plating Mixture Producers	118	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ferrochromium Producers	63	7	0	0	0	0	0
		11.1%	0.0%	0.0%	0.0%	0.0%	0.0%
Steel Mills – Stainless Steel	9,276	1,236	1,180	0	0	0	0
Steel Mills – Carbon Steel	29,368	3,230	3,207	0	0	0	0
Downstream (Forging/Hot Rolling Mills)	1,076	0	0	0	0	0	0
Steel Mills – Grand Total	*39,720*	*4,466*	*4,387*	*0*	*0*	*0*	*0*
		11.2%	*11.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Iron and Steel Foundries	30,222	2,577	0	0	0	0	0
		8.5%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Dye Producers	104	**103**	**103**	**103**	**64**	**58**	**45**
		99.0%	**99.0%**	**99.0%**	**61.5%**	**55.8%**	**43.3%**
Chromium Sulfate Producers	11	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chemical Distributors	3,572	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Textile Dyeing	25,341	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Producers of Glass	5,384	612	612	612	177	177	177
		11.4%	11.4%	11.4%	3.3%	3.3%	3.3%
Printing	6,600	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Catalyst Users	949	**705**	**705**	**705**	0	0	0
		74.3%	**74.3%**	**74.3%**	0.0%	0.0%	0.0%
Producers of Refractory Brick	90	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Wood Working	14,780	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table VIII-3, contd. Estimated Number of Hexavalent Chromium-Exposed Workers Requiring Respirators after Application of Engineering and Work Practice Controls (by Industry and Alternative PEL)

Solid Waste Incinerations	2,391	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Non-Ferrous Metallurgical Uses of Chromium	2,164	39	39	0	0	0	0
		1.8%	1.8%	0.0%	0.0%	0.0%	0.0%
Construction – Other[1]	4,069	90	0	0	0	0	0
		2.2%	0.0%	0.0%	0.0%	0.0%	0.0%
All Industries	*558,431*	*191,290*	*116,697*	*53,123*	*19,702*	*6,682*	*3,065*
		34.3%	*20.9%*	*9.5%*	*3.5%*	*1.2%*	*0.6%*

Bold numbers indicate intermittent use.

[1] "Construction – Other" includes industrial rehabilitation and maintenance, hazardous waste site work, and refractory restoration and maintenance.

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, 2006.

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In determining technological feasibility OSHA has used the median to describe the exposure data. Since the median is a statistical term indicating the central point of a sequence of numbers (50 percent below and 50 percent above) it best describes exposures for most people. The median is also a good substitute for the geometric mean for a log normal distribution which often describes exposure data. As described by the Color Pigments Manufacturers Association, Inc. (CPMA) in an economic impact study by IES Engineers:

> The exposure distribution (assuming it is log normal) can be characterized by the geometric mean and standard deviation. The median (not the average) is a reasonable estimate of the geometric mean (Ex. 47–3, p. 54).

In contrast, the use of an arithmetic mean (or average) may tend to misrepresent the exposure of most people. For example, if there are a few workers with very high exposures due to poor engineering or work practice controls, the arithmetic mean will be artificially high, not representing realistic exposures for the workers.

The technological feasibility chapter of the FEA is broken down into five main parts: Introduction, Exposure Profile, Baseline Controls, Additional Controls and Substitution. The first part is an introduction to the application group, which outlines the major changes in the analysis between the Preliminary Economic Analysis and the Final Economic Analysis and addresses comments specific to the application group.

The next part of the technological feasibility analysis is the exposure profile. The exposure profile describes the prevailing exposures in each application group on a job-by-job basis. The exposure profile represents exposure situations that may be well controlled or poorly controlled. The data used to determine the current exposures were obtained from any of the following sources: OSHA site visits; the OSHA compliance database, Integrated Management Information System (IMIS); NIOSH site visits; NIOSH control technology or health hazard evaluation reports (HHE); information from the U.S. Navy; published literature; submissions by individual companies or associations; or, in a few cases, by consideration of analogous operations. While the exposure profile was developed from current exposures and is not intended to demonstrate feasibility, there were a few instances where the exposure profile was used as ancillary support for technological feasibility if there were a significant number of facilities already meeting the PEL. An example of this case can be seen in the production of colored glass, where over 90 percent of the exposure data were below 0.25 $\mu g/m^3$.

In the cases where analogous operations were used to determine exposures, OSHA used data from industries or operations where materials and exposure routes are similar. OSHA also tended to be conservative (over-estimating exposures). For example, exposure data for the bagging of pigments were used to estimate exposures for the bagging of plastic colorants. In both cases the operation consists of bagging a pigmented powder. However, exposures would tend to be higher for bagging pigments due to the fact that in pigments there is a higher percentage of Cr(VI) and the pigments tend to consist of finer particles than those in plastic colorants where the Cr(VI) particles are diluted with other ingredients. As Mr. Jeff Cox from Dominion Colour Corporation stated:

> Exposure of packers in the pigment industry, who are making a fine powder, is very much higher than packers in the plastics colorants industry, who are basically packing pellets of encapsulated product which are a few millimeters in diameter (Tr. 1710).

The use of operations that are more difficult to control to estimate analogous operations would result in an overestimate of exposures, subsequently resulting in an overestimate of the controls needed to reduce the exposures to Cr(VI) in those analogous operations.

The next section of OSHA's analysis of technological feasibility in the FEA describes the baseline controls. OSHA determined controls to be "baseline" if OSHA believed that such controls are commonly used in the application group. This should not be interpreted to mean that OSHA believes that all firms use these controls, but rather that the controls are common and widely available in the industry. Information on the controls used in each specific application group was obtained from several different sources such as: site visits, NIOSH HHEs, industry experts, industry associations, published literature, submissions to the docket, and published reports from other federal agencies. OSHA used the median to estimate the exposure level associated with the baseline controls. For the majority of the operations, the median was calculated using the exposures directly associated with the baseline controls. However, there were a few cases where the median was calculated from the exposure profile and OSHA determined these exposures reflected the baseline controls (*e.g.*, fiberglass production).

The fourth section of the technological feasibility analysis determined the need for additional controls. If the median exposure was above the PEL with the use of baseline controls, OSHA would recommend additional engineering or work practice controls that would reduce exposures to or below the PEL. The final rule does not require an employer to use these specific controls. The engineering controls or work practices are, however, OSHA's suggestions for possible ways to achieve the PEL. Through this process a few situations could arise when the exposures with baseline exposures are above the PEL:

- Engineering and work practice controls alone: OSHA determined that additional controls would reduce worker's exposure below the PEL if: 1) the proposed additional controls were already in use at other facilities in the same application group and exposures there were below the PEL, or 2) the additional controls were used in analogous industries or operations and they were effective.
- Respiratory protection required to meet the PEL: There were a few instances where workers' exposures would remain above the PEL even with the installation of additional controls. In these cases OSHA indicated that the supplemental use of respirators may be needed (*e.g.* enclosed spray-painting operations in aerospace).
- Intermittent respiratory protection: There were instances where a worker performs specific job-related activities that could result in higher exposures above the PEL for limited periods of time. In these cases OSHA noted that the supplemental use of respirators during these activities may be necessary. For example, an employee who works in pigment production generally, may need to use a respirator only when entering the enclosure where the bagging operations take place because the enclosure is the engineering control in this operation.

The final component of the technological feasibility section in the FEA is a discussion of substitution. Here, OSHA describes the options available for eliminating or reducing the use of ingredients that either contain or can produce Cr(VI) during processing. This is primarily a discussion of the possibility of substitution. In some cases there is no readily available substitute for either chromium metal or Cr(VI) ingredients such as a non-Cr(VI) coating for corrosion control in the aerospace industry. In other cases an application group has been steadily reducing their use of Cr(VI), such as in the printing industry. In some industries there are substitutes available for at least some operations, such as the use of trivalent chromium in some decorative electroplating operations. Finally, through hearing testimony and docket submissions, OSHA received information regarding new technologies that can be used to reduce some of the sources of exposure to the workers.

In most cases OSHA does not rely on material substitution for reducing exposures to Cr(VI) to determine technological feasibility. For example, in the case of some welding operations, OSHA has determined that the use of an alternate welding process that reduces fume generation, such as the switching from shielded metal arc welding (SMAW) to gas metal arc welding (GMAW), could be effective in reducing a worker's exposure to hexavalent chromium to a level at or below the PEL. Alternatively, experiments have also shown that elimination or reduction of sodium and potassium in the flux reduces the production of Cr(VI) in the welding fume (Ex. 50). However, this technology has yet to be commercialized due to potential weld quality problems. Thus, OSHA ultimately determined that material substitution was currently not feasible for SMAW welding operations.

There were comments submitted to the record that did not agree with certain aspects of OSHA's feasibility analysis. These comments addressed:

- OSHA's use of median values to describe exposure data and failure to address costs for exposures above the PEL where the median was below the PEL;
- OSHA's use of the number of workers to determine the number of facilities needing additional controls;
- The use/validity of OSHA's analytical method; and
- The lack of data/site visits to properly characterize an application group.

Several commenters objected to OSHA's use of the median in the technological feasibility analysis. The National Coil Coating association stated:

> It is inappropriate to use median exposure values to reach a conclusion that no coil coating facility will be subject to regulatory requirements associated with exceedances of the proposed PEL. Of the 15 samples supplied, one sample exceeded the proposed PEL and another one was equal to the proposed PEL (Ex. 39–72–1).

Collier Shannon Scott, representing the Specialty Steel Industry of North America, stated:

> OSHA conducted a technological feasibility analysis to determine what engineering or administrative controls would be necessary to achieve the proposed PEL only where the median exposure value for any particular job category exceeded the proposed PEL. If correct, this means that where the median exposure value fell below 1 ug/m3, even though numerous of the exposure values for that job category were above 1 ug/m3, OSHA's analysis does not recognize that controls would have to be implemented for that job category at any facilities where that job is conducted (Ex. 47–27–1).

OSHA believes that these commenters misunderstood OSHA's use of the median value and the term ''additional controls.'' As stated earlier, OSHA used the median value to describe either the overall exposures or the effectiveness of various controls. However, to estimate the cost of controls, OSHA used the entire exposure profile. Thus, if any exposures were over the PEL, then costs for engineering controls would be assigned. If for a job category the ''baseline controls'' have been determined to reduce employee exposures to below the PEL, then OSHA would include costs for ''baseline controls'' for the percentage of the facilities that had exposures over the PEL. However, if the ''baseline'' controls would not be sufficient to reduce worker exposures to below the PEL then OSHA would cost the ''additional controls.''

Collier Shannon Scott, representing the Specialty Steel Industry of North America also stated:

> OSHA wrongly uses percentage distribution by job category to estimate the number of facilities that would be required to install engineering controls. This is a logical error. There is no connection between the number of facilities that must install controls and the percentage of employees above a given exposure level (Ex. 47–27–1).

OSHA was also concerned about accurately using individual exposures to represent the number of facilities that would need to implement either baseline controls or additional controls. Thus, whenever exposure data were associated with individual facilities, OSHA normalized the exposure data by job category to the facility, with each facility having a weighting factor of 1. However, if exposure data varied significantly, OSHA accounted for this. For example, if fifty percent of the exposure data for a job class in a facility was above the PEL and fifty percent below the PEL, then OSHA counted this as representing 0.5 facilities above the PEL and 0.5 facilities below the PEL.

The use of this weighting system ensured that each facility received the same weight so that one facility that supplied a large amount of data would not overwhelm the exposure profile and skew the distribution in an application group. This is particularly important when there is a wide range of sizes of facilities and a large facility could outweigh a smaller facility. OSHA then used this weighting system to determine the percentage of facilities affected, so that the costs were based on a per-facility versus a per-employee basis. However, in a few instances OSHA could not use the weighting factor system because certain exposure data were presented to OSHA as representing the industry. For examples, in maritime welding and aerospace painting the exposure data could not be attributed to individual facilities but were presented to OSHA as representing a group of facilities.

There were comments about several different aspects of OSHA's analytical method. The Policy Group, representing the Surface Finishing Industry Council, was concerned about how OSHA interpreted the term non-detect (ND):

> Appropriate assessment of ND qualitative value would require that the sample specific quantitation limit be lower than any targeted analytical value, such as the new proposed AL and PEL. According to a leading OSHA/NIOSH contract laboratory (DataChem Laboratories) in the field of IH analyses, laboratories only report to the lowest calibration standard. Thus, the lowest standard value in the curve is the quantitation limit or reporting limit. This limit is the minimum value the labs generally report, regardless of any theoretical LOD value (Ex. 47–17–8).

OSHA agrees with The Policy Group's assessment and has updated the exposure profiles to reflect non-detect samples as the Limit of Quantification (LOQ) where the source of the data did not indicate the limit of detection. This is discussed in more detail in the electroplating section of the technological feasibility chapter in the FEA.

Several comments questioned whether OSHA's analytical method truly represents a worker's exposure (Ex. 38–216–1). Several other sources indicate that OSHA's analytical method ID 215 is appropriate and it accurately represents a worker's exposure. In a *Journal of Environmental Monitoring* article the authors conclude:

> * * * a field comparison of three recently developed or modified CrVI sampling and analytical methods showed no statistically significant differences among the means of the three methods based on statistical analysis of variance. The overall performances of the three CrVI methods were comparable in electroplating and spray painting operations where soluble CrVI was present. Although the findings reported herein are representative of workplace operations utilizing soluble forms of CrVI, these analytical methods (using identical sample preparation procedures) also have been shown to quantitatively measure insoluble forms of CrVI in other occupational settings. There were no significant differences observed among CrVI concentrations measured by NIOSH 7605 and OSHA ID 215 (Ex. 40–10–5).

In addition URS Corporation stated:

> The new OSHA method 215 was used to analyze samples collected during the Site Visits for Company 1 and Company 18. This method is far superior to the old OSHA method ID 103 and to other relative older methods. The new method utilizes separations of the hexavalent chromium from potential interferences prior to the analysis. It is also designed to detect much lower CrVI concentrations levels and to remove both positive and negative interferences at these lower concentrations. Furthermore, this method has been fully validated in the presence of interferences over a CrVI concentration range that includes the proposed new AL and PEL values (Ex. 47–17–8).

OSHA's analytical method ID 215 is a fully validated analytical method that can analyze Cr(VI) well below the PEL within the accuracy of measurement as specified in the final standard.

Dr. Joel Barnhart, on behalf of the Chrome Coalition, questioned how the samples were taken during the OSHA-sponsored site visits (Ex. 40–12–1). At all site visits conducted by OSHA's contractors, certified industrial hygienists (CIHs) were responsible for either taking samples or reviewing sampling data provided by the facility visited. All samples were taken following procedures from either NIOSH or OSHA which detail the type of sampler, filter and flow rates appropriate for the analytical methods used. Full details about the samples, operations they represent and engineering controls can be found in each site visit report.

Several commenters mentioned that OSHA relied solely on one site visit for an entire application group (Exs. 38–218; 38–205). While the OSHA/NIOSH site visits were important to OSHA's understanding of the processes used in the different application groups, the site visits were not the sole source of information. OSHA, as stated earlier, used many different sources to properly characterize an application group. These sources included: OSHA site visits, OSHA's compliance data base (IMIS), NIOSH site visits, NIOSH engineering control technology reports or health hazard evaluation reports, published literature, submissions by individual companies, as well as detailed discussions with industry experts. In addition, throughout the rulemaking process OSHA has requested information regarding processes, exposures, engineering controls, substitutes and other information pertinent to Cr(VI) application groups. These requests came in many forms such as stakeholder meetings, site visits, OSHA's 2002 Request for Information, and the SBREFA review. OSHA continued to update the technological feasibility analysis based on information submitted to the docket during the hearings and during the pre- and post-hearing comment periods.

OSHA also received comments specific to application groups regarding issues such as the number of employees potentially exposed, additional exposure data, and the effectiveness of controls. Comments that were application group-specific are addressed in the FEA in the individual sections on those application groups.

The major changes made to the technological feasibility analysis for the Final Economic Analysis are listed below:

- Electroplating—The number of affected workers and establishments was revised, the exposure distribution was revised for hard chrome electroplating, and chromate conversion workers and establishments were added.
- Welding—The number of maritime welders was increased, mild steel welding was added, and control technology for reducing worker exposure was revised.
- Painting—Auto body repair workers were added to general industry and traffic painting was added to construction. Control technology for reducing worker exposure was revised for aerospace spray painting.
- Chromium Catalyst Production—Control technology for reducing worker exposure was revised.

- Steel Mills—OSHA revised the distribution of steel workers, carbon steel workers were added, and downstream users (*e.g.* rolling mills and forging operations) were added to this application group.
- Glass Production—Fiber, flat, and container glass production were added.
- Producers of Pre-Cast Concrete Products—Ready mixed concrete workers were added.
- Throughout the analysis the exposure profiles were updated to reflect additional exposure data submitted to the docket.

Technological Feasibility of the New PEL: There are over 558,000 workers exposed to Cr(VI). Table VIII–2 shows the current exposures to Cr(VI) by application group. There are employers and some entire application groups that already have nearly all exposures below the PEL. However, many others will need to install or improve engineering and work practice controls to achieve the PEL.

OSHA has determined that the primary controls most likely to be effective in reducing employee exposure to Cr(VI) are local exhaust ventilation (LEV), process enclosure, process modification, and improving general dilution ventilation. In some cases, a firm may not need to upgrade its local exhaust system, but instead must ensure that the exhaust system is working to design specification throughout the process. In other cases, employers will need to upgrade or install new LEV. This includes installing duct work, a type of hood and/or a collection system. OSHA estimates that process enclosures may be necessary for difficult-to-control operations such as dusty operations. These enclosures would isolate the employees from high exposure processes and reduce the need for respirators. Process modifications can also be effective in reducing exposures in some industries to a level at or below the PEL.

Below are discussions of the types of engineering and work practice controls that may be needed for the application groups where exposures are more difficult to control.

Electroplating: OSHA has determined that the PEL of 5 $\mu g/m^3$ is technologically feasible for all job categories through the use of a combination of engineering controls. For decorative plating and anodizing the vast majority (over 80 percent) of workers are already below 5 $\mu g/m^3$. For the workers above the PEL, there are several control options to reduce exposures, such as properly maintained ventilation and the use of fume suppressants. Some firms may not need to upgrade their local exhaust systems, but must ensure that their current exhaust systems are working according to design specification. For example, in hard chrome electroplating (where Cr(VI) exposures are highest) nearly 100 percent of hard chrome electroplating baths have LEV at the tank; however, none of the systems inspected during site visits and for NIOSH reports were operating at the designed capabilities. Many had disconnected supply lines or holes in the hoods and were working at 40 percent of their design capabilities. In such cases, OSHA recommends that these facilities perform the proper maintenance necessary to bring the system back to its initial parameters. Even with these deficiencies in engineering controls, over 75 percent of workers are below 5 $\mu g/m^3$.

In addition to improving LEV, the use of fume suppressants can further reduce the volume of Cr(VI) fumes released from the plating bath. However, OSHA was unable to conclude, based on the evidence in the record, that the proposed PEL of 1 $\mu g/m^3$ would have been technologically feasible for all hard chrome electroplating operations. In particular, OSHA has significant concerns about the technological feasibility of the proposed PEL for hard chrome electroplating operations in which fume suppressants cannot be used to control exposures to Cr(VI) because they would interfere with product specifications and render the resulting product unusable.

Welding: The welding operations OSHA expects to trigger requirements under the new Cr(VI) rule are those performed on stainless steel, as well as those performed on high-chrome-content carbon steel and those performed on carbon steel in confined and enclosed spaces. At the time of the proposal, OSHA believed that carbon steel contained only trace amounts of chromium and therefore that welding on carbon steel would not be affected by the standard. Comments and evidence received during the rulemaking, however, led OSHA to conclude that 10 percent of carbon steel contains chromium in more than trace amounts; OSHA adjusted its analysis accordingly. See Tr. 581–82.

OSHA has determined that the PEL of 5 $\mu g/m^3$ is technologically feasible for all affected welding job categories on carbon steel. OSHA has concluded that no carbon steel welders are exposed to Cr(VI) above 5 $\mu g/m^3$, with the exception of a small portion of workers welding on carbon steel in enclosed and confined spaces. Furthermore, OSHA has determined that engineering and work practice controls are available to permit the vast majority (over 95 percent) of welding operations on carbon steel in enclosed and confined spaces to comply with a PEL of 5 $\mu g/m^3$.

Although stainless steel welding generally results in higher exposures than carbon steel welding, OSHA has determined that the PEL of 5 $\mu g/m^3$ is also technologically feasible for all affected welding job categories on stainless steel. Many welding processes, such as tungsten-arc welding (TIG) and submerged arc welding (SAW), already achieve Cr(VI) exposures below the PEL because they inherently generate lower fume volumes. However, the two most common welding processes, shielded metal arc welding (SMAW) and gas metal arc welding (GMAW), generate greater exposures and may require the installation or improvement of LEV (defined to include portable LEV systems such as fume extraction guns (FEG)).

OSHA has found process substitution to be the most effective method of reducing Cr(VI) exposures. For example, the generation of Cr(VI) in GMAW welding fume is approximately 4 percent of the total Cr content, compared to upwards of 50 percent for SMAW. In the proposal, OSHA estimated that all SMAW workers outside of confined spaces (over 90 percent of the welders) could switch welding processes. However, hearing testimony and comments indicated that switching to GMAW is not feasible to the extent that OSHA had originally estimated.

Some comments indicated that this conversion has already taken place where possible. For example, Atlantic Marine stated they have already ‘‘greatly reduced the use of SMAW and replaced it with GMAW over the last several years’ (Ex. 39–60). Other comments indicated it is still an ongoing process. For instance, General Dynamics stated, ‘‘There are ongoing efforts to reduce the use of SMAW and replace it with GMAW for both efficiency and health reasons’’ (Ex. 38–214). In addition, some comments expressed concerns about the quality of the weld if GMAW is used instead of SMAW. (Ex. 39–70).

In view of these concerns OSHA has revised its estimate of the percentage of SMAW welders that can switch to GMAW from 90 percent to 60 percent. This estimate is consistent with the estimate made by Edison Welding Institute in a report for the Department of Defense on Cr(VI) exposures which ‘‘identifies engineering controls that can be effective in reducing worker exposure for many applications in the shipbuilding and repair industry’’ (Ex. 35–410).

For those stainless steel SMAW operations that cannot switch to GMAW, and even for some GMAW operations, the installation or improvement of LEV may be needed and can be used to reduce exposures. OSHA has found that LEV would permit most SMAW and GMAW operations to comply with a PEL of 5 μg/m³. OSHA recognizes that the supplemental use of respirators may still be necessary in some situations. A significant portion of the welders who may need supplemental respiratory protection are working in confined spaces or other enclosed areas, where the use of engineering controls may be limited due to space constraints. However, respirator use in those circumstances will not be extensive and does not undermine OSHA's finding that the PEL of 5 μg/m³ is technologically feasible.

For a more detailed explanation of OSHA's technological feasibility analysis for all welding operations, see Chapter III of the FEA.

Aerospace: OSHA has determined that most operations in the aerospace industry can achieve a PEL of 5 μg/m³. These operations include sanding Cr(VI) coated parts, assembly, and two-thirds of the spray painting operations. Field studies have shown that use of LEV at the sanding source can reduce exposures by close to 90 percent, with workers exposures well below the final PEL of 5 μg/m³. Exposure data provided to the docket show that the spray painting operations in paint booths or paint rooms using optimum engineering controls can achieve worker exposures below the final PEL of 5 μg/m³ (excluding large parts, whole planes, or the interior of the fuselage)

OSHA recognizes that there are certain instances where the supplemental use of respirators may be necessary because engineering and work practice controls are not sufficient to reduce exposures below the PEL. For example, when spray painting large parts or entire planes in hangars, engineering controls become less effective because of the large area needing ventilation and the constantly changing position of workers in relationship to these controls. As a result, OSHA estimates that engineering and work practice controls can limit exposures to approximately 25 μg/m³ under the conditions described above and supplemental use of respirators will be needed to achieve the PEL of 5 μg/m³. Accordingly, OSHA has adopted a provision for the painting of whole aircrafts (interior or exterior) and large aircraft parts that requires employers to reduce exposures to 25 μg/m³ with engineering and work practice controls and supplement these controls with the use of respiratory protection to achieve the PEL. For a more detailed explanation of OSHA's technological feasibility analysis for aerospace painting, see Chapter III of the FEA.

Other Industries: Other application groups that generate fine dusts such as chromate pigment production, chromium catalyst production, and chromium dye production may require new or improved ventilation to achieve the PEL of 5 μg/m³. Housekeeping measures are also important for controlling Cr(VI) exposures in these industries. General housekeeping and the use of HEPA vacuums instead of dry sweeping will minimize background exposures for most job categories. For a more detailed explanation of OSHA's technological feasibility analysis for chromate pigment producers, chromium catalyst producers, and chromium dye producers, see Chapter III of the FEA.

Apart from the aerospace painting operations discussed above, OSHA recognizes that there are a few limited operations where the supplemental use of respirators may be necessary to achieve the PEL of 5 μg/m³. However, OSHA believes that the final PEL can be achieved in most operations most of the time with engineering and work practice controls. As noted previously, Table VIII–3 shows OSHA's estimate of respirator use by industry for each of the PELs that OSHA considered.

Technological Feasibility of the Proposed PEL: As discussed more thoroughly in paragraph (c) of the Summary and Explanation of the Standard and in Chapter III of the FEA, OSHA has determined that the proposed PEL of 1 μg/m³ is not feasible across all industries because it cannot be achieved using engineering and work practice controls in a substantial number of industries and operations employing a large number of workers covered by the standard (in particular, see "Technological Feasibility of the Proposed 1 μg/m³ 8-Hour TWA PEL" in Chapter III of the FEA). Specifically, OSHA has determined that a PEL of 1 μg/m³ is not feasible for welding, which affects the largest number of establishments and employees.

A PEL of 1 μg/m³ is also technologically infeasible for aerospace painting, where two-thirds of all spray painting operations cannot reduce exposures to at or below 1 μg/m³ using engineering and work practice controls. Finally, OSHA was unable to conclude that the proposed PEL was technologically feasible for existing facilities in several other industries or operations, such as pigment production, catalyst production, and some hard chrome electroplating operations, where a PEL of 1 μg/m³ would significantly increase the number of workers requiring respiratory protection.

D. Costs

The costs employers are expected to incur to comply with the final standard are $282 million per year. In addition, OSHA estimates that employers will incur $110 million per year to comply with the personal protective equipment and hygiene requirements already present in existing generic standards. The final requirements to provide protective clothing and equipment and hygiene areas are closely aligned with the requirements of OSHA's current generic PPE and sanitation standards (e.g., 1910.132 and 1926.95 for PPE and 1910.142 and 1926.51 for the hygiene requirements). Therefore, OSHA estimates that the marginal cost of complying with the new PPE and sanitation requirements of the Cr(VI) standard was lower for firms currently subject to and in compliance with existing generic standards. OSHA's research on these current standards, however, uncovered some noncompliance. The baseline chosen for the Cr(VI) regulatory impact analysis reflects this non-compliance with current requirements. Although OSHA estimates that employers would need to spend an additional $110 million per year to bring themselves into compliance with the personal protective equipment and hygiene requirements already prescribed in existing generic standards, this additional expenditure is not attributable to the Cr(VI) rulemaking. However, the rule does require employers to pay for PPE. In some cases where employers do not now pay for PPE, employers will incur costs they did not previously have. However, because these costs were previously borne by employees, this change does not represent a net cost to the country. OSHA estimates that employers would be essentially transferring a benefit to employees of $6 million per year, the value of the portion of the total expense now paid by employees.

All costs are measured in 2003 dollars. Any one-time costs are annualized over a ten-year period, and all costs are annualized at a discount rate of 7 percent. (A sensitivity analysis using a discount rate of 3 percent is presented in the discussion of net benefits.) The derivation of these costs is presented in Chapter IV of the full FEA. Table VIII–4 provides the annualized costs by provision and by industry. Engineering control costs represent 41 percent of the costs of the new provisions of the final standard, and respiratory protection costs represent 25 percent of the costs of the new provisions of the final standard. Costs for the new provisions for general industry are $192 million per year, costs for constructions are $67 million per year, and costs for the shipyard sector are $23 million per year. In developing the costs for construction, OSHA assumed that all work by construction firms would be covered by the construction standard. However, in practice some work by construction firms takes the form of maintenance operations that would be covered by the general industry standard. (OSHA sought comment on this issue but received none.)

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Table VIII-4. Annualized Costs for All Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 5 ug/m^3)

	Application Group	Engineering Controls	Initial Exposure Monitoring	Periodic Exposure Monitoring	Total Exposure Monitoring	Respirator Programs
1	Electroplating	$32,993,514	$1,868,271	$8,037,794	$9,906,066	$3,834,175
2A	Welding (general industry - stainless steel)	$26,194,600	$1,862,872	$2,105,903	$3,968,775	$19,422,964
2B	Welding (maritime industry - stainless steel)	$3,817,884	$59,010	$14,050	$73,060	$13,885,327
2C	Welding (construction industry - stainless steel)	$22,526,110	$214,945	$1,671,735	$1,886,680	$9,881,964
2D	Welding (government - stainless steel)	$70,184	$71,233	$559,456	$630,689	$152,939
2A1	Welding (general industry - carbon steel)	$5,130,000	$2,385,283	$0	$2,385,283	$4,715,849
2B1	Welding (maritime industry - carbon steel)	$109,082	$127,460	$0	$127,460	$95,580
2C1	Welding (construction industry - carbon steel)	$6,628,674	$306,615	$0	$306,615	$2,052,166
3A	Painting (general industry - aerospace)	$1,188,397	$62,640	$274,182	$336,822	$6,282,571
3A1	Painting (general industry - auto repair)	$10,698,340	$189,780	$344,421	$534,201	$767,666
3A2	Painting (general industry - coil coating)	$0	$18,408	$14,751	$33,160	$109,978
3B	Painting (maritime industry)	$140,150	$163,375	$496,135	$659,510	$2,931,363
3C	Painting (construction industry)	$0	$458,367	$2,083,165	$2,541,532	$0
3D	Painting (government)	$0	$53,594	$244,765	$298,359	$0
4	Chromate (chromite ore) production	$0	$3,054	$4,974	$8,029	$8,130
5	Chromate Pigment Producers	$36,867	$4,316	$17,667	$21,983	$47,000
6	Chromated Copper Arsenate (CCA) Producers	$0	$1,665	$3,002	$4,667	$2,680
7	Chromium Catalyst Producers	$1,693,578	$13,742	$45,282	$59,024	$34,844
8	Paint and Coatings Producers	$1,029,714	$65,401	$61,749	$127,150	$32,797
9	Printing Ink Producers	$0	$14,753	$31,046	$45,799	$18,965
10	Plastic Colorant Producers and Users	$0	$161,120	$727,007	$888,126	$267,828
11	Plating Mixture Producers	$0	$6,369	$18,439	$24,808	$6,387
12	Wood Preserving	$0	$0	$0	$0	$0
13	Chromium Material Producers	$6,400	$4,659	$4,288	$8,947	$4,797
14	Steel Mills (stainless)	$42,627	$115,093	$121,954	$237,047	$1,347,550
14A	Steel Mills (carbon)	$123,171	$284,116	$0	$284,116	$132,717
14B	Reshaping	$0	$64,940	$168,866	$233,806	$86,821
15	Iron and Steel Foundries	$940,658	$878,347	$3,546,183	$4,424,531	$2,371,966
16	Chromium Dioxide Producers	$0	$0	$0	$0	$0
17	Chromium Dye Producers	$0	$23,448	$112,263	$135,710	$57,007
18	Chromium Sulfate Producers	$0	$2,734	$3,087	$5,822	$1,919
19	Chemical Distributors	$0	$502,670	$0	$502,670	$0
20	Textile Dyeing	$0	$439,585	$0	$439,585	$0
21	Colored Glass Producers	$0	$20,185	$9,434	$29,619	$3,226
21A	Fiber, Flat, and Container Glass	$24,624	$34,764	$51,629	$86,393	$766,567
22	Printing	$0	$157,113	$0	$157,113	$0
23	Leather Tanning	$0	$0	$0	$0	$0
24	Chromium Catalyst Users	$0	$94,408	$59,347	$153,756	$566
24A	Chromium Catalyst Users (Service)	$0	$28,584	$136,534	$165,118	$0
25	Refractory Brick Producers	$0	$14,484	$0	$14,484	$0
26A	Woodworking (general industry)	$0	$75,840	$0	$75,840	$0
26B	Woodworking (maritime industry)	$0	$19,485	$0	$19,485	$0
26C	Woodworking (construction industry)	$744,793	$2,374,426	$3,235,810	$5,610,236	$0
26D	Woodworking (government)	$12,496	$38,254	$52,143	$90,397	$0
27	Solid Waste Incineration	$0	$298,340	$0	$298,340	$0
27A	Incinerators (government)	$0	$16,688	$0	$16,688	$0
28	Oil and Gas Well Drilling	$0	$0	$0	$0	$0
29	Portland Cement Producers	$0	$0	$0	$0	$0
30	Superalloy Producers	$10,800	$42,068	$0	$42,068	$30,980
31B	Construction (Refractory Repair)	$66,000	$40,440	$237,733	$278,173	$0
31C	Construction (Hazardous Waste Work)	$0	$47,213	$0	$47,213	$0
31CG	Haz. Waste (government)	$0	$51,035	$0	$51,035	$0
31D	Construction (Industrial Rehabilitation)	$0	$1,251	$0	$1,251	$0
31DG	Industrial Rehab. (government)	$0	$33,233	$0	$33,233	$0
32A	Ready-Mixed Concrete	$0	$0	$0	$0	$0
32	Precast Concrete Products Producers	$0	$0	$0	$0	$0
	General Industry (including Government)	$80,195,969	$10,003,090	$16,756,168	$26,759,258	$40,508,889
	Construction	$29,965,577	$3,443,258	$7,228,443	$10,671,701	$11,934,130
	Maritime	$4,067,116	$369,329	$510,185	$879,514	$16,912,270
	Total	$114,228,662	$13,815,677	$24,494,795	$38,310,473	$69,355,289

Table VIII-4. Annualized Costs for All Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 5 ug/m^3)

	Application Group	Housekeeping	Medical Surveillance	Training and Familiarization	Recordkeeping
1	Electroplating	$12,379,200	$1,433,002	$917,183	$268,100
2A	Welding (general industry - stainless steel)	$0	$1,911,121	$1,839,045	$105,900
2B	Welding (maritime industry - stainless steel)	$0	$549,827	$265,467	$44,900
2C	Welding (construction industry - stainless steel)	$0	$3,285,863	$1,726,575	$171,200
2D	Welding (government - stainless steel)	$0	$31,783	$82,026	$11,800
2A1	Welding (general industry - carbon steel)	$0	$646,799	$2,791,713	$208,900
2B1	Welding (maritime industry - carbon steel)	$0	$14,504	$63,508	$2,400
2C1	Welding (construction industry - carbon steel)	$0	$1,729,924	$3,060,321	$317,600
3A	Painting (general industry - aerospace)	$352,200	$596,733	$367,677	$33,600
3A1	Painting (general industry - auto repair)	$4,067,700	$389,289	$1,637,407	$147,400
3A2	Painting (general industry - coil coating)	$375,300	$54,125	$89,051	$7,900
3B	Painting (maritime industry)	$0	$108,410	$214,672	$13,400
3C	Painting (construction industry)	$0	$592,592	$2,068,114	$155,900
3D	Painting (government)	$0	$125,284	$824,567	$43,100
4	Chromate (chromite ore) production	$6,400	$4,345	$2,734	$900
5	Chromate Pigment Producers	$3,150	$4,441	$979	$300
6	Chromated Copper Arsenate (CCA) Producers	$0	$1,157	$460	$130
7	Chromium Catalyst Producers	$16,000	$13,139	$5,872	$1,820
8	Paint and Coatings Producers	$231,160	$31,644	$39,535	$11,120
9	Printing Ink Producers	$16,430	$0	$1,620	$1,130
10	Plastic Colorant Producers and Users	$21,320	$0	$12,608	$2,860
11	Plating Mixture Producers	$27,600	$5,412	$1,829	$510
12	Wood Preserving	$0	$0	$0	$0
13	Chromium Material Producers	$4,190	$1,559	$815	$270
14	Steel Mills (stainless)	$224,500	$712,400	$164,853	$46,200
14A	Steel Mills (carbon)	$670,500	$153,661	$443,738	$120,600
14B	Reshaping	$324,000	$7,600	$15,658	$4,600
15	Iron and Steel Foundries	$720,800	$1,194,114	$421,457	$186,800
16	Chromium Dioxide Producers	$0	$0	$0	$0
17	Chromium Dye Producers	$5,290	$0	$2,009	$580
18	Chromium Sulfate Producers	$10,100	$1,362	$291	$100
19	Chemical Distributors	$3,319,100	$4	$34,858	$0
20	Textile Dyeing	$712,800	$0	$276,803	$76,300
21	Colored Glass Producers	$18,500	$1,289	$1,099	$200
21A	Fiber, Flat, and Container Glass	$256,500	$171,256	$60,601	$14,000
22	Printing	$52,600	$0	$70,307	$18,700
23	Leather Tanning	$0	$0	$0	$0
24	Chromium Catalyst Users	$466,300	$5,404	$6,331	$990
24A	Chromium Catalyst Users (Service)	$71,510	$27,531	$10,593	$3,350
25	Refractory Brick Producers	$12,420	$5	$937	$300
26A	Woodworking (general industry)	$814,900	$5,798	$6,313	$500
26B	Woodworking (maritime industry)	$0	$13	$2,292	$400
26C	Woodworking (construction industry)	$0	$1,241,423	$320,136	$44,700
26D	Woodworking (government)	$0	$18,620	$3,736	$400
27	Solid Waste Incineration	$0	$41	$22,923	$4,820
27A	Incinerators (government)	$0	$2	$1,150	$140
28	Oil and Gas Well Drilling	$0	$0	$0	$0
29	Portland Cement Producers	$0	$0	$0	$0
30	Superalloy Producers	$16,580	$18,828	$11,256	$3,530
31B	Construction (Refractory Repair)	$0	$52,224	$27,554	$4,260
31C	Construction (Hazardous Waste Work)	$0	$25	$34,747	$5,620
31CG	Haz. Waste (government)	$0	$14	$22,405	$3,270
31D	Construction (Industrial Rehabilitation)	$0	$34	$50,939	$8,220
31DG	Industrial Rehab. (government)	$0	$2	$4,740	$490
32A	Ready-Mixed Concrete	$0	$0	$0	$0
32	Precast Concrete Products Producers	$0	$0	$0	$0
	General Industry (including Government)	$25,197,050	$7,567,765	$10,197,180	$1,331,610
	Construction	$0	$6,902,085	$7,288,387	$707,500
	Maritime	$0	$672,753	$545,940	$61,100
	Total	$25,197,050	$15,142,603	$18,031,507	$2,100,210

Table VIII-4. Annualized Costs for All Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 5 ug/m^3)

					Associated Costs due to Non-Compliance with Existing Requirements		
	Application Group	Total Costs to the National Economy	Transfer of PPE Payments	Total Costs to Employers	PPE (not supplied in baseline)	Hygiene Areas	Total for New and Existing Requirements (a)
1	Electroplating	**$61,731,240**	$1,219,625	**$62,950,865**	$0	$4,439,800	**$67,390,665**
2A	Welding (general industry - stainless steel)	**$53,442,406**	$0	**$53,442,406**	$0	$0	**$53,442,406**
2B	Welding (maritime industry - stainless steel)	**$18,636,465**	$0	**$18,636,465**	$0	$0	**$18,636,465**
2C	Welding (construction industry - stainless steel)	**$39,478,391**	$0	**$39,478,391**	$0	$0	**$39,478,391**
2D	Welding (government - stainless steel)	**$979,421**	$0	**$979,421**	$0	$0	**$979,421**
2A1	Welding (general industry - carbon steel)	**$15,878,544**	$0	**$15,878,544**	$0	$0	**$15,878,544**
2B1	Welding (maritime industry - carbon steel)	**$412,533**	$0	**$412,533**	$0	$0	**$412,533**
2C1	Welding (construction industry - carbon steel)	**$14,095,301**	$0	**$14,095,301**	$0	$0	**$14,095,301**
3A	Painting (general industry - aerospace)	**$9,158,001**	$1,628	**$9,159,629**	$11,711,583	$275,400	**$21,146,611**
3A1	Painting (general industry - auto repair)	**$18,242,003**	$1,395,069	**$19,637,072**	$59,784,259	$2,500,700	**$81,922,032**
3A2	Painting (general industry - coil coating)	**$669,513**	$358	**$669,871**	$2,797,183	$116,400	**$3,583,454**
3B	Painting (maritime industry)	**$4,067,505**	$1,220,626	**$5,288,131**	$5,661,140	$407,800	**$11,357,071**
3C	Painting (construction industry)	**$5,358,139**	$930,935	**$6,289,074**	$0	$0	**$6,289,074**
3D	Painting (government)	**$1,291,310**	$256,945	**$1,548,255**	$0	$0	**$1,548,255**
4	Chromate (chromite ore) production	**$30,537**	$30	**$30,567**	$0	$4,400	**$34,967**
5	Chromate Pigment Producers	**$114,720**	$10	**$114,730**	$0	$3,000	**$117,730**
6	Chromated Copper Arsenate (CCA) Producers	**$9,094**	$3	**$9,097**	$12,587	$1,200	**$22,884**
7	Chromium Catalyst Producers	**$1,824,277**	$40	**$1,824,317**	$110,290	$12,700	**$1,947,307**
8	Paint and Coatings Producers	**$1,503,120**	$213	**$1,503,332**	$3,777,438	$142,300	**$5,423,071**
9	Printing Ink Producers	**$83,944**	$1	**$83,946**	$7,570	$7,300	**$98,816**
10	Plastic Colorant Producers and Users	**$1,192,742**	$139	**$1,192,881**	$31,030	$33,600	**$1,257,512**
11	Plating Mixture Producers	**$66,546**	$20	**$66,566**	$0	$9,400	**$75,966**
12	Wood Preserving	**$0**	$0	**$0**	$0	$0	**$0**
13	Chromium Material Producers	**$26,979**	$0	**$26,979**	$0	$0	**$26,979**
14	Steel Mills (stainless)	**$2,775,177**	$0	**$2,775,177**	$0	$0	**$2,775,177**
14A	Steel Mills (carbon)	**$1,928,503**	$0	**$1,928,503**	$0	$0	**$1,928,503**
14B	Reshaping	**$672,485**	$0	**$672,485**	$0	$0	**$672,485**
15	Iron and Steel Foundries	**$10,260,326**	$0	**$10,260,326**	$0	$0	**$10,260,326**
16	Chromium Dioxide Producers	**$0**	$0	**$0**	$0	$0	**$0**
17	Chromium Dye Producers	**$200,596**	$2	**$200,598**	$21,250	$5,800	**$227,648**
18	Chromium Sulfate Producers	**$19,593**	$1	**$19,594**	$36,226	$3,200	**$59,020**
19	Chemical Distributors	**$3,856,632**	$0	**$3,856,632**	$0	$0	**$3,856,632**
20	Textile Dyeing	**$1,505,488**	$44,605	**$1,550,094**	$1,236,379	$1,383,800	**$4,170,272**
21	Colored Glass Producers	**$53,934**	$4	**$53,938**	$2,555	$1,200	**$57,693**
21A	Fiber, Flat, and Container Glass	**$1,379,941**	$0	**$1,379,941**	$0	$0	**$1,379,941**
22	Printing	**$298,720**	$3,857	**$302,577**	$373,708	$171,700	**$847,985**
23	Leather Tanning	**$0**	$0	**$0**	$0	$0	**$0**
24	Chromium Catalyst Users	**$633,348**	$45	**$633,393**	$143,158	$39,200	**$815,751**
24A	Chromium Catalyst Users (Service)	**$278,102**	$8,735	**$286,837**	$0	$33,900	**$320,737**
25	Refractory Brick Producers	**$28,146**	$42	**$28,188**	$29,900	$5,300	**$63,388**
26A	Woodworking (general industry)	**$903,350**	$0	**$903,350**	$0	$0	**$903,350**
26B	Woodworking (maritime industry)	**$22,190**	$0	**$22,190**	$0	$0	**$22,190**
26C	Woodworking (construction industry)	**$7,961,289**	$229,988	**$8,191,277**	$5,444,838	$2,906,900	**$16,543,015**
26D	Woodworking (government)	**$125,649**	$3,997	**$129,646**	$48,096	$27,600	**$205,342**
27	Solid Waste Incineration	**$326,124**	$66,100	**$392,224**	$0	$80,200	**$472,424**
27A	Incinerators (government)	**$17,980**	$5,042	**$23,022**	$0	$19,700	**$42,722**
28	Oil and Gas Well Drilling	**$0**	$0	**$0**	$0	$0	**$0**
29	Portland Cement Producers	**$0**	$0	**$0**	$0	$0	**$0**
30	Superalloy Producers	**$134,042**	$0	**$134,042**	$0	$0	**$134,042**
31B	Construction (Refractory Repair)	**$428,211**	$28,821	**$457,032**	$460,158	$99,800	**$1,016,991**
31C	Construction (Hazardous Waste Work)	**$87,604**	$54,552	**$142,157**	$90,563	$107,500	**$340,219**
31CG	Haz. Waste (government)	**$76,723**	$32,523	**$109,246**	$0	$60,900	**$170,146**
31D	Construction (Industrial Rehabilitation)	**$60,445**	$0	**$60,445**	$0	$0	**$60,445**
31DG	Industrial Rehab. (government)	**$38,466**	$0	**$38,466**	$0	$0	**$38,466**
32A	Ready-Mixed Concrete	**$0**	$0	**$0**	$0	$0	**$0**
32	Precast Concrete Products Producers	**$0**	$0	**$0**	$0	$0	**$0**
	General Industry (including Government)	**$191,757,721**	$3,039,034	**$194,796,756**	$80,123,213	$9,378,700	**$284,298,668**
	Construction	**$67,469,379**	$1,244,297	**$68,713,676**	$5,995,559	$3,114,200	**$77,823,435**
	Maritime	**$23,138,693**	$1,220,626	**$24,359,319**	$5,661,140	$407,800	**$30,428,259**
	Total	**$282,365,793**	$5,503,957	**$287,869,751**	$91,779,911	$12,900,700	**$392,550,362**

(a) Excludes Transfer of PPE Payments.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

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Table VIII–4 also shows the costs by application group. The various types of welding represent the most expensive application group, accounting for 51 percent of the total costs.

Table VIII–5 presents OSHA's final total annualized costs by cost category for each of the alternative PELs considered by OSHA in the proposed rule. At a discount rate of 7 percent, total costs range from $112 million for a PEL of 20 μg/m³ to $1.8 billion for a PEL of 0.25 μg/m³.

OSHA also presents, in Table VIII–6, the distribution of compliance costs at the time they are imposed. Because firms will have the choice of whether to finance expenditures in a single year, or spread them out over four years, OSHA considers it unlikely that a firm would be impacted in an amount equal to the entire startup cost in the year that the initial requirements are imposed. On the other hand, capital markets are not perfectly liquid and particular firms may face additional lending constraints, therefore OSHA believes that identifying startup costs, in addition to the annualized costs, is relevant when exploring the question of economic feasibility and the overall impact of this rulemaking.

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Table VIII-5. Estimated Total Annualized Compliance Costs Associated with the Final Standard for Hexavalent Chromium, by Provision (Discount Rate = 7%)

	PEL Option (µg/m^3)					
Cost Category	**20**	**10**	**5**	**1**	**0.5**	**0.25**
Engineering Controls	$27,254,895	$55,266,244	$114,228,662	$274,563,256	$466,012,632	$1,011,793,069
Exposure Monitoring	$23,831,107	$26,338,265	$38,310,473	$72,500,309	$164,549,329	$186,723,054
Respirator Protection	$11,245,040	$36,634,677	$69,355,289	$152,353,487	$312,409,999	$517,648,026
Housekeeping	$25,197,050	$25,197,050	$25,197,050	$25,197,050	$25,197,050	$25,197,050
Medical Surveillance	$4,344,847	$6,788,931	$15,142,603	$25,421,755	$44,159,876	$52,917,437
Communication of Hazards	$17,881,354	$18,020,404	$18,031,507	$18,134,752	$18,434,375	$18,535,343
Recordkeeping	$2,100,220	$2,100,510	$2,100,210	$2,099,650	$2,099,650	$2,099,350
Total for New Requirements	**$111,854,513**	**$170,346,080**	**$282,365,793**	**$570,270,259**	**$1,032,862,911**	**$1,814,913,330**
PPE (supplied by employers and paid-for by employees prior to reg.)	$5,554,768	$5,503,957	$5,503,957	$5,454,363	$5,434,749	$5,066,306
Total for New Requirements and PPE Supplied in the Baseline (employer costs)	**$117,409,281**	**$175,850,038**	**$287,869,751**	**$575,724,622**	**$1,038,297,660**	**$1,819,979,637**
PPE (not supplied prior to reg.)	$93,453,088	$91,779,911	$91,779,911	$91,161,311	$91,155,875	$85,597,562
Hygiene Areas	$13,001,400	$12,900,700	$12,900,700	$12,850,000	$12,840,700	$9,880,700
Total for New and Existing Requirements	**$223,863,769**	**$280,530,649**	**$392,550,362**	**$679,735,933**	**$1,142,294,235**	**$1,915,457,899**

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

Table VIII-6. Estimated Total First-Year Compliance Costs Associated with the Final Standard for Hexavalent Chromium

Cost Category	General Industry	Government	Construction	Maritime	Total
Engineering Controls	$184,143,569	$264,445	$109,905,359	$15,802,678	$310,116,051
Initial Exposure Assessment	$80,250,132	$1,427,590	$26,133,186	$2,504,284	$110,315,192
Respiratory Protection	$42,185,867	$55,831	$13,390,104	$17,527,846	$73,159,648
Housekeeping	$34,504,957	$0	$0	$0	$34,504,957
Medical Surveillance	$16,135,951	$409,753	$11,901,618	$1,117,960	$29,565,281
Training and Familiarization	$24,158,394	$1,603,776	$14,190,444	$1,203,156	$41,155,771
Recordkeeping	$1,530,408	$56,452	$812,576	$73,647	$2,473,083
Total for New Requirements	**$382,909,278**	**$3,817,848**	**$176,333,286**	**$38,229,571**	**$601,289,983**
PPE (supplied by employers and paid-for by employees prior to reg.)	$2,740,529	$298,506	$1,244,297	$1,220,626	$5,503,957
Total for New Requirements and PPE Supplied in the Baseline	**$385,649,807**	**$4,116,354**	**$177,577,583**	**$39,450,197**	**$606,793,941**
PPE (not supplied in baseline)	$80,075,116	$48,096	$5,995,559	$5,661,140	$91,779,911
Hygiene Areas	$41,818,607	$335,882	$7,813,392	$1,432,863	$51,400,744
Total for New and Existing Requirements	**$507,543,530**	**$4,500,332**	**$191,386,533**	**$46,544,201**	**$749,974,596**

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

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E. Economic Impacts

To determine whether the final rule's projected costs of compliance would raise issues of economic feasibility for employers in affected industries, i.e., would adversely alter the competitive structure of the industry, OSHA first compared compliance costs to industry revenues and profits. OSHA then examined specific factors affecting individual industries where compliance costs represent a significant share of revenue, or where the record contains other evidence that the standard could have significant impact on the competitive structure of the industry.

OSHA compared the baseline financial data with total annualized incremental costs of compliance by computing compliance costs as a percentage of revenues and profits. This impact assessment for all firms is presented in Table VIII–7. This table is considered a screening analysis and is the first step in OSHA's analysis of whether the compliance costs potentially associated with the standard would lead to significant impacts on establishments in the affected industries. The actual impact of the standard on the viability of establishments in a given industry, in a static world, depends, to a significant degree, on the price elasticity of demand for the services sold by establishments in that industry.

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Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^{3})

				Cost per Entity^{BB}				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity^{CC}	Profit per Entity^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
1	Electroplating - General Industry	All General Industry^{B}	All General Industry	$11,434	$11,660	$13,651,252	$784,804	0.08%	1.46%	0.09%	1.49%
		237	Heavy construction (234)	$16,379	$16,727	$12,287,063	$571,194	0.13%	2.87%	0.14%	2.93%
		238	Special trade contractors (235)	$11,519	$11,751	$2,706,583	$105,463	0.43%	10.92%	0.43%	11.14%
		313	Textile mills	$14,643	$14,950	$6,155,761	$176,122	0.24%	8.31%	0.24%	8.49%
		314	Textile product mills	$10,304	$10,506	$5,433,321	$151,258	0.19%	6.81%	0.19%	6.95%
		315	Apparel mfg	$16,379	$16,727	$10,989,677	$563,536	0.15%	2.91%	0.15%	2.97%
		316	Leather & allied product mfg	$18,427	$18,818	$15,620,859	$915,694	0.12%	2.01%	0.12%	2.06%
		321	Wood product mfg	$11,691	$11,923	$5,987,225	$162,789	0.20%	7.18%	0.20%	7.32%
		322	Paper mfg	$23,025	$23,513	$40,006,374	$1,113,192	0.06%	2.07%	0.06%	2.11%
		323	Printing & related support activities	$9,703	$9,889	$3,184,551	$120,430	0.30%	8.06%	0.31%	8.21%
		324	Petroleum & coal products mfg	$15,852	$16,174	$257,242,485	$10,929,407	0.01%	0.15%	0.01%	0.15%
		325	Chemical mfg	$16,185	$16,517	$55,959,548	$5,015,932	0.03%	0.32%	0.03%	0.33%
		326	Plastics & rubber products mfg	$17,950	$18,326	$11,183,005	$372,419	0.16%	4.82%	0.16%	4.92%
		327	Nonmetallic mineral product mfg	$16,379	$16,727	$6,924,808	$247,877	0.24%	6.61%	0.24%	6.75%
		331^{C}	Primary metal mfg	$15,448	$15,767	$25,325,125	$608,526	0.06%	2.54%	0.06%	2.59%
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	$10,637	$10,844	$873,298	$35,972	1.22%	29.57%	1.24%	30.15%
		Other 332^{D}	Fabricated Metal Product Manufacturing	$11,011	$11,228	$4,752,128	$227,923	0.23%	4.83%	0.24%	4.93%
		333^{E}	Machinery Manufacturing	$12,133	$12,376	$11,810,404	$387,110	0.10%	3.13%	0.10%	3.20%
		334	Computer & electronic product mfg	$13,909	$14,194	$38,694,208	$1,695,199	0.04%	0.82%	0.04%	0.84%
		335	Electrical equipment, appliance, & component mfg	$16,101	$16,436	$48,639,174	$1,763,096	0.03%	0.91%	0.03%	0.93%
		336 (except 33661)^{F}	Transportation Equipment Manufacturing	$18,315	$18,700	$108,816,386	$2,728,488	0.02%	0.67%	0.02%	0.69%
		339	Miscellaneous Manufacturing	$8,541	$8,700	$6,545,082	$246,281	0.13%	3.47%	0.13%	3.53%
		423	Wholesale trade, durable goods (421)	$21,142	$21,428	$7,789,912	$194,538	0.27%	10.87%	0.28%	11.01%
		441	Motor vehicle & parts dealers	$4,228	$4,286	$1,826,119	$26,333	0.23%	16.06%	0.23%	16.27%
		442	Furniture & home furnishings stores	$4,228	$4,286	$647,301	$24,357	0.65%	17.36%	0.66%	17.59%
		443	Electronics & appliance stores	$4,228	$4,286	$857,482	$29,158	0.49%	14.50%	0.50%	14.70%
		444	Building material & garden equipment & supplies dealers	$4,228	$4,286	$773,774	$38,341	0.55%	11.03%	0.55%	11.18%
		446	Health & personal care stores	$4,228	$4,286	$973,952	$24,550	0.43%	17.22%	0.44%	17.46%
		453	Miscellaneous store retailers	$4,228	$4,286	$600,302	$18,855	0.70%	22.43%	0.71%	22.73%
		454	Nonstore retailers	$4,228	$4,286	$706,333	$26,766	0.60%	15.80%	0.61%	16.01%
		511	Publishing industries	$21,179	$21,623	$14,166,015	$1,503,303	0.15%	1.41%	0.15%	1.44%
		512	Motion picture & sound recording industries	$11,592	$11,820	$5,799,209	$281,365	0.20%	4.12%	0.20%	4.20%
		519	Information services & data processing services (514)	$4,228	$4,286	$137,552	$12,240	3.07%	34.55%	3.12%	35.01%
		522	Credit intermediation & related activities	$8,785	$8,951	$2,612,075	$305,304	0.34%	2.88%	0.34%	2.93%
		532	Rental & leasing services	$10,304	$10,506	$1,224,506	$30,725	0.84%	33.54%	0.86%	34.20%
		541	Professional, scientific, & technical services	$6,260	$6,364	$751,690	$47,079	0.83%	13.30%	0.85%	13.52%
		561	Administrative & support services	$8,760	$8,922	$853,198	$32,326	1.03%	27.10%	1.05%	27.60%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
	562	Waste management & remediation services	$13,342	$13,617	$3,941,918	$167,638	0.34%	7.96%	0.35%	8.12%
	711	Performing arts, spectator sports, & related industries	$4,228	$4,286	$82,883	$7,802	5.10%	54.19%	5.17%	54.93%
	812	Personal & laundry services	$6,254	$6,359	$246,655	$12,738	2.54%	49.10%	2.58%	49.92%
2A Welding - General Industry (stainless steel)	All General Industry[H]	All General Industry	$3,559	$3,559	$6,504,281	$336,088	0.05%	1.06%	0.05%	1.06%
	113	Forestry and Logging	$2,165	$2,165	$1,559,464	$37,179	0.14%	5.82%	0.14%	5.82%
	221	Utilities	$3,206	$3,206	$21,336,268	$833,617	0.02%	0.38%	0.02%	0.38%
	311[C]	Food Manufacturing	$4,289	$4,289	$25,109,789	$1,014,522	0.02%	0.42%	0.02%	0.42%
	312	Beverage and Tobacco Product Manufacturing	$3,969	$3,969	$115,034,052	$12,139,154	0.00%	0.03%	0.00%	0.03%
	313	Textile mills	$5,377	$5,377	$10,278,254	$294,071	0.05%	1.83%	0.05%	1.83%
	314	Textile product mills	$2,695	$2,695	$5,720,245	$159,246	0.05%	1.69%	0.05%	1.69%
	315	Apparel mfg	$5,396	$5,396	$16,452,407	$843,658	0.03%	0.64%	0.03%	0.64%
	316	Leather & allied product mfg	$5,570	$5,570	$22,061,123	$1,293,222	0.03%	0.43%	0.03%	0.43%
	321	Wood product mfg	$2,277	$2,277	$4,152,006	$112,891	0.05%	2.02%	0.05%	2.02%
	322	Paper mfg	$5,645	$5,645	$42,164,737	$1,173,250	0.01%	0.48%	0.01%	0.48%
	323	Printing & related support activities	$4,898	$4,898	$8,397,177	$317,555	0.06%	1.54%	0.06%	1.54%
	324	Petroleum & coal products mfg	$3,215	$3,215	$205,112,689	$8,714,579	0.00%	0.04%	0.00%	0.04%
	325	Chemical mfg	$6,615	$6,615	$107,720,474	$9,655,521	0.01%	0.07%	0.01%	0.07%
	326	Plastics & rubber products mfg	$6,362	$6,362	$18,172,602	$605,188	0.04%	1.05%	0.04%	1.05%
	327	Nonmetallic mineral product mfg	$8,166	$8,166	$15,139,328	$541,920	0.05%	1.51%	0.05%	1.51%
	332	Fabricated Metal Product Manufacturing	$3,665	$3,665	$7,316,561	$350,919	0.05%	1.04%	0.05%	1.04%
	333	Machinery Manufacturing	$3,318	$3,318	$13,854,999	$454,126	0.02%	0.73%	0.02%	0.73%
	334	Computer & electronic product mfg	$3,868	$3,868	$47,206,416	$2,068,120	0.01%	0.19%	0.01%	0.19%
	335	Electrical equipment, appliance, & component mfg	$5,969	$5,969	$85,083,005	$3,084,129	0.01%	0.19%	0.01%	0.19%
	336 (except 33661)	Transportation Equipment Manufacturing	$5,810	$5,810	$152,338,437	$3,819,770	0.00%	0.15%	0.00%	0.15%
	337	Furniture & Related Product Manufacturing	$2,941	$2,941	$4,601,650	$190,106	0.06%	1.55%	0.06%	1.55%
	339	Miscellaneous Manufacturing	$3,859	$3,859	$15,944,258	$1,120,807	0.02%	0.34%	0.02%	0.34%
	423	Wholesale trade, durable goods (421)	$1,722	$1,722	$2,339,292	$58,419	0.07%	2.95%	0.07%	2.95%
	424	Merchant Wholesalers, nondurable goods (422)	$7,969	$7,969	$33,118,390	$786,510	0.02%	1.01%	0.02%	1.01%
	441	Motor vehicle & parts dealers	$3,659	$3,659	$8,044,423	$116,002	0.05%	3.15%	0.05%	3.15%
	442	Furniture & home furnishings stores	$2,573	$2,573	$1,319,697	$49,658	0.19%	5.18%	0.19%	5.18%
	443	Electronics & appliance stores	$2,638	$2,638	$1,889,646	$64,255	0.14%	4.10%	0.14%	4.10%
	444	Building material & garden equipment & supplies dealers	$3,162	$3,162	$2,363,132	$117,095	0.13%	2.70%	0.13%	2.70%
	445	Food and Beverage Stores	$2,006	$2,006	$2,192,431	$40,880	0.09%	4.91%	0.09%	4.91%
	446	Health & personal care stores	$3,912	$3,912	$2,916,212	$73,507	0.13%	5.32%	0.13%	5.32%
	447	Gasoline Stations	$2,394	$2,394	$1,103,373	$8,111	0.22%	29.52%	0.22%	29.52%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
		448	Clothing and Clothing Accessory Stores	$1,853	$1,853	$552,811	$23,905	0.34%	7.75%	0.34%	7.75%
		451	Sporting Good, Hobby, Book and Music Stores	$2,275	$2,275	$946,299	$24,800	0.24%	9.17%	0.24%	9.17%
		452	General Merchandise Stores	$12,104	$12,104	$36,667,851	$1,168,447	0.03%	1.04%	0.03%	1.04%
		453	Miscellaneous store retailers	$2,511	$2,511	$1,191,862	$37,435	0.21%	6.71%	0.21%	6.71%
		454	Nonstore retailers	$3,000	$3,000	$3,119,956	$118,230	0.10%	2.54%	0.10%	2.54%
		481	Air Transportation	$5,136	$5,136	$33,643,799	$247,511	0.02%	2.08%	0.02%	2.08%
		483	Water Transportation	$15,408	$15,408	$68,445,873	$2,599,985	0.02%	0.59%	0.02%	0.59%
		484	Truck Transportation	$5,820	$5,820	$6,255,490	$126,783	0.09%	4.59%	0.09%	4.59%
		485	Transit and Ground Passenger Transportation	$1,914	$1,914	$1,519,168	$34,017	0.13%	5.63%	0.13%	5.63%
		486	Pipeline Transportation	$3,289	$3,289	$870,009	$174,613	0.38%	1.88%	0.38%	1.88%
		487	Scenic and Sightseeing Transportation	$3,784	$3,784	$3,143,793	$133,120	0.12%	2.84%	0.12%	2.84%
		488	Support Activities for Transportation	$7,199	$7,199	$7,361,217	$311,702	0.10%	2.31%	0.10%	2.31%
		492	Couriers and Messengers	$11,337	$11,337	$22,920,912	$970,560	0.05%	1.17%	0.05%	1.17%
		493	Warehousing and Storage	$7,267	$7,267	$5,473,617	$228,666	0.13%	3.18%	0.13%	3.18%
		511	Publishing industries	$4,503	$4,503	$12,146,612	$1,289,003	0.04%	0.35%	0.04%	0.35%
		512	Motion picture & sound recording industries	$4,087	$4,087	$8,970,624	$435,234	0.05%	0.94%	0.05%	0.94%
		519	Information services & data processing services (514)	$4,564	$4,564	$1,381,550	$122,937	0.33%	3.71%	0.33%	3.71%
		522	Credit intermediation & related activities	$11,142	$11,142	$13,802,641	$1,613,277	0.08%	0.69%	0.08%	0.69%
		531	Real Estate	$2,984	$2,984	$908,528	$107,459	0.33%	2.78%	0.33%	2.78%
		532	Rental & leasing services	$5,832	$5,832	$2,758,990	$69,227	0.21%	8.43%	0.21%	8.43%
		541	Professional, scientific, & technical services	$4,003	$4,003	$2,895,760	$181,364	0.14%	2.21%	0.14%	2.21%
		561	Administrative & support services	$2,583	$2,583	$1,043,558	$39,538	0.25%	6.53%	0.25%	6.53%
		562	Waste management & remediation services	$3,176	$3,176	$3,561,551	$151,463	0.09%	2.10%	0.09%	2.10%
		611	Educational Services	$3,707	$3,707	$605,445	$43,766	0.61%	8.47%	0.61%	8.47%
		621	Ambulatory Health Care Services	$7,570	$7,570	$1,824,605	$93,327	0.41%	8.11%	0.41%	8.11%
		622	Hospitals	$5,188	$5,188	$10,624,362	$549,510	0.05%	0.94%	0.05%	0.94%
		623	Nursing and Residential Care Facilities	$5,764	$5,764	$370,660	$19,171	1.56%	30.07%	1.56%	30.07%
		624	Social Assistance	$6,459	$6,459	$565,406	$28,920	1.14%	22.34%	1.14%	22.34%
		711	Performing arts, spectator sports, & related industries	$3,268	$3,268	$3,913,940	$265,155	0.08%	1.23%	0.08%	1.23%
		713	Amusement, Gambling, and Recreastional Industries	$2,719	$2,719	$913,129	$46,251	0.30%	5.88%	0.30%	5.88%
		722	Food Services and Drinking Places	$4,512	$4,512	$922,426	$37,814	0.49%	11.93%	0.49%	11.93%
		811	Repair and Maintenance	$3,261	$3,261	$814,187	$31,096	0.40%	10.49%	0.40%	10.49%
		812	Personal & laundry services	$3,399	$3,399	$505,655	$26,113	0.67%	13.02%	0.67%	13.02%
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$2,101	$2,101	$53,703	$1,329	3.91%	158.08%	3.91%	158.08%
2B	Welding - Maritime Industry (stainless steel)	336611[1]	Ship Building and Repairing	$66,797	$66,797	$27,134,242	$1,583,890	0.25%	4.22%	0.25%	4.22%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2C	Welding - Construction Industry (stainless steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$16,320	$16,320	$1,770,330	$73,079	0.92%	22.33%	0.92%	22.33%
2D	Welding - Government (stainless steel)	999200	State	$2,540	$2,540	$12,956,109,000	N/A	0.00%	N/A	N/A	N/A
		999300	Local	$1,121	$1,121	$109,399,080	N/A	0.00%	N/A	N/A	N/A
2A1	Welding - General Industry (carbon steel)	All General Industry[H]	All General Industry	$1,057	$1,057	$8,638,561	$446,371	0.01%	0.24%	0.01%	0.24%
		113	Forestry and Logging	$551	$551	$1,627,078	$38,791	0.03%	1.42%	0.03%	1.42%
		221	Utilities	$779	$779	$21,415,156	$836,700	0.00%	0.09%	0.00%	0.09%
		311	Food Manufacturing	$951	$951	$24,833,974	$1,003,378	0.00%	0.09%	0.00%	0.09%
		312	Beverage and Tobacco Product Manufacturing	$1,055	$1,055	$140,025,200	$14,776,386	0.00%	0.01%	0.00%	0.01%
		313	Textile mills	$1,177	$1,177	$10,426,004	$298,298	0.01%	0.39%	0.01%	0.39%
		314	Textile product mills	$642	$642	$5,704,601	$158,810	0.01%	0.40%	0.01%	0.40%
		315	Apparel mfg	$1,136	$1,136	$16,385,476	$840,226	0.01%	0.14%	0.01%	0.14%
		316	Leather & allied product mfg	$1,181	$1,181	$22,378,252	$1,311,813	0.01%	0.09%	0.01%	0.09%
		321	Wood product mfg	$571	$571	$4,177,998	$113,597	0.01%	0.50%	0.01%	0.50%
		322	Paper mfg	$1,233	$1,233	$42,205,291	$1,174,378	0.00%	0.10%	0.00%	0.10%
		323	Printing & related support activities	$1,049	$1,049	$8,323,192	$314,757	0.01%	0.33%	0.01%	0.33%
		324	Petroleum & coal products mfg	$822	$822	$221,931,930	$9,429,175	0.00%	0.01%	0.00%	0.01%
		325	Chemical mfg	$1,446	$1,446	$109,075,559	$9,776,984	0.00%	0.01%	0.00%	0.01%
		326	Plastics & rubber products mfg	$1,363	$1,363	$18,264,715	$608,256	0.01%	0.22%	0.01%	0.22%
		327	Nonmetallic mineral product mfg	$1,773	$1,773	$15,356,956	$549,710	0.01%	0.32%	0.01%	0.32%
		332	Fabricated Metal Product Manufacturing	$827	$827	$7,316,102	$350,897	0.01%	0.24%	0.01%	0.24%
		333	Machinery Manufacturing	$762	$762	$13,857,522	$454,209	0.01%	0.17%	0.01%	0.17%
		334	Computer & electronic product mfg	$866	$866	$47,158,477	$2,066,020	0.00%	0.04%	0.00%	0.04%
		335	Electrical equipment, appliance, & component mfg	$1,277	$1,277	$85,264,448	$3,090,706	0.00%	0.04%	0.00%	0.04%
		336 (except 33661)	Transportation Equipment Manufacturing	$1,249	$1,249	$152,498,975	$3,823,796	0.00%	0.03%	0.00%	0.03%
		337	Furniture & Related Product Manufacturing	$689	$689	$4,599,952	$190,036	0.01%	0.36%	0.01%	0.36%
		339	Miscellaneous Manufacturing	$862	$862	$15,941,779	$1,120,633	0.01%	0.08%	0.01%	0.08%
		423	Wholesale trade, durable goods (421)	$470	$470	$2,339,904	$58,435	0.02%	0.80%	0.02%	0.80%
		424	Merchant Wholesalers, nondurable goods (422)	$1,833	$1,833	$35,834,098	$851,003	0.01%	0.22%	0.01%	0.22%
		441	Motor vehicle & parts dealers	$855	$855	$8,044,789	$116,008	0.01%	0.74%	0.01%	0.74%
		442	Furniture & home furnishings stores	$646	$646	$1,319,077	$49,635	0.05%	1.30%	0.05%	1.30%
		443	Electronics & appliance stores	$656	$656	$1,870,806	$63,615	0.04%	1.03%	0.04%	1.03%
		444	Building material & garden equipment & supplies dealers	$768	$768	$2,379,669	$117,914	0.03%	0.65%	0.03%	0.65%
		445	Food and Beverage Stores	$567	$567	$2,446,342	$45,615	0.02%	1.24%	0.02%	1.24%
		446	Health & personal care stores	$935	$935	$2,937,732	$74,049	0.03%	1.26%	0.03%	1.26%
		447	Gasoline Stations	$636	$636	$1,175,195	$8,639	0.05%	7.37%	0.05%	7.37%
		448	Clothing and Clothing Accessory Stores	$502	$502	$576,779	$24,941	0.09%	2.01%	0.09%	2.01%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
		451	Sporting Good, Hobby, Book and Music Stores	$575	$575	$942,449	$24,699	0.06%	2.33%	0.06%	2.33%
		452	General Merchandise Stores	$3,149	$3,149	$44,633,942	$1,422,292	0.01%	0.22%	0.01%	0.22%
		453	Miscellaneous store retailers	$635	$635	$1,192,175	$37,445	0.05%	1.69%	0.05%	1.69%
		454	Nonstore retailers	$726	$726	$3,119,594	$118,216	0.02%	0.61%	0.02%	0.61%
		481	Air Transportation	$1,307	$1,307	$40,952,914	$301,282	0.00%	0.43%	0.00%	0.43%
		483	Water Transportation	$1,961	$1,961	$41,657,870	$1,582,416	0.00%	0.12%	0.00%	0.12%
		484	Truck Transportation	$1,252	$1,252	$6,128,740	$124,214	0.02%	1.01%	0.02%	1.01%
		485	Transit and Ground Passenger Transportation	$325	$325	$1,232,805	$27,605	0.03%	1.18%	0.03%	1.18%
		486	Pipeline Transportation	$760	$760	$866,469	$173,903	0.09%	0.44%	0.09%	0.44%
		487	Scenic and Sightseeing Transportation	$990	$990	$3,826,782	$162,041	0.03%	0.61%	0.03%	0.61%
		488	Support Activities for Transportation	$1,575	$1,575	$7,373,696	$312,231	0.02%	0.50%	0.02%	0.50%
		492	Couriers and Messengers	$2,940	$2,940	$27,900,480	$1,181,414	0.01%	0.25%	0.01%	0.25%
		493	Warehousing and Storage	$1,421	$1,421	$4,997,070	$208,758	0.03%	0.68%	0.03%	0.68%
		511	Publishing industries	$1,025	$1,025	$12,176,264	$1,292,150	0.01%	0.08%	0.01%	0.08%
		512	Motion picture & sound recording industries	$943	$943	$8,969,582	$435,184	0.01%	0.22%	0.01%	0.22%
		519	Information services & data processing services (514)	$1,054	$1,054	$1,401,409	$124,704	0.08%	0.85%	0.08%	0.85%
		522	Credit intermediation & related activities	$2,515	$2,515	$14,330,490	$1,674,973	0.02%	0.15%	0.02%	0.15%
		531	Real Estate	$721	$721	$901,109	$106,582	0.08%	0.68%	0.08%	0.68%
		532	Rental & leasing services	$1,320	$1,320	$2,752,007	$69,052	0.05%	1.91%	0.05%	1.91%
		541	Professional, scientific, & technical services	$923	$923	$2,900,380	$181,653	0.03%	0.51%	0.03%	0.51%
		561	Administrative & support services	$639	$639	$1,043,437	$39,534	0.06%	1.62%	0.06%	1.62%
		562	Waste management & remediation services	$760	$760	$3,562,338	$151,496	0.02%	0.50%	0.02%	0.50%
		611	Educational Services	$851	$851	$614,148	$44,395	0.14%	1.92%	0.14%	1.92%
		621	Ambulatory Health Care Services	$1,647	$1,647	$1,838,069	$94,016	0.09%	1.75%	0.09%	1.75%
		622	Hospitals	$1,326	$1,326	$12,932,505	$668,891	0.01%	0.20%	0.01%	0.20%
		623	Nursing and Residential Care Facilities	$1,536	$1,536	$451,186	$23,336	0.34%	6.58%	0.34%	6.58%
		624	Social Assistance	$1,788	$1,788	$688,240	$35,203	0.26%	5.08%	0.26%	5.08%
		711	Performing arts, spectator sports, & related industries	$776	$776	$4,049,606	$274,346	0.02%	0.28%	0.02%	0.28%
		713	Amusement, Gambling, and Recreastional Industries	$658	$658	$919,130	$46,555	0.07%	1.41%	0.07%	1.41%
		722	Food Services and Drinking Places	$1,033	$1,033	$935,686	$38,358	0.11%	2.69%	0.11%	2.69%
		811	Repair and Maintenance	$777	$777	$814,577	$31,111	0.10%	2.50%	0.10%	2.50%
		812	Personal & laundry services	$818	$818	$508,978	$26,284	0.16%	3.11%	0.16%	3.11%
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$527	$527	$52,799	$1,307	1.00%	40.34%	1.00%	40.34%
2B1	Welding - Maritime Industry (carbon steel)	336611[I]	Ship Building and Repairing	$1,479	$1,479	$58,561,584	$3,418,379	0.00%	0.04%	0.00%	0.04%
2C1	Welding - Construction Industry (carbon steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$5,827	$5,827	$2,606,248	$107,586	0.22%	5.42%	0.22%	5.42%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2D1	Welding - Government (carbon steel)	999200	State								
		999300	Local								
3A	Painting - General Industry	All General Industry[G]	Manufacturing								
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	$6,317	$6,320	$4,747,957	$195,572	0.13%	3.23%	0.13%	3.23%
		3361[K]	Motor vehicle mfg	$168,005	$168,036	$1,484,173,959	$37,214,531	0.01%	0.45%	0.01%	0.45%
		3362	Motor vehicle body & trailer mfg	$28,956	$28,961	$5,651,802	$141,715	0.51%	20.43%	0.51%	20.44%
		336411	Aircraft mfg	$154,909	$154,937	$629,251,120	$24,568,818	0.02%	0.63%	0.02%	0.63%
		336414	Guided missile & space vehicle mfg	$168,457	$168,488	$1,180,818,762	$46,104,522	0.01%	0.37%	0.01%	0.37%
		336415	Guided missile & space vehicle propulsion unit & parts mfg	$110,799	$110,819	$122,919,091	$4,799,319	0.09%	2.31%	0.09%	2.31%
		336419	Other guided missile & space vehicle parts & auxiliary equip mfg	$36,566	$36,572	$9,886,575	$386,017	0.37%	9.47%	0.37%	9.47%
		336992	Military armored vehicle, tank, & tank component mfg	$90,340	$90,356	$35,542,489	$891,201	0.25%	10.14%	0.25%	10.14%
		44111	New car dealers	$22,949	$25,266	$25,065,411	$307,242	0.09%	7.47%	0.10%	8.22%
		44112	Used car dealers	$5,762	$6,030	$1,461,281	$17,912	0.39%	32.17%	0.41%	33.66%
		811121	Automotive body, paint, & interior repair & maintenance	$6,346	$6,686	$447,001	$17,072	1.42%	37.17%	1.50%	39.16%
3B	Painting - Maritime Industry	336611	Ship building & repairing	$4,846	$6,301	$20,229,517	$1,180,845	0.02%	0.41%	0.03%	0.53%
		336612	Boat building	$4,878	$6,342	$10,779,558	$629,228	0.05%	0.78%	0.06%	1.01%
3C	Painting - Construction Industry	233[S], 234[T].235[U]	Heavy Construction, Special Trade Contractors	$832	$977	$3,713,774	$50,994	0.02%	1.63%	0.03%	1.92%
		234[T]	Heavy Construction	$1,535	$1,892	$8,665,059	$402,816	0.02%	0.38%	0.02%	0.47%
		235[U]	Special Trade Contractors	$711	$820	$381,689	$14,873	0.19%	4.78%	0.21%	5.51%
3D	Painting - Government	999200	State	$6,226	$7,963	$12,956,109,000	N/A	0.00%	N/A	N/A	N/A
		999300	Local	$785	$932	$86,827,088	N/A	0.00%	N/A	N/A	N/A
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	$30,537	$30,567	$114,000,000	$6,498,000	0.03%	0.47%	0.03%	0.47%
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$38,240	$38,243	$47,652,570	$1,410,107	0.08%	2.71%	0.08%	2.71%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	$3,031	$3,032	$115,264,777	$10,331,754	0.00%	0.03%	0.00%	0.03%
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	$608,092	$608,106	$75,725,612	$2,240,828	0.80%	27.14%	0.80%	27.14%
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$8,639	$8,640	$21,359,121	$1,004,400	0.04%	0.86%	0.04%	0.86%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$9,327	$9,327	$11,018,705	$640,603	0.08%	1.46%	0.08%	1.46%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$11,469	$11,470	$13,943,468	$608,024	0.08%	1.89%	0.08%	1.89%
		325991	Custom Compounding of Purchased Resin								
		3261	Plastic Product Mfg.								
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$6,655	$6,657	$22,312,086	$1,297,174	0.03%	0.51%	0.03%	0.51%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity^{BB}				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity^{CC}	Profit per Entity^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	$26,979	$26,979	$37,114,939	$785,793	0.07%	3.43%	0.07%	3.43%
14	Steel Mills (stainless)	331111	Iron and Steel Mills	$51,392	$51,392	$169,158,876	$3,581,411	0.03%	1.43%	0.03%	1.43%
14A	Steel Mills (carbon)	331111	Iron and Steel Mills	$8,726	$8,726	$123,992,415	$2,625,153	0.01%	0.33%	0.01%	0.33%
14B	Reshaping (stainless)	332111	Iron and Steel Forging	$7,730	$7,730	$7,418,762	$346,170	0.10%	2.23%	0.10%	2.23%
15	Iron and Steel foundries	3315	Iron foundries	$33,530	$33,530	$7,985,721	$219,160	0.42%	15.30%	0.42%	15.30%
		331512	Steel Investment foundries								
		331513	Steel foundries (except investment)								
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$66,865	$66,866	$71,154,613	$2,105,565	0.09%	3.18%	0.09%	3.18%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$6,531	$6,531	$3,919,368	$115,980	0.17%	5.63%	0.17%	5.63%
19	Chemical Distributors	42269^{V}	Other Chemical and Allied Products	$3,066	$3,066	$4,856,297	$155,866	0.06%	1.97%	0.06%	1.97%
20	Textile Dyeing	313	Textile Mills	$1,467	$1,511	$4,833,805	$136,030	0.03%	1.08%	0.03%	1.11%
		314	Textile Product Mills								
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$2,345	$2,345	$11,453,217	$328,390	0.02%	0.71%	0.02%	0.71%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.								
21A	Fiber, Flat, and Container Glass	327993	Mineral Wool Manufacturing	$30,665	$30,665	$108,010,560	$3,595,742	0.03%	0.85%	0.03%	0.85%
		327211	Flat Glass Manufacturing								
		327212	Other Pressed and Blown Glass Mfg.								
		327213	Glass Container Manufacturing								
22	Printing	32311	Printing	$603	$611	$1,691,687	$63,974	0.04%	0.94%	0.04%	0.96%
		323113	Commercial Screen Printing								
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users		Petrochemical Mfg., Including Styrene	$8,920	$8,921	$231,093,433	$6,734,694	0.00%	0.13%	0.00%	0.13%
24A	Chromium Catalyst Users - Service Companies	325110	Other Services to Buildings and Dwellings, Including Catalyst handling	$25,282	$26,076	$5,936,912	$224,938	0.43%	11.24%	0.44%	11.59%
25	Refractory Brick Producers	561790	Nonclay Refractory Mfg.	$4,691	$4,698	$10,214,017	$273,374	0.05%	1.72%	0.00%	0.00%
26A	Wood Working -General Industry	321	General Industry	$4,125	$4,125	$7,906,370	$209,534	0.05%	1.97%	0.05%	1.97%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$347	$347	$25,537,085	$1,490,661	0.00%	0.02%	0.00%	0.02%
26C	Wood Working - Construction Industry	2332^{W}, 2333^{X}, 2349^{Y}, 23551^{Z}	Construction	$1,093	$1,124	$4,211,605	$173,854	0.03%	0.63%	0.03%	0.65%
26D	Wood Working - Government	999200	State	$1,049	$1,083	$12,956,109,000	N/A	0.00%	0.00%	0.00%	0.00%
		999300	Local	$1,046	$1,080	$108,838,617	N/A	0.00%	0.00%	0.00%	0.00%
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$3,362	$4,044	$12,660,551	$538,417	0.03%	0.62%	0.03%	0.75%
27A	Solid Waste Incineration - govt	999300	Local Governments	$545	$698	$151,220,000	N/A	0.00%	0.00%	0.00%	0.00%

Table VIII-7. Economic Impacts on All Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$0	$0	$44,269,508	$1,867,204	0.00%	0.00%	0.00%	0.00%
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	$12,186	$12,186	$33,302,695	$799,265	0.04%	1.52%	0.04%	1.52%
		331528	Other Nonferrous Foundries								
31B	Construction - Refractory Brick Restoration and Maintenance	235[U]	Special Trade Contractors	$2,377	$2,537	$960,058	$36,433	0.25%	6.52%	0.26%	6.96%
31C	Construction - Hazardous Waste Site Work	2333[X]	Nonresidential Building Construction	$436	$707	$5,042,375	$212,284	0.01%	0.21%	0.01%	0.33%
31CG	Hazardous Waste Site Work - Government	999200	State	$309	$405	$12,956,109,000	N/A	0.00%	0.00%	0.00%	0.00%
		999300	Local	$338	$482	$109,435,929	N/A	0.00%	0.00%	0.00%	0.00%
31D	Construction - Industrial Rehabilitation and Maintenance	23493[AA]	Industrial Nonbuilding Structure Construction	$215	$215	$24,843,811	$981,815	0.00%	0.02%	0.00%	0.02%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	$381	$381	$12,956,109,000	N/A	0.00%	0.00%	0.00%	0.00%
		999300	Local	$381	$381	$108,554,940	N/A	0.00%	0.00%	0.00%	0.00%
32A	Ready-Mixed Concrete	327320	Ready Mixed Concrete Manufacturing	$0	$0	$8,801,330	$371,223	0.00%	0.00%	0.00%	0.00%
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	$0	$0	$5,535,007	$232,470	0.00%	0.00%	0.00%	0.00%

Footnotes to Table VIII-7

[A] SBA size standards taken from 13 CFR Ch.1 § 121.201. January 1, 2003

[B] Includes industries in NAICS 31-33, NAICS 42, NAICS 51.

[C] Except 311221 "Wet Corn Milling", 311312 "Cane Sugar Refining", 311313 "Beet Sugar Manufacturing", and 311821 Cookie and Cracker Manufacturing, which have an SBA size standard of 750 employees, and also 311223 "Other Oilseed Processing", 311225 "Fats and Oils Refining and Blending", 311230 "Breakfast Cereal Manufacturing", 311422 "Special Canning", which have an SBA size standard of 1,000 employees.

[D] Except 332811 “Metal Heat Treating,” 332991 “Ball and Roller Bearing Manufacturing,” and 332998 “Enameled Iron and Metal Sanitary Ware Manufacturing,” all of which have an SBA size standard of 750 employees; 332431 “Metal Can Manufacturing,” 332992 “Small Arms Ammunition Manufacturing,” and 332994 “Small Arms Manufacturing,” all of which have an SBA size standard of 1,000 employees; and 332993 “Ammunition (except Small Arms) Manufacturing,” the SBA size standard for which is 1,500 employees.

[E] Except 333120 “Construction Machinery Manufacturing,” 333415 “Air-Conditioning and Warm Air Heating Equipment,” and 333924 Industrial Truck, Tractor, Trailer,” all of which have an SBA size standard of 750 employees; and except 333313 Office Machinery Manufacturing," 333611 “Turbine and Turbine Generator Set Unit Manufacturing,” and 333618 “Other Engine Equipment Manufacturing,” all of which have an SBA size standard of 1,000 employees.

[F] Except for 336212 “Truck Trailer Manufacturing,” 336214 “Travel Trailer and Camper Manufacturing,” 336311 “Carburetor, Piston, Piston Ring and Valve Manufacturing,” 336321 “Vehicular Lighting Equipment Manufacturing,” 336360 “Motor Vehicle Seating and Interior Trim Manufacturing,” 336370 “Motor Vehicle Metal Stamping,” 336991 Motorcycle, Bicycle and Parts Manufacturing,” and 336999 “All Other Transportation Equipment Manufacturing,” all of which have an SBA size standard of 500 employees; 336312 “Gasoline Engine and Engine Parts Manufacturing,” 336322 “Other Motor Vehicle Electrical and Electronic Equipment Manufacturing,” 336330 “Motor Vehicle Steering and Suspension Components Manufacturing (except Spring),” 336340 “Motor Vehicle Brake System Manufacturing,” 336350 “Motor Vehicle Transmission and Power Train Parts Manufacturing,” 336391 Motor Vehicle Air-Conditioning Manufacturing,” 336399 “All Other Motor Vehicle Parts Manufacturing, all of which have an SBA size standard of 750 employees; and 336411 “Aircraft Manufacturing,” which has an SBA size standard of 1,500 employees.

[G] Includes industries in NAICS 332, NAICS 336, NAICS 441, and NAICS 811.

[H] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[I] Except 336612 “Boat Building,” which has an SBA size standard of 500 employees.

[J] Except 2331 "Land Subdivision and Land Development," which has an SBA size standard of $6.0 million.

[K] Except 336411 "Aircraft Manufacturing"

[L] Except 336612 “Boat Building,” which has an SBA size standard of 500 employees.

[M] All of NAICS CODE 3261 have an SBA size standard of 500 employees except 326192 "Resilient Floor Covering Mfg.", the size standard for which is 750 employees.

[N] All of NAICS CODE 313 have an SBA size standard of 500 employees except 313210 "Broad Woven Fabric Mills", 313320 "Broad Woven Finishing Mills", and 313320 "Fabric Coating Mills" all of which have a size standard of 1,000 employees.

[O] All of NAICS CODE 314 have an SBA size standard of 500 employees except 314992 "Tire Cord and Tire Fabric Mill", the size standard for which is 1,000 employees.

[P] All of NAICS CODE 3161 have an SBA size standard of 500 employees except 316211 "Rubber and Plastics Footwear Mfg.", the size standard for which is 1,000 employees.

[Q] Except 336612 “Boat Building,” which has an SBA size standard of 500 employees.

[R] Except 23551 which has an SBA size standard of $12 million.

[S] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[T] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[U] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[V] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[W] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[X] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[Y] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[Z] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[AA] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[BB] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industry profiles in Chapter II for the complete list of references.

[CC] Industry revenues were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2002*** (IRS, 2005). Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

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Price elasticity refers to the relationship between the price charged for a service and the demand for that service; that is, the more elastic the relationship, the less able is an establishment to pass the costs of compliance through to its customers in the form of a price increase and the more it will have to absorb the costs of compliance from its profits. When demand is inelastic, establishments can recover most of the costs of compliance by raising the prices they charge for that service; under this scenario, profit rates are largely unchanged and the industry remains largely unaffected. Any impacts are primarily on those using the relevant services. On the other hand, when demand is elastic, establishments cannot recover all the costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean both reductions in the quantity of goods and services produced and in total profits, though the profit rate may remain unchanged. In general, ''when an industry is subject to a higher cost, it does not simply swallow it, it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *American Dental Association* v. *Secretary of Labor* (984 F.2d 823, 829 (7th Cir. 1993)).

The Court's summary is in accordance with micro-economic theory. In the long run, firms can only remain in business if their profits are adequate to provide a return on investment that assures that investment in the industry will continue. Over time, because of rising real incomes and productivity, firms in most industries are able to assure an adequate profit. As technology and costs change, however, the long run demand for some products naturally increases and the long run demand for other products naturally decreases. In the face of rising external costs, firms that otherwise have a profitable line of business may have to increase prices to stay viable. Commonly, increases in prices result in reduced demand, but rarely eliminate all demand for the product. Whether this decrease in the total production of the product results in smaller production for each establishment within the industry, or the closure of some plants within the industry, or a combination of the two, is dependent on the cost and profit structure of individual firms within the industry.

If demand is completely inelastic (*i.e.*, price elasticity is 0), then the impact of compliance costs that are 1 percent of revenues for each firm in the industry would result in a 1 percent increase in the price of the product or service, with no decline in quantity demanded. Such a situation represents an extreme case, but might be correct in situations in which there are few if any substitutes for the product or service in question, or if the products or services of the affected sector account for only a very small portion of the income of its consumers.

If the demand is perfectly elastic (*i.e.*, the price elasticity is infinitely large), then no increase in price is possible and before-tax profits would be reduced by an amount equal to the costs of compliance (minus any savings resulting from improved employee health and/or reduced insurance costs) if the industry attempted to keep producing the same amount of goods and services as previously. Under this scenario, if the costs of compliance are such a large percentage of profits that some or all plants in the industry can no longer invest in the industry with hope of an adequate return on investment, then some or all of the firms in the industry will close. This scenario is highly unlikely to occur, however, because it can only arise when there are other goods and services that are, in the eyes of the consumer, perfect substitutes for the goods and services the affected establishments produce.

A common intermediate case would be a price elasticity of one. In this situation, if the costs of compliance amount to 1 percent of revenues, then production would decline by 1 percent and prices would rise by 1 percent. In this case, the industry revenues would stay the same, with somewhat lower production, but similar profit rates (in most situations where the marginal costs of production net of regulatory costs would fall as well). Consumers would, however, get less of the product or the service for their expenditures, and producers would collect lower total profits; this, as the court described in *ADA* v. *Secretary of Labor*, is the more typical case.

If there is a price elasticity of one, the question of economic feasibility is complicated. On the one hand, the industry will certainly not be ''eliminated'' with the level of costs found in this rulemaking, since under these assumptions the change in total profits is somewhat less than the costs imposed by the regulation. But there is still the question of whether the industry's competitive structure will be significantly altered. For example, given a 20 percent increase in costs, and an elasticity of one, the industry will not be eliminated. However, if the increase in costs is such that all small firms in an industry will have to close, this could reasonably be concluded to have altered its competitive structure. For this reason, when costs are a significant percentage of revenues, OSHA examines the differential costs by size of firm, and other classifications that may be important.

Some commenters (Ex. 38–265; Ex. 38–202; Ex. 40–12) questioned the screening analysis approach for several reasons: (1) It fails to provide for a facility-by-facility analysis; (2) it fails to consider that, in some plants, there may be product lines that do not involve hexavalent chromium; and (3) the concept of cost pass-through is largely negated by foreign competition. It should be noted that almost all commenters arguing for the inadequacy of screening analysis also argued for much higher costs than those estimated by OSHA (criticisms of costs were examined in Chapter 4). No one in the record presented an argument as to why costs representing less than one percent of revenues would be economically infeasible.

First, some commenters (Ex. 38–265; Ex. 40–12; Ex. 47–5) argued that industry ratios of costs to profits or costs to revenues cannot adequately determine economic feasibility—instead the analysis must be conducted on a facility-by-facility basis. OSHA rejects this argument for two reasons. First, the judicial definition of economic feasibility notes that a regulation may be economically feasible and yet cause some marginal facilities to close. (*American Textile Mfrs. Institute, Inc.* v. *Donovan* 452 U.S. 490, 530–532 (1981))

OSHA's obligation is not to determine whether any plants will close, or whether some marginal plants may close earlier than they otherwise might have, but whether the regulation will eliminate or alter the competitive structure of an industry. OSHA has an obligation to examine industries, and to consider its industry definitions carefully, so that they compare like with like. However, OSHA does not have an obligation to conduct facility-by-facility analysis of the thousands of facilities in the dozens of industries covered by a major standard. OSHA criteria can be examined through examination of industry ratios, particularly when the costs represent a very small percentage of revenues. Again, it must be noted that almost all commenters arguing for the inadequacy of screening analysis also argued for much higher costs than those estimated by OSHA, and while not agreeing with the need for facility-by-facility analysis, OSHA agrees that as costs become high as a percentage of revenues, something more than industry ratio analysis may be needed.

Second, some commenters argued that some facilities and industries have some lines of production involving hexavalent chromium, and some that do not, and, in such cases, OSHA should analyze only the revenues and profits associated with the lines using hexavalent chromium. Even if this were desirable, the data for such an analysis is simply not publicly available. No government data source collects data in a way that could be used for this purpose, and there is little privately collected data that could be used for this purpose. Even if such data were available, there are reasons to produce a product line even if it has profits lower than other product lines, and the data to examine this issue is even more unavailable. Further, OSHA's mandates, as interpreted by the courts, focus on the effect of a standard on industries, not on product lines within those industries. (*American Iron & Steel Institute* v. *OSHA*, 939 F.2d 975, 986 (D.C. Cir, 1991))

Finally, some commenters (SFIC, Ex. 38–265; SSINA, Ex. 40–12, Ex. 47–5; Engelhard, Ex. 38–202) questioned the above analysis by bringing up the issue of foreign competition, and some presented the argument that foreign competition made price increases impossible.

While foreign competition is an important issue to consider in analyzing economic feasibility, the presence of foreign competition does not mean that price increases are impossible. In economic terms, the case that foreign competition makes price increases impossible would be an argument that foreign competition puts all firms into the situation of having infinite elasticity of domestic demand, because foreign firms are not subject to the regulation, and, as a result can underprice American firms and drive them out of business.

Is this the case? Both theory and history suggest that it is not. From a theoretical viewpoint, the ability to sell to a consumer is determined by the price at the site, plus the cost of transportation, plus or minus intangible factors (such as quality or timeliness). Under these circumstances, a specific establishment can be competitive even if its cost of production is greater than that of foreign competitors—if the U.S. producer has other advantages.

From a practical viewpoint, econometric studies typically talk about the elasticity of domestic production with respect to foreign prices. No one assumes that a lower foreign price simply and totally assures that the domestic industry will be eliminated. Foreign competition has been a fact for decades—this does not mean that any domestic regulation assures that the domestic industry will be eliminated.

However, foreign competition does mean the elasticity of demand for domestic production will be greater than the total elasticity of demand for the product in question. Thus foreign competition is a factor that can result in greater elasticity of demand for domestic firms, and that needs to be considered in the context of the overall feasibility analysis, just as other factors such as the presence or absence of good substitutes need to be considered in the analysis.

A different problem with the formulation in terms of demand elasticity given above is that it ignores other things besides the regulatory costs that may act to shift either the costs of the production or demand for a product or service. In the normal course of events, neither demand nor supply is static. Costs of inputs needed commonly increase (at least in nominal terms). Productivity may increase or decrease as technology changes. Increases in income or GDP normally serve to increase demand for a good or service from year to year (for the majority of goods with positive income elasticity). In a typical year for most manufacturing industries, some costs will rise, productivity will also improve, and increases in GDP will increase demand. Adjusting to cost increases is thus a part of the normal economic scene. Even a real cost increase brought about by a regulation may be partially offset by productivity improvement. Finally, even real price increases may not decrease the quantities sold (and thus force employers to close) if the price increases are offset by income-driven increased demand for the good or service. A real price increase caused by the costs of a regulation will mean that the quantity sold will be lower than it otherwise would have been, but does not imply that actual quantity sold for the product will decline as compared to past years.

Table VIII–7 provides costs as percentage of revenues and profits for all affected establishments. OSHA believes that this is the best starting point for fulfilling its statutory responsibility to determine whether the standard affects the viability of an industry as a whole.

Table VIII–8 shows costs as a percentage of profits and revenues for firms classified as small by the Small Business Administration and Table VIII–9 shows costs as a percentage of revenues and profits for establishments with fewer than 20 employees. (These tables use costs with a discount rate of 7 percent.) These small-business tables show greater potential impacts, especially for small electroplating establishments. Based on these results, OSHA has prepared a Final Regulatory Flexibility Analysis (see Chapter VII of the FEA) to examine the impacts on small businesses and how they can be alleviated. (Tables V–5, V–6, and V–7 in the FEA show the same information using a discount rate of 3 percent.)

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Table VIII-8. Economic Impacts on Small Business Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^{3})

				Cost per Entity^{BB}				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity^{CC}	Profit per Entity^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
1	Electroplating - General Industry	All General Industry^{B}	All General Industry	$10,758	$10,969	$12,780,874	$734,766	0.08%	1.46%	0.09%	1.49%
		237	Heavy construction (234)	$16,379	$16,727	$12,287,063	$571,194	0.13%	2.87%	0.14%	2.93%
		238	Special trade contractors (235)	$11,519	$11,716	$2,706,583	$105,463	0.43%	10.92%	0.43%	11.11%
		313	Textile mills	$13,342	$13,617	$5,435,028	$155,501	0.25%	8.58%	0.25%	8.76%
		314	Textile product mills	$9,436	$9,618	$4,766,604	$132,697	0.20%	7.11%	0.20%	7.25%
		315	Apparel mfg	$16,379	$16,727	$10,989,677	$563,536	0.15%	2.91%	0.15%	2.97%
		316	Leather & allied product mfg	$18,427	$18,818	$15,620,859	$915,694	0.12%	2.01%	0.12%	2.06%
		321	Wood product mfg	$11,292	$11,515	$5,712,009	$155,306	0.20%	7.27%	0.20%	7.41%
		322	Paper mfg	$16,115	$16,451	$26,996,207	$751,180	0.06%	2.15%	0.06%	2.19%
		323	Printing & related support activities	$9,214	$9,389	$2,970,148	$112,322	0.31%	8.20%	0.32%	8.36%
		324	Petroleum & coal products mfg	$11,009	$11,221	$165,937,873	$7,050,167	0.01%	0.16%	0.01%	0.16%
		325	Chemical mfg	$11,380	$11,605	$36,534,897	$3,274,804	0.03%	0.35%	0.03%	0.35%
		326	Plastics & rubber products mfg	$15,127	$15,440	$9,219,560	$307,032	0.16%	4.93%	0.17%	5.03%
		327	Nonmetallic mineral product mfg	$13,342	$13,617	$5,488,363	$196,459	0.24%	6.79%	0.25%	6.93%
		331^{C}	Primary metal mfg	$12,564	$12,818	$19,721,884	$473,888	0.06%	2.65%	0.06%	2.70%
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	$10,677	$10,885	$878,682	$36,194	1.22%	29.50%	1.24%	30.07%
		Other 332^{D}	Fabricated Metal Product Manufacturing	$10,429	$10,632	$4,443,842	$213,137	0.23%	4.89%	0.24%	4.99%
		333^{E}	Machinery Manufacturing	$11,070	$11,289	$10,521,786	$344,873	0.11%	3.21%	0.11%	3.27%
		334	Computer & electronic product mfg	$12,131	$12,375	$32,552,081	$1,426,112	0.04%	0.85%	0.04%	0.87%
		335	Electrical equipment, appliance, & component mfg	$13,455	$13,730	$39,292,512	$1,424,293	0.03%	0.94%	0.03%	0.96%
		336 (except 33661)^{F}	Transportation Equipment Manufacturing	$14,306	$14,602	$81,763,538	$2,050,158	0.02%	0.70%	0.02%	0.71%
		339	Miscellaneous Manufacturing	$8,106	$8,254	$6,037,788	$227,192	0.13%	3.57%	0.14%	3.63%
		423	Wholesale trade, durable goods (421)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		441	Motor vehicle & parts dealers	$4,228	$4,286	$1,826,119	$26,333	0.23%	16.06%	0.23%	16.27%
		442	Furniture & home furnishings stores	$4,228	$4,286	$647,301	$24,357	0.65%	17.36%	0.66%	17.59%
		443	Electronics & appliance stores	$4,228	$4,286	$857,482	$29,158	0.49%	14.50%	0.50%	14.70%
		444	Building material & garden equipment & supplies dealers	$4,228	$4,286	$773,774	$38,341	0.55%	11.03%	0.55%	11.18%
		446	Health & personal care stores	$4,228	$4,286	$973,952	$24,550	0.43%	17.22%	0.44%	17.46%
		453	Miscellaneous store retailers	$4,228	$4,286	$600,302	$18,855	0.70%	22.43%	0.71%	22.73%
		454	Nonstore retailers	$4,228	$4,286	$706,333	$26,766	0.60%	15.80%	0.61%	16.01%
		511	Publishing industries	$14,939	$15,244	$9,517,777	$1,010,030	0.16%	1.48%	0.16%	1.51%
		512	Motion picture & sound recording industries	$10,040	$10,230	$4,669,612	$226,559	0.22%	4.43%	0.22%	4.52%
		519	Information services & data processing services (514)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		522	Credit intermediation & related activities	$6,832	$6,952	$2,062,875	$241,112	0.33%	2.83%	0.34%	2.88%
		532	Rental & leasing services	$4,228	$4,286	$649,662	$16,301	0.65%	25.94%	0.66%	26.29%
		541	Professional, scientific, & technical services	$5,681	$5,772	$619,297	$38,787	0.92%	14.65%	0.93%	14.88%
		561	Administrative & support services	$7,618	$7,753	$657,196	$24,900	1.16%	30.60%	1.18%	31.14%

Table VIII-8. Economic Impacts on Small Business Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2A Welding - General Industry (stainless steel)	562	Waste management & remediation services	$10,304	$10,506	$2,873,552	$122,204	0.36%	8.43%	0.37%	8.60%
	711	Performing arts, spectator sports, & related industries	$4,228	$4,286	$82,883	$7,802	5.10%	54.19%	5.17%	54.93%
	812	Personal & laundry services	$6,254	$6,359	$246,655	$12,738	2.54%	49.10%	2.58%	49.92%
	All General Industry[H]	All General Industry	$3,269	$3,269	$6,007,957	$310,442	0.05%	1.05%	0.05%	1.05%
	113	Forestry and Logging	$2,033	$2,033	$1,377,305	$32,836	0.15%	6.19%	0.15%	6.19%
	221	Utilities	$1,709	$1,709	$7,823,104	$305,652	0.02%	0.56%	0.02%	0.56%
	311[C]	Food Manufacturing	$3,301	$3,301	$18,313,298	$739,920	0.02%	0.45%	0.02%	0.45%
	312	Beverage and Tobacco Product Manufacturing	$3,196	$3,196	$84,688,514	$8,936,892	0.00%	0.04%	0.00%	0.04%
	313	Textile mills	$4,414	$4,414	$8,281,201	$236,933	0.05%	1.86%	0.05%	1.86%
	314	Textile product mills	$2,510	$2,510	$5,177,567	$144,138	0.05%	1.74%	0.05%	1.74%
	315	Apparel mfg	$5,276	$5,276	$16,079,356	$824,528	0.03%	0.64%	0.03%	0.64%
	316	Leather & allied product mfg	$5,136	$5,136	$20,341,006	$1,192,389	0.03%	0.43%	0.03%	0.43%
	321	Wood product mfg	$2,125	$2,125	$3,724,284	$101,261	0.06%	2.10%	0.06%	2.10%
	322	Paper mfg	$3,990	$3,990	$28,522,480	$793,649	0.01%	0.50%	0.01%	0.50%
	323	Printing & related support activities	$4,600	$4,600	$7,848,404	$296,802	0.06%	1.55%	0.06%	1.55%
	324	Petroleum & coal products mfg	$2,545	$2,545	$147,676,951	$6,274,319	0.00%	0.04%	0.00%	0.04%
	325	Chemical mfg	$4,340	$4,340	$68,053,975	$6,100,016	0.01%	0.07%	0.01%	0.07%
	326	Plastics & rubber products mfg	$5,144	$5,144	$14,557,959	$484,813	0.04%	1.06%	0.04%	1.06%
	327	Nonmetallic mineral product mfg	$5,821	$5,821	$10,648,072	$381,153	0.05%	1.53%	0.05%	1.53%
	332	Fabricated Metal Product Manufacturing	$3,428	$3,428	$6,767,606	$324,589	0.05%	1.06%	0.05%	1.06%
	333	Machinery Manufacturing	$3,024	$3,024	$12,305,294	$403,331	0.02%	0.75%	0.02%	0.75%
	334	Computer & electronic product mfg	$3,320	$3,320	$39,081,515	$1,712,167	0.01%	0.19%	0.01%	0.19%
	335	Electrical equipment, appliance, & component mfg	$4,745	$4,745	$66,815,847	$2,421,972	0.01%	0.20%	0.01%	0.20%
	336 (except 33661)	Transportation Equipment Manufacturing	$4,327	$4,327	$110,841,183	$2,779,258	0.00%	0.16%	0.00%	0.16%
	337	Furniture & Related Product Manufacturing	$2,777	$2,777	$4,266,182	$176,247	0.07%	1.58%	0.07%	1.58%
	339	Miscellaneous Manufacturing	$3,557	$3,557	$14,501,511	$1,019,389	0.02%	0.35%	0.02%	0.35%
	423	Wholesale trade, durable goods (421)	$1,625	$1,625	$2,143,754	$53,536	0.08%	3.04%	0.08%	3.04%
	424	Merchant Wholesalers, nondurable goods (422)	$6,229	$6,229	$25,602,778	$608,026	0.02%	1.02%	0.02%	1.02%
	441	Motor vehicle & parts dealers	$3,323	$3,323	$7,223,413	$104,163	0.05%	3.19%	0.05%	3.19%
	442	Furniture & home furnishings stores	$2,054	$2,054	$1,054,738	$39,688	0.19%	5.18%	0.19%	5.18%
	443	Electronics & appliance stores	$1,814	$1,814	$1,276,222	$43,397	0.14%	4.18%	0.14%	4.18%
	444	Building material & garden equipment & supplies dealers	$2,359	$2,359	$1,707,859	$84,625	0.14%	2.79%	0.14%	2.79%
	445	Food and Beverage Stores	$1,645	$1,645	$1,427,294	$26,613	0.12%	6.18%	0.12%	6.18%
	446	Health & personal care stores	$1,884	$1,884	$1,430,291	$36,052	0.13%	5.23%	0.13%	5.23%
	447	Gasoline Stations	$2,113	$2,113	$1,065,024	$7,829	0.20%	26.99%	0.20%	26.99%
	448	Clothing and Clothing Accessory Stores	$1,257	$1,257	$393,323	$17,008	0.32%	7.39%	0.32%	7.39%

Table VIII-8. Economic Impacts on Small Business Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m³)

			Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
	451	Sporting Good, Hobby, Book and Music Stores	$1,899	$1,899	$771,125	$20,209	0.25%	9.40%	0.25%	9.40%
	452	General Merchandise Stores	$1,257	$1,257	$811,413	$25,856	0.15%	4.86%	0.15%	4.86%
	453	Miscellaneous store retailers	$1,989	$1,989	$945,311	$29,691	0.21%	6.70%	0.21%	6.70%
	454	Nonstore retailers	$2,299	$2,299	$2,200,168	$83,375	0.10%	2.76%	0.10%	2.76%
	481	Air Transportation	NA	NA	NA	NA	NA	NA	NA	NA
	483	Water Transportation	$10,272	$10,272	$45,630,582	$1,733,323	0.02%	0.59%	0.02%	0.59%
	484	Truck Transportation	$4,398	$4,398	$4,571,979	$92,662	0.10%	4.75%	0.10%	4.75%
	485	Transit and Ground Passenger Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	486	Pipeline Transportation	$1,257	$1,257	$317,275	$63,678	0.40%	1.97%	0.40%	1.97%
	487	Scenic and Sightseeing Transportation	$3,843	$3,843	$3,084,792	$130,622	0.12%	2.94%	0.12%	2.94%
	488	Support Activities for Transportation	$4,626	$4,626	$4,570,396	$193,528	0.10%	2.39%	0.10%	2.39%
	492	Couriers and Messengers	$4,480	$4,480	$8,289,959	$351,029	0.05%	1.28%	0.05%	1.28%
	493	Warehousing and Storage	$5,764	$5,764	$4,241,432	$177,190	0.14%	3.25%	0.14%	3.25%
	511	Publishing industries	$3,023	$3,023	$7,364,933	$781,570	0.04%	0.39%	0.04%	0.39%
	512	Motion picture & sound recording industries	$2,662	$2,662	$5,080,375	$246,488	0.05%	1.08%	0.05%	1.08%
	519	Information services & data processing services (514)	$2,884	$2,884	$776,569	$69,103	0.37%	4.17%	0.37%	4.17%
	522	Credit intermediation & related activities	$4,517	$4,517	$5,474,177	$639,831	0.08%	0.71%	0.08%	0.71%
	531	Real Estate	$2,693	$2,693	$801,972	$94,856	0.34%	2.84%	0.34%	2.84%
	532	Rental & leasing services	$2,898	$2,898	$1,401,144	$35,157	0.21%	8.24%	0.21%	8.24%
	541	Professional, scientific, & technical services	$3,124	$3,124	$2,134,390	$133,679	0.15%	2.34%	0.15%	2.34%
	561	Administrative & support services	$2,012	$2,012	$683,585	$25,900	0.29%	7.77%	0.29%	7.77%
	562	Waste management & remediation services	$2,386	$2,386	$2,462,347	$104,717	0.10%	2.28%	0.10%	2.28%
	611	Educational Services	$3,301	$3,301	$523,248	$37,824	0.63%	8.73%	0.63%	8.73%
	621	Ambulatory Health Care Services	$5,960	$5,960	$1,420,465	$72,656	0.42%	8.20%	0.42%	8.20%
	622	Hospitals	$5,136	$5,136	$10,622,191	$549,397	0.05%	0.93%	0.05%	0.93%
	623	Nursing and Residential Care Facilities	$5,764	$5,764	$370,660	$19,171	1.56%	30.07%	1.56%	30.07%
	624	Social Assistance	$6,393	$6,393	$560,708	$28,680	1.14%	22.29%	1.14%	22.29%
	711	Performing arts, spectator sports, & related industries	$3,156	$3,156	$3,746,443	$253,808	0.08%	1.24%	0.08%	1.24%
	713	Amusement, Gambling, and Recreastional Industries	$2,472	$2,472	$798,440	$40,442	0.31%	6.11%	0.31%	6.11%
	722	Food Services and Drinking Places	$3,833	$3,833	$769,405	$31,541	0.50%	12.15%	0.50%	12.15%
	811	Repair and Maintenance	$2,814	$2,814	$691,995	$26,429	0.41%	10.65%	0.41%	10.65%
	812	Personal & laundry services	$2,709	$2,709	$401,265	$20,722	0.68%	13.08%	0.68%	13.08%
	813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$2,055	$2,055	$52,037	$1,288	3.95%	159.61%	3.95%	159.61%
2B Welding - Maritime Industry (stainless steel)	336611[I]	Ship Building and Repairing	$61,051	$61,051	$24,764,671	$1,445,573	0.25%	4.22%	0.25%	4.22%
2C Welding - Construction Industry (stainless steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$14,970	$14,970	$1,602,444	$66,149	0.93%	22.63%	0.93%	22.63%

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				Cost per Entity^{BB}				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Entity^{CC}	Profit per Entity^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2D	Welding - Government (stainless steel)	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	$1,121	$1,121	$3,670,000	N/A	0.03%	0.00%	0.03%	0.00%
2A1	Welding - General Industry (carbon steel)	All General Industry^{H}	All General Industry	$745	$745	$6,007,957	$310,442	0.01%	0.24%	0.01%	0.24%
		113	Forestry and Logging	$671	$671	$1,995,586	$47,577	0.03%	1.41%	0.03%	1.41%
		221	Utilities	$465	$465	$7,828,442	$305,861	0.01%	0.15%	0.01%	0.15%
		311	Food Manufacturing	$727	$727	$17,170,341	$693,741	0.00%	0.10%	0.00%	0.10%
		312	Beverage and Tobacco Product Manufacturing	$725	$725	$84,688,514	$8,936,892	0.00%	0.01%	0.00%	0.01%
		313	Textile mills	$1,015	$1,015	$8,716,457	$249,386	0.01%	0.41%	0.01%	0.41%
		314	Textile product mills	$611	$611	$5,233,697	$145,701	0.01%	0.42%	0.01%	0.42%
		315	Apparel mfg	$1,108	$1,108	$16,058,309	$823,449	0.01%	0.13%	0.01%	0.13%
		316	Leather & allied product mfg	$1,074	$1,074	$20,341,006	$1,192,389	0.01%	0.09%	0.01%	0.09%
		321	Wood product mfg	$542	$542	$3,770,807	$102,526	0.01%	0.53%	0.01%	0.53%
		322	Paper mfg	$889	$889	$28,471,015	$792,217	0.00%	0.11%	0.00%	0.11%
		323	Printing & related support activities	$986	$986	$7,757,351	$293,359	0.01%	0.34%	0.01%	0.34%
		324	Petroleum & coal products mfg	$597	$597	$133,981,259	$5,692,433	0.00%	0.01%	0.00%	0.01%
		325	Chemical mfg	$953	$953	$67,944,104	$6,090,167	0.00%	0.02%	0.00%	0.02%
		326	Plastics & rubber products mfg	$1,095	$1,095	$14,431,734	$480,609	0.01%	0.23%	0.01%	0.23%
		327	Nonmetallic mineral product mfg	$1,253	$1,253	$10,582,768	$378,816	0.01%	0.33%	0.01%	0.33%
		332	Fabricated Metal Product Manufacturing	$778	$778	$6,766,007	$324,513	0.01%	0.24%	0.01%	0.24%
		333	Machinery Manufacturing	$702	$702	$12,312,089	$403,554	0.01%	0.17%	0.01%	0.17%
		334	Computer & electronic product mfg	$754	$754	$39,038,241	$1,710,271	0.00%	0.04%	0.00%	0.04%
		335	Electrical equipment, appliance, & component mfg	$1,020	$1,020	$66,927,291	$2,426,012	0.00%	0.04%	0.00%	0.04%
		336 (except 33661)	Transportation Equipment Manufacturing	$939	$939	$110,867,403	$2,779,916	0.00%	0.03%	0.00%	0.03%
		337	Furniture & Related Product Manufacturing	$654	$654	$4,261,140	$176,039	0.02%	0.37%	0.02%	0.37%
		339	Miscellaneous Manufacturing	$800	$800	$14,529,688	$1,021,369	0.01%	0.08%	0.01%	0.08%
		423	Wholesale trade, durable goods (421)	$450	$450	$2,155,310	$53,825	0.02%	0.84%	0.02%	0.84%
		424	Merchant Wholesalers, nondurable goods (422)	$1,436	$1,436	$27,865,631	$661,765	0.01%	0.22%	0.01%	0.22%
		441	Motor vehicle & parts dealers	$781	$781	$7,186,276	$103,628	0.01%	0.75%	0.01%	0.75%
		442	Furniture & home furnishings stores	$539	$539	$1,062,031	$39,962	0.05%	1.35%	0.05%	1.35%
		443	Electronics & appliance stores	$477	$477	$1,237,227	$42,071	0.04%	1.13%	0.04%	1.13%
		444	Building material & garden equipment & supplies dealers	$593	$593	$1,704,734	$84,471	0.03%	0.70%	0.03%	0.70%
		445	Food and Beverage Stores	$537	$537	$2,129,440	$39,706	0.03%	1.35%	0.03%	1.35%
		446	Health & personal care stores	$499	$499	$1,422,620	$35,859	0.04%	1.39%	0.04%	1.39%
		447	Gasoline Stations	$529	$529	$1,025,108	$7,535	0.05%	7.02%	0.05%	7.02%
		448	Clothing and Clothing Accessory Stores	$376	$376	$393,323	$17,008	0.10%	2.21%	0.10%	2.21%
		451	Sporting Good, Hobby, Book and Music Stores	$483	$483	$713,957	$18,711	0.07%	2.58%	0.07%	2.58%
		452	General Merchandise Stores	$376	$376	$811,413	$25,856	0.05%	1.45%	0.05%	1.45%

Table VIII-8. Economic Impacts on Small Business Entities Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
	453	Miscellaneous store retailers	$522	$522	$941,781	$29,581	0.06%	1.76%	0.06%	1.76%
	454	Nonstore retailers	$585	$585	$2,238,291	$84,819	0.03%	0.69%	0.03%	0.69%
	481	Air Transportation	NA	NA	NA	NA	NA	NA	NA	NA
	483	Water Transportation	$1,611	$1,611	$34,222,937	$1,299,992	0.00%	0.12%	0.00%	0.12%
	484	Truck Transportation	$958	$958	$4,453,657	$90,264	0.02%	1.06%	0.02%	1.06%
	485	Transit and Ground Passenger Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	486	Pipeline Transportation	$376	$376	$317,275	$63,678	0.12%	0.59%	0.12%	0.59%
	487	Scenic and Sightseeing Transportation	$841	$841	$3,084,792	$130,622	0.03%	0.64%	0.03%	0.64%
	488	Support Activities for Transportation	$1,035	$1,035	$4,578,518	$193,872	0.02%	0.53%	0.02%	0.53%
	492	Couriers and Messengers	$993	$993	$8,289,959	$351,029	0.01%	0.28%	0.01%	0.28%
	493	Warehousing and Storage	$1,199	$1,199	$4,150,619	$173,397	0.03%	0.69%	0.03%	0.69%
	511	Publishing industries	$729	$729	$7,626,762	$809,355	0.01%	0.09%	0.01%	0.09%
	512	Motion picture & sound recording industries	$664	$664	$5,285,087	$256,421	0.01%	0.26%	0.01%	0.26%
	519	Information services & data processing services (514)	$668	$668	$738,285	$65,696	0.09%	1.02%	0.09%	1.02%
	522	Credit intermediation & related activities	$1,088	$1,088	$5,784,296	$676,079	0.02%	0.16%	0.02%	0.16%
	531	Real Estate	$644	$644	$765,229	$90,510	0.08%	0.71%	0.08%	0.71%
	532	Rental & leasing services	$702	$702	$1,388,156	$34,831	0.05%	2.01%	0.05%	2.01%
	541	Professional, scientific, & technical services	$736	$736	$2,130,910	$133,461	0.03%	0.55%	0.03%	0.55%
	561	Administrative & support services	$520	$520	$683,388	$25,892	0.08%	2.01%	0.08%	2.01%
	562	Waste management & remediation services	$597	$597	$2,470,039	$105,044	0.02%	0.57%	0.02%	0.57%
	611	Educational Services	$776	$776	$540,546	$39,074	0.14%	1.99%	0.14%	1.99%
	621	Ambulatory Health Care Services	$1,325	$1,325	$1,453,809	$74,361	0.09%	1.78%	0.09%	1.78%
	622	Hospitals	$1,074	$1,074	$10,622,191	$549,397	0.01%	0.20%	0.01%	0.20%
	623	Nursing and Residential Care Facilities	$1,262	$1,262	$370,660	$19,171	0.34%	6.58%	0.34%	6.58%
	624	Social Assistance	$1,450	$1,450	$560,708	$28,680	0.26%	5.05%	0.26%	5.05%
	711	Performing arts, spectator sports, & related industries	$762	$762	$3,975,325	$269,314	0.02%	0.28%	0.02%	0.28%
	713	Amusement, Gambling, and Recreastional Industries	$611	$611	$814,582	$41,259	0.08%	1.48%	0.08%	1.48%
	722	Food Services and Drinking Places	$897	$897	$786,761	$32,253	0.11%	2.78%	0.11%	2.78%
	811	Repair and Maintenance	$684	$684	$693,181	$26,475	0.10%	2.58%	0.10%	2.58%
	812	Personal & laundry services	$673	$673	$404,462	$20,887	0.17%	3.22%	0.17%	3.22%
	813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$524	$524	$52,176	$1,291	1.01%	40.62%	1.01%	40.62%
2B1 Welding - Maritime Industry (carbon steel)	336611[I]	Ship Building and Repairing	$644	$644	$24,764,671	$1,445,573	0.00%	0.04%	0.00%	0.04%
2C1 Welding - Construction Industry (carbon steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$3,699	$3,699	$1,602,444	$66,149	0.23%	5.59%	0.23%	5.59%
2D1 Welding - Government (carbon steel)	999200	State								
	999300	Local								

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				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
3A	Painting - General Industry	All General Industry[G]	Manufacturing								
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	$6,040	$6,044	$4,495,592	$185,177	0.13%	3.26%	0.13%	3.26%
		3361[K]	Motor vehicle mfg	$114,572	$114,593	$1,004,986,355	$25,199,267	0.01%	0.45%	0.01%	0.45%
		3362	Motor vehicle body & trailer mfg	$26,733	$26,737	$5,331,013	$133,671	0.50%	20.00%	0.50%	20.00%
		336411	Aircraft mfg	$123,940	$123,963	$500,994,405	$19,561,094	0.02%	0.63%	0.02%	0.63%
		336414	Guided missile & space vehicle mfg	$319,405	$319,464	$2,242,883,343	$87,572,341	0.01%	0.36%	0.01%	0.36%
		336415	Guided missile & space vehicle propulsion unit & parts mfg	$109,108	$109,128	$120,406,840	$4,701,229	0.09%	2.32%	0.09%	2.32%
		336419	Other guided missile & space vehicle parts & auxiliary equip mfg	$5,279	$5,279	$2,203,954	$86,052	0.24%	6.13%	0.24%	6.13%
		336992	Military armored vehicle, tank, & tank component mfg	$5,279	$5,279	$2,757,538	$69,143	0.19%	7.63%	0.19%	7.63%
		44111	New car dealers	$22,617	$24,899	$24,692,592	$302,672	0.09%	7.47%	0.10%	8.23%
		44112	Used car dealers	$5,719	$5,985	$1,490,024	$18,264	0.38%	31.31%	0.40%	32.77%
		811121	Automotive body, paint, & interior repair & maintenance	$6,339	$6,679	$448,283	$17,121	1.41%	37.03%	1.49%	39.01%
3B	Painting - Maritime Industry	336611	Ship building & repairing	$4,429	$5,755	$17,321,275	$1,011,084	0.03%	0.44%	0.03%	0.57%
		336612	Boat building	$4,678	$6,081	$10,106,010	$589,912	0.05%	0.79%	0.06%	1.03%
3C	Painting - Construction Industry	233[S], 234[T],235[U]	Heavy Construction, Special Trade Contractors	$819	$960	$3,503,386	$47,763	0.02%	1.71%	0.03%	2.01%
		234[T]	Heavy Construction	$1,530	$1,885	$8,608,997	$400,210	0.02%	0.38%	0.02%	0.47%
		235[U]	Special Trade Contractors	$700	$805	$351,026	$13,678	0.20%	5.12%	0.23%	5.88%
3D	Painting - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	$785	$932	$3,670,000	N/A	0.02%	0.03%	N/A	N/A
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	NA	NA
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$54,728	$54,733	$70,484,649	$2,085,740	0.08%	2.62%	0.08%	2.62%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	$3,031	$3,032	$115,264,777	$10,331,754	0.00%	0.03%	0.00%	0.03%
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	$608,092	$608,106	$75,725,612	$2,240,828	0.80%	27.14%	0.80%	27.14%
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$8,043	$8,044	$16,147,253	$759,315	0.05%	1.06%	0.05%	1.06%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$9,623	$9,623	$11,223,090	$652,485	0.09%	1.47%	0.09%	1.47%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$8,559	$8,560	$9,535,725	$415,819	0.09%	2.06%	0.09%	2.06%
		325991	Custom Compounding of Purchased Resin								
		3261	Plastic Product Mfg.								
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$6,655	$6,657	$22,312,086	$4,675,601	0.03%	0.14%	0.03%	0.14%
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	NA	NA

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				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
14	Steel Mills (stainless)	331111	Iron and Steel Mills	$35,783	$35,783	$115,098,842	$2,436,859	0.03%	1.47%	0.03%	1.47%
14A	Steel Mills (carbon)	331111	Iron and Steel Mills	$9,255	$9,255	$131,154,307	$2,776,783	0.01%	0.33%	0.01%	0.33%
14B	Reshaping (stainless)	332111	Iron and Steel Forging	$7,301	$7,301	$6,337,536	$295,718	0.12%	2.47%	0.12%	2.47%
15	Iron and Steel foundries	3315	Iron foundries	$29,282	$29,282	$6,698,033	$183,821	0.44%	15.93%	0.44%	15.93%
		331512	Steel Investment foundries								
		331513	Steel foundries (except investment)								
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$66,865	$66,866	$71,154,613	$2,105,565	0.09%	3.18%	0.09%	3.18%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$3,919	$3,919	$2,351,621	$69,588	0.17%	5.63%	0.17%	5.63%
19	Chemical Distributors	42269[V]	Other Chemical and Allied Products	$2,740	$2,740	$4,072,739	$130,718	0.07%	2.10%	0.07%	2.10%
20	Textile Dyeing	313	Textile Mills	$1,325	$1,360	$3,918,743	$110,279	0.03%	1.20%	0.03%	1.23%
		314	Textile Product Mills								
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$1,712	$1,713	$6,271,390	$179,815	0.03%	0.95%	0.03%	0.95%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.								
21A	Fiber, Flat, and Container Glass	327993	Mineral Wool Manufacturing	$14,094	$14,094	$42,052,552	$1,399,957	0.03%	1.01%	0.03%	1.01%
		327211	Flat Glass Manufacturing								
		327212	Other Pressed and Blown Glass Mfg.								
		327213	Glass Container Manufacturing								
22	Printing	32311	Printing	$593	$601	$1,630,512	$61,661	0.04%	0.96%	0.04%	0.97%
		323113	Commercial Screen Printing								
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users		Petrochemical Mfg., Including Styrene	$5,181	$5,181	$134,213,773	$3,911,356	0.00%	0.13%	0.00%	0.13%
24A	Chromium Catalyst Users - Service Companies	325110	Other Services to Buildings and Dwellings, Including Catalyst handling	$10,926	$11,230	$2,256,834	$85,507	0.48%	12.78%	0.50%	13.13%
25	Refractory Brick Producers	561790	Nonclay Refractory Mfg.	$4,691	$4,698	$10,214,017	$273,374	0.05%	1.72%	0.00%	0.00%
26A	Wood Working -General Industry	321	General Industry	$3,659	$3,659	$6,800,418	$180,224	0.05%	2.03%	0.05%	2.03%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$307	$307	$28,884,637	$1,686,065	0.00%	0.02%	0.00%	0.02%
26C	Wood Working - Construction Industry	2332[W], 2333[X], 2349[Y], 23551[Z]	Construction	$1,080	$1,111	$3,942,758	$162,756	0.03%	0.66%	0.03%	0.68%
26D	Wood Working - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	NA	NA
		999300	Local	$1,046	$1,080	$3,670,000	N/A	0.03%	0.04%	0.03%	0.00%
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$1,081	$1,331	$3,655,700	$155,466	0.03%	0.70%	0.04%	0.86%
27A	Solid Waste Incineration - govt	999300	Local Governments	N/A	N/A	$3,670,000	N/A	N/A	0.09%	#VALUE!	0.00%
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$0	$0	$22,048,830	$929,978	0.00%	0.00%	0.00%	0.00%

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				Cost per Entity[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Entity[CC]	Profit per Entity[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	$7,447	$7,447	$20,351,647	$488,440	0.04%	1.52%	0.04%	1.52%
		331528	Other Nonferrous Foundries								
31B	Construction - Refractory Brick Restoration and Maintenance	235[U]	Special Trade Contractors	$2,297	$2,442	$898,618	$34,102	0.26%	6.74%	0.27%	7.16%
31C	Construction - Hazardous Waste Site Work	2333[X]	Nonresidential Building Construction	$417	$671	$4,621,489	$194,565	0.01%	0.21%	0.01%	0.35%
31CG	Hazardous Waste Site Work - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	NA	NA
		999300	Local	$338	$482	$3,670,000	N/A	0.01%	0.02%	0.01%	0.00%
31D	Construction - Industrial Rehabilitation and Maintenance	23493[AA]	Industrial Nonbuilding Structure Construction	$183	$183	$16,804,508	$664,106	0.00%	0.03%	0.00%	0.03%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	$381	$381	$3,670,000	N/A	0.01%	0.01%	0.01%	0.00%
32A	Ready-Mixed Concrete	327320	Ready Mixed Concrete Manufacturing	$0	$0	$8,332,111	$351,433	0.00%	0.00%	0.00%	0.00%
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	$0	$0	$4,861,559	$204,185	0.00%	0.00%	0.00%	0.00%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Establishment[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Establishment[CC]	Profit per Establishment[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
1 Electroplating - General Industry	All General Industry[B]	All General Industry	$4,228	$4,286	$4,012,512	$230,677	0.11%	1.83%	0.11%	1.86%
	237	Heavy construction (234)	$4,228	$4,286	$1,105,508	$51,392	0.38%	8.23%	0.39%	8.34%
	238	Special trade contractors (235)	$4,228	$4,286	$438,154	$17,073	0.97%	24.77%	0.98%	25.10%
	313	Textile mills	$4,228	$4,286	$389,896	$11,155	1.08%	37.90%	1.10%	38.42%
	314	Textile product mills	$4,228	$4,286	$766,302	$21,333	0.55%	19.82%	0.56%	20.09%
	315	Apparel mfg	$4,228	$4,286	$1,041,838	$53,424	0.41%	7.91%	0.41%	8.02%
	316	Leather & allied product mfg	$4,228	$4,286	$973,613	$57,073	0.43%	7.41%	0.44%	7.51%
	321	Wood product mfg	$4,228	$4,286	$1,054,932	$28,683	0.40%	14.74%	0.41%	14.94%
	322	Paper mfg	$4,228	$4,286	$2,312,079	$64,334	0.18%	6.57%	0.19%	6.66%
	323	Printing & related support activities	$4,228	$4,286	$659,756	$24,950	0.64%	16.95%	0.65%	17.18%
	324	Petroleum & coal products mfg	$4,228	$4,286	$38,111,417	$1,619,232	0.01%	0.26%	0.01%	0.26%
	325	Chemical mfg	$4,228	$4,286	$4,572,791	$409,882	0.09%	1.03%	0.09%	1.05%
	326	Plastics & rubber products mfg	$4,228	$4,286	$1,003,297	$33,412	0.42%	12.66%	0.43%	12.83%
	327	Nonmetallic mineral product mfg	$4,228	$4,286	$1,179,027	$42,204	0.36%	10.02%	0.36%	10.15%
	331[C]	Primary metal mfg	$4,228	$4,286	$1,682,243	$40,422	0.25%	10.46%	0.25%	10.60%
	332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	$4,228	$4,286	$249,240	$10,266	1.70%	41.19%	1.72%	41.74%
	Other 332[D]	Fabricated Metal Product Manufacturing	$4,228	$4,286	$958,974	$45,995	0.44%	9.19%	0.45%	9.32%
	333[E]	Machinery Manufacturing	$4,228	$4,286	$1,612,607	$52,857	0.26%	8.00%	0.27%	8.11%
	334	Computer & electronic product mfg	$4,228	$4,286	$2,410,222	$105,592	0.18%	4.00%	0.18%	4.06%
	335	Electrical equipment, appliance, & component mfg	$4,228	$4,286	$2,985,596	$108,223	0.14%	3.91%	0.14%	3.96%
	336 (except 33661)[F]	Transportation Equipment Manufacturing	$4,228	$4,286	$3,248,984	$81,466	0.13%	5.19%	0.13%	5.26%
	339	Miscellaneous Manufacturing	$4,228	$4,286	$1,226,872	$46,165	0.34%	9.16%	0.35%	9.28%
	423	Wholesale trade, durable goods (421)	$4,228	$4,286	$1,557,982	$38,908	0.27%	10.87%	0.28%	11.01%
	441	Motor vehicle & parts dealers	$4,228	$4,286	$1,826,119	$26,333	0.23%	16.06%	0.23%	16.27%
	442	Furniture & home furnishings stores	$4,228	$4,286	$647,301	$24,357	0.65%	17.36%	0.66%	17.59%
	443	Electronics & appliance stores	$4,228	$4,286	$857,482	$29,158	0.49%	14.50%	0.50%	14.70%
	444	Building material & garden equipment & supplies dealers	$4,228	$4,286	$773,774	$38,341	0.55%	11.03%	0.55%	11.18%
	446	Health & personal care stores	$4,228	$4,286	$973,952	$24,550	0.43%	17.22%	0.44%	17.46%
	453	Miscellaneous store retailers	$4,228	$4,286	$600,302	$18,855	0.70%	22.43%	0.71%	22.73%
	454	Nonstore retailers	$4,228	$4,286	$706,333	$26,766	0.60%	15.80%	0.61%	16.01%
	511	Publishing industries	$4,228	$4,286	$964,373	$102,340	0.44%	4.13%	0.44%	4.19%
	512	Motion picture & sound recording industries	$4,228	$4,286	$879,086	$42,651	0.48%	9.91%	0.49%	10.05%
	519	Information services & data processing services (514)	$4,228	$4,286	$137,552	$12,240	3.07%	34.55%	3.12%	35.01%
	522	Credit intermediation & related activities	$4,228	$4,286	$1,330,610	$155,524	0.32%	2.72%	0.32%	2.76%
	532	Rental & leasing services	$4,228	$4,286	$649,662	$16,301	0.65%	25.94%	0.66%	26.29%
	541	Professional, scientific, & technical services	$4,228	$4,286	$311,962	$19,538	1.36%	21.64%	1.37%	21.93%
	561	Administrative & support services	$4,228	$4,286	$134,173	$5,084	3.15%	83.18%	3.19%	84.30%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Establishment[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Establishment[CC]	Profit per Establishment[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
	562	Waste management & remediation services	$4,228	$4,286	$736,821	$31,335	0.57%	13.49%	0.58%	13.68%
	711	Performing arts, spectator sports, & related industries	$4,228	$4,286	$82,883	$7,802	5.10%	54.19%	5.17%	54.93%
	812	Personal & laundry services	$4,228	$4,286	$180,227	$9,307	2.35%	45.43%	2.38%	46.05%
2A Welding - General Industry (stainless steel)	All General Industry[H]	All General Industry	$1,257	$1,257	$739,228	$38,197	0.17%	3.29%	0.17%	3.29%
	113	Forestry and Logging	$1,257	$1,257	$599,844	$14,301	0.21%	8.79%	0.21%	8.79%
	221	Utilities	$1,257	$1,257	$3,437,806	$134,317	0.04%	0.94%	0.04%	0.94%
	311[C]	Food Manufacturing	$1,257	$1,257	$1,402,737	$56,675	0.09%	2.22%	0.09%	2.22%
	312	Beverage and Tobacco Product Manufacturing	$1,257	$1,257	$6,093,071	$642,981	0.02%	0.20%	0.02%	0.20%
	313	Textile mills	$1,257	$1,257	$389,896	$11,155	0.32%	11.26%	0.32%	11.26%
	314	Textile product mills	$1,257	$1,257	$766,302	$21,333	0.16%	5.89%	0.16%	5.89%
	315	Apparel mfg	$1,257	$1,257	$1,041,838	$53,424	0.12%	2.35%	0.12%	2.35%
	316	Leather & allied product mfg	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	321	Wood product mfg	$1,257	$1,257	$1,054,932	$28,683	0.12%	4.38%	0.12%	4.38%
	322	Paper mfg	$1,257	$1,257	$2,312,079	$64,334	0.05%	1.95%	0.05%	1.95%
	323	Printing & related support activities	$1,257	$1,257	$659,756	$24,950	0.19%	5.04%	0.19%	5.04%
	324	Petroleum & coal products mfg	$1,257	$1,257	$38,111,417	$1,619,232	0.00%	0.08%	0.00%	0.08%
	325	Chemical mfg	$1,257	$1,257	$4,572,791	$409,882	0.03%	0.31%	0.03%	0.31%
	326	Plastics & rubber products mfg	$1,257	$1,257	$1,003,297	$33,412	0.13%	3.76%	0.13%	3.76%
	327	Nonmetallic mineral product mfg	$1,257	$1,257	$1,179,027	$42,204	0.11%	2.98%	0.11%	2.98%
	332	Fabricated Metal Product Manufacturing	$1,257	$1,257	$980,705	$47,037	0.13%	2.67%	0.13%	2.67%
	333	Machinery Manufacturing	$1,257	$1,257	$1,612,607	$52,857	0.08%	2.38%	0.08%	2.38%
	334	Computer & electronic product mfg	$1,257	$1,257	$2,410,222	$105,592	0.05%	1.19%	0.05%	1.19%
	335	Electrical equipment, appliance, & component mfg	$1,257	$1,257	$2,985,596	$108,223	0.04%	1.16%	0.04%	1.16%
	336 (except 33661)	Transportation Equipment Manufacturing	$1,257	$1,257	$3,140,751	$78,752	0.04%	1.60%	0.04%	1.60%
	337	Furniture & Related Product Manufacturing	$1,257	$1,257	$521,576	$21,548	0.24%	5.83%	0.24%	5.83%
	339	Miscellaneous Manufacturing	$1,257	$1,257	$1,226,872	$86,243	0.10%	1.46%	0.10%	1.46%
	423	Wholesale trade, durable goods (421)	$1,257	$1,257	$1,311,756	$32,759	0.10%	3.84%	0.10%	3.84%
	424	Merchant Wholesalers, nondurable goods (422)	$1,257	$1,257	$2,198,505	$52,211	0.06%	2.41%	0.06%	2.41%
	441	Motor vehicle & parts dealers	$1,257	$1,257	$1,826,119	$26,333	0.07%	4.77%	0.07%	4.77%
	442	Furniture & home furnishings stores	$1,257	$1,257	$647,301	$24,357	0.19%	5.16%	0.19%	5.16%
	443	Electronics & appliance stores	$1,257	$1,257	$857,482	$29,158	0.15%	4.31%	0.15%	4.31%
	444	Building material & garden equipment & supplies dealers	$1,257	$1,257	$773,774	$38,341	0.16%	3.28%	0.16%	3.28%
	445	Food and Beverage Stores	$1,257	$1,257	$640,255	$11,938	0.20%	10.53%	0.20%	10.53%
	446	Health & personal care stores	$1,257	$1,257	$973,952	$24,550	0.13%	5.12%	0.13%	5.12%
	447	Gasoline Stations	$1,257	$1,257	$785,609	$5,775	0.16%	21.76%	0.16%	21.76%
	448	Clothing and Clothing Accessory Stores	$1,257	$1,257	$393,323	$17,008	0.32%	7.39%	0.32%	7.39%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

			Cost per Establishment[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Establishment[CC]	Profit per Establishment[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
	451	Sporting Good, Hobby, Book and Music Stores	$1,257	$1,257	$485,283	$12,718	0.26%	9.88%	0.26%	9.88%
	452	General Merchandise Stores	$1,257	$1,257	$811,413	$25,856	0.15%	4.86%	0.15%	4.86%
	453	Miscellaneous store retailers	$1,257	$1,257	$600,302	$18,855	0.21%	6.66%	0.21%	6.66%
	454	Nonstore retailers	$1,257	$1,257	$706,333	$26,766	0.18%	4.69%	0.18%	4.69%
	481	Air Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	483	Water Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	484	Truck Transportation	$1,257	$1,257	$435,716	$8,831	0.29%	14.23%	0.29%	14.23%
	485	Transit and Ground Passenger Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	486	Pipeline Transportation	$1,257	$1,257	$317,275	$63,678	0.40%	1.97%	0.40%	1.97%
	487	Scenic and Sightseeing Transportation	$1,257	$1,257	$268,756	$11,380	0.47%	11.04%	0.47%	11.04%
	488	Support Activities for Transportation	$1,257	$1,257	$594,413	$25,170	0.21%	4.99%	0.21%	4.99%
	492	Couriers and Messengers	$1,257	$1,257	$391,942	$16,596	0.32%	7.57%	0.32%	7.57%
	493	Warehousing and Storage	$1,257	$1,257	$544,880	$22,763	0.23%	5.52%	0.23%	5.52%
	511	Publishing industries	$1,257	$1,257	$964,373	$102,340	0.13%	1.23%	0.13%	1.23%
	512	Motion picture & sound recording industries	$1,257	$1,257	$879,086	$42,651	0.14%	2.95%	0.14%	2.95%
	519	Information services & data processing services (514)	$1,257	$1,257	$137,552	$12,240	0.91%	10.27%	0.91%	10.27%
	522	Credit intermediation & related activities	$1,257	$1,257	$1,330,610	$155,524	0.09%	0.81%	0.09%	0.81%
	531	Real Estate	$1,257	$1,257	$255,664	$30,239	0.49%	4.16%	0.49%	4.16%
	532	Rental & leasing services	$1,257	$1,257	$649,662	$16,301	0.19%	7.71%	0.19%	7.71%
	541	Professional, scientific, & technical services	$1,257	$1,257	$311,962	$19,538	0.40%	6.43%	0.40%	6.43%
	561	Administrative & support services	$1,257	$1,257	$134,173	$5,084	0.94%	24.72%	0.94%	24.72%
	562	Waste management & remediation services	$1,257	$1,257	$736,821	$31,335	0.17%	4.01%	0.17%	4.01%
	611	Educational Services	$1,257	$1,257	$43,194	$3,122	2.91%	40.25%	2.91%	40.25%
	621	Ambulatory Health Care Services	$1,257	$1,257	$175,607	$8,982	0.72%	13.99%	0.72%	13.99%
	622	Hospitals	$1,257	$1,257	$52,347	$2,707	2.40%	46.41%	2.40%	46.41%
	623	Nursing and Residential Care Facilities	$1,257	$1,257	$35,341	$1,828	3.56%	68.75%	3.56%	68.75%
	624	Social Assistance	$1,257	$1,257	$86,175	$4,408	1.46%	28.51%	1.46%	28.51%
	711	Performing arts, spectator sports, & related industries	$1,257	$1,257	$210,822	$14,282	0.60%	8.80%	0.60%	8.80%
	713	Amusement, Gambling, and Recreastional Industries	$1,257	$1,257	$158,513	$8,029	0.79%	15.65%	0.79%	15.65%
	722	Food Services and Drinking Places	$1,257	$1,257	$179,284	$7,350	0.70%	17.10%	0.70%	17.10%
	811	Repair and Maintenance	$1,257	$1,257	$249,849	$9,543	0.50%	13.17%	0.50%	13.17%
	812	Personal & laundry services	$1,257	$1,257	$180,227	$9,307	0.70%	13.50%	0.70%	13.50%
	813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$1,257	$1,257	$18,820	$466	6.68%	269.82%	6.68%	269.82%
2B Welding - Maritime Industry (stainless steel)	336611[1]	Ship Building and Repairing	$3,826	$3,826	$918,207	$53,598	0.42%	7.14%	0.42%	7.14%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Establishment[BB]				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Establishment[CC]	Profit per Establishment[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2C	Welding - Construction Industry (stainless steel)	233[S], 234[T],235[U]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$7,792	$7,792	$664,150	$27,416	1.17%	28.42%	1.17%	28.42%
2D	Welding - Government (stainless steel)	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2A1	Welding - General Industry (carbon steel)	All General Industry[H]	All General Industry	$376	$376	$739,228	$38,197	0.05%	0.98%	0.05%	0.98%
		113	Forestry and Logging	$376	$376	$599,844	$14,301	0.06%	2.63%	0.06%	2.63%
		221	Utilities	$376	$376	$3,437,806	$134,317	0.01%	0.28%	0.01%	0.28%
		311	Food Manufacturing	$376	$376	$1,402,737	$56,675	0.03%	0.66%	0.03%	0.66%
		312	Beverage and Tobacco Product Manufacturing	$376	$376	$6,093,071	$642,981	0.01%	0.06%	0.01%	0.06%
		313	Textile mills	$376	$376	$389,896	$11,155	0.10%	3.37%	0.10%	3.37%
		314	Textile product mills	$376	$376	$766,302	$21,333	0.05%	1.76%	0.05%	1.76%
		315	Apparel mfg	$376	$376	$1,041,838	$53,424	0.04%	0.70%	0.04%	0.70%
		316	Leather & allied product mfg	NA	NA	NA	NA	NA	NA	N/A	N/A
		321	Wood product mfg	$376	$376	$1,054,932	$28,683	0.04%	1.31%	0.04%	1.31%
		322	Paper mfg	$376	$376	$2,312,079	$64,334	0.02%	0.58%	0.02%	0.58%
		323	Printing & related support activities	$376	$376	$659,756	$24,950	0.06%	1.51%	0.06%	1.51%
		324	Petroleum & coal products mfg	$376	$376	$38,111,417	$1,619,232	0.00%	0.02%	0.00%	0.02%
		325	Chemical mfg	$376	$376	$4,572,791	$409,882	0.01%	0.09%	0.01%	0.09%
		326	Plastics & rubber products mfg	$376	$376	$1,003,297	$33,412	0.04%	1.12%	0.04%	1.12%
		327	Nonmetallic mineral product mfg	$376	$376	$1,179,027	$42,204	0.03%	0.89%	0.03%	0.89%
		332	Fabricated Metal Product Manufacturing	$376	$376	$980,705	$47,037	0.04%	0.80%	0.04%	0.80%
		333	Machinery Manufacturing	$376	$376	$1,612,607	$52,857	0.02%	0.71%	0.02%	0.71%
		334	Computer & electronic product mfg	$376	$376	$2,410,222	$105,592	0.02%	0.36%	0.02%	0.36%
		335	Electrical equipment, appliance, & component mfg	$376	$376	$2,985,596	$108,223	0.01%	0.35%	0.01%	0.35%
		336 (except 33661)	Transportation Equipment Manufacturing	$376	$376	$3,140,751	$78,752	0.01%	0.48%	0.01%	0.48%
		337	Furniture & Related Product Manufacturing	$376	$376	$521,576	$21,548	0.07%	1.74%	0.07%	1.74%
		339	Miscellaneous Manufacturing	$376	$376	$1,226,872	$86,243	0.03%	0.44%	0.03%	0.44%
		423	Wholesale trade, durable goods (421)	$376	$376	$1,311,756	$32,759	0.03%	1.15%	0.03%	1.15%
		424	Merchant Wholesalers, nondurable goods (422)	$376	$376	$2,198,505	$52,211	0.02%	0.72%	0.02%	0.72%
		441	Motor vehicle & parts dealers	$376	$376	$1,826,119	$26,333	0.02%	1.43%	0.02%	1.43%
		442	Furniture & home furnishings stores	$376	$376	$647,301	$24,357	0.06%	1.54%	0.06%	1.54%
		443	Electronics & appliance stores	$376	$376	$857,482	$29,158	0.04%	1.29%	0.04%	1.29%
		444	Building material & garden equipment & supplies dealers	$376	$376	$773,774	$38,341	0.05%	0.98%	0.05%	0.98%
		445	Food and Beverage Stores	$376	$376	$640,255	$11,938	0.06%	3.15%	0.06%	3.15%
		446	Health & personal care stores	$376	$376	$973,952	$24,550	0.04%	1.53%	0.04%	1.53%
		447	Gasoline Stations	$376	$376	$785,609	$5,775	0.05%	6.51%	0.05%	6.51%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Establishment^{BB}				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Establishment^{CC}	Profit per Establishment^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
		448	Clothing and Clothing Accessory Stores	$376	$376	$393,323	$17,008	0.10%	2.21%	0.10%	2.21%
		451	Sporting Good, Hobby, Book and Music Stores	$376	$376	$485,283	$12,718	0.08%	2.95%	0.08%	2.95%
		452	General Merchandise Stores	$376	$376	$811,413	$25,856	0.05%	1.45%	0.05%	1.45%
		453	Miscellaneous store retailers	$376	$376	$600,302	$18,855	0.06%	1.99%	0.06%	1.99%
		454	Nonstore retailers	$376	$376	$706,333	$26,766	0.05%	1.40%	0.05%	1.40%
		481	Air Transportation	NA	NA	NA	NA	NA	NA	N/A	N/A
		483	Water Transportation	NA	NA	NA	NA	NA	NA	N/A	N/A
		484	Truck Transportation	$376	$376	$435,716	$8,831	0.09%	4.26%	0.09%	4.26%
		485	Transit and Ground Passenger Transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		486	Pipeline Transportation	$376	$376	$317,275	$63,678	0.12%	0.59%	0.12%	0.59%
		487	Scenic and Sightseeing Transportation	$376	$376	$268,756	$11,380	0.14%	3.30%	0.14%	3.30%
		488	Support Activities for Transportation	$376	$376	$594,413	$25,170	0.06%	1.49%	0.06%	1.49%
		492	Couriers and Messengers	$376	$376	$391,942	$16,596	0.10%	2.26%	0.10%	2.26%
		493	Warehousing and Storage	$376	$376	$544,880	$22,763	0.07%	1.65%	0.07%	1.65%
		511	Publishing industries	$376	$376	$964,373	$102,340	0.04%	0.37%	0.04%	0.37%
		512	Motion picture & sound recording industries	$376	$376	$879,086	$42,651	0.04%	0.88%	0.04%	0.88%
		519	Information services & data processing services (514)	$376	$376	$137,552	$12,240	0.27%	3.07%	0.27%	3.07%
		522	Credit intermediation & related activities	$376	$376	$1,330,610	$155,524	0.03%	0.24%	0.03%	0.24%
		531	Real Estate	$376	$376	$255,664	$30,239	0.15%	1.24%	0.15%	1.24%
		532	Rental & leasing services	$376	$376	$649,662	$16,301	0.06%	2.31%	0.06%	2.31%
		541	Professional, scientific, & technical services	$376	$376	$311,962	$19,538	0.12%	1.92%	0.12%	1.92%
		561	Administrative & support services	$376	$376	$134,173	$5,084	0.28%	7.39%	0.28%	7.39%
		562	Waste management & remediation services	$376	$376	$736,821	$31,335	0.05%	1.20%	0.05%	1.20%
		611	Educational Services	$376	$376	$43,194	$3,122	0.87%	12.04%	0.87%	12.04%
		621	Ambulatory Health Care Services	$376	$376	$175,607	$8,982	0.21%	4.18%	0.21%	4.18%
		622	Hospitals	$376	$376	$52,347	$2,707	0.72%	13.88%	0.72%	13.88%
		623	Nursing and Residential Care Facilities	$376	$376	$35,341	$1,828	1.06%	20.56%	1.06%	20.56%
		624	Social Assistance	$376	$376	$86,175	$4,408	0.44%	8.53%	0.44%	8.53%
		711	Performing arts, spectator sports, & related industries	$376	$376	$210,822	$14,282	0.18%	2.63%	0.18%	2.63%
		713	Amusement, Gambling, and Recreational Industries	$376	$376	$158,513	$8,029	0.24%	4.68%	0.24%	4.68%
		722	Food Services and Drinking Places	$376	$376	$179,284	$7,350	0.21%	5.11%	0.21%	5.11%
		811	Repair and Maintenance	$376	$376	$249,849	$9,543	0.15%	3.94%	0.15%	3.94%
		812	Personal & laundry services	$376	$376	$180,227	$9,307	0.21%	4.04%	0.21%	4.04%
		813	Religious, Grantmaking, Civil, Professional, and Similar Organizations	$376	$376	$18,820	$466	2.00%	80.68%	2.00%	80.68%
2B1	Welding - Maritime Industry (carbon steel)	336611[1]	Ship Building and Repairing	$362	$376	$918,207	$53,598	0.04%	0.67%	0.04%	0.70%

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^{3})

				Cost per Establishment^{BB}				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Establishment^{CC}	Profit per Establishment^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
2C1	Welding - Construction Industry (carbon steel)	233^{S}, 234^{T},235^{U}	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$2,195	$2,195	$664,150	$27,416	0.33%	8.00%	0.33%	8.00%
2D1	Welding - Government (carbon steel)	999200	State								
		999300	Local								
3A	Painting - General Industry	All General Industry^{G}	Manufacturing								
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	$4,078	$4,079	$560,978	$23,107	0.73%	17.65%	0.73%	17.65%
		3361^{K}	Motor vehicle mfg	$5,279	$5,279	$7,565,616	$189,702	0.07%	2.78%	0.07%	2.78%
		3362	Motor vehicle body & trailer mfg	$5,279	$5,279	$1,956,533	$49,059	0.27%	10.76%	0.27%	10.76%
		336411	Aircraft mfg	$5,279	$5,279	$2,608,704	$101,856	0.20%	5.18%	0.20%	5.18%
		336414	Guided missile & space vehicle mfg	$5,279	$5,279	$4,302,791	$168,000	0.12%	3.14%	0.12%	3.14%
		336415	Guided missile & space vehicle propulsion unit & parts mfg	$5,279	$5,279	$2,811,191	$109,762	0.19%	4.81%	0.19%	4.81%
		336419	Other guided missile & space vehicle parts & auxiliary equip mfg	$5,279	$5,279	$2,203,954	$86,052	0.24%	6.13%	0.24%	6.13%
		336992	Military armored vehicle, tank, & tank component mfg	$5,279	$5,279	$2,757,538	$69,143	0.19%	7.63%	0.19%	7.63%
		44111	New car dealers	$4,932	$5,107	$3,632,387	$44,524	0.14%	11.08%	0.14%	11.47%
		44112	Used car dealers	$4,932	$5,107	$1,199,947	$14,708	0.41%	33.53%	0.43%	34.72%
		811121	Automotive body, paint, & interior repair & maintenance	$4,932	$5,107	$359,394	$13,726	1.37%	35.93%	1.42%	37.21%
3B	Painting - Maritime Industry	336611	Ship building & repairing	$2,357	$3,045	$878,951	$51,306	0.27%	4.59%	0.35%	5.93%
		336612	Boat building	$2,357	$3,045	$1,065,669	$62,206	0.22%	3.79%	0.29%	4.89%
3C	Painting - Construction Industry	233^{S}, 234^{T},235^{U}	Heavy Construction, Special Trade Contractors	$644	$734	$926,295	$8,339	0.07%	7.73%	0.08%	8.80%
		234^{T}	Heavy Construction	$644	$734	$583,757	$27,137	0.11%	2.37%	0.13%	2.70%
		235^{U}	Special Trade Contractors	$644	$734	$230,007	$8,962	0.28%	7.19%	0.32%	8.19%
3D	Painting - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$5,263	$5,264	$1,988,410	$58,840	0.26%	8.95%	0.26%	8.95%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$9,375	$9,375	$3,180,817	$149,576	0.29%	6.27%	0.29%	6.27%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$5,320	$5,321	$3,678,924	$213,884	0.14%	2.49%	0.14%	2.49%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$5,468	$5,468	$1,123,400	$48,987	0.49%	11.16%	0.49%	11.16%
		325991	Custom Compounding of Purchased Resin								
		3261	Plastic Product Mfg.								

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^{3})

				Cost per Establishment^{BB}				Impacts on the National Economy		Impacts on Employers	
Application Group		NAICS	Category	National Costs	Employer Costs	Revenue per Establishment^{CC}	Profit per Establishment^{CC}	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$5,641	$5,641	$3,133,805	$182,192	0.18%	3.10%	0.18%	3.10%
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14	Steel Mills (stainless)	331111	Iron and Steel Mills	$6,239	$6,239	$1,414,331	$29,944	0.44%	20.84%	0.44%	20.84%
14A	Steel Mills (carbon)	331111	Iron and Steel Mills	$5,370	$5,370	$1,414,331	$29,944	0.38%	17.93%	0.38%	17.93%
14B	Reshaping (stainless)	332111	Iron and Steel Forging	$5,314	$5,314	$837,023	$39,057	0.63%	13.61%	0.63%	13.61%
15	Iron and Steel foundries	3315	Iron foundries	$12,285	$12,285	$361,695	$9,926	3.40%	123.76%	3.40%	123.76%
		331512	Steel Investment foundries								
		331513	Steel foundries (except investment)								
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$17,876	$17,876	$1,959,383	$57,981	0.91%	30.83%	0.91%	30.83%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$3,919	$3,919	$2,351,621	$69,588	0.17%	5.63%	0.17%	5.63%
19	Chemical Distributors	42269^{V}	Other Chemical and Allied Products	$2,045	$2,045	$1,448,223	$46,482	0.14%	4.40%	0.14%	4.40%
20	Textile Dyeing	313	Textile Mills	$982	$985	$433,726	$12,206	0.23%	8.05%	0.23%	8.07%
		314	Textile Product Mills								
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$1,127	$1,127	$658,799	$18,889	0.17%	5.97%	0.17%	5.97%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.								
21A	Fiber, Flat, and Container Glass	327993	Mineral Wool Manufacturing	$10,307	$10,307	$1,853,380	$61,700	0.56%	16.70%	0.56%	16.70%
		327211	Flat Glass Manufacturing								
		327212	Other Pressed and Blown Glass Mfg.								
		327213	Glass Container Manufacturing								
22	Printing	32311	Printing	$428	$429	$513,430	$19,416	0.08%	2.20%	0.08%	2.21%
		323113	Commercial Screen Printing								
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users		Petrochemical Mfg., Including Styrene	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24A	Chromium Catalyst Users - Service Companies	325110	Other Services to Buildings and Dwellings, Including Catalyst handling	$7,776	$7,966	$1,399,415	$53,021	0.56%	14.67%	0.57%	15.02%
25	Refractory Brick Producers	561790	Nonclay Refractory Mfg.	$0	$0	NA	NA	0.00%	0.00%	0.00%	0.00%
26A	Wood Working -General Industry	321	General Industry	$3,131	$3,131	$1,140,938	$30,237	0.27%	10.36%	0.27%	10.36%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$271	$271	$918,207	$53,598	0.03%	0.51%	0.03%	0.51%
26C	Wood Working - Construction Industry	2332^{W}, 2333^{X}, 2349^{Y}, 23551^{Z}	Construction	$1,045	$1,067	$926,140	$38,231	0.11%	2.73%	0.12%	2.79%
26D	Wood Working - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table VIII-9. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Final Standard for Hexavalent Chromium (by Application Group for a PEL of 5 ug/m^3)

				Cost per Establishment[BB]				Impacts on the National Economy		Impacts on Employers	
	Application Group	NAICS	Category	National Costs	Employer Costs	Revenue per Establishment[CC]	Profit per Establishment[CC]	Cost/Revenue Impact	Cost/Profit Impact	Cost/Revenue Impact	Cost/Profit Impact
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$566	$719	$1,623,290	$69,034	0.03%	0.82%	0.04%	1.04%
27A	Solid Waste Incineration govt	999300	Local Governments	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$0	$0	$3,453,886	$145,678	0.00%	0.00%	0.00%	0.00%
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		331528	Other Nonferrous Foundries								
31B	Construction - Refractory Brick Restoration and Maintenance	235[U]	Special Trade Contractors	$1,781	$1,803	$441,435	$16,752	0.40%	10.63%	0.41%	10.76%
31C	Construction - Hazardous Waste Site Work	2333[X]	Nonresidential Building Construction	$338	$473	$1,219,945	$51,360	0.03%	0.66%	0.04%	0.92%
31CG	Hazardous Waste Site Work - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
31D	Construction - Industrial Rehabilitation and Maintenance	23493[AA]	Industrial Nonbuilding Structure Construction	$56	$56	$3,122,851	$123,414	0.00%	0.05%	0.00%	0.05%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
32A	Ready-Mixed Concrete	327320	Ready Mixed Concrete Manufacturing	$0	$0	$525,584	$22,168	0.00%	0.00%	0.00%	0.00%
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	$0	$0	$1,436,042	$60,314	0.00%	0.00%	0.00%	0.00%

Footnotes to Tables VIII-8 and VIII-9

[A] SBA size standards taken from 13 CFR Ch.1 § 121.201. January 1, 2003

[B] Includes industries in NAICS 31-33, NAICS 42, NAICS 51.

[C] Except 311221 "Wet Corn Milling", 311312 "Cane Sugar Refining", 311313 "Beet Sugar Manufacturing", and 311821 Cookie and Cracker Manufacturing, which have an SBA size standard of 750 employees, and also 311223 "Other Oilseed Processing", 311225 "Fats and Oils Refining and Blending", 311230 "Breakfast Cereal Manufacturing", 311422 "Special Canning", which have an SBA size standard of 1,000 employees.

[D] Except 332811 "Metal Heat Treating," 332991 "Ball and Roller Bearing Manufacturing," and 332998 "Enameled Iron and Metal Sanitary Ware Manufacturing," all of which have an SBA size standard of 750 employees; 332431 "Metal Can Manufacturing," 332992 "Small Arms Ammunition Manufacturing," and 332994 "Small Arms Manufacturing," all of which have an SBA size standard of 1,000 employees; and 332993 "Ammunition (except Small Arms) Manufacturing," the SBA size standard for which is 1,500 employees.

[E] Except 333120 "Construction Machinery Manufacturing," 333415 "Air-Conditioning and Warm Air Heating Equipment," and 333924 Industrial Truck, Tractor, Trailer," all of which have an SBA size standard of 750 employees; and except 333313 Office Machinery Manufacturing," 333611 "Turbine and Turbine Generator Set Unit Manufacturing," and 333618 "Other Engine Equipment Manufacturing," all of which have an SBA size standard of 1,000 employees.

[F] Except for 336212 "Truck Trailer Manufacturing," 336214 "Travel Trailer and Camper Manufacturing," 336311 "Carburetor, Piston, Piston Ring and Valve Manufacturing," 336321 "Vehicular Lighting Equipment Manufacturing," 336360 "Motor Vehicle Seating and Interior Trim Manufacturing," 336370 "Motor Vehicle Metal Stamping," 336991 Motorcycle, Bicycle and Parts Manufacturing," and 336999 "All Other Transportation Equipment Manufacturing," all of which have an SBA size standard of 500 employees; 336312 "Gasoline Engine and Engine Parts Manufacturing," 336322 "Other Motor Vehicle Electrical and Electronic Equipment Manufacturing," 336330 "Motor Vehicle Steering and Suspension Components Manufacturing (except Spring)," 336340 "Motor Vehicle Brake System Manufacturing," 336350 "Motor Vehicle Transmission and Power Train Parts Manufacturing," 336391 Motor Vehicle Air-Conditioning Manufacturing," 336399 "All Other Motor Vehicle Parts Manufacturing, all of which have an SBA size standard of 750 employees; and 336411 "Aircraft Manufacturing," which has an SBA size standard of 1,500 employees.

[G] Includes industries in NAICS 332, NAICS 336, NAICS 441, and NAICS 811.

[H] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[I] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[J] Except 2331 "Land Subdivision and Land Development," which has an SBA size standard of $6.0 million.

[K] Except 336411 "Aircraft Manufacturing"

[L] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[M] All of NAICS CODE 3261 have an SBA size standard of 500 employees except 326192 "Resilient Floor Covering Mfg.", the size standard for which is 750 employees.

[N] All of NAICS CODE 313 have an SBA size standard of 500 employees except 313210 "Broad Woven Fabric Mills", 313320 "Broad Woven Finishing Mills", and 313320 "Fabric Coating Mills" all of which have a size standard of 1,000 employees.

[O] All of NAICS CODE 314 have an SBA size standard of 500 employees except 314992 "Tire Cord and Tire Fabric Mill", the size standard for which is 1,000 employees.

[P] All of NAICS CODE 3161 have an SBA size standard of 500 employees except 316211 "Rubber and Plastics Footwear Mfg.", the size standard for which is 1,000 employees.

[Q] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[R] Except 23551 which has an SBA size standard of $12 million.

[S] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[T] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[U] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[V] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[W] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[X] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[Y] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[Z] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[AA] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[BB] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industry profiles in Chapter II for the complete list of references.

[CC] Industry revenues were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2002*** (IRS, 2005). Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on Shaw, 2006.

BILLING CODE 4510–26–C

Economic Feasibility for Many Industries With Low Potential Impacts

To determine whether a rule is economically feasible, OSHA evaluates evidence from a number of sources. And while there is no hard and fast rule, in the absence of evidence to the contrary OSHA generally considers a standard economically feasible when the costs of compliance are less than one percent of revenues. Common-sense considerations indicate that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure particularly since most industries have at least some ability to raise prices to reflect increased costs. Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis. In addition, as a second check, OSHA also looks to see whether even such low costs may represent more than ten percent of the profit in a particular industry. If either of these factors is present, or if there is other evidence of industry demise or potential disruption in an industry's competitive structure because of the standard, OSHA examines the effect of the rule on that industry more closely. Finally, OSHA reviews the record for any other unusual circumstances, such as excellent substitutes of equal cost that might make an industry particularly sensitive to price change. In this case, the only argument of this kind that OSHA noted was an argument by one commenter that trivalent chromium plating might be substituted in some applications for hexavalent chromium. However, even if this is the case (some in the record did not agree), a plating operation could switch to trivalent plating with minimal capital investment and thus remain in business.

OSHA believes that a potential one percent revenue effect is an appropriate way to begin the analysis in light of the fact that the United States has a dynamic and constantly changing economy. There is an enormous variety of year-to-year events that could cause a one percent increase in a business's costs, *e.g.*, increasing fuel costs, an unusual one-time expense, changes in costs of materials, increased rents, increased taxes, etc. Table V–8, which shows year to year changes in prices for a number of industries affected by the standard, reflects this phenomenon.

Changes in profits are also subject to the dynamics of the economy. A recession, or a downturn in a particular industry, will typically cause profit declines in excess of ten percent for several years in succession. Table V–9, which shows annual profits for several years in succession, illustrates this phenomenon. While a permanent loss of profits presents a greater problem than a temporary loss, these year-to-year variations do serve to show that small changes in profits are quite normal without affecting the viability of industries.

The potential impacts of this regulation on the affected employers, for the most part, are within the range of normal year-to-year variation that firms and industries expect and survive. Table V–8 in the FEA shows year-to-year price variations for selected industries with hexavalent chromium exposure, and Table V–9 (in the FEA) shows year-to-year profit variations for selected industries with hexavalent chromium exposures. Table V–8 serves the purpose of showing that, for many industries, annual price changes of one percent or more are commonplace without affecting the viability of the industry. Table V–9 serves to show that temporary profit swings of significantly more than ten percent are also well within the boundaries of normal year-to-year change.

Because a permanent decrease in profits is much more significant than a temporary swing of the same magnitude, OSHA has also used the fact that a very large short term decline can be compared in effect to a smaller long-term decrease in profits to calculate the extent to which the temporary changes shown in Table V–9 may demonstrate an industry's ability to withstand a long-term change. For example, using a 7 percent discount rate, and the assumption that profits return to the long term average following a temporary decline, the following short term declines are approximately equivalent to a 10 percent long-term decline:

50 percent decline for one year;
30 percent decline for two years;
20 percent decline for three years.

Looking at profits of the average corporation for the period of 1990 to 2002, events of one of the above magnitudes have occurred twice in that 12-year period without threatening industrial viability. (Based on corporate profit rate data from IRS, Statistics of Income: Corporate Income Tax Returns, as Reported in U.S. Department of Commerce, U.S. Statistical Abstract 2006). And since, as discussed below, demand is not perfectly elastic in any of the affected industries, it is unlikely that the actual effect on profits will be as high as indicated in Table VIII–7.

The record does not contain evidence that any of the affected industries for which OSHA found that the costs of complying with the standard will be less than both one percent of prior revenue and ten percent of prior profits will in fact be threatened by the standard. Although some industry representatives asserted that compliance would threaten their existence, these assertions (with one exception, discussed below) were not supported by empirical evidence that even the proposed PEL of 1 would be economically infeasible. As noted above, cost changes of less than one percent are routinely passed on and impacts that are less than 10 percent of profits have not been shown to be likely to affect the viability or competitive structure of any of the industries affected by this standard.

Economic Feasibility for Industries With Higher Potential Impacts

In Table VIII–7, OSHA found that there were 9 industries in three application groups in which costs were greater than 1 percent of revenues, and an additional 22 industries in six application groups in which costs were greater than 10 percent of profits.

However, this number of industries is somewhat misleading. Seven of the industries in which costs exceed one percent of revenues, and an additional twelve of those in which costs exceeded 10 percent of profits (without exceeding 1 percent of revenues) are industries in the plating and welding application groups in which plating or welding are exceedingly rare, such as electroplating in the performing arts, spectator sports and related industries (NAICS 711) and welding in religious, governmental, civil, and professional organizations (NAICS 813). In both cases, only one establishment in the entire industry reported engaging in either welding or plating. It is difficult to determine whether reports of welding or plating in such industries represent an extremely unusual situation or, perhaps, simply someone inadvertently checking the wrong box on a survey. In either case, OSHA concludes that if such establishments do indeed engage in welding or plating, they could maintain their primary line of business, as almost everyone else in their industries does, by dropping welding or plating operations if such operations represented any threat whatsoever to the viability of their businesses.

The same is true of the other industries that are in the general category of extremely rare and unusual users of plating operations: Specialty trade contractors (NAICS 238); wholesale trade and durable goods (NAICS 423); motor vehicle and parts dealers (NAICS 441); furniture and home furnishing stores (NAICS 442); electronics and appliance stores (NAICS 443); building materials and garden equipment dealers (NAICS 444); health and personal care stores (NAICS 446); miscellaneous store retailers (NAICS 453); nonstore retailers (NAICS 454); information services and data processing service (NAICS 519); rental and leasing services (NAICS 532); professional, scientific and technical services (NAICS 541); performing arts, spectator sports and related industries (NAICS 711); and personal and laundry services (NAICS 812). In the welding application groups, the industries in this category are: gasoline stations (NAICS 447); nursing and residential care (NAICS 623); social assistance (NAICS 624); food services and drinking places (NAICS 722); and religious, governmental, civil, and professional organizations (NAICS 813).

The remainder of this section examines those industries with higher potential impacts where their businesses may be dependent on Cr (VI) applications.

Electroplating Job Shops: Electroplating job shops (NAICS 332813: electroplating, plating, polishing anodizing and coloring services) are a service industry for the manufacturing sector, and, to a lesser extent, to those maintaining, restoring, or customizing objects with metal parts. At a PEL of 5, job shops have costs as a percentage of profits of 30 percent and costs as a percentage of revenues of 1.24 percent. These firms sell a service rather than a product. (Firms that directly sell the products they plate end up in other NAICS codes.) As a result, plating firms are primarily affected by foreign competition through the loss of other manufacturing in the United States, rather than through their customers sending products or their component parts abroad for electroplating. However, some commenters noted that there may be cases of sending products abroad for the sole purpose of electroplating. This seems unlikely to be commonplace however, because of the shipping times and costs for a process that normally represents a very small part of the value added for the ultimate product. In addition, because electroplating is essential to the manufacture of most plated products, the ultimate demand for plating services is unlikely to decrease significantly.

Finally, independent electroplating shops have been subject to annual profit changes larger in magnitude than those associated with this standard. Table V–9 in the FEA shows that, over the past ten years, profits in this industry have risen and fallen as much as 49 percent in one year without affecting the viability of the industry. Although these kinds of temporary changes would not have the effect of permanent decline of profits by 30 percent, OSHA believes that all of the factors discussed above indicate that there is sufficient price elasticity and other flexibility in this industry to absorb these costs.

The price increase of 1.24 percent required to fully restore profits at a PEL of five is significantly less than the average annual increase in price of electroplating services, as shown by Table V–8 in the FEA. Further, during the period shown in Table V–8, the industry successfully survived, without any real price increase, the regulatory costs imposed by EPA's Chrome MACT standard. The costs of that standard are somewhat uncertain. Some commenters argued that that standard could be quite expensive. One commenter suggested that one facility had incurred costs of $80,000 per year to meet that standard, and that such high costs were not atypical. (Tr. 2003) Another commenter noted, however, that ''the effect of the MACT Standard was minimized when people realized that the combination of a mist suppressant and the development of a mist suppressant that would work in a hard chrome installation along with the use of mesh pads puts you below the MACT standard.'' (Tr. 2203) The commenter apparently felt that, in the latter case, the costs would not have been significant. Nevertheless, in either event, probably due to productivity improvement in other aspects of the industry, there was no real price increase or massive dislocation in the industry.

SFIC (Ex. 38–265) also argued that it was difficult to pass on costs in electroplating based on an EPA study that estimated a cost pass through elasticity of 0.58. This study was based on pre-1996 data, and found a statistical relationship between nominal price increases and increases in a nominal cost index. Whatever the difficulties in passing increased costs to its customers the industry might have had before 1996, since that time nominal prices have increased in ways that did not have the effects on profit predicted by the EPA study.

Even in the event of a real price increase, we believe that demand for electroplating services is relatively inelastic. For most products that are plated, plating is basically essential to the function of the product. The EPA study for the MACT standard found that products incorporating electroplating had relatively inelastic demand, on the order of less than 0.5, and the cost of plating represented a very small percentage of the total costs of the products in question. In this situation, the chief danger associated with a real cost increase of less than 1 percent is that there would be some increased foreign penetration of U.S. markets. However, the small size of the change, and the difficulty of sending products abroad solely for plating services, assures that the price change in question would not eliminate the industry, and is unlikely to alter the competitive structure of the industry.

However, OSHA is concerned about the economic feasibility of the standard for electroplating at a PEL of 1. At this lower PEL, costs of the standard represent 2.7 percent of revenues and 65 percent of profits. In almost all OSHA health standards in which this figure was developed, the costs for the most affected industry have been less than 2 percent of revenues. (The major exception was brass and bronze foundries, where the lead standard PEL was found economically infeasible with the use of engineering controls.) Further, in standards where the costs might have been in excess of 2 percent of revenues, OSHA has sought ways to lower the cost through long term phase-ins of engineering controls. OSHA examined this possibility for job-shop electroplaters, and found that even allowing the use of respirators rather than engineering controls would not significantly lower the costs as percentage of revenues. OSHA also examined the issue of whether there were particular types of platers that might have unusually high or low costs, and found that even quite different plating shop configurations with respect to the type of plating done would have approximately equal average costs.

Given the high level of costs as a percentage of revenues and profits, and the inability to alleviate those impacts without a higher PEL, OSHA further examined the economic feasibility of the standard at a PEL of 1. It seems unlikely that a price increase of 2.7 percent, although significantly larger than the average nominal price increases in recent years, would eliminate the industry entirely. OSHA has concluded, however, that the costs associated with such a PEL could alter the competitive structure of the industry. OSHA has concluded this because these costs substantially exceed the average nominal price increases in the industry, and the reasons for these nominal price increases—increases in the cost of labor and energy, for example—will continue. Thus a price increase that would assure continued profitability for the entire industry would require almost tripling the annual nominal price increase. (The long term average price increase for plating, as shown in Table V–9, is 1.6 percent per year. Assuming this continues to be needed, an increase that would leave profits unchanged would require a cost increase of 4.2 percent (1.6 plus 2.6), almost three times as much.) That would represent a significant real price increase that might not be passed forward, particularly by older and less profitable segments of the industry.

Welding (Stainless Steel) in Construction: OSHA calculated that the costs of the standard could equal 22.3 percent of profits in this industry, but only 0.92 percent of revenues. The maximum price increases required to fully restore profits (0.92 percent) is unlikely to significantly alter the demand for construction welding services which are essential for many projects and not subject to foreign competition. Further, costs of using stainless steel (the chief source of welding exposure) already vary significantly from year to year, and often from month to month. Table V–10 shows the producer price index for steel prices. Prices of steel have changed by more than 10 percent within a single year a number of times in the past ten years without affecting the viability of the use of stainless steel in construction.

Welding in General Industry: There are a significant number of establishments engaged in welding in repair and maintenance (NAICS 811) and in personal and laundry services (NAICS 812). For repair and maintenance services, the costs as a percentage of revenues are 0.40 percent and the costs as a percentage of profits are 10.5 percent. For personal and laundry services the costs as a percentage of revenues are 0.67 percent and costs as a percentage of profits are 13 percent. (All costs include the costs of any respirators welders will need to use.) These two sectors conduct maintenance and repair welding. Even if costs cannot be passed on, the resulting declines in profits are unlikely to affect the viability of an otherwise viable employer. Further, businesses of this kind are more likely to be able to increase costs because of the absence of foreign competition. While some loss of revenue is possible with a price increase, it is unlikely that the quantity of routine repairs would be significantly affected by price increases of this magnitude.

Painting and Corrosion Protection: Four sectors in the painting application groups have costs as a percentage of revenues in excess of one percent or costs as a percentage of profits in excess of 10 percent. These are motor vehicle body and trailer manufacturing (NAICS 3362) with costs of 0.51 percent and 20 percent; military armored vehicle and tank manufacturers (NAICS 336992) with costs of 0.25 percent and 10 percent; used car dealers (NAICS 44112) with costs of 0.41 percent and 34 percent; and automotive body, paint and interior repair (NAICS 81121) with costs of 1.5 percent and 39 percent. These costs are incurred in part for the use of hexavalent chromium pigments, but largely for using hexavalent chromium coating (applied like paint) as undercoats for corrosion protection. In the case of the first two NAICS codes, these are part of manufacturing processes. For both of these manufacturing industries, while the costs of hexavalent chromium coatings may be significant in the establishments where they are applied, the costs of Hexavalent chromium coatings represent an insignificant percentage of the costs of a car or a tank. While manufacturers may seek substitutes for hexavalent chromium coatings, additional expenses for such coatings are unlikely to affect the ultimate demand for cars or tanks. The latter two affected industries involve repair and refurbishing of existing automobiles. The cost analysis assumes all firms who currently use hexavalent chromium in these industries will continue to do so. In each case, there are choices that would avoid the costs in question. One choice would be to use non-hexavalent chromium pigments or non-hexavalent chromium corrosion protection. A variety of substitutes have been developed, and the use of hexavalent chromium based coatings for these purposes is already banned in California. (Tr. 1913) Although these substitutes have not yet been subject to long term use and their protectiveness is currently less certain than that of hexavalent chromium, it is likely that products that are equivalent to hexavalent chromium will be developed, particularly if demand for such products increases as a result of the standard. In addition, applying hexavalent chromium coatings represents a very small portion of the business of either auto body repair shops or used car dealers. A firm whose viability was seriously threatened as a result of this standard could retain most of its core businesses without continuing to use hexavalent chromium.

In addition, it is also reasonable to suppose that both used cars and auto body repair do not have highly elastic demand, such that a small change in prices would result in a very large drop in the number of cars repaired. As a result, the required increases in price can be accommodated without such significant losses as to alter the competitive structure of the industries.

Chromium Catalyst Producers (0.8 percent; 27 percent) and Service Companies (0.44 percent; 12 percent): Chromium catalyst production and service companies are also unlikely to be affected by costs of the relative magnitude found here. Most companies are locked into the use of specific catalysts without major new investments. As a result, while there may be some small long-term shift away from the use of chromium catalysts, a price change of one percent is unlikely to immediately prompt such a change. This also means that the market for chrome catalyst services is likely to be maintained. Further, faced with a new regulation, companies are more rather than less likely to turn to a service company to handle chromium products. Based on these considerations, OSHA determined that the standard is economically feasible in these sectors.

Iron and Steel Foundries: Iron and steel foundries (NAICS 3315) have costs that are 0.42 percent of revenues and 15 percent of profits. An oddity of the estimated costs for this industry is that 44 percent of the costs are associated with monitoring costs. In this cost estimate, OSHA assumes that iron and steel foundries will use scheduled periodic monitoring rather than adopting the option of performance-based monitoring. Adopting a performance-based monitoring approach rather than scheduled monitoring might well reduce costs as a percentage of profits to less than 10 percent of profits. As noted above, cost changes of less than one percent are routinely passed on and impacts that are less than 10 percent of profits have not been shown to be likely to affect the viability or competitive structure of any of the industries affected by this standard.

Even if costs are not reduced, the industry has demonstrated its ability to survive real cost increases by remaining viable in the face of a 32 percent increase in the price of its basic input, steel, over the last two years. Based on these considerations, OSHA concludes the standard is feasible for this sector.

F. Benefits and Net Benefits

OSHA estimated the benefits associated with alternative PELs for Cr(VI) by applying the dose-response relationship developed in the risk assessment to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile for industries with Cr(VI) exposures using OSHA inspection and site visit data, and then applying this profile to the total current worker population. The industry-by-industry exposure profile was given in Table VIII–2 above.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of lung cancers expected to occur in the worker population given current exposures (the ''baseline''), and the number of these cases that would be avoided under alternative, lower PELs. OSHA assumed that exposures below the limit of detection (LOD) are equivalent to no exposure to Cr(VI), thus assigning no baseline or avoided lung cancers (and hence, no benefits) to these exposures. For exposures above the current PEL and for purposes of determining the benefit of reducing the PEL, OSHA assumed exposure at exactly the PEL.

Consequently, the benefits computed below are attributable only to a change in the PEL. No benefits are assigned to the effect of a new standard increasing compliance with the current PEL. OSHA estimates that between 3,167 and 12,514 lung cancers attributable to Cr(VI) exposure will occur during the working lifetime of the current worker population. Table VIII–10 shows the number of avoided lung cancers by PEL. At the final PEL of 5 μg/m^3, an estimated 1,782 to 6,546 lung cancers would be prevented over the working lifetime of the current worker population.

Note that the Agency based these estimates on a worker who is employed in a Cr(VI)-exposed occupation for his entire working life, from age 20 to 65. The calculation also does not allow workers to enter or exit Cr(VI) jobs, nor switch to other exposure groups during their working lives. While the assumptions of 45 years of exposure and no mobility among exposure groups may seem restrictive, these assumptions actually are likely to yield somewhat conservative (lower) estimates of the number of avoided cancers, given the nature of the risk assessment model.

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Table VIII-10. Estimated Avoided Lung Cancers, by PEL, Resulting from a Reduction in Exposure to Hexavalent Chromium

PEL (µg/m^3)	**0.25**	**0.5**	**1**	**5**	**10**	**20**
Total Avoided Lung Cancer Deaths	2,958 - 11,597	2,806 - 10,935	2,614 - 10,098	1,782 - 6,546	1,222 - 4,258	658 - 2,096
Annual Avoided Lung Cancer Deaths	66 - 258	62 - 243	58 - 224	40 - 145	27 - 95	15 - 47
Annual Avoided Non-Fatal Cancers	9 - 35	8 - 33	8 - 31	5 - 20	4 - 13	2 - 6

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, 2006.

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For example, consider the case of job covered by five workers, each working nine years rather than one worker for 45 years. The former situation will likely yield a slightly higher rate of lung cancers, since more workers are exposed to the carcinogen (albeit for a shorter period of time) and the average age of the workers exposed is likely to decrease. This is due to: (1) The linearity of the estimated dose-response relationship, and (2) once an individual accumulates a dose, the increase in relative risk persists for the remainder of his lifetime. For example, a worker exposed from age 20 to 30 will have a constant increased relative risk for about 50 or so years (from age 30 on, assuming no lag between exposure and increased risk and death at age 80), whereas a person exposed from age 40 to 50 will have only about 30 years of increased risk (again assuming no lag and death at age 80). The persistence of the increased relative risk for a lifetime follows directly from the risk assessment and is typical of life table analysis.

For informational purposes only, OSHA has estimated the monetary value of the benefits associated with the final rule. These estimates are informational because OSHA cannot use benefit-cost analysis as a basis for determining the PEL for a health standard. In order to estimate monetary values for the benefits associated with the final rule, OSHA reviewed the approaches taken by other regulatory agencies for similar regulatory actions. OSHA found that occupational illnesses are analogous to the types of illnesses targeted by EPA regulations and has thus used them in this analysis.

OSHA is adopting EPA's approach, applying a value of $6.8 million to each premature fatality avoided. The $6.8 million value represents individuals' willingness-to-pay (WTP) to reduce the risk of premature death.

Nonfatal cases of lung cancer can be valued using a cost of illness (COI) approach, using data on associated medical costs. The EPA Cost of Illness Handbook (Ex.35–333) reports that the medical costs for a nonfatal case of lung cancer are, on average, $136,460. Updating the EPA figure to 2003 dollars yields the value of $160,030. Including values for lost productivity, the total COI which is applied to the OSHA estimate of nonfatal cases of lung cancer is $188,502.

An important limitation of the COI approach is that it does not measure individuals' WTP to avoid the risk of contracting nonfatal cancers or illnesses. As an alternative approach, nonfatal cancer benefits may be estimated by adjusting the value of lives saved estimates. In its Stage 2 Disinfection and Disinfection Byproducts water rule, EPA used studies on the WTP to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing nonfatal cancers. In sum, EPA valued nonfatal cancers at 58.3 percent of the value of a fatal cancer. Using WTP information would yield a higher estimate of the benefits associated with the reduction in nonfatal lung cancers, as the nonfatal cancers would be valued at $4 million rather than $188,502 per case. These values represent the upper and lower bound values for nonfatal cases of lung cancer avoided.

Using these assumptions, latency periods of 15, 20, 25, and 30 years—and adjustments to the value of statistical life to today—OSHA estimated the total annual benefits of the standard at various PELS in Table VIII–11, considering the benefits from preventing both fatal and non-fatal cases of lung cancer.

Occupational exposure to Cr(VI) has also been linked to a multitude of other health effects, including irritated and perforated nasal septum, skin ulceration, asthma, and dermatitis. Current data on Cr(VI) exposure and health effects are insufficient to quantify the precise extent to which many of these ailments occur. However, it is possible to provide an upper bound estimate of the number of cases of dermatitis that occur annually and an upper estimate of the number that will be prevented by a standard. This estimate is an upper bound because it uses data on incidence of dermatitis among cement workers, where dermatitis is more common than it would be for other exposures to Cr(VI). It is important to note that if OSHA were able to quantify all Cr(VI)-related health effects, the quantified benefits would be somewhat higher than the benefits presented in this analysis.

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Table VIII-11. Total Annual Monetized Benefits Associated with a Reduction in Exposure to Hexavalent Chromium (millions of 2003 dollars)

PEL (ug/m^3)	0.25	0.5	1	5	10	20
Undiscounted	$455 - $1,921	$432 - $1,811	$403 - $1,672	$275 - $1,085	$188 - $706	$102 - $348
Discounted at 3%	$189 - $1,587	$176 - $1,496	$164 - $1,382	$112 - $896	$77 - $584	$41 - $288
Discounted at 7%	$60 - $891	$57 - $841	$53 - $776	$36 - $504	$25 - $328	$13 - $162

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, 2006.

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Using National Institute for Occupational Safety and Health (NIOSH) data, Ruttenberg and Associates (Ex. 35–332) estimate that the incidence of dermatitis among concrete workers is between 0.2 and 1 percent. Applying the 0.2 percent-1 percent incidence rate indicates that there are presently 418–2,089 cases of dermatitis occurring annually. This approach represents an overestimate for cases of dermatitis in other application groups, since some dermatitis among cement workers is caused by other known factors, such as the high alkalinity of cement. If the measures in this final standard are 50 percent effective in preventing dermatitis, then there would be an estimated 209–1,045 cases of Cr(VI) dermatitis avoided annually.

To assign values to the cases of avoided dermatitis OSHA applied the COI approach. Ruttenberg and Associates computed that, on average, the medical costs associated with a case of dermatitis are $119 (in 2003 dollars) and the indirect and lost productivity costs are $1,239 (Ex. 35–332). These estimates were based on an analysis of BLS data on lost time associated with cases of dermatitis, updated to current dollars. Based on the Ruttenberg values, OSHA estimates that a Cr(VI) standard will yield $0.3 million to $1.4 million in annual benefits due to reduced incidence of dermatitis.

Occupational exposure to Cr(VI) can lead to nasal septum ulcerations and nasal septum perforations. As with cases of dermatitis, the data were insufficient to conduct a formal quantitative risk assessment to relate exposures and incidence. However, previous studies provide a basis for developing an approximate estimate of the number of nasal perforations expected under the current PEL as well as PELs of 0.25 μg/m³, 0.5 μg/m³, 1.0 μg/m³, 5.0 μg/m³, 10.0 μg/m³ and 20.0 μg/m³. Cases of nasal perforations were computed only for workers in electroplating and chrome production. The percentage of workers with nasal tissue damage is expected to be over 50 percent for those regularly exposed above approximately 20 μg/m³. Less than 25 percent of workers could reasonably be expected to experience nasal tissue damage if Cr(VI) exposure was kept below an 8-hour TWA of 5 μg/m³ and regular short-term exposures (*e.g.* an hour or so) were below 10 μg/m³. Less than 10 percent of workers could reasonably be expected to experience nasal tissue damage at a TWA Cr(VI) below 2 μg/m³ [and short-term exposures below 10 μg/m³]. It appears likely that nasal damage might be avoided completely if all Cr(VI) exposures were kept below 1 μg/m³.

OSHA estimates that 1,728 nasal perforations/ulcerations occur annually under current exposure levels. OSHA estimates that 1,140 of these would be prevented under the final PEL of 5 μg/m³. Due to insufficient data, it was not possible to monetize the benefits. Thus, the benefits associated with a reduction in nasal perforations/ulcerations are excluded from the net benefits analysis presented below.

Finally, for informational purposes, OSHA examined the net benefits of the standard, based on the benefits and costs presented above, and the costs per case of cancer avoided, as shown in Table VIII–12.

As noted above, the OSH Act requires OSHA to set standards based on eliminating significant risk to the extent feasible. That criterion or a criterion of maximizing net (monetary) benefits may result in very different regulatory outcomes. Thus, these analyses of net benefits cannot be used as the basis for a decision concerning the choice of a PEL for a Cr(VI) standard.

Table VIII-12. Annual Monetized Net Benefits and Costs per Cancer Avoided from a Reduction in Exposure to Hexavalent Chromium

(millions of 2003 dollars)

PEL (ug/m^3)	0.25	0.5	1	5	10	20
Discount Rate = 3 Percent						
Costs at 3 percent discount rate						
	$1,762	$996	$552	$273	$165	$109
Net Benefits at 3 Percent						
Minimum	-$1,573	-$820	-$388	-$161	-$88	-$68
Maximum	-$175	$500	$830	$623	$418	$179
Midpoint	-$874	-$160	$221	$231	$165	$56
Cost per Cancer Avoided						
Minimum	$6.0	$3.6	$2.2	$1.7	$1.5	$2.1
Maximum	$23.6	$14.1	$8.4	$6.1	$5.3	$6.6
Average	$14.8	$8.8	$5.3	$3.9	$3.4	$4.3
Discount Rate = 7 Percent						
Costs at 7 percent discount rate						
	$1,815	$1,033	$570	$282	$170	$112
Net Benefits at 7 percent						
Minimum	-$1,755	-$976	-$517	-$246	-$145	-$99
Maximum	-$924	-$192	$206	$222	$158	$50
Midpoint	-$1,340	-$584	-$156	-$12	$6	-$24
Cost per Cancer Avoided						
Minimum	$6.2	$3.7	$2.2	$1.7	$1.6	$2.1
Maximum	$24.3	$14.6	$8.6	$6.3	$5.5	$6.7
Average	$15.3	$9.2	$5.4	$4.0	$3.5	$4.4

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, 2006.

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Nevertheless, the Agency agrees that additional information concerning the circumstances in which monetary benefits exceed costs would be a useful addition to the above table. OSHA found the following conditions key to determining whether benefits exceed costs:

- If the risk is at the lowest end of the range considered, then benefits do not exceed costs no matter what other variables are used.
- If the risk is at the high end of the range, and a discount rate of 7 percent is used, then benefits exceed costs for PELs of 1 and 20 if the latency period is less than 20 years, and for PELs of 5 and 10 if the latency period is less than 25 years.
- If the risk is at the high end of the range, and a discount rate of 3 percent is used, then benefits exceed costs for a PEL of 0.5 if the latency period is twenty years or less, and benefits exceed costs for all latency periods for all higher PELs.

Incremental costs and benefits are those that are associated with increasing stringency of the standard. Comparison of incremental benefits and costs provides an indication of the relative efficiency of the various PELs. OSHA cannot use this information in selecting a PEL, but it has conducted these calculations for informational purposes. Incremental costs, benefits, net benefits and cost per cancer avoided are presented in Table VIII–13.

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These alternatives are discussed in the summary of the Final Regulatory Flexibility Analysis in the next section.

Table VIII-13. Incremental Benefits: Benefits, Costs, Net Benefits, and Cost/Cancer Avoided from a Reduction in Exposure to Hexavalent Chromium

Change in PEL:	20 to 10	10 to 5	5 to 1	1 to 0.5	0.5 to 0.25
3% Discount Rate:					
Change in Benefits	$165.4	$173.9	$268.7	$63.2	$52.0
Change in Costs	$56.0	$108.0	$279.0	$444.0	$766.0
Change in Net Benefits (ΔBenefits - ΔCosts)	$109.4	$65.9	-$10.3	-$380.8	-$714.0
Difference in Avg. Cancers Avoided	36	34	55	13	11
Change in Costs/Additional Cancers Avoided	$1.6	$3.2	$5.1	$34.2	$69.6
7% Discount Rate:					
Change in Benefits	$88.6	$93.4	$144.6	$34.1	$26.9
Change in Costs	$58.0	$112.0	$288.0	$463.0	$782.0
Change in Net Benefits (ΔBenefits - ΔCosts)	$30.6	-$18.6	-$143.4	-$428.9	-$755.1
Difference in Avg. Cancers Avoided	36	34	55	13	11
Change in Costs/Additional Cancers Avoided	$1.6	$3.3	$5.2	$35.6	$71.1

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, 2006.

G. Summary of the Final Regulatory Flexibility Analysis

The full final regulatory flexibility analysis is presented in Chapter VII of the FEA. Many of the topics discussed there, such as the legal authority for the rule; the reasons OSHA is going forward with the rule; and economic impacts on small business have been presented in detail elsewhere in the Preamble. As a result, this section focuses on two issues: duplicative, overlapping, or conflicting rules; and alternatives OSHA considered.

Federal Rules That May Duplicate, Overlap, or Conflict With the Final Rules

OSHA's SBREFA panel for this rule suggested that OSHA address a number of possible overlapping or conflicting rules: EPA's Maximum Achievable Control Technology (MACT) standard for chromium electroplaters; EPA's standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for Chromium Copper Arsenate (CCA) applicators; and state use of OSHA PELs for setting fence line air quality standards. The Panel was also concerned that, in some cases, other OSHA standards might overlap and be sufficient to assure that a new final standard would not be needed, or that some of the final standard's provisions might not be needed.

OSHA has thoroughly studied the provisions of EPA's MACT standard and has also consulted with EPA. The standards are neither duplicative nor conflicting. The rules are not duplicative because they have different goals—environmental protection and protection against occupation exposure. It is quite possible, as many electroplaters are now doing, to achieve environmental protection goals without achieving occupational protection goals. The regulations are not conflicting because there exist controls that can achieve both goals without interfering with one another. However, it is possible that meeting the final OSHA standard would cause someone to incur additional costs for the MACT standard. If an employer has to make major changes to install LEV, this could result in significant expenses to meet EPA requirements not accounted for in OSHA's cost analysis. In its final cost estimates, OSHA has included costs for additional MACT testing in cases where it may be needed. OSHA has also allowed all facilities four years to install engineering controls, with the result that electroplaters can better coordinate their EPA and OSHA requirements and avoid the need for extra testing.

OSHA examined the potential problem of overlapping jurisdiction for CCA applicators, and found that there would indeed be overlapping jurisdiction. As a result, OSHA had excluded CCA applicators from the scope of the coverage of the rule. OSHA has been unable to find a case where a state, as a matter of law, bases fence line standards on OSHA PELs. OSHA notes that the OSHA PEL is designed to address the risks associated with life long occupational exposure only.

OSHA has also examined other OSHA standards, and where standards are overlapping, referred to them by reference in the final standard in order to eliminate the possibility of overlapping, duplicative or conflicting standards. Existing OSHA standards that may duplicate the final provisions in some respect include the standards addressing respiratory protection (29 CFR 1910.134); hazard communication (29 CFR 1910.1200); access to medical and exposure records (29 CFR 1910.1020); general requirements for personal protective equipment in general industry (29 CFR 1910.132), construction (29 CFR 1926.95), and shipyards (29 CFR 1915.152); and sanitation in general industry (29 CFR 1910.141), construction (29 CFR 1926.51), and shipyards (29 CFR 1915.97).

Regulatory Alternatives

This section discusses various alternatives to the final standard that OSHA considered, with an emphasis on those suggested by the SBREFA Panel as potentially alleviating impacts on small firms. (A discussion on the costs of some of these alternatives to OSHA's final regulatory requirements for the hexavalent chromium standard can be found in Section III.3 Costs of Regulatory Alternatives in the final report by OSHA's contractor, Shaw (Shaw, 2006). In the Shaw report, costs are analyzed by regulatory alternative and major industry sector at discount rates of 7 percent and 3 percent.)

Scope: The proposed standard covered exposure to all types of Cr(VI) compounds in general industry, construction, and shipyard. Cement work in construction was excluded.

OSHA considered the Panel recommendation that sectors where there is little or no known exposure to Cr(VI) be excluded from the scope of the standard. OSHA decided against this option. The costs for such sectors are relatively small—probably even smaller than OSHA has estimated because OSHA did not assume that any industry would use objective data to demonstrate that initial assessment was not needed. However, it is possible that changes in technology and production processes could change the exposure of employees in what are currently low exposure industries. If this happens, OSHA would need to issue a new standard to address the situation. As a result, OSHA is reluctant to exempt industries from the scope of the standard.

However, OSHA has rewritten the scope of the standard for the final rule so that it exempts from the scope of the standard any employer who can demonstrate that a material containing Cr(VI) or a specific process, operation, or activity involving Cr(VI) will not result in concentrations at or above 0.5 μg/m³ under any condition of use. As a result, industries are exempted from all provisions of the standard and all costs if the industry can demonstrate that exposure is always at relatively low levels. This approach seems the best way to minimize the costs for the standard for industries where exposure is currently minimal, but could change in the future.

As stated above, the final standard does not cover exposures to hexavalent chromium resulting solely from exposure to portland cement. OSHA's assessment of the data indicates that the primary exposure to cement workers is dermal contact that can lead to irritant or contact allergic dermatitis. Current information indicates that the exposures in cement work are well below 0.25 μg/m³. Moreover, unlike other exposures in construction, general industry or shipyards, exposures from cement are most likely to be solely from dermal contact. There is little potential for airborne exposures and unlikely to be any in the future, as Cr(VI) appears in cement in only minute quantities naturally. Given these factors, the final standard excludes cement from the scope of the standard. OSHA has determined that addressing the dermal hazards from these exposures to Cr(VI) through guidance materials and enforcement of existing personal protective equipment and hygiene standards may be a more effective approach. Such guidance materials would include recommendations for specific work practices and personal protective equipment for cement work in construction.

OSHA's analysis suggests that there are 2,093 to 10,463 cases of dermatitis among cement workers annually. Using a cost of illness (COI) approach, avoiding 95 percent of these dermatoses would be valued at $2.5 million to $12.6 million annually, and avoiding 50 percent of these dermatoses would be valued $1.3 million to $6.6 million annually.

The costs of including cement would depend on what requirements were applied to wet cement workers. OSHA estimates that the costs associated with existing standards (e.g., requirements for PPE and hygiene practices) could range from $80 million to $300 million per year. Placing wet cement within the scope of the standard would cost an additional $33 million per year for compliance with such provisions as initial monitoring; those costs would be incurred even if the employer has no airborne exposures.

PELS: Section F of this preamble summary presented data on the costs and benefits of alternative PELS for all industries. The full FEA contains detailed data on the impacts on small firms at each PEL.

The SBREFA Panel also suggested alternatives to a uniform PEL across all industries and exposures. The Panel recommended that OSHA consider alternative approaches to industries that are intermittent users of Cr(VI). OSHA has adopted the concept of permitting employers with intermittent exposures to meet the requirements of the standard using respirators rather than engineering controls. This approach has been used in other standards and does not require workers to routinely wear respirators.

The SBREFA Panel also recommended considering Separate Engineering Control Airborne Limits (SECALs). OSHA has adopted this approach for applications in the aerospace industry. OSHA considered a SECAL for electroplating when the Agency was considering setting PELs lower than 5, but found a SECAL would not significantly lower costs because respirator use would be almost as expensive as using engineering controls. The expense of respirator use would also be a problem with SECALs for this sector at any PEL. OSHA's reasons for not using the SECAL approach in other sectors are provided in the Summary and Explanation. The SBREFA Panel also suggested that OSHA consider different PELs for different Cr(VI) compounds leading to exposure to Cr(VI). This issue is fully discussed in VI. Quantitative Risk Assessment. Here, it will only be noted that this would result in lower PELs than OSHA is setting in at least some industries, and thus potentially increase impacts on some small businesses.

Special Approaches to the Shipyard and Construction Industries: The SBREFA Panel was concerned that changing work conditions in the shipyard and construction industry would make it difficult to apply some of the provisions that OSHA suggested at the time of the Panel. OSHA has decided to change its approach in these sectors. OSHA is proposing three separate standards, one for general industry, one for construction, and one for shipyards. OSHA initially proposed that, in shipyards and construction, medical surveillance would be required only for persons with signs and symptoms, and regulated areas would not be required. In the final standard, OSHA has provided for the same medical surveillance standard in all sectors. The reasons for doing this are discussed in the Summary and Explanation section of the Preamble. However, employers must still meet the PEL with engineering controls and work practices where feasible. OSHA's proposed rule did not require exposure monitoring in the construction and maritime sectors. In light of comments, OSHA has shifted from this approach to requiring all sectors to conduct exposure monitoring, but allowing a performance-oriented option to exposure monitoring.

Timing of the Standard: The SBREFA Panel also recommended considering a multi-year phase-in of the standard. OSHA has solicited comment and examined the comments on this issue. OSHA has decided to allow employers four years (rather than two years) to comply with the engineering control provisions of the standard. This expanded phase-in of engineering controls has several advantages from a viewpoint of impacts on small businesses. First, it reduces the one-time initial costs of the standard by spreading them out over time. This would be particularly useful for small businesses that have trouble borrowing large amounts of capital in a single year. A phase-in is also useful in the electroplating sector by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. See the Summary and Explanation section of this Preamble for further discussion of this issue.

SBREFA Panel

Table VIII–14 lists all of the SBREFA Panel recommendations and notes OSHA responses to these recommendations.

Table VIII-14. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that, as time permits, OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the Small Entity Representative (SER) comments on underestimation of costs and that the Agency compare the OSHA revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA extensively reviewed its cost estimates, and changed many of them in response to SER comments and solicited comments on these revised cost estimates. A few examples of OSHA's cost changes are given in the responses to specific issues, below (e.g., medical exams, training and familiarization). As a result of comments on the proposed rule, OSHA has further increased its costs to reflect a variety of issues.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that, to the extent time permits, OSHA should carefully consider the ability of each potentially affected industry to meet any proposed PEL for Cr(VI) and solicit comment on the costs and technological feasibility of the PEL.	The FEA reflects OSHA's judgment on technological feasibility and includes responses to specific issues raised by the Panel and SERs. OSHA solicited comment on the accuracy and reasonableness of these judgments, and has significantly altered both its cost and technological feasibility assessments in light of these comments.
The Panel recommends that OSHA carefully review the basis for its estimated medical surveillance compliance costs, consider these concerns raised by the SERs, and ensure that its estimates are revised, as appropriate and time permits, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA has increased the estimated time for a limited medical exam from 1.5 hours to 3 hours and solicited comment on all other cost projections for medical surveillance. See **Chapter IV OF THE FEA; COSTS OF COMPLIANCE, COSTS BY PROVISION** - Medical Surveillance, for details of OSHA's unit costs for medical surveillance.
The Panel recommends that, as time permits, OSHA consider alternatives that would alleviate the need for extensive monitoring on construction sites, and solicit comment on this issue. If OSHA does not adopt such alternatives, then OSHA should consider increasing the estimated costs of such monitoring in construction, and solicit comment on the costs of monitoring.	OSHA revised the standard to allow all sectors to develop performance oriented approaches to exposure assessment; for all sectors, OSHA believes that its unit cost estimates are realistic in light of the comments OSHA received. See **Chapter IV OF THE FEA: COSTS OF COMPLIANCE, COSTS BY PROVISION** - Exposure Monitoring (Initial and Periodic), for details of OSHA's unit costs for exposure monitoring in general industry.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	**OSHA Response**
The Panel recommends that OSHA carefully review the basis for its estimated hygiene compliance costs, consider the concerns raised by the SERs, and, to the extent time permits, ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA's proposed standard allowed hand washing as a hygiene option; OSHA has eliminated the requirement for special wording for labels of contaminated clothing, thus reducing any cost premium related to handling contaminated waste water or laundry.
The Panel recommends that OSHA examine and solicit comment on possible underestimates of the costs of regulated areas.	In the proposed rule, OSHA recognized costs for training and familiarization to cover a better understanding of the costs of regulated areas, and solicited comment on the issue. See **Chapter IV OF THE FEA; COSTS OF COMPLIANCE, COSTS BY PROVISION** - Communication of Hazards to Employees - Training and Familiarization, for details of OSHA's unit costs for this provision, public comments and responses to these comments.
The Panel recommends that OSHA examine and solicit comment on the costs of laundering PPE.	See above—OSHA has eliminated the labeling requirement for contaminated PPE, and thus reduced any premium of costs for labeled PPE. See **Chapter IV OF THE FEA; COSTS OF COMPLIANCE, COSTS BY PROVISIONS** - Housekeeping, Protective Work Clothing and Equipments, and Table IV-8 for details of OSHA's unit costs for laundering PPE and other related costs.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA examine whether its cost estimates reflect the full costs of complying with the hazard communication standard.	OSHA's analysis assumes that employers will need time for familiarization with the standard, training on the standard, and increased initial supervision.
The Panel recommends that OSHA thoroughly review the economic impacts of compliance with a proposed Cr(VI) standard and develop more detailed feasibility analyses where appropriate. The Panel also recommends that OSHA, to the extent permitted by time and the availability of economic data, reexamine its estimates of profits and revenues in light of SER comments, and update economic data to better reflect recent changes in the economic status of the affected industries, consistent with its statutory mandate. The Panel also recommends that OSHA examine, to the extent feasible with the time available, the possibility that users will substitute non-Cr(VI) products for Cr(VI) products. The Panel recommends that OSHA solicit comment on the extent to which foreign competition may or may not impact what is feasible for the industries affected by this rule.	OSHA reviewed and revised many of its revenue and profit estimates in the light of specific SER comments. Examples of application groups with revised revenue and profit estimates include Group 4, Chromate Production; Group 5, Chromate Pigment Producers; and Group 17, Chromium Dye Producers. For the final rule, OSHA has updated revenue and profit impacts across the board To the most recent year fully available – 2002.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA consider and solicit comments on selective exemption of some industries from the proposed standard, especially those industries whose inclusion is not supported by the industry-specific data or in which inhalation exposure to Cr(VI) is minimal.	OSHA is reluctant to exempt industries where exposures are minimal because changes in technology could change exposures in the future. However, OSHA has allowed industries to exempt themselves from the rule based on data demonstrating that exposure levels can be expected to be less than 0.5 as an 8-hour TWA.
The Panel recommends that OSHA exempt applicators of CCA given that they are already regulated by EPA as pesticide applicators under FIFRA. In addition, OSHA should clarify and seek comment as to why users of CCA-treated wood should be covered under the Cr(VI) proposal given that the use of CCA-treated wood was previously excluded by OSHA in its standard for inorganic arsenic.	OSHA has decided to exempt applicators of CCA in this rule.
The Panel recommends that OSHA clearly explain the way that Cr(VI) exposure and risk for the worker cohort studies used in the quantitative risk assessment were calculated, and should consider and seek comment as to whether the major assumptions used in these calculations are reasonable.	The Quantitative Risk Assessment section of the Preamble addresses this issue, and the comments OSHA received on it.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA consider the available information on reduction of inhaled Cr(VI) to Cr(III) in the body, to determine whether exposures below a threshold concentration can be shown not to cause the genetic alterations that are believed to cause cancer. In addition, OSHA should review epidemiological analyses relevant to the question of threshold dose, to determine whether such a dose is identifiable from the available human data. OSHA should further consider and seek comment on these findings in relation to the risk assessment and the proposed PEL, allowing for a higher PEL than those presented in the draft standard if the risk assessment so indicates.	The Quantitative Risk Assessment of this Preamble addresses the issue of possible threshold effects and comments OSHA received on this issue.
The Panel recommends that OSHA should clarify the meaning of the projected lung cancer risk estimates used to support the proposed standard. In particular, OSHA should explain these estimates, which are based on a working lifetime of 45 years' exposure at the highest allowable Cr(VI) concentration, and, where appropriate, note projected excess cancers that may result from shorter periods of occupational Cr(VI) exposure.	OSHA is required by law to set health standards so that they avoid significant risk over a working lifetime. Both in the QRA and in the Benefits Chapter of the FEA, OSHA has examined alternative exposure scenarios. See **VI. Quantitative Risk Assessment** in the Preamble and **Chapter VI of the FEA; BENEFITS and NET BENEFITS**, Lung Cancers Avoided in this FEA.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	**OSHA Response**
The Panel recommends that OSHA solicit information to better characterize the exposure patterns and Cr(VI) compounds encountered in the maritime environment, and should encourage input from marine chemists at appropriate points in the rulemaking.	OSHA has added information provided by firms in the shipyard industry since the Panel meeting. (See **Chapter II** of the FEA; **PROFILE OF AFFECTED INDUSTRIES, PROCESSES, AND APPLICATIONS GROUPS, AFFECTED INDUSTRIES** – **Welding** and **Painting** and **Chapter III: Technological Feasibility, Welding** and **Painting**). OSHA solicited comment on shipyard issues and from maritime chemists, and has modified its estimates in light of the data received.
The Panel recommends that OSHA consider the appropriateness of separate PELs for specific Cr(VI) compounds, with attention to the weight and extent of the best available scientific evidence regarding their relative carcinogenic potency.	OSHA considered this possibility and decided against it, in part, because it would require lower PELs and result in many persons in respirators. OSHA solicited comment on this issue, and responded to these comments in the technological feasibility section and in Summary and Explanation for the Rule.
The Panel recommends that OSHA solicit information to better define construction activities likely to be above and below the PEL (for initial exposure monitoring purposes) to minimize the amount of respiratory protection that would need to be used for compliance.	OSHA has set forth a rule that allows a performance-oriented approach to monitoring in all sectors. OSHA considered a control banding approach to construction, but lacked the data to fully implement this approach, even after soliciting comment on the issue.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	**OSHA Response**
The Panel recommends that OSHA provide a better explanation of how to implement an exposure assessment program for construction activities. Also, OSHA should provide further explanation on monitoring-related topics like the selection of sampling and analytical methods, the selection of plus-or-minus 25 percent as a confidence interval, and the use of objective data in lieu of monitoring.	OSHA has decided to allow a performance-oriented approach to exposure monitoring in all sectors. The monitoring-related topics are further discussed in the Preamble, XVII. **Summary and Explanation of the Standard.**
The Panel recommends that OSHA consider less frequent monitoring for exposures above the PEL, especially in situations where the employer has already engineered down to the lowest feasible level and is not able to maintain levels below the PEL.	OSHA has left the monitoring frequency unchanged, but has developed a performance-oriented alternative to scheduled monitoring.
The Panel recommends that OSHA review the technologies used to reduce Cr(VI) exposure to ensure that they are available or reasonably anticipated to be available in the future.	OSHA reviewed its technological feasibility analysis and solicited comment on it. In light of these comments, OSHA has changed the PEL based on technological feasibility considerations.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA clarify the purpose of the prohibition on the use of employee rotation to meet the PEL and take into account the needs expressed by the SERs on the issue. The Panel recommends that OSHA clarify the methods of compliance section.	The Summary and Explanation of the Preamble explains further the prohibition on employee rotation and the methods of compliance.
The Panel recommends that OSHA clarify how to implement the use of regulated areas particularly for construction activities. OSHA should better explain how employers would delineate boundaries for regulated areas and should better clarify the use of respiratory protection, personal protective clothing and equipment, and hygiene facilities and practices in regulated areas.	OSHA has eliminated the requirement for regulated areas in construction and shipyards. The Summary and Explanation section of the Preamble explains the regulated area requirements in General Industry.
The Panel recommends that OSHA provide a clearer explanation of why it is necessary to remove Cr(VI)-contaminated protective clothing and wash hands prior to entering non-Cr(VI) work areas and eating, drinking or smoking and take into account lost time and costs associated with conducting such activities. The Panel recommends that OSHA clarify its definition of contaminated clothing or waste, provide evidence supporting the view that "contaminated" clothing presents a hazard, and better	These issues are addressed in the Summary and Explanation section of the Preamble.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
explain the special treatment of such items and why the treatment is necessary.	
The Panel recommends that OSHA clarify its definition of reasonably anticipated skin and eye contact. The Panel recommends that OSHA clarify the circumstances under which the proposed rule would require the use of personal protective equipment to prevent dermal exposures to solutions containing Cr(VI). In particular, OSHA should reconsider the requirements for the use of dermal protection when the PEL is exceeded; consider alternatives that are more clearly risk based; and determine whether the use of very dilute Cr(VI) solutions, as used in some laboratories, requires the use of personal protective equipment.	OSHA has changed the rule from the SBREFA draft in order to clarify when PPE is required and to assure that it is not required except where a dermal hazard exists.
The Panel recommends that OSHA provide a clearer explanation of the benefits and the need for its proposed medical surveillance provisions. The Panel recommends that OSHA provide clearer guidance as to which employees are intended to be covered under the medical surveillance provisions and, in particular, how the standard is intended to cover employees who work for	OSHA has maintained routine medical surveillance in the shipyard and construction industries. The Preamble Summary and Explanation section clarifies what is required of medical surveillance, and the extent to which the same medical examination can be used to meet the requirements of different standards.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
several different employers during the course of a year. The Panel recommends that OSHA clarify the qualifications necessary to provide a medical examination (including what knowledge of Cr(VI) is necessary) and what the elements of such a medical examination should be. The Panel recommends that OSHA design the medical surveillance provisions to be consistent with existing OSHA standards (e.g., lead and arsenic) wherever possible, in order to minimize the need for duplicative medical examinations. The Panel also recommends that OSHA clarify that differences in medical surveillance requirements that may be unavoidable across OSHA standards nevertheless often will not require completely separate medical examinations.	
With respect to the EPA electroplating standards, the Panel recommends that OSHA examine whether important costs have been omitted, seek to develop alternatives that minimize these costs, and seek comment on the issue. With respect to possible dual jurisdiction with FIFRA, the	OSHA discusses the impact of EPA's electroplating standard in the FEA, (See **Chapter III: Technological Feasibility, Electroplating, Chapter IV: Costs of Compliance,** and **Chapter VIII: Environmental Impacts**) and sought comments on this issue. In light of these comments, OSHA significantly increased its estimated costs for the electroplating application group.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
Panel recommends that OSHA consider dropping CCA applicators from the scope of the rule, and seek comment on this issue. With respect to the issue of using OSHA PELs as a basis for fence line standards, the Panel recommends that OSHA make clear the purpose of its PELs, and explain that they are not developed or examined in terms of their validity as a basis for air quality standards.	OSHA has decided to exclude CCA applicators from the scope of the standard. OSHA solicited comment on the "fence line" standard issue, but received no evidence that any state sets "fence line" standards in a way dependent on OSHA PELs.
The Panel recommends that OSHA examine whether existing standards are adequate to cover occupational exposure to Cr(VI), and, if not, develop the Cr(VI) standard in such a way as to eliminate duplicative and overlapping efforts on the part of employers.	OSHA has determined that, except for CCA applicators and cement workers, other standards cannot provide the worker protection needed, but has sought to avoid duplication of effort between standards.
The Panel recommends that OSHA consider the scientific evidence in favor of a higher PEL, analyze the costs and economic impacts of a PEL of 20 or greater, and solicit comment on this option.	OSHA has included an analysis of the scientific evidence in the health Effects and Quantitative Risk Assessment section of this Preamble, summarizes the costs and benefits, of a PEL of 20 in this Preamble summary, and has a full analysis of the costs, benefits and impacts of this option in the FEA.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA carefully examine the entire issue of intermittent exposures, consider options that can alleviate the burden on such firms while meeting the requirements of the OSH Act, and solicit comment on such options.	OSHA determined that intermittent users need not use engineering controls to assure compliance with the PEL.
Some SERs argued that some Cr(VI) compounds offer lesser risks of cancer than others, and should be subject to different PELs. The Panel recommends that OSHA consider these arguments and seek comment on the issue.	OSHA had preliminarily determined that all Cr(VI) compounds should have the same PEL, but sought comment on the issue. In response to comments (summarized in the Health Effects section of this preamble), OSHA decided that the final rule applies to Cr(VI) in all forms and compounds except exposures that occur in pesticide application, exposures to portland cement, and situations where objective data demonstrate that materials or a process, operation, or activity involving chromium cannot release dusts, fumes, or mists in concentrations at or above 0.5 $\mu g/m^3$ under expected conditions of use.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA continue to exempt wet cement from the scope of the standard, and that if OSHA seeks comment on this option, OSHA should note the Panel's recommendation and the reasons for the recommendation. The Panel also recommends that OSHA seek ways of adapting the standard better to the dynamic working conditions of the construction industry, examine the extent to which Cr(VI) exposures are already covered by other standards, and seek comment on these issues. The Panel also recommends that OSHA consider the alternative of developing a construction standard in a separate rulemaking.	OSHA has determined to exempt all cement exposure from the scope of the standard. OSHA made a number of changes to the construction standard in the final rule, including allowing a performance oriented approach to exposure assessment, and eliminating the regulated area requirement and the action level.
The Panel recommends that OSHA consider, and solicit comment on, approaches to their special problems; that OSHA consider the possibility of making the maritime proposed standard more similar to the construction draft standard, or consider the alternative of developing a maritime standard in a separate rulemaking.	OSHA has made a number of changes to the shipyard standard in the final rule, including allowing a performance-oriented approach to exposure assessment and eliminating the regulated area requirement.
The Panel recommends that OSHA consider and seek comment on multi-year phase-in alternatives.	OSHA has chosen to allow all firms four years before they need to implement engineering controls to meet the standard.

Table VIII-14, contd. SBREFA Panel Recommendations and OSHA Responses

SBREFA Panel Recommendation	OSHA Response
The Panel recommends that OSHA better explain the action level, including its role in ensuring workers are protected.	OSHA has included an action level in the general industry, construction, and shipyard standards and explains its role in the general industry standard in the Summary and Explanation section of the Preamble.
The Panel recommends that OSHA consider the use of SECALs and solicit comment on whether and in what industries they are appropriate using the Cadmium standard as a model.	OSHA has allowed a SECAL for certain aerospace painting applications.

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H. Need for Regulation

Employees in work environments addressed by the final standards are exposed to a variety of significant hazards that can and do cause serious injury and death. The risks to employees are excessively large due to the existence of market failures, and existing and alternative methods of alleviating these negative consequences have been shown to be insufficient. After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA concludes that in this case the final mandatory standards represent the best choice for reducing the risks to employees. In addition, rulemaking is necessary in this case in order to replace older existing standards with updated, clear, and consistent health standards.

IX. OMB Review Under the Paperwork Reduction Act of 1995

The final Cr(VI) rule contains collection of information (paperwork) requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA–95), 44 U.S.C. 3501 *et seq.*, and OMB's regulations at 5 CFR part 1320. The Paperwork Reduction Act defines "collection of information" as "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format * * *" (44 U.S.C. 3502(3)(A)). The collection of information requirements (paperwork) associated with the proposed Cr(VI) rule were submitted to OMB on October 1, 2004. On November 30, 2004 OMB did not approve the Cr(VI) paperwork requirements, and instructed OSHA to examine "public comment in response to the NPRM, including paperwork requirements," and address any public comments on the paperwork in the preamble. OMB assigned the control number 1218–0252 for the Agency to use in future submissions.

The major information collection requirements in the Standard include conducting employee exposure assessment (§§ 1910.1026 (d)(1)–(3), 1915.1026 (d)(1)–(3), and 1926.1126 (d)(1)–(3)), notifying employees of their Cr(VI)exposures when employee exposures exceed the PEL (§§ 1910.1026 (d)(4), 1915.1026 (d)(4), and 1926.1126 (d)(4)), providing respiratory protection (§§ 1910.1026 (g), 1915.1026 (f), and 1926.1126 (f)), labeling bags or containers of contaminated protective clothing or equipment (§§ 1910.1026 (h)(2), 1915.1026 (g)(2), and 1926.1126 (g)(2)), informing persons who launder or cleans protective clothing or equipment contaminated with Cr(VI) of the potential harmful effects (§§ 1910.1026 (h)(3), 1915.1026 (g)(3), and 1926.1126 (g)(3)), implementing medical-surveillance of employees (§§ 1910.1026 (k), 1915.1026 (i), and 1926.1126 (i)), providing physician or other licensed health care professional (PLHCP) with information (§§ 1910.1026 (k)(4), 1915.1026 (i)(4), and 1926.1126 (i)(4)), ensuring that employees receive a copy of their medical-surveillance results (§§ 1910.1026 (k)(5), 1915.1026 (i)(5), and 1926.1126 (i)(5)), maintaining employees' exposure-monitoring and medical-surveillance records for specific periods, and maintaining historical monitoring and objective data (§§ 1910.1026 (m), 1915.1026 (k), and 1926.1126 (k)). The collection of information requirements in the rule are needed to assist employers in identifying and controlling exposures to Cr(VI) in the workplace, and to address Cr(VI)-related adverse health effects. OSHA will also use records developed in response to this standard to determine compliance.

The final rule imposes new information collection requirements for purposes of the PRA. In response to comments on the proposed rule, OSHA has revised provisions of the final rule that affect collection of information requirements. These revisions include:

- The final rule exempts exposures to portland cement in general industry and shipyards;
- An exemption is included in the final rule where the employer can demonstrate that Cr(VI) exposures will not exceed 0.5 $\mu g/m^3$ under any expected conditions;

- The final PEL of 5 μg/m^3 has been revised from the proposed 1 μg/m^3;
- Requirements for exposure determination have been added to the construction and shipyard standards, and a performance-oriented option for exposure determination is included in the standards for each sector (general industry, construction, and shipyards);
- Medical surveillance must be provided to employees exposed to Cr(VI) above the action level (rather than the PEL) for 30 or more days per year in general industry, construction, and shipyards;
- Requirements to maintain records used for exposure determination have been added to the construction and shipyard standards, while requirements for training records have been removed for all sectors.

OSHA has revised the paperwork package to reflect these changes, and estimates the total burden hours associated with the collection of information to be approximately 940,000 and estimates the cost for maintenance and operation to be approximately $126 million.

Potential respondents are not required to comply with the information collection requirements until they have been approved by OMB. OMB is currently reviewing OSHA's request for approval of the final rule's paperwork requirements. OSHA will publish a subsequent **Federal Register** document when OMB takes further action on the information collection requirements in the Cr(VI) rule.

X. Federalism

The Agency reviewed the final Cr(VI) standard according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order allows federal agencies to preempt state law only with the expressed consent of Congress; in such cases, federal agencies must limit preemption of state law to the extent possible. Under section 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act''), Congress expressly provides that OSHA preempt state occupational safety and health standards to the extent that the Agency promulgates a federal standard under section 6 of the Act. Accordingly, under section 18 of the Act OSHA preempts state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA approved occupational safety and health plan (i.e., is a state-plan state) [see *Gade* v. *National Solid Wastes Management Association*, 112 S. Ct. 2374 (1992)]. Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this final rule falls under the preemption provisions of the Act. Additionally, section 18 of the Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that this final rulemaking does not expand this limitation. OSHA has authority under Executive Order 13132 to promulgate a Cr(VI) standard because the problems addressed by these requirements are national in scope.

As explained in section VII of this preamble, employees face a significant risk from exposure to Cr(VI) in the workplace. These employees are exposed to Cr(VI) in general industry, construction, and shipyards. Accordingly, the final rule would establish requirements for employers in every state to protect their employees from the risks of exposure to Cr(VI). However, section 18(c)(2) of the Act permits state-plan states to develop their own requirements to deal with any special workplace problems or conditions, provided these requirements are at least as effective as the requirements in this final rule.

XI. State Plans

The 26 states and territories with their own OSHA-approved occupational safety and health plans must adopt comparable provisions within six months of the publication date of the final hexavalent chromium standard. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey and New York have OSHA approved State Plans that apply to state and local government employees only. Until a state-plan state promulgates its own comparable provisions, Federal OSHA will provide the state with interim enforcement assistance, as appropriate.

XII. Unfunded Mandates

The Agency reviewed the final Cr(VI) standard according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed in section VIII of this preamble, OSHA estimates that compliance with this final rule would require private-sector employers to expend about $288 million each year. However, while this final rule establishes a federal mandate in the private sector, it is not a significant regulatory action within the meaning of section 202 of the UMRA (2 U.S.C. 1532). OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt an OSHA-approved state occupational safety and health plan. Consequently, the provisions of the final rule do not meet the definition of a ''Federal intergovernmental mandate'' [see section 421(5) of the UMRA (2 U.S.C. 658(5))]. Therefore, based on a review of the rulemaking record, the Agency believes that few, if any, of the employers affected by the final rule are state, local, or tribal governments. Therefore, the Cr(VI) requirements promulgated herein do not impose unfunded mandates on state, local, or tribal governments.

XIII. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (i.e., a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities, and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (e.g., through air, food, water, soil, product use). The final Cr(VI) standard is economically significant under Executive Order 12866 (see section VIII of this preamble). However, after reviewing the final

Cr(VI) standard, OSHA has determined that the standard would not impose environmental health or safety risks to children as set forth in Executive Order 13045. The final standard requires employers to limit employee exposure to Cr(VI) and take other precautions to protect employees from adverse health effects associated with exposure to Cr(VI). To the best of OSHA's knowledge, no employees under 18 years of age work under conditions that involve exposure to Cr(VI). However, if such conditions exist, children who are exposed to Cr(VI) in the workplace would be better protected from exposure to Cr(VI) under the final rule than they are currently. Based on this determination, OSHA believes that the final Cr(VI) standard does not constitute a covered regulatory action as defined by Executive Order 13045.

XIV. Environmental Impacts

The Agency reviewed the final Cr(VI) standard according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11).

As a result of this review, OSHA has made a final determination that the final Cr(VI) standard will have no impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. Therefore, OSHA concludes that the final Cr(VI) standard will have no significant environmental impacts.

XV. Summary and Explanation of the Standards

(a) Scope

OSHA is issuing separate standards addressing hexavalent chromium (also referred to as chromium (VI) or Cr(VI)) exposure in general industry, construction, and shipyards. The standard for shipyards also applies to marine terminals and longshoring. The standards for construction and shipyards are very similar to each other, but differ in some respects from the standard for general industry. OSHA believes that certain conditions in these two sectors warrant requirements that are somewhat different than those that apply to general industry. This summary and explanation will describe the final rule for general industry and will note differences between it and the standards for construction and shipyards.

Commenters were generally supportive of OSHA's decision to propose separate standards for general industry, construction, and shipyards (*e.g.*, Exs. 38–199–1; 38–212; 38–214; 38–220–1; 38–236; 38–244; 39–19), although one commenter believed that a single standard should apply to all sectors (Ex. 39–51). Where concerns were expressed about the establishment of separate standards, they focused on the provisions of the standards and their application, rather than the concept of establishing separate standards. Some commenters argued that certain activities or industries should be covered by the construction standard rather than the general industry standard (*e.g.*, Exs. 38–203; 38–228–1, p. 18; 39–52–2; 39–56); others considered the proposed construction and shipyard standards to be less protective than the proposed general industry standard (Exs. 38–222; 39–71; 47–23, pp. 16–17; 47–28).

OSHA has long recognized a distinction between the construction and general industry sectors, and has issued standards specifically applicable to construction work under 29 CFR Part 1926. The Agency has provided a definition of the term ''construction work'' at 29 CFR 1910.12(b), has explained the terms used in that definition at 29 CFR 1926.13, and has issued numerous interpretations over the years explaining the classification of activities as either general industry or construction. OSHA recognizes that in some circumstances, general industry activities and conditions in workplaces where general industry tasks are performed may be comparable to those found in construction. However, the Agency believes the longstanding delineation between sectors is appropriate. The distinction between sectors is generally well understood by both OSHA enforcement personnel and the regulated community, and any attempt to create exceptions or to provide different criteria in this final rule would not improve upon the current criteria but would rather cause confusion.

OSHA is issuing the construction and shipyard standards to account for the particular conditions found in those sectors. The Agency intends to ensure that Cr(VI)-exposed workers in construction and shipyards are provided protection that, to the extent feasible, is comparable to the protection afforded workers in general industry. OSHA believes that concerns raised about differences between the Cr(VI) proposed standard for general industry and the proposed standards for construction and shipyards will be lessened because the final standards are more consistent with one another than as originally proposed. Specifically, OSHA proposed explicit exposure assessment requirements for general industry, but not for construction and shipyard workplaces. The requirements of the final rule for exposure determination are nearly identical for all sectors (see discussion of exposure determination under paragraph (d) of this section). In addition, OSHA proposed a requirement for periodic medical examinations in general industry, but not in construction and shipyards. The final rule includes requirements for periodic medical examinations in all sectors (see discussion of medical surveillance requirements under paragraph (k) of this section). The final standards for construction and shipyards provide the most adequate protection within the constraints of feasibility.

The final rule applies to occupational exposures to Cr(VI), that is, any chromium species with a valence of positive six, regardless of form or compound. Examples of Cr(VI) compounds include chromium oxide (CrO_2), ammonium dichromate ($(NH_4)_2Cr_2O_7$), calcium chromate ($CaCrO_4$), chromium trioxide (CrO_3), lead chromate ($PbCrO_4$), potassium chromate (K_2CrO_4), potassium dichromate ($K_2Cr_2O_7$), sodium chromate (Na_2CrO_4), strontium chromate ($SrCrO_4$), and zinc chromate ($ZnCrO_4$).

Some commenters supported the proposal to include all chromium compounds within the scope of the new rule. (See, *e.g.*, Exs. 38–214; 39–60). Other commenters, however, contended that specific Cr(VI) compounds should be excluded from the scope of the final rule. Notably, the Color Pigments Manufacturers Association and Dominion Colour Corporation argued that differences in the bioavailability and toxicity of lead chromate pigments when compared to other Cr(VI) compounds warrant unique treatment (Exs. 38–201; 38–205). The Boeing Company also argued that OSHA should consider the bioavailability of different Cr(VI) compounds (Ex. 38–106). Boeing indicated that exposures to strontium chromate and zinc chromate used in aerospace manufacturing are not equivalent to Cr(VI) exposures in other industries.

OSHA considers all Cr(VI) compounds to be carcinogenic. This conclusion is based upon careful consideration of the epidemiological, animal, and mechanistic evidence in the rulemaking record, and is discussed in section V, ''Health Effects,'' of this preamble. OSHA's conclusion that all Cr(VI) compounds are carcinogenic is consistent with the findings of IARC, NTP, and NIOSH. These organizations have each found Cr(VI) compounds to be carcinogenic, without exception. OSHA therefore sees no reason to exempt any Cr(VI) compounds from the final rule.

Several commenters argued that existing standards provide adequate protection for employees exposed to Cr(VI), citing in particular OSHA's current welding and lead standards (Exs. 38–203; 38–254; 38–124; 39–19; 39–47; 39–48; 39–52, p. 22; 39–54; 39–56). However, none of these standards provide the full range of protections afforded by the Cr(VI) rule. For example, OSHA's welding requirements (29 CFR Subpart Q for general industry; 1926 Subpart J for construction; 1915 Subpart D for shipyards) include provisions for ventilation, but do not address other aspects of worker protection included in the Cr(VI) rule such as exposure determination or medical surveillance. OSHA's lead standards (29 CFR 1910.1025 for general industry; 29 CFR 1926.62 for construction) have a PEL of 50 μg/m^3, which effectively limits Cr(VI) exposure from lead chromate to 12.5 μg/m^3; however, this value is more than double the PEL in the Cr(VI) rule. Other standards therefore do not provide protection equivalent to the final Cr(VI) rule. Moreover, even though other requirements may affect Cr(VI) occupational exposure, Cr(VI) exposure in the current workplace still results in a significant risk that can be substantially reduced in a feasible manner by the requirements of this final rule.

Portland Cement

The final rule does not cover exposure to Cr(VI) in portland cement. OSHA proposed to exclude exposure to portland cement in construction; the final rule extends this exclusion to all sectors. In the proposal, OSHA identified two general industry application groups where all employee exposure to Cr(VI) is from portland cement: Portland Cement Producers and Precast Concrete Products. (A third application group, Ready-Mixed Concrete, was later identified.) OSHA proposed to cover exposures to portland cement in general industry because the Agency's preliminary exposure profile indicated that some employees in these application groups were exposed to Cr(VI) levels associated with a significant risk of lung cancer. However, evidence in the record indicating the low Cr(VI) content of portland cement has led OSHA to conclude that the current PEL for portland cement effectively limits inhalation exposures from work with portland cement.

Cement ingredients (clay, gypsum, and chalk), chrome steel grinders used to crush ingredients, refractory bricks lining the cement kiln, and ash may serve as sources of chromium that may be converted to Cr(VI) during kiln heating, leaving trace amounts of Cr(VI) in the finished product (Ex. 35–317, p. 148). The amount of Cr(VI) in American portland cement is generally less than 20 g Cr(VI)/g cement (Exs. 9–57; 9–22; 35–417). Because the Cr(VI) concentration in portland cement is so low, OSHA's current PEL for portland cement (15 mg/m^3 for total dust, 29 CFR 1910.1000) effectively limits the Cr(VI) inhalation exposure from cement to levels below the new Cr(VI) PEL and Action Level (*i.e.*, if an employee is exposed at the PEL for portland cement and the Cr(VI) concentration in that cement is below 20 μg/g, the employee's exposure to Cr(VI) will be below 0.3 μg/m^3). Because the evidence in the record demonstrates that current requirements for portland cement are as protective as the new PEL with regard to Cr(VI) inhalation exposures, OSHA considers it reasonable to exclude portland cement from the scope of the final rule. This position was supported by a number of commenters (*e.g.*, Exs. 38–127; 38–217; 38–227; 38–229; 38–235).

A number of other commenters, including over 200 laborers, requested that portland cement be covered under the scope of the final rule (*e.g.*, Exs. 38–10; 38–35; 38–50; 38–110; 38–222). These comments generally, but not exclusively, focused on dermal hazards associated with exposure to portland cement. For example, the Building and Construction Trades Department, AFL–CIO (BCTD) stated:

> To provide construction employees with protection from predictable exposures to hexavalent chromium, the construction standard must include portland cement within its scope. Portland cement represents both a dermal and inhalation hazard in construction, and reduction of exposures would greatly benefit construction employees (Ex. 38–219).

Commenters favoring coverage of portland cement in the final rule argued that a number of the proposal's provisions would serve to protect cement workers, such as requirements for appropriate protective clothing (Exs. 47–26, pp. 26–27; 35–332, pp. 22–23; 40–4–2, p. 20), hygiene facilities (particularly washing facilities)(Exs. 38–219–1, p. 14; 47–26, pp. 26–27; 35–332, p. 19; 40–4–2, p. 19), and training and education (Exs. 47–26, pp. 26–27; 35–332, p. 19; 40–4–2, p. 19). Some commenters also favored medical surveillance requirements for workers exposed to portland cement (38–219–1, p. 18; 47–26, pp. 26–27) and requirements to reduce the Cr(VI) content of portland cement through the addition of ferrous sulfate (Exs. 38–199–1, p. 43; 38–219–1, p. 14–15; 38–222; 35–332, p. 23–24). Some noted that OSHA's Advisory Committee on Construction Safety and Health had recommended that the Agency apply certain provisions of the Cr(VI) rule to portland cement exposures in construction (Ex. 38–199–1, p. 30).

The primary intent of this rule is to protect workers from lung cancer resulting from inhalation of Cr(VI). The Agency has established that exposure to Cr(VI) at the previous PEL results in a significant risk of lung cancer among exposed workers, and compliance with the new PEL will substantially reduce that risk. As indicated previously, the existing PEL for portland cement protects employees against inhalation of Cr(VI) that is present in portland cement as a trace contaminant. Therefore, OSHA does not believe further requirements addressing inhalation exposure to Cr(VI) in portland cement are warranted.

The Agency does recognize, however, that in addition to respiratory effects resulting from Cr(VI) inhalation, Cr(VI) is also capable of causing serious dermal effects (see discussion in section V of this preamble). In previous chemical-specific health standards, OSHA typically has addressed serious health effects associated with exposure to a chemical, even if those effects are not the focus of the rule. For example, OSHA issued a standard for cadmium primarily based on lung cancer and kidney damage associated with inhalation exposures to cadmium; however, contact with cadmium can also cause irritation of the skin and OSHA included a provision in the final cadmium rule addressing protective clothing and equipment to prevent skin irritation. OSHA has followed a similar approach in the Cr(VI) rule, incorporating provisions for protective clothing and equipment that will address potential dermal hazards, and including consideration of dermal effects in medical surveillance requirements. The Agency believes this is a reasonable approach to protecting workers when a chemical causes a variety of adverse health effects.

The dermal hazards from contact with portland cement, however, are not related solely to the Cr(VI) content of cement. Portland cement is alkaline, abrasive, and hygroscopic (water-absorbing). Cement dermatitis may be irritant contact dermatitis induced by these properties, allergic contact dermatitis elicited by an immunological reaction to Cr(VI), or a combination of the two (Exs. 35–317; 46–74). Although reports vary, the weight of the evidence indicates that the vast majority of cement dermatitis cases do not involve Cr(VI) sensitization (Ex. 46–74). Dermatitis associated with exposure to portland cement is thus substantially, perhaps even primarily, related to factors other than Cr(VI) exposure.

Moreover, OSHA believes that appropriate requirements are already in place elsewhere in OSHA standards, to protect workers from dermal effects associated with exposure to portland cement. The Agency has existing requirements for the provision and use of personal protective equipment (PPE) (29 CFR 1910.132 for general industry; 29 CFR 1915.152 for shipyards; 29 CFR 1926.95 for construction). These requirements are essentially equivalent to the requirements of the final Cr(VI) rule with respect to provision of protective clothing and equipment.

OSHA also has existing requirements for washing facilities that are comparable to those found in the final Cr(VI) rule (29 CFR 1910.141(d) for general industry and shipyards; 29 CFR 1926.51(f) for construction). For example, in operations where contaminants may be harmful to employees, the Sanitation standard for construction requires employers to provide adequate washing facilities in near proximity to the worksite. With only limited exceptions for mobile crews and normally unattended worksites, lavatories with running water, hand soap or similar cleansing agents, and towels or warm air blowers must be made available in all places of employment covered by the standard. The Sanitation requirements that apply to general industry and shipyards provide equivalent protections.

OSHA's Hazard Communication standard (29 CFR 1910.1200) requires training for all employees potentially exposed to hazardous chemicals, including mixtures such as portland cement. This training must cover the physical and health hazards of the chemicals and measures employees can take to protect themselves from these hazards, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

Concerns raised in the record with regard to protective clothing, washing facilities, and training on cement dermatitis hazards appear to relate to lack of compliance with these existing requirements, rather than any inadequacy in the requirements themselves. For example, BCTD representatives indicated that in spite of current requirements, washing facilities are rarely provided on construction sites (Tr. 1464, 1470–1471, 1474, 1479–1480). By covering portland cement in the final Cr(VI) rule, BCTD argued that compliance would improve (Tr. 1519–1522).

OSHA recognizes that reiterating the requirements of generic rules such as the Sanitation standard in a chemical-specific standard like the Cr(VI) rule can be useful in some instances by providing employers with a comprehensive reference of applicable requirements. However, the Agency does not consider the Code of Federal Regulations to be the best tool for raising awareness about existing standards. Rather, OSHA believes guidance documents, compliance assistance efforts, and enforcement of existing requirements are the best mechanisms for accomplishing this objective.

Some commenters argued that requirements not included in the generic standards were needed to protect employees working with portland cement. The International Brotherhood of Teamsters (IBT) stated that absent coverage under the standard, portland cement workers would be responsible for purchasing and maintaining their own PPE. If there is no requirement for an employer to purchase and provide required PPE, IBT argued, most employees would elect not to purchase it (Ex. 38–199–1, p. 30). Of course many employers choose to pay for the PPE so that they can be sure of its effectiveness. The important factors are that the PPE must be suitable for the job and must be used correctly. Moreover, even when employees provide their own protective equipment, OSHA's PPE standards specify that the employer is responsible for ensuring its adequacy, including proper maintenance and sanitation (see 29 CFR 1910.132(b); 29 CFR 1926.95(b)).

Other commenters believed that medical surveillance was needed for employees exposed to portland cement (Exs. 38–219–1, p. 18; 47–26, pp. 26–27). However, irritant contact dermatitis and allergic contact dermatitis present the same clinical appearance, and it is difficult to determine if an employee with dermatitis is sensitized to Cr(VI). Because cement dermatitis is often related to the irritant properties of cement rather than Cr(VI), medical surveillance requirements for portland cement would necessarily involve covering health effects not solely, or even primarily, attributable to Cr(VI) exposure. OSHA therefore does not consider a requirement for medical surveillance for portland cement workers to be appropriate within the context of the Cr(VI) rule.

Ferrous Sulfate

Finally, some commenters suggested it would be appropriate to require the addition of ferrous sulfate to portland cement (Exs. 38–199–1, p. 43; 38–219–1, pp. 14–15; 38–222; 35–332, pp. 23–24; 47–26, p. 8). Cr(VI) concentrations in portland cement can be lowered by the addition of ferrous sulfate, which reduces Cr(VI) to Cr(III). Residual Cr(VI) concentrations of less than 2 ppm are typical. As discussed in section V of this preamble, reports from two researchers suggest that the addition of ferrous sulfate to cement in Scandinavian countries reduces the incidence of Cr(VI)-related allergic contact dermatitis in cement workers (Exs. 9–131; 48–8).

It is reasonable to believe that a reduction in the Cr(VI) concentration of portland cement would reduce the potential for Cr(VI)-induced allergic contact dermatitis. However, the lack of available information regarding a dose-response relationship between Cr(VI) exposure and allergic contact dermatitis makes it impossible to estimate how substantial that reduction might be. For instance, a portion of cement samples already have relatively low Cr(VI) concentrations. Analyses of 42 samples of American portland cement reported by Perone *et al.* indicated that 33 of the samples had Cr(VI) concentrations below 2 ppm (Ex. 9–57); the benefit of adding ferrous sulfate to cement with already low Cr(VI) concentrations is unclear.

Moreover, it is not clear that the addition of ferrous sulfate to cement would be successful in reducing Cr(VI) to Cr(III) under conditions found in the U.S. Attempts in the U.S. to reduce Cr(VI) in cement to Cr(III) with ferrous sulfate have been unsuccessful, due to oxidation of the ferrous sulfate in the production process (Ex. 35–417). Methods used to handle and store cement have also been shown to influence the effectiveness of ferrous sulfate in reducing Cr(VI). When cement is exposed to moisture during storage, the ferrous sulfate in it is likely to be oxidized, and as a result, the Cr(VI) will not be reduced to Cr(III) when the cement is mixed with water (Ex. 9–91). Handling and storage of cement in silos can have this effect (Tr. 1363). Because a substantial amount of cement in the U.S. is produced in winter and stored for use during warmer weather, ferrous sulfate added to the cement at the time of production could be oxidized during that time, rendering it ineffective (Tr. 1363).

Considering this evidence, OSHA does not believe the record demonstrates that the addition of ferrous sulfate to portland cement in the U.S. would necessarily result in a reduction in the incidence of Cr(VI)-induced allergic contact dermatitis. Therefore, OSHA does not believe that requiring the addition of ferrous sulfate to cement is warranted.

In any event, even if ferrous sulfate was completely effective in eliminating the potential for Cr(VI)-induced allergic contact dermatitis from portland cement, the potential for portland cement to induce *irritant contact dermatitis* would not be affected. (See section V(D) of this preamble for additional discussion.) Therefore, appropriate protective clothing, good hygiene practices, and training on hazards and control methods would still be necessary and these are adequately covered by OSHA's generic standards.

Pesticides

The final rule does not cover exposures to Cr(VI) that occur in the application of pesticides. Some Cr(VI)-containing chemicals, such as chromated copper arsenate (CCA) and acid copper chromate (ACC), are used for wood treatment and are regulated by EPA as pesticides. Section 4(b)(1) of the OSH Act precludes OSHA from regulating working conditions of employees where other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. Therefore, OSHA specifically excludes those exposures to Cr(VI) resulting from the application of a pesticide regulated by EPA from coverage under the final rule.

The exception for exposures that occur in the application of pesticides was limited to the proposed standard for general industry. At the time, OSHA was not aware of exposures to Cr(VI) from application of pesticides in other sectors. Exposures to Cr(VI) from pesticide application outside of general industry were brought to OSHA's attention during the public comment period (Exs. 39–47, p. 9; 39–48, p. 4; 39–52). This provision excluding coverage or exposures occurring in the application of pesticides has therefore been added to the standards for construction and shipyards as well.

The exemption pertains to the application of pesticides only. The manufacture of pesticides containing Cr(VI) is not considered pesticide application, and is covered under the final rule. The use of wood treated with pesticides containing Cr(VI) is also covered. In this respect, the Cr(VI) standard differs from OSHA's Inorganic Arsenic standard (29 CFR 1910.1018). The Inorganic Arsenic standard explicitly exempts the use of wood treated with arsenic. When the Inorganic Arsenic standard was issued in 1978, OSHA found that the evidence in the record indicated ''the arsenic in the preserved wood is bound tightly to the wood sugars, exhibits substantial chemical differences from other pentavalent arsenicals after reaction, and appears not to leach out in substantial amounts'' (43 FR 19584, 19613 (5/5/78)). Based on the record in that rulemaking, OSHA did not consider it appropriate to regulate the use of preserved wood. A number of commenters argued that a similar exception should be included in the final rule for use of wood preserved with Cr(VI) compounds (Exs. 38–208; 38–231; 38–244; 43–28). However, OSHA's exposure profile indicates that work with wood treated with pesticides containing Cr(VI) can involve Cr(VI) exposures above the new PEL (see FEA, Chapter III). OSHA therefore considers a blanket exception from the scope of the final rule for use of wood treated with Cr(VI) to be unjustified.

Other Requested Exemptions

In addition to those who maintained that Cr(VI)-treated wood should be exempted from the final rule, a number of commenters requested exemptions from the final rule for other operations or industries (*e.g.*, welding, electric utilities, Cr(VI) pigment production, residential construction, and telecommunications (Exs. 38–124; 38–203; 38–205; 38–211; 38–230; 38–244; 38–254; 39–14; 39–15; 39–47; 47–25; 47–37). OSHA does not believe that the evidence in the record supports a blanket exception from the final rule for these operations and industries. In no case have commenters submitted data demonstrating that the operations or industries for which an exception was requested do not involve exposures to Cr(VI) that present significant risk to the health of employees. Rather, the data presented in Chapter III of the FEA indicate that exposures in these sectors can and do involve exposures at levels that entail significant risk to workers, and may exceed the new PEL. OSHA therefore has not included exceptions for these operations or industries in the final rule.

One commenter argued that the provisions of the standard, including the new PEL, should apply only where Cr(VI) exposures occur on more than 30 days per year (Ex. 38–233, pp. 43–44). However, exposures of 30 or fewer days per year may involve cumulative exposures associated with significant risk of lung cancer. For example, if an employee was exposed to 50 μg/m^3 Cr(VI) for 30 days during a year, that employee s cumulative exposure for the year would exceed that of an employee exposed at the new PEL of 5 μg/m^3 working five days a week through the entire year. Therefore, OSHA does not believe such an exemption is appropriate because it would deny workers exposed to relatively high levels of Cr(VI) for 30 or fewer days per year the protections afforded by the Cr(VI) rule. The Agency does include exceptions from certain requirements of the rule for exposures occurring on fewer than 30 days per year (*e.g.*, with regard to requirements for engineering controls and periodic medical surveillance). However, these exceptions are related to the practical aspects of implementing protective measures, and not to an absence of risk for exposures occurring on fewer than 30 days per year.

Other commenters suggested that materials or substances containing trace amounts of Cr(VI) (*e.g.*, less than 0.1% or 1%) be exempted from the final rule (Exs. 38–203; 38–254; 39–19; 39–47; 39–48; 39–52; 39–54; 39–56). In particular, some utilities argued that fly ash produced by the incineration of coal contains trace amounts of Cr(VI) that are so low as to be insignificant, and that an exclusion from the final rule for coal ash was warranted (Ex. 39–40). Edison Electric Institute supported this argument by submitting sampling data and material safety data sheets that indicated the Cr(VI) concentrations in ash by-products of the coal combustion process (Exs. 47–25–1; 47–25–2; 47–25–3; 47–25–4; 47–25–5; 47–25–6; 47–25–7).

OSHA does not believe that it would be appropriate to establish a threshold Cr(VI) concentration for coverage of substances under the scope of this final rule. The evidence in the rulemaking record is not sufficient to lead OSHA to conclude that the suggested concentration thresholds would be protective of employee health. While OSHA has recognized that the Cr(VI) content of portland cement is sufficiently low to warrant an exception from the standard, a threshold concentration of 0.1% for Cr(VI) would be more than 50-fold higher than Cr(VI) levels typically found in portland cement (<0.002%). See above discussion of the extremely low Cr(VI) concentration in portland cement (<20 μg/g).

Although evidence submitted to the record indicates that Cr(VI) levels in coal ash may be comparable to levels in portland cement, OSHA does not believe that the evidence is sufficient to establish that all coal ash from all sources will necessarily have comparable Cr(VI) content.

A threshold concentration is also not reasonable because many operations where Cr(VI) exposures occur are the result of work with materials that do not contain any Cr(VI). Welders, who represent nearly half of the workers covered by this final rule, do not ordinarily work with materials that contain Cr(VI). Rather, the high temperatures created by welding oxidize chromium in steel to the hexavalent state. An exception based on a specified Cr(VI) concentration could be interpreted to exclude these workers from the scope of the standard. This would be particularly inappropriate in view of the fact that data in the record show that many welders have significant Cr(VI) exposures.

OSHA does, however, appreciate the concerns of commenters regarding situations where they believe exposures are minimal and represent very little threat to the health of workers. The Agency believes that a reasonable approach is to have an exception based on Cr(VI) exposure level. OSHA is therefore including in the final rule an exception for those circumstances where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of chromium (VI) in concentrations at or above 0.5 $\mu g/m^3$ as an 8-hour TWA under any expected conditions of use.

OSHA believes this approach is sensible because it provides an exception for situations where airborne exposures are not likely to present significant risk and thus allows employers to focus resources on the exposures of greatest occupational health concern. The Agency has added a definition for ''objective data'' (discussed with regard to paragraph (b) of the final rule) to clarify what information and data can be used to satisfy the obligation to demonstrate that Cr(VI) exposures will be below 0.5 $\mu g/m^3$.

Other standards which have included similar exceptions (*e.g.*, Acryolitrile, 29 CFR 1019.1045; Ethylene Oxide, 29 CFR 1910.1047; 1,3-Butadiene, 29 CFR 1910.1051) have generally relied upon the action level as an exposure threshold. A threshold lower than the action level has been selected for the Cr(VI) rule because OSHA believes this to be more protective of worker health given the existing significant risk at the action level. Although OSHA understands the difficulties of developing objective data to demonstrate that exposures will be below a given level, the Agency believes that the 0.5 $\mu g/m^3$ coverage threshold represents an exposure level where it is still reasonably possible to develop objective data to take advantage of this exception if Cr(VI) exposure levels are minimal. For instance, variation in exposures even in well controlled workplaces requires that typical exposures be below 0.25 $\mu g/m^3$ in order for an employer to be reasonably sure that exposures will consistently be below 0.5 $\mu g/m^3$ (see Exs. 46–79; 46–80; 46–81). Where typical exposures are below 0.25 $\mu g/m^3$, an industry survey might be used to show that exposures for a given operation would be below 0.5 $\mu g/m^3$ under any expected conditions of use.

When using the phrase ''any expected conditions of use'' OSHA is referring to situations that can reasonably be foreseen. The criteria are not intended to be so circumscribed that it is impossible to meet them. OSHA acknowledges that a constellation of unforeseen circumstances can occur that might lead to exposures above 0.5 $\mu g/m^3$ even when the objective data demonstration has been correctly made, but believes that such occurrences will be extremely rare.

(b) Definitions

''Action level'' is defined as an airborne concentration of Cr(VI) of 2.5 micrograms per cubic meter of air (2.5 $\mu g/m^3$) calculated as an eight-hour time-weighted average (TWA). The action level triggers requirements for exposure monitoring and medical surveillance.

Because employee exposures to airborne concentrations of Cr(VI) are variable, workers may sometimes be exposed above the PEL even if exposure samples (which are not conducted on a daily basis) are generally below the PEL. Maintaining exposures below the action level provides increased assurance that employees will not be exposed to Cr(VI) at levels above the PEL on days when no exposure measurements are made in the workplace. Periodic exposure measurements made when the action level is exceeded provide the employer with a degree of confidence in the results of the exposure monitoring. The importance of the action level is explained in greater detail in the exposure determination and medical surveillance discussions of this section (paragraphs (d) and (k) respectively).

As in other standards, the action level has been set at one-half of the PEL. The Agency has had successful experience with an action level of one-half the PEL in other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

Following the publication of the proposed rule, which included a proposed action level of 0.5 $\mu g/m^3$ (½ the proposed PEL of 1 $\mu g/m^3$), OSHA received several comments pertaining to the definition of the action level. Commenters such as the International Brotherhood of Teamsters (IBT) supported OSHA s preliminary determination that the action level should be set at one-half the permissible exposure limit (Exs. 38–199–1, p. 9; 38–219, p. 16–17; 38–228–1; 40–10–2). The IBT stated that the action level set at one-half the PEL has been successful historically in OSHA's standards such as inorganic arsenic, cadmium, benzene, ethylene oxide, methylenedianiline, and methylene chloride (Ex. 38–199–1, pp. 9, 44). NIOSH also supported OSHA's approach, stating that the action level of one-half the PEL is the appropriate level to indicate sufficient probability that an employee's exposure does not exceed the PEL on other days (Ex. 40–10–2, p. 17). The North American Insulation Manufacturer's Association (NAIMA) agreed that an action level of one-half the PEL is appropriate (in conjunction with a higher PEL than that proposed) (Ex. 38–228–1, pp. 23–24).

Previous standards have recognized a statistical basis for using an action level of one-half the PEL (*see, e.g.*, acrylonitrile, 29 CFR 1910.1045; ethylene oxide, 29 CFR 1910.1047). In brief, OSHA previously determined (based in part on research conducted by Leidel *et al.*) that where exposure measurements are above one-half the PEL, the employer cannot be reasonably confident that the employee is not exposed above the PEL on days when no measurements are taken (Ex. 46–80).

Following the publication of the proposed rule, the United Automobile, Aerospace, and Agricultural Implement Workers of America (UAW) requested an action level of one-tenth of the permissible exposure limit (PEL) (Tr. 791; Exs. 39–73; 39–73–2, pp. 3, 10; 40–19–1). The UAW argued that the lower action level is appropriate because variability in exposures is greater than was previously believed in some occupational settings. While OSHA previously assumed a geometric standard deviation (GSD) of 1.4, the UAW stated that a GSD of 2 should be assumed as a matter of policy. They concluded that this GSD implies an action level of one-tenth the PEL to minimize the frequency of exposures above the PEL on days when measurements are not taken (Ex. 39–73–2, p. 12).

If the variability of workplace exposures is typically as high as the UAW suggests, an action level less than one-half the PEL would be required to give employers a high degree of confidence that employees' exposures are below the PEL on most workdays. Leidel *et al.*, calculated that for exposures with a GSD of 2.0, an action level of 0.115 times the PEL would be required to limit to 5% the probability that 5% or more of an employee's unmeasured daily exposure averages will exceed the PEL (Ex. 46–80, p. 29). However, the evidence in the record is insufficient to permit OSHA to conclude that a GSD of 2.0 is typical of workplace Cr(VI) exposures. Furthermore, while OSHA recognizes the value of high (95%) confidence that exposures exceed the PEL very infrequently (< 5%), the Agency believes that the action level should be set at a value that effectively encourages employers to reduce exposures below the action level while still providing reasonable (though possibly < 95%) assurance that workers' exposures are typically below the PEL. OSHA's experience with past rules and the comments and testimony of NIOSH and other union representatives indicate that reasonable assurance of day-to-day compliance with the PEL is achieved with an action level of one-half the PEL (Exs. 40–10–2, p. 17; 199–1, pp. 9, 44).

The Agency's experience with previous standards also indicates that an action limit of one-half the PEL effectively encourages employers, where feasible, to reduce exposures below the action level to avoid the added costs of required compliance with provisions triggered by the action level. Where there is continuing significant risk at the PEL, the decision in the Asbestos case (*Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F. 2d 1258 (D.C. Cir 1988)) indicates that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than de minimus incremental benefit to workers' health. OSHA believes that the action level will result in a very real and necessary further reduction in risk beyond that provided by the PEL alone.

The action level improves employee protection while increasing the cost-effectiveness and performance orientation of the standard. The action level will encourage employers who can, in a cost-effective manner, identify approaches or innovative methods to reduce their employees' exposures to levels below the action level, because this will eliminate the costs associated with exposure monitoring and medical surveillance. The employees of such employers will have greater protection against adverse health effects because their exposures to Cr(VI) will be less than half of those permitted by the permissible exposure limit. Employees of those employers who are not able to lower exposures below the action level will have the additional protection provided by medical surveillance, exposure monitoring, and the other provisions of the standard that are triggered by the action level.

''Chromium (VI) [hexavalent chromium or Cr(VI)]'' means chromium with a valence of positive six, in any form or chemical compound in which it occurs. This term includes Cr(VI) in all states of matter, in any solution or other mixture, even if encapsulated by another or several other substances. The term also includes Cr(VI) when created by an industrial process, such as when welding of stainless steel generates Cr(VI) fume.

For regulatory purposes, OSHA is treating Cr(VI) generically, instead of addressing specific compounds individually. This is based on OSHA's determination that the toxicological effect on the human body is similar from Cr(VI) in any of the substances covered under the scope of this standard, regardless of the form or compound in which it occurs. As discussed in Section V of this preamble, some variation in potency may result due to differences in the solubility of compounds. Other factors, such as encapsulation, may have some effect on the bioavailability of Cr(VI). However, OSHA believes that these factors do not result in differences that merit separate provisions for different Cr(VI) compounds. OSHA considers it appropriate to apply the requirements of the standard uniformly to all Cr(VI) compounds.

''Emergency'' means any occurrence that results, or is likely to result, in an uncontrolled release of Cr(VI), such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment. To constitute an emergency, the exposure to Cr(VI) must be unexpected and significant. If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency. Similarly, if an incidental release of Cr(VI) may be safely cleaned up by employees at the time of release, it is not considered to be an emergency situation for the purposes of this section. Those instances that constitute an emergency trigger certain requirements in this standard (*e.g.*, medical surveillance) that are discussed later in this section.

In comments submitted to OSHA following the publication of the proposed Cr(VI) rule, the International Brotherhood of Teamsters (IBT) disagreed with OSHA's definition of ''emergency''. IBT stated that all spills and leaks involving Cr(VI) are unexpected and significant, and should be considered emergencies (Ex. 38–199–1, pp. 20–21).

OSHA does not agree with the IBT's position that every spill or leak should be considered an emergency. Not all spills and leaks are significant; the particular circumstances of the release, such as the quantity involved, confined space considerations, and the adequacy of ventilation will have an impact on the amount of Cr(VI) to which employees are exposed when a spill or leak occurs. For example, a minor spill that can be quickly cleaned up by an employee with minimal airborne or dermal exposure to Cr(VI) is clearly not an emergency. In addition, factors such as the personal protective equipment available, pre-established standard operating procedures for responding to releases, and engineering controls that employees can activate to assist them in controlling and stopping the release are all factors that must be considered in determining whether a release is incidental or an emergency.

The IBT also stated that the person who determines whether a spill or leak constitutes an emergency situation should be qualified with specific training, knowledge, and experience regarding the hazards associated with exposure to Cr(VI) and the appropriate response measures that must be implemented to prevent Cr(VI) exposures during the spill or leak remediation (Ex. 38–199–1, pp. 20–21). OSHA believes that the provisions of the Hazard Communication standard adequately address the IBT's concern (29 CFR 1910.1200). Paragraph (h)(3) of that standard directs employers to provide employees who are exposed or potentially exposed to a hazardous chemical (such as Cr(VI)) with training on the physical and health hazards of the chemical and

> [t]he measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used * * * (29 CFR 1910.1200 (h)(3)(iii)).

The Agency expects that employers and employees equipped with the training required by the Hazard Communication standard will be sufficiently knowledgable to determine whether an emergency has occurred, and that it is not necessary to mandate additional specialized training for this purpose.

''Employee exposure'' means exposure to airborne Cr(VI) that would occur if the employee were not using a respirator. This definition is included to clarify the fact that employee exposure is measured outside any respiratory protection worn. It is consistent with OSHA's previous use of the term in other standards.

''Historical monitoring data'' means data from chromium (VI) monitoring conducted prior to May 30, 2006, obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. To demonstrate employees' exposures, historical monitoring data must satisfy all exposure monitoring requirements of this section (*e.g.*, accuracy and confidence requirements).

''Objective data'' means information other than employee monitoring that demonstrates the expected employee exposure to chromium (VI) associated with a particular product or material or a specific process, operation, or activity. Types of information that may serve as objective data include, but are not limited to, air monitoring data from industry-wide surveys; data collected by a trade association from its members; or calculations based on the composition or chemical and physical properties of a material.

''Physician or other licensed health care professional'' [PLHCP] is an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by the medical surveillance provisions of this final rule. This definition is consistent with several recent OSHA standards, including the respiratory protection standard (29 CFR 1910.134), the bloodborne pathogens standard (29 CFR 1910.1030), and the methylene chloride standard (29 CFR 1910.1052). In these standards, the Agency determined that any professional licensed by state law to do so may perform the medical evaluation procedures required by the standard. OSHA recognizes that the personnel qualified to provide the required medical evaluation may vary from state to state, depending on state licensing laws.

At the public hearing, the 3M Company (3M) expressed concern with OSHA's interpretation of licensing requirements for PLHCPs. In the recent standards discussed above, OSHA has interpreted the requirements to mean that PLHCPs must be licensed in the states of residence for the employees they evaluate. This interpretation is based on OSHA's recognition of state licensing laws that require PHLCP's to be licensed in the state in which they practice. 3M encouraged OSHA to adopt an expanded definition of PLHCP for the Cr(VI) standard, allowing PLHCPs licensed in any U.S. state to evaluate employees residing in that or any other state, arguing that other federal agencies such as the Department of Transportation permitted similar allowances. 3M argued that this arrangement ''* * * would permit one medical director to oversee the program in several states'' where a company has operations (Tr. 1592, Ex. 47–36). Moreover, 3M added that OSHA has no authority to enforce state licensing requirements.

Despite the concerns raised by 3M, OSHA continues to believe that it is appropriate to establish PLHCP requirements consistent with state requirements for medical practice. OSHA's goal is that the medical surveillance provisions of the final Cr(VI) rule be conducted by or under the supervision of a health care professional who is appropriately licensed to perform those provisions and is therefore operating under his or her legal scope of practice. OSHA also continues to believe that issues regarding a PLCHP's legal scope of practice reside most appropriately with state licensing boards. While OSHA does not enforce state licensing requirements (*e.g.*, fining an individual PHCLP for operating outside their legal state license), OSHA can cite, using the Cr(VI) standard, an employer for using a health care professional who is not operating under his or her legal scope of practice. Thus, the Agency believes that the proposed definition for PHLCP is reasonable, and has retained it in the final rule. OSHA's experience with other standards using this definition supports the Agency's determination in this matter.

''Regulated area'' means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of Cr(VI) exceeds, or can reasonably be expected to exceed the PEL. This definition is consistent with the use of the term in other standards, including those for cadmium (29 CFR 1910.1027), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

OSHA has not included a requirement for regulated areas in construction and shipyards. This definition is therefore not included in the standards for construction and shipyards.

The definitions for ''Assistant Secretary'', ''Director'', ''High-efficiency particulate air [HEPA] filter'', and ''This section'' are consistent with OSHA's previous use of these terms found in other health standards.

(c) Permissible Exposure Limit (PEL)

Introduction

Paragraph (c) of the final rule establishes an 8-hour time-weighted average (TWA) exposure limit of 5 micrograms of Cr(VI) per cubic meter of air (5 $\mu g/m^3$). This limit means that over the course of any 8-hour work shift, the average exposure to Cr(VI) cannot exceed 5 $\mu g/m^3$. The new limit applies to Cr(VI), as opposed to the previous PEL which was measured as CrO_3. The previous PEL of 1 milligram per 10 cubic meters of air (1 $mg/10m^3$, or 100 $\mu g/m^3$) reported as CrO_3 is equivalent to a limit of 52 $\mu g/m^3$ as Cr(VI).

OSHA proposed a PEL of 1 $\mu g/m^3$ for Cr(VI). This PEL was proposed because the Agency made a preliminary determination that occupational exposure to Cr(VI) at the previous PEL resulted in a significant risk of lung cancer among exposed workers, and compliance with the proposed PEL was expected to substantially reduce that risk. Based on the information available to OSHA at the time, a PEL of 1 $\mu g/m^3$ was believed to be economically and technologically feasible for affected industries.

The PEL was a focus of comment in the rulemaking process, revealing sharply divided opinion on the justification for a PEL of 1 $\mu g/m^3$. Some support was expressed for the proposed PEL (Exs. 38–199–1, p. 42; 38–219–1, p. 2; 39–73–1). The vast majority of commenters, however, did not believe the proposed PEL was appropriate. Some maintained that a higher PEL was warranted, arguing that the proposed limit was infeasible or was not justified by the health and risk evidence (*e.g.*, Exs. 38–205; 38–215; 38–231; 38–228; 38–233). Several commenters suggested alternative PELs that they considered appropriate, such as 10 $\mu g/m^3$ (Exs. 38–134; 38–135; 38–195; 38–203; 38–212; 38–250; 38–254), 20 $\mu g/m^3$ (Ex. 38–204), 23 $\mu g/m^3$ (*e.g.*, Exs. 38–7; 43–22; 43–23; 43–25; 43–39), or 26 $\mu g/m^3$ (Ex. 38–263). Others maintained that the remaining risk at the proposed PEL was excessive and believed OSHA should adopt a lower PEL, suggesting 0.2 or 0.25 μg/m^3 (Exs. 39–71; 40–10–2; 47–23; 47–28).

After careful consideration of the evidence in the rulemaking record, OSHA has established a final PEL of 5 μg/m^3. OSHA s examination of the health effects evidence, discussed in section V of this preamble, reaffirms the Agency's preliminary conclusion that exposure to Cr(VI) causes lung cancer, as well as other serious adverse health effects. OSHA's quantitative risk assessment, presented in section VI, indicates that the most reliable lifetime estimate of risk from exposure to Cr(VI) at the previous PEL is 101 to 351 excess lung cancer deaths per 1000 workers. As discussed in section VII, this clearly represents a significant risk of material impairment of health. OSHA believes that lowering the PEL to 5 μg/m^3 will substantially reduce this risk. OSHA estimates the lifetime excess risk of death from lung cancer at the new PEL to be between 10 and 45 per 1000 workers.

The Agency considers the level of risk remaining at the new PEL to be significant. However, based on evidence evaluated during the rulemaking process, OSHA has concluded that a uniform PEL of 5 μg/m^3 is appropriate. The new PEL is technologically and economically feasible for all industry sectors. In only two operations within one of those sectors, the painting of aircraft and large aircraft parts in the aerospace industry, is a PEL of 5 μg/m^3 infeasible. In accordance with section 6(b)(5) of the OSH Act, OSHA has determined that the new PEL is the lowest limit that employers can generally achieve, consistent with feasibility constraints. Additional requirements are included in the final rule to further reduce any remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by the new PEL alone.

OSHA's rationale for adopting a uniform PEL of 5 μg/m^3 is set forth in greater detail below. The discussion is organized around the issues of primary importance to commenters: (a) Whether a uniform PEL is appropriate for all chromium compounds, (b) the technologic and economic feasibility of various PELs, (c) the requirement of section 6(b)(5) to promulgate the most protective standard consistent with feasibility, and (d) whether there is a need for a short-term exposure limit.

A Uniform PEL Is Appropriate for All Chromium Compounds

OSHA believes that it is appropriate to establish a single PEL that applies to all Cr(VI) compounds. OSHA's preferred estimates of risk are derived from two cohorts of chromate production workers that were predominantly exposed to sodium chromate and sodium dichromate. A number of commenters argued that risk estimates from these cohorts were not applicable to certain other Cr(VI) compounds (Exs. 38–106; 38–201–1; 38–205; 38–215–2).

After carefully evaluating the epidemiological, animal and mechanistic evidence in the rulemaking record, OSHA considers all Cr(VI) compounds to be carcinogenic. (For additional discussion see section V of this preamble.) OSHA has determined that the risk estimates developed from the chromate production cohorts are reasonably representative of the risks expected from equivalent exposures to different Cr(VI) compounds in other industries. OSHA finds that the risks estimated from the Gibb and Luippold cohorts of chrome production workers adequately represent the risks to workers in other industries who are exposed to equivalent levels of Cr(VI) compounds. (The rationale supporting these conclusions is discussed in detail in sections V and VI of this preamble. In particular, see Section VI(H) of the Quantitative Risk Assessment.) Because OSHA's estimates of risk are reasonably representative of all occupational Cr(VI) exposures, the Agency considers it appropriate to establish a single PEL applicable to all Cr(VI) compounds. A number of rulemaking participants supported this approach (Exs. 38–214; 38–220; 39–20; 39–60; 40–10; 40–19). *See also, e.g., Color Pigments Mfr. Ass'n, Inc.* v. *OSHA*, 16 F.3d 1157, 1161 (11th Cir. 1994):

> Given the absence of definiteness on the issue, the volume of evidence that points at least implicitly to the dangers of cadmium pigments, and the serious potential health risks present if cadmium exposure is as great in pigment form as in other compounds, we believe that OSHA was justified in choosing to include cadmium pigments in the PEL * * * ;

Asarco, Inc. v. *OSHA*, 746 F.2d 483, 495 (9th Cir. 1984) (permissible for OSHA to ''use trivalent arsenic studies and conclusions to support inclusion of pentavalent arsenic in the standard'').

The Final PEL of 5 μg/m^3 Is Technologically and Economically Feasible for all Affected Industries; the Proposed PEL Is Not

OSHA has concluded that a PEL of 5 μg/m^3 is economically and technologically feasible for all the affected industries. OSHA has also concluded, based on the comments and evidence submitted to the record, that the proposed PEL of 1 μg/m^3 is not feasible in all industries. OSHA's feasibility determinations are explained below.

Technologic feasibility of the final PEL. In making its determination of technological feasibility, OSHA relied upon guidance provided by the courts that have reviewed previous standards. In particular, the decision of the U.S. Court of Appeals for the District of Columbia on OSHA's Lead standard (*United Steelworkers of America* v. *Marshall*, 647 F.2d 1189 (D.C. Cir. 1981)) established a benchmark that the Agency has relied on for evaluating technological feasibility. The court explained that OSHA has ''great discretion * * * in determining the feasibility of a chosen PEL.'' 647 F.2d at 1309. Both technological and economic feasibility are ''to be tested industry-by-industry.'' 647 F.2d at 1301. In order to establish that a standard is technologically feasible, ''OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.'' 647 F.2d at 1272. The court allowed that ''insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine'' OSHA's finding of technological feasibility. *Id.*

Applying this definition of feasibility, OSHA has evaluated each affected industry and has concluded that a PEL of 5 μg/m^3 can be achieved through engineering and work practice controls, with only limited respirator use, in every industry. The primary evidentiary support for this conclusion is the report of Shaw Environmental, Inc., discussed in depth in the Final Economic and Regulatory Flexibility Analysis (FEA). Based on the data collected by Shaw, OSHA concludes that engineering controls, such as local exhaust ventilation (LEV), process control, and process modification or substitution can be used to control exposures in most operations.

OSHA recognizes that there are certain instances in which supplemental respirator use will be required because engineering and work practice controls are not always sufficient to reduce airborne exposures below the PEL. Summary information regarding the extent of respirator usage expected at various potential PELs is presented in Table VIII–3 (see section VIII, summary of the FEA). Considering this information together with other data and analysis presented in the FEA, OSHA has concluded that a PEL of 5 μg/

m³ is technologically feasible in all affected industry sectors and in virtually all operations, with the limited exception of some aerospace painting operations discussed more fully below. In only three sectors would respirator use be required by more than 5% of exposed employees. In two of these sectors, chromate pigment producers and chromium dye producers, use of respirators will be intermittent. The third sector, stainless steel welding, presents technological challenges in certain operations. However, the new PEL can clearly be achieved in most operations with engineering and work practice controls.

OSHA recognizes that for two distinct operations within the aerospace industry, painting aircraft and painting large aircraft parts, engineering and work practice controls cannot control exposures below 25 μg/m³ and respirators would be required for most employees performing these operations. (See additional discussion of aerospace painting below.) For that reason OSHA is adopting a provision for those specific operations requiring employers to use engineering and work practice controls to limit employee exposures to 25 μg/m³. Respiratory protection must then be used to achieve the PEL.

OSHA did not set the PEL at 25 μg/m³, a level achievable in *every* operation in *every* industry with engineering and work practice controls alone. That approach is inappropriate because it would leave the vast majority of affected employees exposed to Cr(VI) levels above those that could feasibly be achieved in most industries and operations. As discussed above, the lower PEL of 5 μg/m³ is feasible within the meaning of the case law, although it will result in limited use of respirators in some industries and significant respirator use in two painting operations in the aerospace industry. The two aerospace painting operations with significant respirator use are covered by the provision discussed above. For those operations, OSHA weighed the added protection provided by respirators against the negative aspects of respiratory protection requirements, and decided that the additional respirator use was acceptable.

Technological feasibility of the proposed PEL. OSHA concludes that the proposed PEL of 1 μg/m³ is not technologically feasible for all industries under the criteria in the D.C. Circuit's *Lead* decision. The court's definition of technological feasibility recognizes that for a standard based on a hierarchy of controls, a particular PEL is not technologically feasible simply because it can be achieved through the widespread use of respirators. 647 F.2d at 1272. This is consistent with OSHA's long-held view that it is prudent to avoid requirements that will result in extensive respirator use.

In its post-hearing brief, Public Citizen argued that a PEL should be considered technologically feasible if respirator use would be necessary to achieve compliance in a significant number of operations within an industry, or even if the PEL could only be achieved through use of respirators alone (Ex. 47–23, pp. 12–15). That position is inconsistent with the established test for feasibility for standards based on the hierarchy of controls. Moreover, as discussed in the preamble explanation of paragraph (f) on methods of compliance, use of respirators in the workplace presents a number of independent safety and health concerns. The vision of workers wearing respirators may be diminished, and respirators can impair the ability of employees to communicate with one another. Respirators can impose physiological burdens on employees due to the weight of the respirator and increased breathing resistance experienced during operation. The level of physical work effort required, the use of protective clothing, and environmental factors such as temperature extremes and high humidity can interact with respirator use to increase the physiological strain on employees. Inability to cope with this strain as a result of medical conditions such as cardiovascular and respiratory diseases, reduced pulmonary function, neurological or musculoskeletal disorders, impaired sensory function, or psychological conditions can place employees at increased risk of illness, injury, and even death. Routine use of respirators for extended periods of time is regarded by the Agency to be of greater significance than intermittent use for short time periods.

OSHA also believes that respirators are inherently less reliable than engineering and work practice controls. To consistently provide adequate protection, respirators must be appropriately selected and fitted, properly used, and properly maintained. Because these conditions can be difficult to attain, and are subject to human error, OSHA does not believe respirators provide the same degree of protection as do engineering and work practice controls.

Based on evidence and comment submitted in response to the proposal, OSHA finds that a PEL of 1 μg/m³ is not technologically feasible for a substantial number of industries and operations employing a large number of the workers covered by the standard. The record shows that a PEL of 1 μg/m³ is technologically infeasible for welding and aerospace painting because engineering and work practice controls cannot reduce exposures below 1 μg/m³ for many operations. OSHA also finds that the record contains insufficient evidence to establish the technologic feasibility of the proposed PEL for four other industries: chromate pigment producers, chromium catalyst producers, chromium dye producers and some hard chrome electroplaters. OSHA's findings on the technologic feasibility of the proposed PEL are summarized below, and are discussed more extensively in Chapter III of the FEA (in particular, see section titled: ''Technological Feasibility of the Proposed 1 μg/m³ 8-Hour TWA PEL.'').

Welding. OSHA has concluded that a PEL of 1 μg/m³ is not technologically feasible for shielded metal arc welding (SMAW) on stainless steel because engineering and work practice controls cannot generally reduce employee exposures to below 1 μg/m³. Almost one third (29%) of all stainless steel SMAW operations would need to use respirators at a PEL of 1 μg/m³. In general industry alone, more than half (52%) of stainless steel SMAW processes would be unable to use engineering or work practice controls to reduce Cr(VI) exposures below 1 μg/m³. Notably, stainless steel welding is widespread throughout the economy; it occurs in over 20,000 establishments employing approximately 127,000 workers in over sixty-five 3-digit NAICS codes. SMAW is the most common type of stainless steel welding and is performed by more than 67,000 employees—more than half of the total number of stainless steel welders and one quarter of all welders covered by the standard.

OSHA initially recommended the substitution of gas metal arc welding (GMAW) for SMAW as the cheapest and most effective method to reduce Cr(VI) exposures. GMAW, like SMAW, is a common type of welding, but GMAW tends to produce lower exposures than SMAW. However, based on hearing testimony and evidence submitted to the record, OSHA now believes that only 60% of SMAW operations can switch to GMAW (Exs. 38–220–1, p. 8; 39–60, p. 3; 39–70, p. 2; 35–410, p. 4). Moreover, even among the SMAW operations with current exposures above 1 μg/m³ that can switch to GMAW, only a portion (40% in general industry and 59% in construction and maritime) would be able to achieve a PEL of 1 μg/m³ without respirators.

OSHA has also determined that a PEL of 1 μg/m³ is technologically infeasible for stainless steel welding that is performed in confined or enclosed spaces due to limitations on the availability of ventilation. Because engineering and work practice controls cannot consistently reduce exposures to below 1 μg/m³, a large percentage of stainless steel welding operations in confined or enclosed spaces would require respirators at a PEL of 1 μg/m³. In general industry, for example, 60% of welding tasks done on stainless steel in confined spaces would be unable to comply with the proposed PEL by using engineering or work practice controls.

In sum, OSHA has concluded that it is infeasible for some of the most common welding operations to achieve a PEL of 1 μg/m³. For a more detailed explanation of OSHA's technological feasibility analysis for welding operations, see Chapter III of the FEA. OSHA has also decided that although it may be feasible for some of the less common types of welding operations to achieve a PEL of 1 μg/m³ with engineering and work practice controls, the ubiquitous nature of welding necessitates a finding that a PEL of 1 μg/m³ is generally infeasible for all welding operations. In particular, OSHA believes that the proposed PEL is infeasible for welding operations generally because welding is not easily separated into high and low exposure operations. Welders may perform different types of welding in the same day, making it difficult or impossible for employers to monitor them on an operation by operation basis. See, e.g., Ex. 39–22. In addition, because workers doing different types of welding often work alongside one another, what is technologically feasible for a welding operation considered in isolation may not be technologically feasible for that operation when it is performed next to SMAW on stainless steel or another operation for which a PEL of 1 μg/m³ is technologically infeasible.

Welding occurs in over 40,000 establishments spanning sixty-five different 3-digit NAICS codes. Welding is done in a variety of sites throughout many diverse workplaces (Ex. 38–8, p. 5). Stainless steel SMAW is commonly done in close proximity to other welding or cutting operations, which could expose nearby workers to the higher exposures generated by the SMAW welder (Ex. 38–214, p. 7). The Specialty Steel Industry of North America commented that, ''workers in job categories other than those evaluated by OSHA may spend significant time in areas of potential exposure'' (Ex. 38–233, p. 10). The Integrated Waste Services Association similarly indicated that inspectors, scaffold workers, laborers, pipe fitters, and refractory workers may pass through areas with potential Cr(VI) exposure during nickel chrome alloy overlay (Ex. 38–258, p. 2). The Building and Construction Trades Department of the AFL–CIO also stated that ''workers may be exposed to hazards even if they are not directly performing tasks associated with Cr VI exposure via close proximity exposure'' (Ex. 31–6–1).

Moreover, OSHA is aware that welders sometimes weld in many different environments on a variety of types of base metal using different welding methods in the course of a project or even during a single work shift (Exs. 34–10, 38–235). In those situations, the employee's overall exposure levels are inevitably influenced by the variety of exposures present during the various welding tasks he or she performs. Therefore, depending on how much time the employee spends doing welding operations for which a PEL of 5 μg/m³ is the lowest feasible level, even the use of engineering and work practice controls to comply with a PEL of 1 μg/m³ in the other welding operations would not necessarily reduce the employee's overall exposure levels below that mark.

Because of these factors, welding is not easily separated into high and low exposure operations in the real work site. For these reasons, OSHA believes the record demonstrates that the proposed PEL of 1 μg/m³ is infeasible for welding operations generally. Almost 270,000 of the employees covered by the new standard engage in these welding operations (Table VIII–2).

Aerospace painting. There are approximately 8300 exposed employees in aerospace painting (Table VIII–2). A PEL of 1 μg/m³ is not feasible for approximately two thirds of all aerospace painting operations. At a PEL of 5 μg/m³, only ⅓ of aerospace painting operations would require substantial respirator use.

Exposures in aerospace painting are controlled by enclosing the operations in painting booths or dedicated rooms with LEV. This is feasible for small parts, but as the size of the parts increases it becomes more difficult to control exposures. For example, when painting most small parts, exposures below 1 μg/m³ are achievable, but for larger parts exposures can only be reduced to between 1 μg/m³ and 5 μg/m³ using engineering and work practice controls. This group that can achieve levels between 1 μg/m³ and 5 μg/m³ (approximately ⅓ of total aerospace painting operations) can use LEV, but as the size of the part increases it becomes increasingly difficult to provide good air flow around the entire part, such as underneath large horizontal structures. Moreover, as the size of the part increases, it becomes increasingly difficult for the painter to position him or herself to avoid being downstream of the paint overspray due to the geometry of the parts.

When painting even larger parts, such as fuselages, wings or the entire aircraft, exposures below 5 μg/m³ are no longer achievable without supplementary respiratory protection. Because these large parts do not fit into enclosures or painting rooms, they must be painted in oversized workspaces, typically hangers that can reach the size of a football field (Ex. 38–106–2, p. 2). In oversized workspaces the ventilation system becomes less effective and generally, the larger the space, the more difficult it is to ventilate.

Moreover, when ventilation is put into such areas, the simple solution of increasing air flow is not feasible because the amount of air that is needed to dilute or diffuse the contaminated air can adversely affect the quality of the job to the point where the paint or coating is unacceptable for its purpose of protecting the part or plane (Ex. 38–106, p. 38). Thus, simply increasing the air flow in these sites and situations is not a viable alternative. As discussed above, OSHA has established a provision to address the situation where exposures cannot be brought below 25 μg/m³ through engineering and work practice controls alone. However, a PEL of 5 μg/m³ can be achieved using respiratory protection for these operations.

In short, OSHA believes a PEL of 5 μg/m³ is feasible for aerospace painting operations. Although one-third of those operations will need to use respiratory protection to achieve the PEL, the remainder can do so with engineering and work practice controls alone. Half of that remaining group cannot achieve a PEL of 1 μg/m³ because, even though they can take advantage of enclosures such as paint rooms with LEV, the LEV becomes less effective as the part becomes larger. For this reason lowering the PEL from 5 μg/m³ to 1 μg/m³ would result in the above-described substantial increase in the number of employees required to wear respirators. OSHA has therefore concluded that a PEL of 1 is not generally feasible for aerospace painting. For a more detailed explanation of OSHA's technological feasibility analysis for aerospace painting operations, see Chapter III of the FEA.

Other industries. There are other major industries or applications where OSHA is confident the PEL of 5 μg/m^3 can be met with engineering and work practice controls, but the record does not establish that a PEL of 1 μg/m^3 would be technologically feasible. In particular, chromate pigment producers, chromium catalyst producers, and chromium dye producers would have difficulty meeting the proposed PEL. A significant portion of operations in these industries are conducted in open and often large areas that are very dusty, making exposures hard to control. Just as in aerospace painting above, the primary control is to enclose the operation and then ventilate. However, some of the operations cannot be enclosed because of the physical configuration of the plant, especially in older facilities (Ex. 47–3, p. 55). Moreover, because the medium containing the Cr(VI) tends to be a fine powder, additional LEV in any worksite potentially can result in significant and intolerable product loss. In other words, the product could be drawn up through the ventilation system (Ex. 38–12, pp. 12–14).

Thus, depending in large part on the number of facilities that can accommodate enclosures, these operations could potentially require extensive respirator use in order to meet a PEL of 1 μg/m^3; at 1 μg/m^3, OSHA expects that 44% of employees in these three industries would need to wear respirators on at least an intermittent basis. This number could be even higher if there are a large number of facilities that cannot enclose troublesome operations.

To find the proposed PEL technologically feasible for an industry, OSHA must ''prove a reasonable possibility'' that the typical firm can meet it with engineering and work practice controls in most operations. *United Steelworkers*, 647 F.2d at 1272. Table VIII–3 indicates that intermittent respirator use would be required to reach the proposed PEL of 1 μg/m^3 for chromate pigment producers, chromium catalyst producers, and chromium dye producers. The extent of daily respirator usage that would be required to meet the proposed PEL is not clear if the recommended controls of enclosures and automation of the key operations are not feasible for existing facilities, but could be substantial depending upon the variables discussed above. On balance, OSHA does not believe that the record establishes the likelihood that the typical firm in these industries can meet the proposed PEL with engineering and work practice controls. There are a total of approximately 469 exposed employees in these three industries (Table VIII–2). For a more detailed explanation of OSHA's technological feasibility analysis for chromate pigment producers, chromium catalyst producers, and chromium dye producers, see Chapter III of the FEA.

Technological feasibility is also an issue for hard chrome electroplating operations where fume suppressants cannot be used to control Cr(VI) exposures because they would interfere with the product specifications, making the resulting product unusable.

In conclusion, OSHA has determined that while a PEL of 5 μg/m^3 is technologically feasible for all affected industries, the record does not support the feasibility of the proposed PEL of 1 μg/m^3 for welding operations, aerospace painting, chromate pigment producers, chromium catalyst producers, chromium dye producers, and some hard chrome electroplating operations.

Economic feasibility of the final and proposed PELs. OSHA has also evaluated the economic feasibility of the proposed and final PELs. With regard to economic feasibility, OSHA must ''provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry,'' so as to ''demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms.'' *AFL–CIO* v. *OSHA*, 965 F.2d 982 (11th Cir. 1992). OSHA believes that the final PEL of 5 μg/m^3 is feasible for all affected industries. (For a more detailed discussion of OSHA's economic feasibility analysis, see Chapter VIII, Summary of the Final Economic Analysis and Regulatory Flexibility Analysis, Sections D and E.) In the majority of industries, costs will be less than 1% of revenues. For fewer than 10 of the approximately 250 NAICS (North American Industry Classification System) categories affected by the rule, costs are estimated to exceed 1% of revenues. OSHA has concluded that all affected industries will be able to absorb these costs without threatening their existence or competitive structure. Accordingly, OSHA has concluded that the new standard is economically feasible for all industries.

By contrast, the proposed PEL of 1 μg/m^3 would not be economically feasible for a significant industry-electroplating job shops (NAICS 332813; electroplating, plating, polishing anodizing and coloring services). Electroplating establishments can be broadly classified into two categories: (1) Job shops and (2) captive shops, with roughly half of establishments falling into each category. Job shops perform electroplating services for others, while captive shops provide plating services to the facility of which they are part.

A PEL of 1 μg/m^3 would result in costs exceeding 2.7% of revenues and 65% of profits for electroplating job shops. As explained further in section VIII of this preamble, and in the FEA, OSHA does not believe that options for reducing impacts (e.g., phase-ins or allowing use of respirators) would significantly alleviate the burden of the proposed PEL. OSHA is concerned that these costs could alter the competitive structure of the industry. Approximately 33,400 workers are employed in electroplating job shops.

Summary of the technological and economic feasibility of the final and proposed PELs. To summarize, OSHA concludes that the final PEL of 5 μg/m^3 is technologically and economically feasible for the affected industries. On the other hand, the proposed PEL of 1 μg/m^3 would be technologically or economically infeasible or is of unproven feasibility in a large number of industries and operations covered by the standard, including welding, aerospace painting, chromate pigment production, chromium catalyst production, chromium dye production, some hard chrome electroplating operations, and electroplating job shops. These operations affect approximately 312,170 exposed employees, or almost 56% of the total number of employees occupationally exposed to Cr(VI) (Table VIII–2). This figure includes 270,000 employees in welding, 8,300 employees in aerospace painting operations, 33,400 employees in electroplating job shops, and 469 employees in the other three industries. (Note that this number does not include a separate count for employees performing hard chrome electroplating in order to avoid double counting employees performing that operation who are employed in the electroplating job shop category). OSHA did not receive data or recommendations regarding setting the PEL at any levels between 1 and 5 μg/m^3.

A Uniform PEL of 5 μg/m^3 Is Consistent With the Feasibility Constraint of Section 6(b)(5)

Section 6(b)(5) of the OSH Act requires OSHA to set the standard which most adequately assures, to the extent feasible * * * that no employee will suffer material impairment of health.'' This provision requires the agency to eliminate or reduce significant risk, to the extent feasible. *See*

American Textile Mfr. Inst., Inc. v. *Donovan*, 452 U.S. 490, 506–22(1981). OSHA has always interpreted Section 6(b)(5) to accord the agency substantial discretion to set the PEL at the lowest level that is feasible for industries and operations as a whole. OSHA has not interpreted the provision to require setting multiple PELs based on the lowest level particular industries or operations could achieve. Because Congress did not speak to the precise issue in the statute, OSHA has authority to adopt the reasonable interpretation that it judges will best carry out the purposes of the Act. *Chevron U.S.A.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984).

The new Cr(VI) standard meets the requirements of Section 6(b)(5) because the PEL of 5 μg/m³ is the lowest feasible limit for many operations and sectors employing a large number of covered employees in fact, a majority of affected employees. In addition, the record does not afford a basis for any further disaggregation.

OSHA recognizes that, according to the determination made in Section VII of this preamble, significant risk remains at a PEL of 5 μg/m³. As indicated in Table VII–3 in the Significance of Risk section, the remaining risk for a worker exposed at the PEL throughout a 45-year working lifetime is comparable to or greater than the remaining risk in previous OSHA health standards where quantitative estimates have been presented. Although OSHA anticipates that the ancillary provisions of the standard will reduce this residual risk, the Agency realizes that lower PELs might be achievable in some industries and operations, which would reduce this risk even further. As explained below, however, OSHA concludes that these benefits would be offset by the significant disadvantages of attempting to establish and apply multiple PELs for the diverse group of industries and operations covered by the standard. *See Building & Constr. Trades Dep't* v. *U.S. Dep't of Labor*, 838 F.2d 1258, 1273 (D.C. Cir. 1988) (administrative difficulties, if appropriately spelled out, could justify a decision to select a uniform PEL).

Requiring OSHA to set multiple PELs—taking into account the feasibility considerations unique to each industry or operation or group of them—would impose an enormous evidentiary burden on OSHA to ascertain and establish the specific situations, if any, in which a lower PEL could be reached. Such an onerous obligation would inevitably delay, if not preclude, the adoption of important health standards. In addition, the demanding burden of setting multiple PELs would be complicated by the difficulties inherent in precisely defining and clearly distinguishing between affected industries and operations where the classification determines legal obligations. The definitional and line-drawing problem is far less significant when OSHA merely uses a unit of industries and operations for analytical but not compliance purposes, and when it sets a PEL in the aggregate, *i.e.*, when its analysis is limited to determining whether a particular PEL is the lowest feasible level for affected industries as a whole. If OSHA had to set multiple PELs, and assign industries or operations to those PELs, the problem would become much more pronounced as the consequences of imprecise classifications would become much more significant.

The North American Industry Classification System (NAICS), which has replaced the Standard Industrial Classification (SIC) system as the standard Federal statistical agencies use in classifying business establishments, is not an appropriate basis for establishing multiple PELs. NAICS classifications are based on generally-worded definitions and it is not always clear which definition best fits a particular establishment. Moreover, an establishment's NAICS classification is based on its primary activity. The establishment may include many other activities, however, and what is the lowest feasible level for operations in one activity may not be so for other activities. In addition, the primary activity in an establishment may change over time and the NAICS system itself is subject to revision every five years. Definitional uncertainties, the presence of multiple and changing business activities, and periodic revisions in individual codes could have important consequences for enforcement of the standard over time. For these reasons, OSHA has historically been reluctant to disaggregate coverage of a standard by SIC classification. See 58 FR 166620–16621 (March 30, 1993) (discussing disaggregation of coverage of lockout/tagout standard).

Similarly, disaggregation by operation has major practical disadvantages. In addition to definitional complexities, a significant problem with the use of operations for disaggregating the PEL is that many firms have exposures in two or more different categories. Welding, for example, is widely used in manufacturing operations in general industry, maritime and construction. So, for instance, setting the PEL at 5 for welding applications and 1 for other applications would mean that some firms would have to attain two different PELs for Cr(VI) exposures within the same workplace, and possibly even for the same employees. As another example, chromium conversion is a process where a treated metal surface is converted to a layer containing a complex mixture of chromium compounds. Unlike electroplating, chromium conversion is an entirely chemical process, and results in lower Cr(VI) exposures than are typically associated with chromium electroplating. Where chromium conversion is performed along with chromium electroplating in a single establishment, it may be virtually impossible to distinguish exposures from one source versus the other. The same workers may even perform both tasks. Exposures from hard chrome electroplating inevitably affect other nearby workers because hard chrome plating is often done in the same workplaces or areas and even at the same time as other operations involving lower Cr(VI) exposures such as decorative plating and chrome conversion. In fact, in many circumstances it can be virtually impossible to distinguish the different sources that contribute to a particular employee's exposure levels.

These are just a few examples of the many instances reflected in the record in which individual employers will have Cr(VI) exposures emanating from two or more different operations (Exs. 38–233, pp. 9–10; 39–52, p. 4; 47–24, p. 2; 39–20, p. 5). If multiple PELs were established for different operations, employers would be forced to monitor for compliance with two or more PELs within the same workplace—a task rendered all the more difficult by the fact that the exposure of an employee may not be tied exclusively to a single task; different processes may be performed in close proximity to one another and each may contribute to the exposure of an individual.

OSHA also believes that a uniform PEL will ultimately make the standard more effective by making it easier for affected employers to understand and comply with the standard's requirements. A uniform PEL also makes it easier for OSHA to provide clear guidance to the regulated community and to identify non-compliant conditions.

Finally, OSHA is concerned that adopting multiple PELS could result in a great number of subcategories that would have to be tracked for enforcement purposes. Apart from welding and electroplating, which present particularly severe dissagregation problems, there are over thirty other industry sectors with exposure to Cr(VI). None of these sectors individually accounts for more than 6% of the total of exposed employees; in fact, several of those groups employ fewer than 100 employees.

For these reasons, OSHA has historically interpreted section 6(b)(5) to accord the Agency substantial discretion to set the PEL at the lowest level feasible for industries or operations as a whole. In adopting the arsenic standard, for example, OSHA expressly declined to set different PELS, finding that ''[s]uch an approach would be extremely difficult to implement.'' 43 FR 19584, 19601 (May 5, 1978). In that instance, OSHA explained:

> The approach OSHA believes appropriate and has chosen for this and other standards is the lowest level achievable through engineering controls and work practices in the majority of locations. This approach is intended to provide maximum protection without excessively heavy respirator use. *Id.*

Similarly, when OSHA initially lowered the PEL for benzene from 10 ppm to 1 ppm, it considered, but rejected, the idea of establishing additional lower PELs, concluding that ''different levels for different industries would result in serious administrative difficulties.'' 43 FR 5918, 5947 (Feb. 10, 1978). And when OSHA subsequently reconsidered the benzene standard after it was remanded for a more specific finding of significant risk, OSHA considered, but rejected, a PEL of 0.5 ppm, noting:

> The unions have pointed out some situations where controls might do somewhat better than 1 ppm * * * [but] OSHA believes it has chosen the correct balance at 1 ppm as the level it can have a high degree of confidence is generally achievable. 52 FR 34460, 34519 (Sept. 11, 1987).

In the case of cotton dust, where OSHA did set different PELs for certain discrete groups, the groups involved exposures to different kinds of cotton dust and different degrees of risk. Even so, OSHA declined to adopt a unique PEL for every single affected sector. *See* 43 FR 27350, 37360–61 (June 23, 1978) (OSHA set one PEL for textile industries and a separate PEL for non-textile industries, but expressly rejected the option of adopting different exposure limits for each non-textile industry).

In conclusion, the new PEL is the lowest level that can feasibly be attained for many industries and operations employing a large number of covered workers, in fact a majority of employees exposed to hexavalent chromium. Considering all of the factors outlined above, OSHA finds that a uniform PEL of 5 $\mu g/m^3$ is consistent with section 6(b)(5) and that further dissagregation is not warranted.

A Short-term Exposure Limit is Unnecessary. Several commenters recommended that OSHA establish a short-term exposure limit (STEL) for Cr(VI) (Exs. 38–219; 38–222; 39–38; 39–50; 40–19). By restricting potential high magnitude exposures of short duration, a STEL is intended to protect against health effects associated with relatively high exposures, as well as to reduce cumulative exposures. The UAW indicated that the high residual risk of cancer justified a STEL (Ex. 40–19), while NIOSH stated that short-term exposures to high levels of Cr(VI) can cause severe respiratory effects (40–10–2, p. 17). Other commenters did not believe a STEL was justified, in some cases noting that neither NIOSH nor ACGIH recommends a STEL for Cr(VI) (Exs. 38–214; 38–220; 39–19; 39–20; 39–40; 39–41; 39–47; 39–51; 39–52; 39–60; 43–26).

OSHA decided not to include a STEL in the final Cr(VI) standard for three reasons. First, employers already are required to reduce exposures to levels at or below the new PEL, which is expected to limit the occurrence of high exposure excursions. Although it will not eliminate all risk from peak exposures, the Agency anticipates that compliance with the new PEL will substantially reduce the frequency and magnitude of high exposure excursions, and thereby minimize the likelihood of adverse health effects resulting from peak exposures. Second, although in theory imposing a STEL might further lower cumulative exposures to Cr(VI), there is little record evidence supporting this supposition. Third, in some application groups, such as plastic colorant producers, employees are typically exposed to Cr(VI) not only for short durations but also intermittently. The industry has estimated that only 5% of pigments used contain Cr(VI) (Ex. 47–24–1). For these users, compliance with a STEL might require the expenditure of considerable resources without providing much additional protection to workers. These resources could more effectively be allocated to other forms of worker protection.

Without better justification, OSHA does not consider establishment of a STEL to be reasonably necessary or appropriate. OSHA has concluded that a STEL would provide at most a *de minimis* health benefit.

(d) Exposure Determination

Paragraph (d) of the final rule sets forth requirements for determining employee exposures to Cr(VI). The requirements are issued pursuant to Section 6(b)(7) of the OSH Act (29 U.S.C. 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.''

The purpose of requiring an assessment of employee exposures to Cr(VI) includes: determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure to Cr(VI); collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed to Cr(VI) in excess of the permissible exposure level and to notify employees of their exposure levels, as required by section 8(c)(3) of the Act. In addition, the availability of exposure data enables the PLHCP performing medical examinations to be informed of the extent of occupational exposures.

The final requirements have been revised from those proposed in response to comments received. In the proposed general industry standard, OSHA included a requirement for initial exposure monitoring in all workplaces covered by the rule, unless monitoring had been performed in the previous 12 months, or the employer had data to demonstrate that exposures would be below the action level. Periodic monitoring was required at intervals determined by monitoring results (*i.e.*, at least every 6 months if exposures were at or above the action level, at least every 3 months if exposures were above the PEL), and additional monitoring was required when changes in the workplace resulted in new or additional exposures to Cr(VI). These requirements are similar to requirements for monitoring found in previous OSHA substance-specific health standards, such as those for methylene chloride (29 CFR 1910.1052) and 1,3-butadiene (29 CFR 1910.1051).

The proposed standards for construction and shipyards did not include provisions for exposure monitoring. OSHA did not propose specific exposure monitoring requirements for construction and shipyards because operations in these sectors are often of short duration, and are performed under varying environmental conditions.

In omitting exposure monitoring requirements from the proposed standards for construction and shipyards, OSHA intended to provide construction and shipyard employers with the flexibility to assess Cr(VI) exposures in any manner they considered appropriate. It was not the Agency's intent that employers ignore substantial exposures to Cr(VI). Because the obligation to comply with the PEL would remain, the employer would have to accurately characterize Cr(VI) exposures in order to determine if they were in compliance. At the time of the proposal, OSHA considered this performance-oriented approach a reasonable way to determine employee exposures to Cr(VI) while avoiding the more infeasible requirements of a scheduled monitoring approach that might not be useful in construction and shipyard workplaces. This performance-based approach was consistent with OSHA's standard for air contaminants (29 CFR 1910.1000), which establishes PELs for over 400 substances but does not include specific requirements for exposure monitoring.

Construction and shipyard employers who expressed an opinion on the issue generally supported the absence of specific exposure monitoring requirements (*e.g.*, Exs. 38–220; 38–235; 38–244). In addition to those operations that involved changing conditions, employers argued that periodic monitoring requirements were unnecessary when conditions did not change (Exs. 38–124; 38–213, 38–215; 38–189, 38–191). For example, the U.S. Navy stated:

> The prescriptive schedule of required air sampling has not proved beneficial in assessing risks in shipyards * * * where there has been virtually no change in conditions, yet costs for consistent air sampling have been incurred on an annual basis without informational benefit or added protection for workers. The performance-based sampling approach * * * is protective, efficient, and logical (Ex. 38–220).

A number of employers also supported a performance oriented approach for exposure determination in general industry workplaces (Exs. 38–189; 38–191; 38–213; 38–215; 39–48). Some of these commenters argued that Cr(VI) exposures in their workplaces were intermittent, variable, and of short duration, and therefore similar to those found in construction and shipyards (Exs. 38–203; 38–254; 39–19; 39–48; 39–56). Other comments focused on requirements for periodic monitoring that were considered to be excessive (*e.g.*, Exs. 38–124; 38–189; 38–191; 38–213; 38–215; 38–233). For example, the Color Pigments Manufacturers Association stated:

> OSHA continues to require repeated monitoring at great cost in general industry under circumstances where no change in procedure, process, equipment or exposure has occurred to warrant repeated exposure monitoring. This requirement is unnecessary and punitive. It forces general industry to expend valuable resources on continual monitoring without reason (Ex. 38–205).

Some employers, while maintaining that periodic monitoring requirements were not warranted, indicated that initial exposure monitoring or an initial hazard assessment would be appropriate (Exs. 38–214; 38–245–1).

Other commenters, including unions, Public Citizen, and NIOSH, supported explicit requirements for exposure assessment (Exs. 38–199–1; 38–222; 40–10–2; 47–23, p. 16). These parties argued that employers will not know whether or not they are in compliance with the standard without mandated exposure monitoring. For example, the Building and Construction Trades Department, AFL–CIO, stated:

> If OSHA indeed intends construction employers to conduct an exposure assessment, this requirement must be explicitly stated in the regulation. To suggest that employers will attempt to characterize exposure routinely without an explicit requirement in the regulation is ludicrous (Ex. 38–219).

Even where controls are implemented, it was argued, exposure assessment is still necessary to ensure that those controls are adequately protective (Ex. 38–219). NIOSH suggested that OSHA might want to consider developing alternative means for assessing exposures, such as the use of interim protection provisions in construction for certain tasks until exposure monitoring could be done (see the lead standard, 29 CFR 1926.62(d)) and the use of grouped tasks and grouping job types into classes based on exposure potential (see the asbestos standard, 29 CFR 1926.1101) (Ex. 40–10–2, p. 19).

After considering the evidence and arguments advanced by rulemaking participants, OSHA is convinced that requirements for scheduled initial and periodic Cr(VI) exposure monitoring are not appropriate in all circumstances. In particular, OSHA believes that the evidence in this rulemaking, as discussed earlier in this section in paragraph (c), permissible exposure limit, demonstrates the varied nature of Cr(VI) exposures across a number of different work operations. However, OSHA also believes that valid concerns have been raised regarding the adequacy of exposure assessments that would be performed in the absence of explicit requirements. The Agency is therefore including in the final rule two alternative options for all affected employers to follow for determining employee exposures to Cr(VI). The first option, referred to as the ''scheduled monitoring option'', consists of requirements for initial monitoring and periodic monitoring at intervals based on monitoring results. This approach is similar to that proposed for general industry in this rulemaking and with exposure assessment requirements in previous OSHA substance-specific standards. The second option, referred to as the ''performance-oriented option'', allows employers to use any combination of air monitoring data (i.e., data obtained from initial and periodic monitoring performed in accordance with the requirements of the Cr(VI) standard), historical monitoring data, or objective data to determine employee exposures to Cr(VI), as long as the data are sufficient to accurately characterize exposures.

OSHA believes that by including explicit requirements for exposure determination in the standards for general industry, construction, and shipyards, the Agency makes clear the obligation of employers to accurately assess employee exposures to Cr(VI) in all sectors. By offering two options for achieving this goal, the final rule provides a framework that is familiar to many employers and has been successfully applied in the past, as well as flexibility for employers who are able to characterize employee exposures through alternative methods.

OSHA has chosen not to use the task-based approaches suggested by NIOSH (Ex. 40–10–2) that the Agency has used in several previous health standards covering construction. While OSHA believes that these approaches are effective in certain construction settings, there was not sufficient information in this rulemaking record for OSHA to develop classes of exposures that would apply across the many varied work operations with Cr(VI) exposures. While it was not possible to develop specific classes of operations to apply across all industries, OSHA believes that an individual employer, with specific information about the work processes at his worksite, may be able to use such an approach in using the performance-based option allowed by this final rule.

Paragraph (d)(2) contains requirements for employers who choose the scheduled monitoring option. Employers who select this option must conduct initial monitoring to determine employee exposure to Cr(VI). OSHA has not established a separate compliance date for initial monitoring to allow employers flexibility in scheduling this activity. However, employers must allow sufficient time after initial monitoring is performed to achieve compliance (e.g., establish regulated areas, provide appropriate respiratory protection) by the start-up dates specified in paragraph (n) (paragraph (l) for construction and shipyards). Monitoring to determine employee exposures must represent the employee's time-weighted average exposure to airborne Cr(VI) over an eight-hour workday. Samples must be taken within the employee's breathing zone (i.e., ''personal breathing zone samples'' or ''personal samples''), and must represent the employee's exposure without regard to the use of respiratory protection.

Employers must accurately characterize the exposure of each employee to Cr(VI). In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of ''representative'' employees is sufficient. Representative exposure sampling is permitted when a number of employees perform essentially the same job under the same conditions. For such situations, it may be sufficient to monitor a fraction of these employees in order to obtain data that are ''representative'' of the remaining employees. Representative personal sampling for employees engaged in similar work with Cr(VI) exposure of similar duration and magnitude is achieved by monitoring the employee(s) reasonably expected to have the highest Cr(VI) exposures. For example, this may involve monitoring the Cr(VI) exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Exposure monitoring should include, at a minimum, one full-shift sample taken for each job function in each job classification, in each work area, for each shift. These samples must consist of at least one sample characteristic of the entire shift or consecutive representative samples taken over the length of the shift. Where employees are not performing the same job under the same conditions, representative sampling will not adequately characterize actual exposures, and individual monitoring is necessary.

Employers who have workplaces covered by the standard must determine if any of their employees are exposed to Cr(VI) at or above the action level. Further obligations under the standard are based on the results of this assessment. These may include obligations for periodic monitoring, establishment of regulated areas, implementation of control measures, and provision of medical surveillance.

Requirements for periodic monitoring depend on the results of initial monitoring. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring is required unless changes in the workplace result in new or additional exposures. If the initial determination reveals employee exposures to be at or above the action level but at or below the PEL, the employer must perform periodic monitoring at least every six months. If the initial monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring at least every three months.

The scheduled monitoring option also includes provisions to adjust the frequency of periodic monitoring based on monitoring results. If periodic monitoring results indicate that employee exposures have fallen below the action level, and those results are confirmed by consecutive measurements taken at least seven days apart, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. Similarly, if periodic monitoring measurements indicate that exposures are at or below the PEL but at or above the action level, the employer may reduce the frequency of the monitoring to at least every six months.

OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring provides the employer with assurance that employees are not experiencing higher exposures that may require the use of additional control measures. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to Cr(VI).

Because of the fluctuation in exposures, OSHA believes that when initial monitoring results equal or exceed the action level but are at or below the PEL, employers should continue to monitor employees to ensure that exposures remain at or below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an accurate profile of employee exposures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA believes that the frequency of six months for subsequent periodic monitoring for exposures at or above the action level but at or below the PEL, and three months for exposures above the PEL, provides intervals that are both practical for employers and protective for employees. This belief is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048).

OSHA recognizes that monitoring can be a time-consuming, expensive endeavor and therefore offers employers the incentive of discontinuing monitoring for employees whose sampling results indicate exposures are below the action level. The Agency does not believe that periodic monitoring is generally necessary when monitoring results show that exposures are below the action level because there is a low probability that the results of future samples would exceed the PEL. Therefore the final rule provides an incentive for employers to control their employees' exposures to Cr(VI) below the action level to minimize their exposure monitoring obligations while maximizing the protection of employees' health.

Under the scheduled monitoring option, employers are to perform additional monitoring when there is a change in production process, raw materials, equipment, personnel, work practices, or control methods, that may result in new or additional exposures to Cr(VI). For example, if an employer has conducted monitoring for an electroplating operation while using fume suppressants, and the use of fume suppressants is discontinued, then additional monitoring would be necessary to determine employee exposures under the modified conditions. In addition, there may be other situations which can result in new or additional exposures to Cr(VI) which are unique to an employer's work situation. For instance, a welder may move from an open, outdoor location to an enclosed or confined space. Even though the task performed and materials used may remain constant, the changed environment could reasonably be expected to result in higher exposures to Cr(VI). In order to cover those special situations, OSHA requires the employer to perform additional monitoring whenever the employer has any reason to believe that a change has occurred which may result in new or additional exposures. This additional monitoring is necessary to ensure that monitoring results accurately represent existing exposure conditions. This information will enable the employer to take appropriate action to protect exposed employees, such as instituting additional engineering controls or providing appropriate respiratory protection. On the other hand, additional monitoring is not required simply because a change has been made, if the change is not reasonably expected to result in new or additional exposures to Cr(VI). For example, monitoring may be conducted in an establishment when welding was performed on steel with 15% Cr content. If the establishment switches to a steel with 10% Cr content without changing any other aspect of the work operation, then additional exposures to Cr(VI) would not reasonably be expected, and additional monitoring would not be required.

The performance-oriented option allows the employer to determine the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data, historical monitoring data, or objective data sufficient to accurately characterize employee exposure to Cr(VI). This option is intended to allow employers flexibility in assessing the Cr(VI) exposures of their employees. Where the employer elects to follow this option, the exposure determination must be performed prior to the time the work operation commences, and must provide the same degree of assurance that employee exposures have been correctly characterized as air monitoring would. The employer is expected to reevaluate employee exposures when there is any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to Cr(VI).

When using the term ''air monitoring data'' in this paragraph, OSHA refers to initial and periodic Cr(VI) monitoring conducted to comply with the requirements of this standard, including the prescribed accuracy and confidence requirements. Historical monitoring data refers to Cr(VI) monitoring data that was obtained prior to the effective date of the final rule, where the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations, and where that monitoring satisfies all other requirements of this section, including the accuracy and confidence requirements described below.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating employee exposure to Cr(VI) associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Objective data demonstrate the Cr(VI) exposures associated with a work operation or product under the range of expected conditions of use. For example, data collected by a trade association from its members may be used to determine exposures to Cr(VI) provided the data meet the definition of objective data in the standard.

Previous OSHA substance-specific health standards have usually allowed employers to use objective data to characterize employee exposures, but have generally limited its use to demonstrating that exposures would be below the action level (*e.g.*, the Cadmium standard, 29 CFR 1910.1027(d)(2)(iii)). Likewise, use of historical monitoring data has typically been allowed, but has usually been limited to data obtained within the previous 12 months (*e.g.*, the Methylene Chloride standard, 29 CFR 1910.1052(d)(2)(ii)). In this instance, OSHA does not place these limitations on the use of historical monitoring data or objective data. However, the burden is on the employer to show that the data comply with the requirements of this section. For example, historical monitoring data obtained 18 months prior to the effective date of the standard could be used to determine employee exposures, but only if the employer could show that the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations, and that the monitoring satisfies all other requirements of this section, including the accuracy and confidence requirements. OSHA's intent is to allow employers the greatest possible flexibility in methods used to determine employee exposures to Cr(VI), but to ensure that the methods used are accurate in characterizing employee exposures.

Under paragraph (d)(4) of the final rule, employers covered by the general industry standard must notify each affected employee within 15 working days if the exposure determination indicates that employee exposure exceeds the PEL. In construction and shipyards, employers must notify each affected employee as soon as possible but not more than 5 working days after the exposure determination indicates that employee exposure exceeds the PEL. A shorter time period for notification is provided in construction and shipyards in recognition of the often short duration of operations and employment in particular locations in these sectors. The time allowed for notification is consistent with the harmonized notification times established for these sectors in Phase II of OSHA's Standards Improvement Project (70 FR 1112 (1/5/05)). Where the employer follows the scheduled monitoring option, the 15 (or 5) working day period commences when monitoring results are received. For employers following the performance-oriented option, the 15 (or 5) working day period commences when the determination is made (*i.e.*, prior to the time the work operation commences, and when exposures are reevaluated).

When using the term ''affected employees'' in this provision, OSHA is referring to all employees considered to be above the PEL. This would include employees who are not actually subject to personal monitoring, but are represented by an employee who is sampled. Affected employees also include employees whose exposures have been deemed to be above the PEL on the basis of historical or objective data. The employer shall either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce the employee's exposure to or below the PEL. The requirement to inform employees of the corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the Act.

Paragraph (d)(5) of the final rule requires the employer to use monitoring and analytical methods that can measure airborne levels of Cr(VI) to within an accuracy of plus or minus 25% (±25%) and can produce accurate measurements to within a statistical confidence level of 95% for airborne concentrations at or above the action level. Many laboratories presently have methods to measure Cr(VI) at the action level with at least the required degree of accuracy. One example of an acceptable method of monitoring and analysis is OSHA method ID215, which is a fully validated analytical method used by the Agency. (See Chapter III of the FEA for a discussion of issues regarding methods of sampling and analysis). Rather than specifying a particular method that must be used, OSHA allows the employer to use any method as long as the chosen method meets the accuracy specifications. This is consistent with the general performance approach favored in the OSH Act.

Paragraph (d)(6) requires the employer to provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to Cr(VI), whether the employer uses the scheduled monitoring option or the performance-oriented option. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, and assure that the observer uses such clothing or equipment and complies with all other required safety and health procedures.

The requirement for employers to provide employees or their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the OSH Act mandates that regulations developed under Section 6 provide employees or their representatives with the opportunity to observe monitoring or measurements. Also, Section 6(b)(7) of the OSH Act states that where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

(e) Regulated Areas

Paragraph (e) of the final rule requires general industry employers to establish regulated areas wherever an employee's exposure to airborne concentrations of Cr(VI) is, or can reasonably be expected to be, in excess of the PEL. Regulated areas are to be demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees to the boundaries of these areas. Access to regulated areas is to be limited to persons authorized by the employer and required by work duties to be present in the regulated area; any person entering the regulated area to observe monitoring procedures; or any person authorized by the OSH Act or regulations issued under it to be in a regulated area.

The purpose of a regulated area is to ensure that the employer makes employees aware of the presence of Cr(VI) at levels above the PEL, and to limit Cr(VI) exposure to as few employees as possible. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to have carcinogenic effects. Because of the potentially serious results of exposure and the need for persons exposed above the PEL to be properly protected, the number of persons given access to the area must be limited to those employees needed to perform the job. Limiting access to regulated areas also has the benefit of reducing the employer's obligation to implement provisions of this standard to as few employees as possible.

In keeping with the performance orientation of this standard, OSHA has not specified how employers are to demarcate regulated areas. OSHA proposed that warning signs be posted at all approaches to regulated areas, and set forth specific language in paragraph (1) of the proposed standard to be included on the warning signs. However, OSHA has determined that other means of demarcation such as barricades, lines and textured flooring, or signs using other language can be equally effective in identifying the boundaries of regulated areas and notifying employees of associated hazards, the need to restrict access to such areas, and protective measures to be implemented. The specific language for warning signs included in paragraph (1) of the proposal, and the reference to that language in this provision, have therefore been deleted from the final rule.

In the final rule, OSHA thus has provided employers with the flexibility to use the methods of demarcation that are most appropriate for identifying regulated areas in their workplace. Factors that the Agency believes are appropriate for employers to consider in determining how to mark their areas include the configuration of the area, whether the regulated area is permanent, the airborne Cr(VI) concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on their knowledge of the specific conditions of their workplaces. Whatever methods are chosen, the demarcation must effectively warn employees not to enter the area unless they are authorized, and then only if they are using the proper personal protective equipment. Allowing employers to demarcate and limit access to the regulated areas as they choose is consistent with OSHA's two most recent substance-specific health standards, addressing occupational exposure to methylene chloride (29 CFR 1910.1052(e)) and 1,3-butadiene (29 CFR 1910.1051(e)).

Access to the regulated area is restricted to ''authorized persons.'' For the purposes of this standard, these are persons required by their job duties to be present in the area, as authorized by the employer. This may include maintenance and repair personnel, management, quality control engineers, or other personnel if job duties require their presence in the regulated area. In addition, persons exercising the right to observe monitoring procedures are allowed to enter regulated areas when exposure monitoring is being conducted. Persons authorized under the OSH Act, such as OSHA compliance officers, are also allowed access to regulated areas.

In the final rule, OSHA has not included a requirement for regulated areas in construction and shipyard workplaces, due to the expected practical difficulties of establishing regulated areas for operations in these sectors. OSHA raised the issue of requiring regulated areas for these workplaces and received comments and testimony from a variety of sources. A number of commenters supported not requiring regulated areas in construction and shipyards (Exs. 38–214; 38–220; 38–235; 38–236; 38–244; 39–37; 39–20; 39–40; 39–48; 39–64; 39–65). The National Association of Home Builders, for example, indicated that regulated areas are not feasible on residential construction jobsites because the area where exposures would exceed the PEL could not be accurately determined, stating:

> Because of the fluid nature of construction work and the ever-changing work environment, a regulated area could never be accurately determined due to the fact that construction areas are mostly exposed to the ambient environment. Factors such as shifting winds, tight work areas and multiple operations adjacent to the regulated area would create changes in air movement and would make establishment of a regulated area unattainable (Ex. 38–244).

Associated Builders and Contractors concurred with this assessment, and maintained that establishment of regulated areas could interfere with construction operations:

> The nature of construction sites makes it extremely difficult to close off certain areas from others without shutting down or interfering with significant construction activities (Ex. 39–65).

Some commenters maintained that certain activities should not be subject to requirements for regulated areas (Exs. 38–7, p. 5; 38–124; 38–203; 38–205; 38–228; 38–233; 38–238; 38–254; 39–19; 39–56; 39–62). The Office of Advocacy of the Small Business Administration, for example, stated that requirements for regulated areas should be limited to industries and processes where they would likely reduce exposures, arguing that establishment of regulated areas would have the effect of requiring respirators or other controls for more employees than necessary (Ex. 38–7). Because regulated areas are required only where exposures exceed the PEL, OSHA considers that these requirements are limited to situations where they can reduce exposures. As mentioned previously, making employees aware of potential exposures in excess of the PEL and limiting the number of employees present in regulated areas will effectively reduce exposures to Cr(VI). Moreover, establishment of regulated areas will not result in additional requirements for respirators or other controls, because requirements for these other control measures are not directly related to the establishment of regulated areas. Simply entering a regulated area, for example, does not trigger a requirement for use of respiratory protection.

Other commenters maintained that certain general industry activities, or general industry as a whole, should not be subject to the proposed requirements for regulated areas. Alabama Power, for example, indicated that the same rationale used to justify the absence of regulated area requirements in construction and shipyards also applied to general industry environments such as power plants (Exs. 38–254; 38–203). Others argued that regulated areas were not appropriate for specific activities such as welding (Ex. 38–124), job shop fabrication (Exs. 38–238; 39–62), or glass manufacturing (Ex. 38–228).

Other commenters expressed support for regulated area requirements, arguing that they were a feasible and useful means of protecting workers, and should apply to construction and shipyards as well as general industry workplaces (Exs. 38–199–1; 38–219; 38–222; 39–38; 39–71; 40–10–2; 47–28). For example, NIOSH indicated that regulated areas help minimize exposures to bystanders in construction and shipyard worksites:

> * * * regulated areas are important on construction and shipyard worksites because of the potential for ‘‘bystander’’ exposures given that it is common for employees from different trades to work in close proximity. For construction, bystander employees may work for different employers, thus complicating control efforts (Ex. 40–10–2).

Regulated areas, it was argued, are not unduly burdensome. Dr. Franklin Mirer of the United Auto Workers, when asked if he foresaw problems with requirements for regulated areas, stated:

> * * * you put a sign [up] and you tell people who don’t have to be there not to be there * * * what’s burdensome about that? It’s like * * * putting up a sign on the ladies room. Certain people can’t go in that regulated area (Tr. 837).

OSHA believes, however, that Dr. Mirer oversimplifies the situation. The difficulty is not with the mere physical act of putting up a sign at a regulated area, but rather with determining where, when, and for how long a duration to establish a regulated area. Making these determinations is very problematic given the varied and changing nature of the operations involving Cr(VI) exposures at construction and shipyard worksites. Moreover, areas where employees are exposed above the PEL might change on a daily or even hourly basis and may occur at different sites on the worksite than they did the day before, making it unreasonably difficult to keep up with the posting (and removal) of signs, barricades or other warning in a manner that would effectively let employees know about the hazard.

OSHA has concluded that requirements for regulated areas are appropriate for general industry, but not for construction and shipyards, because the work sites and conditions and other factors, such as environmental variability normally present in construction and shipyard employment, differ substantially from those typically found in general industry. Construction and shipyard tasks are often of relatively short duration; are commonly performed outdoors, sometimes under adverse environmental conditions (*e.g.*, wind, rain); and are often performed at non-fixed workstations or work sites. Collectively, these factors make establishment of regulated areas impracticable for many construction and shipyard operations.

These difficulties are particularly evident with regard to welding operations in construction and shipyard workplaces. Welding is the predominant source of Cr(VI) exposures in these sectors, accounting for over 82% of employees exposed above the PEL in construction and over 73% of employees exposed above the PEL in shipyards. Welding operations in construction and shipyards often involve movement to different locations during the workday, and welding fumes are highly subject to changes in air currents, meaning the exposure patterns can shift rapidly.

In the typical shipyard and construction project involving exposure, it is difficult to determine appropriate boundaries for regulated areas because the work and worksite are varied and subject to environmental influences. Moreover, workers are often moving from place to place throughout the site on a regular basis. While each employer has the obligation under the requirements of paragraph (d) of this final rule to determine Cr(VI) exposures for all employees, accurately demarcating all areas where Cr(VI) exposures could potentially exceed the PEL is a separate and potentially much more difficult undertaking. In general industry environments, which are typically more stable, likely to be indoors, and usually at a fixed location, this can generally be accomplished with minimal difficulty. In construction and shipyard workplaces, for the reasons described above, OSHA has determined that establishing regulated areas to control exposures to Cr(VI) can not reasonably be accomplished, and has therefore not included a requirement for regulated areas for these sectors in the final rule.

The Agency realizes that in some cases general industry work operations and work environments may be comparable to those found in construction and shipyards, and where the general industry employer can show compliance is not feasible, regulated areas will not have to be established. However, OSHA believes its longstanding distinction between these sectors provides an appropriate line for delineating between those operations where the employer generally is reasonably able to establish regulated areas where exposures to Cr(VI) exceed the PEL versus operations where regulated areas are generally not practicable.

OSHA recognizes that the determination not to include requirements for regulated areas for construction and shipyards in this final rule differs from the determinations made in previous rulemakings. The AFL–CIO pointed out that a number of previous standards including those for asbestos, cadmium, benzene, 1,2-dibromo-3-chloropropane, ethylene oxide, methylenedianiline, formaldehyde, and 1,3 butadiene, included provisions for regulated areas in construction (Exs. 38–222; 47–28–1). It is important to note, however, that many of these standards such as benzene, 1,2-dibromo-3-chloropropane, ethylene oxide, methylenedianiline, and formaldehyde involved relatively few exposures in construction operations. For example, in the preamble to the final benzene standard OSHA concluded that while the standard would cover construction, ''The standard has virtually no impact on construction'' (52 FR at 34527). Similarly, requirements for regulated areas in the standard for cadmium in construction did not pose major problems for employers, because few workers were expected to be exposed above the PEL and thus subject to requirements for regulated areas. More importantly, in the cadmium rulemaking as in others discussed below, regulated areas for construction were not at issue because so few employees were potentially exposed above the PEL. Thus, the Agency did not address the factors that were presented in this rulemaking.

OSHA's standards for lead in construction and asbestos in construction, on the other hand, affect relatively large numbers of employers and employees. The standard for lead in construction is a notable exception to the AFL–CIO's list. OSHA did not include requirements for regulated areas in that standard (see 29 CFR 1926.62). While the asbestos construction standard does include requirements for regulated areas, the classification scheme for asbestos construction operations (*i.e.*, Class I, II, III and IV) and requirements for enclosing many work operations makes establishment of regulated areas easier for employers. (see 29 CFR 1926.1101). The Agency believes that the broad scope of the Cr(VI) final rule for construction, similar to the standard covering lead construction operations, would make application of regulated area requirements substantially more difficult than is the case for a standard with a much more limited scope, such as the standards for cadmium or benzene in construction.

Finally, in none of the previous health standards were the particular difficulties of implementing regulated areas for shipyard and construction work specifically considered as they have been in this rulemaking. In this rulemaking, the establishment of regulated areas was a major issue with a significant volume of comments and testimony, allowing OSHA to fully consider the matter in light of the specific nature of Cr(VI) exposures. First, OSHA's proposal did not include regulated areas in construction and shipyard employment. Secondly, in the proposal, OSHA included two general questions, numbers 31 and 32, on modifying the requirements for construction and shipyard employment and one very specific question, number 47, on whether regulated areas should be included for construction and shipyard employment (69 FR 59452, 59310). Thus, the public had sufficient notice and OSHA was able to weigh the evidence, ultimately finding the reasons for excluding regulated areas from construction and shipyard employment persuasive.

(f) Methods of Compliance

Paragraph (f) of the final rule (paragraph (e) for construction and shipyards) establishes which methods must be used by employers to comply with the PEL. It requires that employers institute effective engineering and work practice controls as the primary means to reduce and maintain employee exposures to Cr(VI) to levels that are at or below the PEL unless the employer can demonstrate that such controls are not feasible. Where the employer demonstrates that such controls are not feasible, the final rule requires the employer to institute engineering and work practice controls to reduce exposures to the lowest feasible level. The employer is then required to supplement these controls with respiratory protection to achieve the PEL.

A number of commenters supported OSHA's inclusion of the hierarchy of controls in the final Cr(VI) rule (*e.g.*, Tr. 826, Exs. 38–232; 38–235; 38–238; 39–20; 39–47; 40–10–2; 47–23; 47–26). For example, NIOSH endorsed the use of engineering and work practice controls as primary methods of controlling exposures to Cr(VI) (Ex. 40–10–2). Personal protective equipment such as respirators was regarded by NIOSH as the last line of defense, to be used only when engineering controls are not feasible. Other commenters objected to OSHA's proposed application of the hierarchy of controls in the Cr(VI) rule, arguing that use of respiratory protection instead of engineering controls should be allowed in a variety of different situations (*e.g.*, Exs. 38–204; 38–215; 38–216–1; 38–218; 38–233; 39–51; 39–66; 43–14; 47–30; 47–31; 47–32). For example, the National Paint and Coatings Association contended that respirator use should be permitted in paint and coatings manufacture:

> * * * exposures to hexavalent chromium compounds are limited in time and place, and their handling is seldom encountered by other[sic] than a relatively small number of workers, whose use of respirators would not pose most of the problems OSHA associates with respirators * * * (Ex. 39–66).

OSHA is requiring primary reliance on engineering controls and work practices because reliance on these methods is consistent with good industrial hygiene practice, with the Agency's experience in assuring that workers have a healthy workplace, and with the Agency's traditional adherence to a hierarchy of preferred controls. Engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored, allow for predictable performance levels, and can efficiently remove a toxic substance from the workplace. Once removed, the toxic substance no longer poses a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of equipment is not as vulnerable to human error as is personal protective equipment.

Engineering controls can be grouped into three main categories: (1) Substitution; (2) isolation; and (3) ventilation, both general and localized. Quite often a combination of these controls can be applied to an industrial hygiene control problem to achieve satisfactory air quality. It may not be necessary to apply all these measures to any specific potential hazard.

Substitution can be an ideal control measure. One of the best ways to prevent workers from being exposed to a toxic substance is to stop using it entirely. Although substitution is not always possible, replacement of a toxic material with a less hazardous alternative should always be considered.

In those cases where substitution of a less toxic material is not possible, substituting one type of process for another process may provide effective control of an air contaminant. For example, process changes from batch operations to continuous operations will usually reduce exposures. This is true primarily because the frequency and duration of workers' potential contact with process materials is reduced in continuous operations. Similarly, automation of a process can further reduce the potential hazard.

In addition to substitution, isolation should be considered as an option for controlling employee exposures to

Cr(VI). Isolation can involve containment of the source of a hazard, thereby separating it from most workers. Workers can be isolated from Cr(VI) by working in a clean room or booth, or by placing some other type of barrier between the source of exposure and the employee. Employees can also be protected by being placed at a greater distance from the source of Cr(VI) emissions.

Frequently, isolation enhances the benefits of other control methods. For example, Cr(VI) compounds may be used in the formulation of certain paints. If the mixing operation is conducted in a small, enclosed room the airborne Cr(VI) potentially generated by the operation could be confined to a small area. By ensuring containment, local exhaust ventilation is more effective.

Ventilation is a method of controlling airborne concentrations of a contaminant by supplying or exhausting air. A local exhaust system is used to remove an air contaminant by capturing the contaminant at or near its source before it spreads throughout the workplace. General ventilation (dilution ventilation), on the other hand, allows the contaminant to spread throughout the work area but dilutes it by circulating large quantities of air into and out of the area. A local exhaust system is generally preferred to dilution ventilation because it provides a cleaner and healthier work environment.

Work practice controls involve adjustments in the way a task is performed. In many cases, work practice controls complement engineering controls in providing worker protection. For example, periodic inspection and maintenance of process equipment and control equipment such as ventilation systems is an important work practice control. Frequently, equipment which is in disrepair or near failure will not perform normally. Regular inspections can detect abnormal conditions so that timely maintenance can then be performed. If equipment is routinely inspected, maintained, and repaired or replaced before failure is likely, there is less chance that hazardous exposures will occur.

Workers must know the proper way to perform their job tasks in order to minimize their exposure to Cr(VI) and to maximize the effectiveness of control measures. For example, if an exhaust hood is designed to provide local ventilation and a worker performs a task that generates a contaminant away from the exhaust hood, the control measure will be of no use. Workers can be informed of proper operating procedures through information and training. Good supervision further ensures that proper work practices are carried out by workers. By persuading a worker to follow proper procedures, such as positioning the exhaust hood in the correct location to capture the contaminant, a supervisor can do much to minimize unnecessary exposure.

Employees' exposures can also be controlled by scheduling operations with the highest exposures at a time when the fewest employees are present. For example, routine clean-up operations that involve Cr(VI) releases might be performed at night or at times when the usual production staff is not present.

Respirators are another important, although less preferred, method of compliance. However, to be effective, respirators must be individually selected; fitted and periodically refitted; conscientiously and properly worn; regularly maintained; and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any of these conditions can reduce or eliminate the protection the respirator provides to some of all of the employees.

Respirator effectiveness ultimately relies on the good work practices of individual employees. In contrast, the effectiveness of engineering controls does not rely so routinely on actions of individual employees. Engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace as a whole, while respirators protect only the employees who are wearing them correctly. Furthermore, engineering and work practice controls permit the employer to evaluate their effectiveness directly through air monitoring and other means. It is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. OSHA therefore considers the use of respirators to be the least satisfactory approach to exposure control.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators can impose substantial physiological burdens on employees, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and odor sensations; and isolation from the workplace environment. Job and workplace factors such as the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity can also impose physiological burdens on workers wearing respirators. These stressors may interact with respirator use to increase the physiological strain experienced by employees.

Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. These medical conditions include cardiovascular and respiratory diseases (*e.g.*, a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), reduced pulmonary function caused by other factors (*e.g.*, smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (*e.g.*, epilepsy, lower back pain), and impaired sensory function (*e.g.*, a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease.

These concerns about the burdens placed on workers by the use of respirators were acknowledged in OSHA's revision of its Respiratory Protection standard, and are the basis for the requirement that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace (63 FR 1152, 1/8/98). Although experience in industry shows that most healthy workers do not have physiological problems wearing properly chosen and fitted respirators, nonetheless common health problems can cause difficulty in breathing while an employee is wearing a respirator.

In addition, safety problems created by respirators that limit vision and communication must always be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult, annoying, and fatiguing. In addition, movement of the jaw in speaking can cause leakage, thereby reducing the efficiency of the respirator and decreasing the protection afforded the employee. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to workers and can cause workers to refrain from wearing the respirator, thereby rendering it ineffective.

Because respirators are less reliable than engineering and work practice controls and may create additional problems, OSHA believes that primary reliance on respirators to protect workers is generally inappropriate when feasible engineering and work practice controls are available. All OSHA substance-specific health standards have recognized and required employers to observe the hierarchy of controls, favoring engineering and work practice controls over respirators. Moreover, OSHA's enforcement experience with these standards has reinforced the importance of this concept in the protection of employee health.

The Color Pigment Manufacturers Association suggested that supplied air respirators provide an acceptable alternative to engineering controls in many circumstances (Ex. 38–205, p. 44). The American Foundry Society concurred with this opinion (Ex. 43–14). They claimed that supplied air hoods do not present the problems and limitations associated with the use of other respirators and are more reliable and effective than most engineering controls (Tr. 1713–1717, Exs. 38–205; 43–14). The National Paint and Coatings Association (NPCA) indicated that Cr(VI) exposures in paint and coatings manufacturing are sporadic and are limited to a small number of processes and a few workers (Ex. 39–66). NPCA believed these exposures could be effectively controlled with modern air purifying or supplied air respirators (Ex. 39–66).

While OSHA acknowledges that certain types of respirators may lessen problems associated with breathing resistance and skin discomfort, these respirators may still present safety concerns of their own. OSHA does not believe that respirators provide employees with a level of protection that is equivalent to engineering controls, regardless of the type of respirator used. To summarize: engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace; respirators only protect the employees who are wearing them. In addition, the effectiveness of respiratory protection always depends on the actions of employees, while the efficacy of engineering controls is generally independent of the individual.

It is well-recognized that certain types of respirators are superior to other types of respirators with regard to the level of protection offered, or impart other advantages. OSHA is currently evaluating the level of protection offered by different types of respirators in the Agency's Assigned Protection Factors rulemaking (68 FR 34036, 6/6/03). However, OSHA believes that engineering controls offer more reliable and consistent protection to a greater number of workers, and are therefore preferable to any type of respiratory protection.

Collier Shannon Scott, on behalf of various steel industry groups, maintained that OSHA should allow use of respiratory protection as a primary control to achieve the PEL where respiratory protection is currently used to comply with another OSHA standard (Exs. 38–233; 40–12). Without such an allowance, it was claimed, employers would have to add additional controls where employees are already wearing respirators, which would impose ''significant burden and expense on the employer with no attendant benefit to the employee'' (Ex. 38–233, p. 34). If an employer has adopted all feasible engineering controls to address other workplace exposures (e.g., lead, cadmium), and no other feasible engineering controls are available to limit Cr(VI) exposures, the final Cr(VI) rule would not require additional engineering controls to meet the new Cr(VI) PEL. On the other hand, if additional feasible engineering controls are available that would reduce Cr(VI) exposures that exceed the PEL, then these controls would justifiably be required. OSHA believes these additional engineering controls would better protect employees. As discussed previously, OSHA considers engineering controls to be the most effective method of protecting employees and allows respiratory protection only where such controls have been found infeasible.

A number of responses to the proposal commented on the possibility of including separate engineering control air limits, or SECALs, in the final Cr(VI) rule. Several commenters maintained that SECALs were unnecessary (Exs. 38–214; 38–220; 39–20). The majority of respondents who expressed an opinion on this issue supported the use of SECALs (Tr. 373, 1701, 1732, Exs. 38–205; 38–215; 38–216; 38–218; 38–231; 39–43; 47–30). However, it was apparent that these commenters did not have a common understanding of the basis for establishing SECALs or their application in the workplace.

SECALs were included in one previous OSHA rule, the Cadmium standard for general industry (29 CFR 1910.1027). In that rule, SECALs were based on a two tiered approach to controlling worker exposures. As described in the preamble to the final rule:

> The first tier would be a PEL, set at the level required by the health science data to protect workers' health. The PEL, in the case of industries where compliance by means of engineering and work practice controls was infeasible, could be achieved by any allowable (e.g., not worker rotation) combination of work practice and engineering controls and respirators. The second tier would be set above the PEL at the lowest feasible level that could be achieved by engineering and work practice controls (57 FR 42389, 9/14/92).

Thus, employers in all industries covered by the cadmium standard were required to use engineering and work practice controls to the extent feasible to achieve the PEL. For specified processes in particular industries, SECALs provided explicit recognition of the lowest exposure level that could feasibly be achieved with engineering and work practice controls. Respirators could then be used as supplementary controls to reduce exposures to the PEL.

While the cadmium standard is the only standard to use the term ''SECAL'' other standards have adopted the same approach. For example, although the PEL in the lead standard is set at 50 $\mu g/m^3$ (29 CFR 1910.1025(c)) the brass and bronze ingot manufacture industry sector is only required to achieve a lead in air concentration of 75 $\mu g/m^3$ through engineering and work practice controls (29 CFR 1910.1025(e)(1) Table I, n.3). As with all industry sectors, brass and bronze ingot manufacture must provide respiratory protection to supplement engineering and work practice controls if they cannot achieve the PEL. Similarly, the asbestos standard exempts certain specified operations from meeting the PEL of 0.1 fiber per cubic centimeter of air (0.1 fiber/cm^3) through engineering controls, but requires such operations to use such controls to get down to 0.5 fiber/cm^3 or 2.5 fibers/cm^3 for short term exposures and to provide supplemental respiratory protection (29 CFR 1910.1001(f)(1)(iii)).

Public Citizen maintained that SECALs could be used to provide a more protective PEL. According to Public Citizen, technological feasibility considerations applicable to a relatively small number of workers should not form the basis for establishing a PEL. They said that if OSHA determines that a lower PEL is not feasible in limited applications through use of engineering and work practice controls, the Agency should use SECALs to allow for use of respirators in those applications (Tr. 721, Ex. 47–23). However, SECALs (or equivalent provisions) can only be applied to discrete operations that can be distinguished from other sources of Cr(VI) exposure. As discussed with regard to the PEL in paragraph (c) of this Summary and Explanation, this is not the case for most operations involving Cr(VI) exposure. Moreover, and also as discussed with regard to paragraph (c), the established test for technological feasibility for standards requires that the PEL be achieved in most operations with engineering and work practice controls.

On the other hand, a number of commenters supported SECALs in the belief that they would lessen the burdens imposed on employers. These parties appeared to believe that SECALs would allow them to circumvent the hierarchy of controls and use respiratory protection to achieve the PEL, even when feasible engineering controls were available. This approach was advocated by Elementis Chromium and the Chrome Coalition (Exs. 38–216; 38–231).

As discussed previously, OSHA considers engineering and work practice controls to be superior to respiratory protection for controlling workplace exposures to Cr(VI). The Agency, therefore, does not consider it appropriate to allow regular use of respirators to achieve the PEL when feasible engineering and work practice controls are available. The scenario envisioned by some commenters, which apparently involves a SECAL established at some point higher than the lowest level achievable with engineering and work practice controls, would therefore compromise worker safety by allowing an inferior method of control to substitute for a superior and feasible method.

OSHA does recognize, however, that an administrative burden can be relieved by providing explicit recognition in the final rule of operations where the PEL cannot be achieved through use of engineering and work practice controls alone. In these instances, absent recognition of infeasibility in the standard, the employer would need to be able to demonstrate that feasible engineering and work practice controls could not achieve the PEL.

As discussed in Chapter III of the Final Economic Analysis, OSHA has determined that during certain painting operations in the aerospace industry, the PEL of 5 μg/m^3 cannot be achieved with engineering and work practice controls (Ex. 49). In these operations, the evidence indicates that employee exposure to Cr(VI) can feasibly be reduced to 25 μg/m^3 using engineering and work practice controls; respiratory protection is necessary to supplement these controls to achieve the PEL. Accordingly, a provision has been added to the final rule recognizing the limitations of engineering and work practice controls in controlling Cr(VI) exposures where painting of aircraft or large aircraft parts is performed in the aerospace industry. In using the term ''aircraft or large aircraft parts'' OSHA is referring to the interior or exterior of whole aircraft, aircraft wings, tail sections, wing panels and rocket sections, large aircraft body sections, control surfaces such as rudders, elevators, and ailerons, or comparably sized aircraft parts. Thus, in these operations employee exposures must be reduced to 25 μg/m^3 or less using engineering and work practice controls. Respiratory protection will then need to be used to achieve the PEL.

There may even be some situations where the engineering and work practice controls cannot achieve exposures of 25 μg/m^3. The final rule recognizes this and addresses this by permitting the employer to demonstrate the infeasibility of achieving 25 μg/m^3 with these controls. In these limited circumstances the employer would be permitted to further rely on respirators to protect employees.

OSHA acknowledges that engineering and work practice controls cannot feasibly achieve the PEL in some specific operations. In particular, OSHA is aware that the use of engineering and work practice controls to comply with the PEL is infeasible for some maintenance and repair operations and during emergency situations. These situations are recognized in paragraph (g) of the final rule (paragraph (f) for construction and shipyards), which addresses use of respiratory protection where employers can demonstrate that engineering and work practice controls are not feasible. In such situations, the burden of proof is appropriately placed on the employer to make and support a claim of infeasibility because the employer has better access to information specific to the particular operation that is relevant to the issue of feasibility.

An exception to the general requirement for primary reliance on engineering and work practice controls is included in the final rule for employers who do not have employee exposures above the PEL for 30 or more days per year (during 12 consecutive months) in a particular process or task. Thus, if a particular process or task causes employee exposures to Cr(VI) that exceed the PEL on 29 or fewer days during any 12 consecutive months, the employer is allowed to use any combination of controls, including respirators alone, to achieve the PEL. The obligation to implement engineering and work practice controls to comply with the PEL is not triggered until a process or task causes employees to be exposed above the PEL on 30 or more working days during a year.

The employer may use this exception if he or she can demonstrate that a process or task will not cause employee exposures above the PEL for 30 or more days per year (12 consecutive months). The burden of proof is on the employer to show that exposures do not exceed the PEL on 30 or more days per year. OSHA believes this provision provides needed flexibility to employers, while still providing adequate protection for workers.

Under current exposure conditions, the primary adverse health effect addressed by this final rule (i.e., lung cancer) is associated with cumulative exposure to Cr(VI). Thus, assuming stable exposure levels, the fewer number of days that a worker is exposed, the lower the risk incurred. Consequently, some exception based on the number of days of exposure is justified.

OSHA realizes that in some industries (e.g., color pigment manufacturing), exposure to Cr(VI) is typically infrequent (i.e., fewer than 30 days, over 12 consecutive months). For example, certain Cr(VI) processes may occur only several days a year when production of a particular product is needed. Under such conditions, it may not be cost effective or very beneficial to workers' health for employers to invest the monies needed to install engineering controls to control Cr(VI) to the PEL. Without this exception, employers would be required to implement feasible engineering controls and work practice controls wherever employees are exposed to Cr(VI) above the PEL, even if they are only exposed on one or several days a year. OSHA believes that the expense of implementing engineering controls in such circumstances is not reasonable.

A number of commenters expressed general support for this exception (*e.g.*, Tr. 1426–1427, 1730; Exs. 38–205; 38–218; 38–220; 38–235; 39–19; 39–20; 39–47; 39–51; 40–1; 47–31). For example, the Navy expressed the view that this provision allowed employers to focus on the most serious hazards:

> This 30-day threshold approach reflects the reality and challenges of the Maritime Industry and has value in the shipbuilding and repair industry. The concept allows employers to focus engineering and work practice controls on those operations having the potential to result in the greatest cumulative exposure while providing the

flexibility to address lower-exposure operations based on a hazard assessment approach (Ex. 38–220).

Some commenters requested that the parameters of the exception be expanded to apply to exposures that occur more frequently, but for short durations of time (e.g., a few minutes per day), or to a longer time period (i.e., a greater number of days)(Tr. 558–559, 1807–1809, Exs. 38–218; 38–205; 47–31). Another commenter argued that, if an exception was to be included in the final rule, it should be limited to situations where exposure at *any* level occurs on fewer than 30 days (Ex. 39–71).

OSHA believes that the threshold exposure duration of fewer than 30 days per year is appropriate. With this exception, OSHA intends to provide relief exclusively to employers whose operations result in employee exposure to Cr(VI) at or above the PEL only for short periods of time. Because the PEL is expressed as an 8-hour time-weighted average, it is appropriate to express this exception in terms of a given number of days. Exposures that occur for short durations of time during the day are balanced by longer time periods when no exposure occurs. The PEL therefore already addresses most situations where exposures occur for only a few minutes during the day. If the brief exposures are so high that they cause the 8-hour time weighted average exposure to exceed the PEL, it is appropriate that they be considered equivalent to other exposure scenarios where the PEL is exceeded.

The question, then, is what number of days should be selected as the maximum, above which engineering and work practice controls must be implemented. There is no simple, scientifically definitive answer to this question. OSHA believes that the choice of 30 or more working days per year provides a reasonable balance between the preference for the more reliable engineering and work practice controls, and the desire to focus resources on those exposures that present the greatest risks to workers.

The choice of providing the limited exception for exposures on fewer than 30 working days per year is also consistent with the lead and cadmium standards, which incorporate a similar exception. Further, the 30 day exception is congruent with the 30 day exposure trigger for medical surveillance included in paragraph (k) of this standard (paragraph (i) for construction and shipyards), which simplifies the application of these provisions where employee exposures are tied to a single process or task. For example, if an employer has employees exposed to Cr(VI) while performing a single process or task, and the employer determines that exposures do not occur on 30 or more days per year, the employer has established that (1) any combination of controls can be used to achieve the PEL; and (2) no medical surveillance is necessary unless an employee develops signs or symptoms of the adverse health effects associated with Cr(VI) exposure or is exposed in an emergency situation. In any event, OSHA believes that the 30 day designation is reasonable and no other number of days would be a more appropriate benchmark. The Agency concludes the 30 working day exclusion will make the standard more flexible in workplaces where exposure days are limited.

Several commenters did not believe that an exception to the general requirement for use of engineering and work practice controls should be included in the final Cr(VI) rule (Tr. 558–559, 766, 1433, 1807, Exs. 38–199; 38–214; 38–219; 39–71; 40–10–2; 40–18–1; 40–19–1). For example, NIOSH maintained that such a provision would represent a significant weakening of the requirement for priority of engineering controls in preference to respirators (Ex. 40–10–2). OSHA agrees that engineering and work practice controls are generally superior to respirators. However, as discussed earlier, the Agency believes an exception for a limited duration of exposure is a reasonable way to focus resources on areas where the highest exposures are likely to occur and that the requirement for respirator use in these situations will provide sufficient protection for these workers.

Several respondents contended that it would be difficult to track employee exposure days, apparently believing that the exemption would be based on the exposures of individual workers, rather than the exposures created by a process or task (e.g., Tr. 1433, Ex. 40–19–1). OSHA intends for this exception to be process-or task-based: i.e., it is specific to a process where engineering controls might be implemented to reduce exposures to or below the PEL. For example, an employer might have two processes, A and B, where A involves an ongoing process in the facility with exposures above the PEL for 30 or more days and another process, B, that results in exposures above the PEL for 29 or fewer days per year. The fact that the employer has employees exposed above the PEL for more than 30 days in process A will not be used to determine that engineering and work practice controls have to be used for process B. OSHA intends this exception to be similarly applied by process or task in the construction and shipyard environments where employees may move from one work site to another.

By basing the exception on the process or task being performed, OSHA aims to preclude employers from using job rotation as a means of limiting the number of days individual employees are exposed above the PEL. Job rotation does not reduce the risk faced by workers, but only distributes that risk among a larger worker population. Therefore, OSHA considers the process or task to be the appropriate basis for applying this exception, rather than basing an exception on the number of days that an individual worker is exposed.

Some responses to the proposal did not consider the criteria used to qualify for the exception to be sufficiently clear (Tr. 765, Exs. 39–65; 40–18–1). The proposal indicated that this exception would apply where the employer ‘‘has a reasonable basis for believing that no employee in a process or task will be exposed above the PEL for 30 or more days per year.’’ To clarify the Agency’s intent, this language has been modified to indicate that the employer can take advantage of the exception when he or she ‘‘can demonstrate that no employee in a process or task will be exposed above the PEL for 30 or more days per year.’’ This revised language makes clear that the employer has the burden to demonstrate that a process or task does not result in employee exposures above the PEL for 30 or more days per year. The burden of proof is placed on the employer because the employer has access to the necessary information about employee exposure levels and processes and tasks at the worksite. Where existing information is inadequate, the employer is also in the best position to develop the necessary information.

Historical data, objective data, or exposure monitoring data may be used to demonstrate that employees will not be exposed above the PEL for 30 or more days per year. Other information, such as production orders showing that processes involving Cr(VI) exposures are conducted on fewer than 30 days per year, may also demonstrate that employees will not be exposed above the PEL for 30 or more days per year. The obligation to demonstrate that employees in a process or task will not be exposed above the PEL for 30 or more days per year is the same for general industry, construction, and shipyard employers.

OSHA has included a provision in the final rule prohibiting the rotation of employees to different jobs as a means of achieving the PEL. Although rotation of employees may reduce the risk of cancer among individual workers, the practice places a larger pool of workers at risk. Since no threshold has been established for the carcinogenic effects of Cr(VI), rotation would not be expected to reduce the risk to the population of workers when considered as a whole. A prohibition on worker rotation to achieve the PEL was supported by several responses to the proposal (e.g., Exs. 38–199–1; 40–10–2) and is consistent with good industrial hygiene practice. A prohibition on worker rotation to achieve the PEL is also consistent with many OSHA standards regulating carcinogens such as those for 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), asbestos (29 CFR 1910.1001), and cadmium (29 CFR 1910.1027).

A number of commenters, however, objected to a prohibition on worker rotation to achieve the PEL (e.g., Exs. 38–205; 38–214; 38–218; 38–228; 38–233; 39–51; 39–60; 47–30–1). For example, the Society for the Plastics Industry argued that employers should be allowed to implement employee rotation where it will result in exposure levels that are not associated with a significant risk of cancer (Ex. 38–218, pp. 29–30). However, worker rotation to lower the exposures of individual employees simply distributes exposures among a larger number of workers. The intent of this final rule is not simply to achieve a PEL, but to protect the largest number of workers possible from the adverse health effects of Cr(VI) exposure, particularly lung cancer. If the exposures of individual employees are reduced, but a corresponding increase occurs in the total number of employees exposed, then the intent of the final rule would be undermined.

Several commenters argued that job rotation has been allowed in previous OSHA health standards such as those for arsenic, formaldehyde, and lead, and should be allowed in this case as well (e.g., Exs. 38–218; 38–228; 47–30). With regard to arsenic and formaldehyde, although worker rotation was not specifically prohibited, the preamble discussions for each of these final standards indicated that the Agency did not consider worker rotation to be an appropriate control strategy (43 FR 19584, 19617(5/5/78); 52 FR 46168, 46263–46264 (12/4/87)).

OSHA's Lead standard was issued in 1978, and was based on a range of adverse health effects including damage to the nervous, urinary, and reproductive systems and inhibition of heme synthesis. Based on the information available at that time, lead was not recognized by OSHA as a carcinogen, and worker rotation was regarded as ''a relatively safe and effective means of maintaining TWA levels below permissible limits'' (43 FR 52952, (11/14/78)). The preamble to the final lead rule noted that such practices were unacceptable ''when the contaminant is one for which no effect levels are unknown, e.g., carcinogens'' (43 FR 52952, (11/14/78)). The Lead standard therefore does not set a precedent for allowing worker rotation for a carcinogen such as Cr(VI).

OSHA recognizes that employers rotate workers for a variety of reasons. For example, an employer may rotate workers in order to provide cross-training on different tasks, or to allow workers to alternate physically demanding tasks with less strenuous activities. OSHA does not place any restrictions on worker rotation when it is conducted for reasons other than compliance with the PEL. The Agency does not intend for this provision to be interpreted as a general prohibition on employee rotation where workers are exposed to Cr(VI).

Some commenters believed that the hierarchy of controls should apply to dermal as well as inhalation exposures to Cr(VI)(Exs. 38–199–1; 38–219). OSHA agrees that engineering and work practice controls can often be useful in controlling dermal Cr(VI) exposures. In fact, the Agency believes that engineering and work practice controls used to limit inhalation exposures to or below the PEL will often be effective in limiting dermal exposures as well. Substitution, isolation, and ventilation all serve to control dermal as well as inhalation exposures.

As discussed in section V of this preamble, OSHA recognizes that dermal exposures to Cr(VI) are capable of causing serious adverse health effects. However, dermal exposures do not present the same level of risk as inhalation exposures. Moreover, OSHA does not anticipate that engineering and work practice controls will eliminate the need for protective clothing and equipment and hygiene facilities for protection from dermal hazards. Therefore, due to the limited benefits that would be expected from such a provision, OSHA does not believe that a requirement for preferential use of engineering and work practice controls to reduce dermal exposures is reasonably necessary in this final rule. This determination is consistent with previous OSHA health standards, including standards addressing adverse dermal effects (e.g., formaldehyde (29 CFR 1910.1048) and 1,2-dibromo-3-chloropropane (29 CFR 1910.1044)).

Several commenters advocated a task-based approach for specifying required methods of compliance (Exs. 38–219; 38–235; 40–10–2). Others indicated that they did not see any benefit to this approach (Exs. 38–220; 39–20). Under a task-based approach, appropriate control measures would be specified for particular tasks and employers would be required to implement the specified controls when employees perform that task. This approach was used in OSHA's standards for exposure to asbestos in construction (29 CFR 1926.1101) and shipyards (29 CFR 1915.1001). However, sufficient information is not available in this rulemaking record to allow OSHA to establish the specific and detailed requirements that would be necessary to address the various tasks covered under the rule.

In the standards for asbestos in construction and shipyards, OSHA was able to divide the vast majority of activities involving asbestos exposure into four classes, and to identify control measures that were generally appropriate for each of the four classes of work. The Agency is unable to make comparable categorizations for the types of work covered in this rulemaking. For example, welding operations may involve substantially different potential Cr(VI) exposures depending upon the chromium content of the steel being welded and consumables used, the type of welding being performed, and the environment where the welding takes place. Appropriate control measures will vary based on these factors. Because OSHA is unable to specify generally applicable controls for common tasks involving exposure to Cr(VI), the Agency considers the performance-oriented approach used in this final rule to be the only reasonable approach for methods of compliance to control exposures to Cr(VI). The approach used in this rule is consistent with most other OSHA substance-specific health standards, including those for cadmium in construction (29 CFR 1926.1127) and lead in construction (29 CFR 1926.62).

OSHA has not included a requirement for a written compliance program in the final rule. In some previous standards, the Agency has required that employers prepare a written document detailing the measures used to achieve compliance. This document typically was required to include a description of operations that result in exposure; specific methods used to control exposures; a detailed implementation schedule; a work practice program; a plan for emergencies; and other information. The purpose of requiring an employer to establish a written compliance program is to promote compliance with the standard. Some urged OSHA to include a provision for a written compliance program in the Cr(VI) standard (Ex. 38–199–1; 39–71; 40–19–1).

OSHA has not included a provision for compliance plans in the Cr(VI) standard in order to limit the amount of paperwork employers would be required to complete. The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires agencies to minimize paperwork burdens imposed on the public. Preparation of written compliance plans would be classified as paperwork under that Act. Although a written program may be useful to some employers, OSHA does not believe that the lack of a written compliance program will substantially reduce the effectiveness of the standard. This finding is consistent with OSHA health standards such as those for formaldehyde (29 CFR 1910.1048) and methylene chloride (29 CFR 1910.1052). Compliance with this standard will be promoted through outreach, which OSHA has concluded will be effective in assisting employers and employees to comply.

(g) Respiratory Protection

Paragraph (g) of the general industry standard (paragraph (f) for construction and shipyards) establishes the final rule's requirements for use of respiratory protection. Employers are required to provide employees with respiratory protection when engineering controls and work practices cannot reduce employee exposure to Cr(VI) to within the PEL. Specifically, respirators are required during the installation and implementation of engineering and work practice controls; during work operations where engineering and work practice controls are not feasible; when all feasible engineering and work practice controls have been implemented, but are not sufficient to reduce exposure to or below the PEL; during work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; and during emergencies. Where respirator use is required, the employer must institute a respiratory protection program in accordance with OSHA's Respiratory Protection standard (29 CFR 1910.134).

These requirements for the use of respirators are identical to those proposed and are generally consistent with other OSHA health standards, such as those for 1,3 butadiene (29 CFR 1910.1051) and methylene chloride (29 CFR 1910.1052). They reflect the Agency's determination, discussed in the section on methods of compliance, that respirators are inherently less reliable than engineering and work practice controls. OSHA therefore will allow reliance on respirators only in limited situations.

OSHA received relatively few comments specifically addressing the proposed respiratory protection requirements. A numbers of comments focused on the use of respiratory protection in lieu of engineering and work practice controls (e.g., Exs. 38–199; 38–214; 38–219; 38–220; 38–231; 38–232; 38–233; 39–47; 39–51; 39–57; 39–60; 39–65; 39–66; 40–1; 40–7; 40–18; 40–19; 47–3; 47–31). This issue is addressed in the methods of compliance section above.

OSHA recognizes that respirators may be essential to reduce worker exposure in certain circumstances where engineering and work practice controls cannot be used to achieve the PEL (e.g., in emergencies, or during periods when equipment is being installed), or where engineering controls may not be reasonably necessary (e.g., where employees are exposed above the PEL for fewer than 30 days per year), and provision is made for their use as primary controls in these situations. In other circumstances, where feasible work practices and engineering controls alone cannot reduce exposure levels to the PEL, respirators must be used for supplemental protection. In these situations, the burden of proof is placed on the employer to demonstrate that engineering and work practice controls are not feasible.

OSHA anticipates that engineering and work practice controls will generally be in place within four years of the effective date of the standard, as specified in paragraph (n) of the final rule (paragraph (l) for construction and shipyards). The Agency realizes that in some cases employers may commence operations that involve employee Cr(VI) exposures after that date, may install new or modified equipment, or make other workplace changes that result in new or additional exposures to Cr(VI). In these cases, a reasonable amount of time may be needed before appropriate engineering controls can be installed and proper work practices implemented and paragraph (g)(1)(i) addresses this situation. Employers are expected to provide respirators to protect workers during such periods.

Respiratory protection is also required during work operations where engineering and work practice controls are not feasible. OSHA anticipates that there will be few situations where no engineering and work practice controls are feasible to limit employee exposure to Cr(VI). However, the Agency recognizes that it may be infeasible to control Cr(VI) exposure with engineering and work practice controls during certain work operations, such as maintenance and repair activities. Respirators are required in these situations. Several commenters supported allowing the use of respiratory protection in these circumstances (e.g., Exs. 38–254; 39–47; 39–56).

In other cases, some engineering and work practice controls may be feasible, but these controls may not be capable of lowering employee exposures to or below the PEL. For example, OSHA recognizes that in certain welding operations such as welding stainless steel in confined spaces, the PEL cannot always be achieved with feasible engineering and work practice controls. In these cases, the employer must install engineering controls and implement work practice controls where such controls are feasible to reduce exposures, even if these controls cannot reduce exposures to the PEL. Respirators must also be provided to supplement the engineering and work practices controls to achieve the PEL.

The requirement to provide respiratory protection when feasible engineering controls are not sufficient to reduce exposures to within the PEL also applies in instances where effective engineering controls have been installed and are being maintained or repaired. In these situations, controls may not be effective while maintenance or repair is underway. Where exposures exceed the PEL, the employer is required to provide respirators.

As discussed earlier with regard to methods of compliance, OSHA is including an exception from the general requirement for use of engineering and work practice controls where employee exposures do not exceed the PEL on 30 or more days per year. Where this exception applies, the employer is then required to provide respiratory protection to achieve the PEL.

OSHA also believes that respirators must be used to protect employees in emergencies. Since an emergency, by definition, involves or is likely to involve an uncontrolled release of Cr(VI), it is important for employers to have procedures to protect employees from the significant exposures that may occur.

Whenever respirators are used to comply with the requirements of the standard, the employer must implement a comprehensive respiratory protection program in accordance with the

Agency's Respiratory Protection standard (29 CFR 1910.134). The respiratory protection program is designed to ensure that respirators are properly used in the workplace, and are effective in protecting workers. The program must include procedures for selecting respirators for use in the workplace; medical evaluation of employees required to use respirators; fit testing procedures for tight-fitting respirators; procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; procedures and schedules for maintaining respirators; procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of employees in the proper use of respirators; and procedures for evaluating the effectiveness of the program. This provision serves as a reminder to employers covered by the Cr(VI) rule that they must also comply with the Respiratory Protection standard when respirators are provided to employees.

OSHA has proposed to revise the Respiratory Protection standard to include assigned protection factors (APFs) (68 FR 34036 (6/6/03)). The proposed revision includes a table which indicates the level of respiratory protection that a given respirator or class of respirators is expected to provide, and will apply to employers whose employees use respirators for protection against Cr(VI) when it becomes a final rule (68 FR 34036, 34115 (6/6/03)).

A number of commenters supported the reference to the Respiratory Protection standard (e.g., Tr. 1586–1589, Exs. 38–232; 39–38; 39–57; 47–36). For example, the 3M Company stated:

> Many of our customers use respirators to help protect workers from exposures to multiple contaminants and the reference in the Cr(VI) standard to the requirements of 1910.134 brings uniformity that will result in better compliance and protection for workers such as welders that have exposures to other metals besides Cr(VI) and workers in the pigment industry that may have exposures to both cadmium and Cr(VI) (Ex. 38–232).

In contrast, the AFL–CIO suggested specific changes to the proposed respiratory protection requirements. The AFL–CIO recommended that OSHA require HEPA filters for all air purifying respirators required in the final rule (Ex. 38–222). They argued that HEPA filters would provide the highest level of protection, and a requirement to provide HEPA filters would be consistent with similar provisions in other OSHA health standards such as those for asbestos, lead, and cadmium.

OSHA does not believe that a specific requirement mandating use of HEPA filters for air purifying respirators used for protection from Cr(VI) is justified, and has not included such a requirement in the final rule. For air-purifying respirators, in addition to the option of providing a respirator equipped with a filter certified by NIOSH under 30 CFR Part 11 as a HEPA filter, the Respiratory Protection standard allows employers several alternatives. Under 1910.134 the employer may also provide either (1) An air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR Part 84; or (2) an air-purifying respirator equipped with any filter certified for particulates by NIOSH where dealing with contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers. OSHA believes these requirements are appropriate for protection from exposures to Cr(VI).

NIOSH published revised requirements for testing and certification procedures for non-powered, air-purifying, particulate-filter respirators and recodified the previous certification standards for other respirator classes as 42 CFR Part 84 on June 8, 1995. Respirators certified under Part 84 have passed a more demanding certification test than was previously required, involving the most penetrating particle size of 0.3 micrometers. OSHA believes that these testing and certification requirements ensure that particulate filters certified under 42 CFR Part 84 are efficient in preventing the penetration of submicron-sized particles, and recognized this when the Agency's revised Respiratory Protection standard was issued on January 8, 1998. OSHA likewise believes that an air-purifying respirator equipped with any filter certified for particulates by NIOSH will be efficient in preventing the penetration of particles with diameters of 2 micrometers or more, because filters will be more efficient in protecting against particles larger than 0.3 micrometers in diameter. These findings were established for air contaminants in general during the rulemaking that revised the Respiratory Protection standard, and OSHA does not find any basis in this rulemaking record to make an exception for Cr(VI).

The AFL–CIO suggested that the final Cr(VI) rule should prohibit the use of disposable particulate (filtering facepiece) respirators for protection against Cr(VI) exposures (Ex. 38–222). The AFL–CIO indicated that they believed the record for OSHA's APFs rulemaking (Docket H049C) supports the position that disposable particulate respirators do not provide the same level of protection as do elastomeric half mask respirators, and noted that OSHA does not allow the use of disposable respirators under the Agency's Asbestos standard.

As noted above, OSHA is in the process of establishing respirator selection provisions in the APFs rulemaking, which will modify the Agency's Respiratory Protection standard. It is the Agency's intent that substance-specific standards, such as this final Cr(VI) rule, should refer to provisions of the Respiratory Protection standard (including the generic APFs) where possible instead of establishing their own separate respirator selection requirements. The record for the Cr(VI) rulemaking contains no evidence to support separate respirator selection requirements for Cr(VI), such as a prohibition or restriction on the use of disposable particulate respirators. As no basis has been established for distinguishing Cr(VI) from other air contaminants, OSHA believes it is appropriate for employers required to provide respirators for protection against Cr(VI) to follow the provisions of the Respiratory Protection standard.

Pinnacle West Capital Corporation, parent company of Arizona Public Service Company, expressed the view that the respiratory protection requirements of the proposed rule could conflict with requirements of the Nuclear Regulatory Commission (NRC). Referring to operations in the firm's nuclear power plant, Pinnacle West stated:

> * * * the potential exists for respiratory requirements under this rule to be in conflict with Nuclear Regulatory Commission expectations for keeping radiation exposures ''As Low as Reasonably Achievable'' (ALARA). In some cases, the use of a respirator can increase the stay time in a radioactive area, thus increasing the time exposed to an external radiation dose. In such cases, ALARA practice requires that a respirator not be used (Ex. 39–40).

OSHA does not forsee a conflict between the final rule's requirements for use of respiratory protection and NRC requirements for minimizing radiation exposure. NRC and OSHA share jurisdiction over occupational safety and health at NRC-licensed facilities. With regard to respiratory protection, NRC standards apply when the hazard is radiation. However, the NRC standards explicitly recognize in Appendix A to 10 CFR Part 20 that respirator use must comply with Department of Labor requirements when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. The responsibilities of each agency for worker protection are discussed in a memorandum of understanding (MOU) between NRC and OSHA (available at *http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=MOU&p_id=233*). As NRC's Regulatory Guide 8.15—Acceptable Programs for Respiratory Protection indicates, ''The MOU makes it clear that if an NRC licensee is using respiratory protection to protect workers against nonradiological hazards, the OSHA requirements apply'' (see *http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8–15/#_1_6*). NRC thus recognizes that respiratory protection for chemical hazards may be required, and the provisions for respirator use in the final Cr(VI) rule do not conflict with NRC requirements.

Several commenters expressed the opinion that respiratory protection should be provided at no cost to employees (e.g., Exs. 38–219; 38–222; 39–50). OSHA's Respiratory Protection standard explicitly requires that respirators, as well as associated training and medical evaluations, be provided at no cost to employees (29 CFR 1910.134(c)(4)). The Agency believes that the Respiratory Protection standard adequately establishes this requirement; therefore, repetition of the requirement in this Cr(VI) standard is unnecessary.

(h) Protective Work Clothing and Equipment

Paragraph (h) of the final rule (paragraph (g) for construction and shipyards) sets forth requirements for the provision of protective clothing and equipment. The rule requires the employer to provide appropriate protective clothing and equipment at no cost to employees where a hazard is present or is likely to be present from skin or eye contact with Cr(VI). Ordinary street clothing and work uniforms or other accessories that do not serve to protect workers from Cr(VI) hazards are not considered protective clothing and equipment under this standard. The employer is also required to ensure that employees use the clothing and equipment provided, and follow a number of specified practices to ensure that protective clothing and equipment is used and handled in a manner that is protective of employee health.

These requirements are intended to prevent the adverse health effects associated with dermal exposure to Cr(VI) (described in Section V.D of this preamble) and the potential for inhalation of Cr(VI) that would otherwise be deposited on employees' street clothing. The requirements further serve to minimize exposures to Cr(VI) that may occur as a result of improper handling of contaminated protective clothing or equipment. The requirements of this paragraph are based upon widely accepted principles and conventional practices of industrial hygiene, and are similar to provisions for protective clothing and equipment in other OSHA health standards such as those for cadmium (29 CFR 1910.1027) and methylenedianiline (29 CFR 1910.1050). The requirements are also consistent with Section 6(b)(7) of the OSH Act which states that, where appropriate, standards shall prescribe suitable protective equipment to be used in connection with hazards.

A number of responses to the proposal expressed the view that requirements for protective clothing and equipment in a final Cr(VI) standard would duplicate OSHA's existing generic requirements for personal protective equipment (Tr. 1320–1321, 1389, Exs. 38–124; 38–127; 38–214; 38–217; 38–218, p. 23; 38–229; 38–233, p. 39; 39–20; 47–25). OSHA acknowledges that the Agency's generic personal protective equipment standards (29 CFR 1910.132 for general industry; 29 CFR 1915.152 for shipyards; 29 CFR 1926.95 for construction) currently have requirements for provision of protective clothing and equipment that are essentially equivalent to the requirement in this final rule. However, OSHA believes that the additional requirements contained in this paragraph which address practices associated with the use of protective clothing and equipment (*e.g.*, removal and storage, cleaning and replacement) are necessary and appropriate to provide adequate protection from the hazards related to Cr(VI) exposure. Because these additional provisions are closely associated with requirements for protective clothing and equipment, including the protective clothing and equipment requirements in this paragraph helps to make the additional provisions clear and understandable. Also, OSHA believes it is useful and appropriate for this rule to provide a consolidated set of requirements for protective clothing and equipment that apply to Cr(VI) exposures in the workplace, to the extent that this is reasonably possible and beneficial. This provides an administratively convenient source of information on these regulatory requirements, will enable employers to more easily and effectively identify and implement the measures necessary to protect employees, and will clarify that additional requirements for protective clothing and equipment in this standard are linked to the requirements currently in place.

One commenter maintained that OSHA had not shown that dermal exposures present a significant risk, or that the proposed controls (including provisions for change rooms and washing facilities included in a subsequent paragraph of this standard) are reasonably necessary and appropriate to address that risk (Ex. 38–218). OSHA disagrees. While there were insufficient data to perform a quantitative risk assessment on dermatitis, OSHA has established in the preamble discussion of health effects that Cr(VI) is capable of causing serious adverse effects to the skin and eyes, resulting in material impairment of the health of affected individuals. Further, as discussed in regard to significance of risk (Section VII of this preamble), without appropriate control measures the effect of dermal exposures could contribute to the significant risk presented by other workplace exposures to Cr(VI). Moreover, as discussed below, these provisions are not only reasonable and necessary but to a great extent reflect requirements in existing generic standards. This approach is consistent with other health standards where dermal hazards were present, where OSHA has included requirements for protective clothing and equipment (e.g., methylene chloride, formaldehyde).

One commenter suggested that the term ''protective clothing and equipment'' be changed to ''protective clothing and protective equipment'' (Ex. 39–65). OSHA has retained the term ''protective clothing and equipment'' as proposed because the Agency believes it is sufficiently clear, and is consistent with longstanding use of this term by the Agency. The term ''protective'' serves to modify both the word ''clothing'' and the word ''equipment''. When using the term ''protective clothing and equipment'' OSHA is referring only to clothing and equipment that serves to protect workers from Cr(VI) hazards. Other clothing, work uniforms, tools, or other apparatus that do not serve to protect workers from Cr(VI) hazards are not considered protective clothing and equipment under this rule.

The final rule requires the employer to provide appropriate protective clothing and equipment where a hazard is present or is likely to be present from skin or eye contact with Cr(VI), but does not specify criteria to be used for determining when a hazard is present or is likely to be present. To make this determination, the employer must evaluate the workplace. This performance-oriented requirement is consistent with the current requirements of the Agency's standards for use of personal protective equipment in general industry and shipyards, which require the employer to assess the workplace to determine if hazards (including hazards associated with eye and skin contact with chemicals) are present, or are likely to be present (see, e.g., 29 CFR 1910.132(d)(1)).

To determine whether there is a hazard (or likely to be a hazard) from skin or eye contact with Cr(VI) in a particular workplace, the employer should ''exercise common sense and appropriate expertise'' in assessing the hazards. (See non-mandatory appendices providing guidance on hazard assessment in 29 CFR 1910 Subpart I Appendix B; 29 CFR 1915 Subpart I Appendix A). The recommended approach involves a walk-through survey to identify sources of hazards to workers. Review of injury/accident data is also recommended. Information obtained during this process provides a basis for the evaluation of potential hazards.

Several commenters supported this approach to assessing Cr(VI) hazards to the skin and eyes (Exs. 38–214; 38–220; 38–245–1; 39–19; 39–20; 39–40; 39–47; 39–48; 39–52). Electric Boat Corporation, for example, stated:

> Electric Boat believes the approach is sound in that the employer should perform a hazard assessment, like it does for many other potential hazards in the workplace, and decide if protective clothing and equipment is necessary to protect from adverse health effects associated with the skin and eyes (Ex. 38–214).

The U.S. Navy also supported this method, indicating that ''It is appropriate to expect an employer to exercise common sense and appropriate expertise to determine if a hazard is present or likely to be present'' (Ex. 38–220).

On the other hand, other commenters believed that such a requirement was vague and subjective, and did not adequately indicate when personal protective clothing was necessary (Tr. 626, Exs. 38–218; 38–233). One commenter complained that the proposal provided no objective or quantitative basis for determining when a hazard exists, and requirements for protective clothing and equipment could be triggered by exposure to a few particles of dust (Ex. 38–233). Another commenter requested that OSHA describe the conditions it believes constitute skin and eye hazards, suggesting the inclusion of descriptive phrases such as ''a light dusting on the skin and work surfaces'' (Ex. 39–51).

One commenter suggested that protective clothing and equipment should be required for employees exposed above the PEL (Ex. 39–71). Other commenters argued that a blanket requirement that protective clothing and equipment be provided for any exposures above the PEL was not warranted (Exs. 38–214; 38–220; 38–245–1; 39–19; 39–20; 39–40; 39–47; 39–48; 39–51; 39–52). Still other commenters considered that a threshold concentration for the Cr(VI) content of mixtures should be established, below which protective clothing would not be required (Exs. 39–56; 38–254; 39–60). Establishing a threshold concentration, it was argued, would help define where and when protective clothing would be beneficial (Exs. 39–56; 38–254).

OSHA has not established quantitative thresholds for exposure to Cr(VI) that would trigger the requirement for provision of protective clothing and equipment. Cr(VI) is present in a large number of different chemical compounds, each with differing physical and chemical properties. These compounds themselves can be contained in a wide variety of mixtures in various concentrations. The characteristics of these compounds and mixtures can have substantial influence on the ability of Cr(VI) to elicit adverse health effects to the skin and eyes. Therefore, it is not possible to specify appropriate thresholds for dermal or ocular effects from Cr(VI) containing compounds. Exposures must be evaluated on a case-by-case basis, taking into account factors such as the acidity or alkalinity of the compound or mixture as well as the magnitude and duration of exposure. Clearly, the employer, with knowledge of the workplace, work practices, and Cr(VI) compounds used, is in the best position to evaluate whether personal protective clothing or equipment are necessary and appropriate for his or her workplace exposures.

OSHA is not aware of any evidence that would allow establishment of a threshold concentration of Cr(VI) below which adverse skin or eye effects would not occur. Likewise, the Agency does not have sufficient evidence to demonstrate that a skin or eye hazard will necessarily occur when exposures exceed the PEL. Therefore, OSHA believes that a performance-oriented requirement for provision of protective clothing and equipment is most appropriate for exposures to Cr(VI) covered by this rule.

As part of this performance-oriented requirement, once a determination has been made that a hazard is present or likely to be present in the workplace, the employer must determine what clothing and equipment are necessary to protect employees. The employer has flexibility to select the clothing and equipment most suitable for his or her particular workplace. The type of protective clothing and equipment needed to protect employees from Cr(VI) hazards will depend on the potential for exposure and the conditions of use in the workplace. Examples of protective clothing and equipment that may be necessary include, but are not limited to gloves, aprons, coveralls, foot coverings, and goggles.

The employer must exercise reasonable judgment in selecting the appropriate clothing and equipment to protect employees from Cr(VI) hazards. In some instances gloves may be all that is necessary to prevent hazardous Cr(VI) exposure. In other situations, such as when a worker is performing abrasive blasting on a structure covered with Cr(VI)-containing paint, more extensive measures such as coveralls, head coverings, and goggles may be needed. Where exposures to Cr(VI) are minute, such as in typical welding operations, no protective clothing or equipment may be necessary. The chemical and physical properties of the compound or mixture may also influence the choice of protective clothing and equipment. For example, a chrome plater may require an apron, gloves, and goggles to protect against possible splashes of chromic acid that could result in both Cr(VI) exposure and chemical burns. Other factors such as size, dexterity, and cut and tear resistance should be considered in the selection process as well (Ex. 40–10–2).

This performance approach is consistent with OSHA's current standards for provision of personal protective equipment and with methods currently utilized to select appropriate protective clothing and equipment. For example, several parties testified that they already make qualitative determinations or exercise professional judgment in selecting protective clothing and equipment in their workplaces (Tr. 924–925, 1259–1260, 1414–1416).

The final rule requires employers to provide clothing and equipment necessary to protect against Cr(VI) hazards at no cost to employees. Some commenters agreed with this approach (Tr. 1107–1108, 1438–1441, Exs. 39–50; 38–199–1; 38–219–1; 38–222; 39–71; 40–10–2; 47–26). Others disagreed, arguing either that the Agency should not include a provision requiring employer payment or should defer to the outcome of OSHA's ongoing rulemaking addressing payment for personal protective equipment in all workplaces (64 FR 15401 (3/31/99))(e.g., Exs. 38–214, p. 20; 38–244, p.11–12; 39–19; 39–47; 39–60).

OSHA has included a requirement that the employer pay for protective clothing and equipment in the final rule because the Agency believes that the employer is generally in the best position to select and obtain the proper type of protective clothing and equipment for protection from Cr(VI) hazards and to retain control over them. The protective clothing and equipment at issue is designed and intended to protect against Cr(VI) hazards at work. Because of the serious health hazards associated with Cr(VI) exposure, employees may not remove contaminated clothing and equipment from the worksite (except for the employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment). The employer is responsible for cleaning or disposing of the protective clothing and equipment and retains complete control over it. OSHA believes that by providing and owning this protective clothing and equipment, the employer will maintain control over the inventory of these items, conduct periodic inspections, and, when necessary, repair or replace it to maintain its effectiveness.

Employer payment for PPE has been a continuing issue for OSHA. OSHA notes that in the generic rulemaking, the Agency has raised for public comment, among other issues, whether employers should not be required to pay for PPE that is personal in nature and used off the job, or that is a ''tool of the trade'' typically supplied by the employee and carried from job site to job site or employer to employer (65 FR 15401, 3/31/1999; 69 FR 41221, 7/8/2004). OSHA has not made a final determination on any of the issues raised in the generic rulemaking. The Agency notes that the protective clothing and equipment involved here do not fall into either of these categories. Employees are not allowed even to take the contaminated PPE home.

The determination that the protective clothing and equipment required by the final standard is to be provided at no cost to employees is specific to this Cr(VI) rule. It reflects the particular considerations presented by workplace exposures to Cr(VI). The determination is made without prejudice to the ongoing generic rulemaking addressing payment for personal protective equipment.

The employer must ensure that protective clothing and equipment contaminated with Cr(VI) is removed at the completion of the work shift or at the completion of tasks involving Cr(VI) exposure, whichever comes first. For example, if employees perform work tasks involving Cr(VI) exposure for the first two hours of a work shift, and then perform tasks that do not involve Cr(VI) exposure, they must remove their protective clothing after the exposure period (in this case, the first two hours of the shift). If, however, employees are performing tasks involving Cr(VI) exposure intermittently throughout the day, or if employees are exposed to other contaminants where protective clothing and equipment are needed, this provision does not prevent them from wearing the clothing and equipment until the completion of their shift. This provision is intended to limit the duration of employees' exposure, and to prevent contamination from Cr(VI) residues on protective clothing reaching areas of the workplace where exposures would not otherwise occur.

To limit exposures outside the workplace, the final rule requires the employer to ensure that Cr(VI)-contaminated protective clothing and equipment is removed from the workplace only by those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment. This provision is intended to ensure that clothing contaminated with Cr(VI) is not carried to employees' cars and homes, increasing the worker's exposure as well as exposing other individuals to Cr(VI) hazards. Furthermore, the standard requires that clothing and equipment that is to be laundered, cleaned, maintained, or disposed of be placed in closed, impermeable containers to minimize contamination of the workplace and ensure employees who later handle these items are protected. Those cleaning the Cr(VI)-contaminated clothing and equipment will be further protected by warning labels placed on containers to inform them of the potential hazards of exposure to Cr(VI).

The proposed provision addressing labels on containers of contaminated clothing and equipment has been modified to reference the requirements of OSHA's Hazard Communication standard (HCS)(29 CFR 1910.1200). Rather than requiring the specific language proposed, the final rule indicates that bags or containers are to be labeled in accordance with the requirements of the HCS. As indicated in the discussion of paragraph (l) of this standard below, OSHA believes that it is appropriate maintain the labeling requirement but to allow employers to retain the flexibility provided by the HCS with regard to the language used on labels. The reference to the HCS is included to remind employers of their obligation under that standard to label containers of hazardous chemicals such as Cr(VI).

Several commenters objected to requirements for storage and transport of contaminated items in impermeable bags or other impermeable containers, as well as the associated labeling requirements. The Textile Rental Services Association (TRSA) maintained that such requirements were not justified, and that no evidence indicated that laundry workers could be exposed to levels of Cr(VI) that would be cause for concern (Tr. 1566–1572, Ex. 38–252). TRSA claimed that the short processing time and minimal handling of garments limits the potential exposure of laundry workers, and that reduction of Cr(VI) to Cr(III) over time further limits potential exposure. Moreover, TRSA argued that labels would cause unwarranted concerns and lead to unnecessary testing. The Color Pigments Manufacturers Association contended that the labeling required in the proposal would lead to commercial laundries refusing to accept items contaminated with Cr(VI), or accepting them only at significantly increased cost (Ex. 38–205). Atlantic Marine also believed that laundries would refuse to accept contaminated clothing (Tr. 926). It was also alleged that contractors who repair and maintain equipment might refuse to accept Cr(VI)-contaminated items (Ex. 38–233, p.39).

OSHA believes that the requirements of the final rule for use of impermeable bags or other impermeable containers for the storage and transport of Cr(VI)-contaminated items are clearly justified, as are the requirements for labeling containers in accordance with the HCS. As discussed previously, this rule requires protective clothing and equipment when the employer has determined that a skin or eye hazard is present or is likely to be present from exposure to Cr(VI). Thus, protective clothing and equipment are only used under this rule in situations where exposure to Cr(VI) is at least likely to cause a hazardous exposure. The contamination of protective clothing and equipment that results from such exposures poses a threat to the health of workers who handle such clothing and equipment, just as it does to the workers who use the clothing and equipment. Measures to minimize the likelihood of hazardous exposures to workers who handle these items, such as requirements for the use of impermeable containers, are therefore reasonably necessary and appropriate.

Moreover, OSHA believes it is reasonable to use labels to inform employers and employees who handle hazardous substances such as Cr(VI) of the identity of these substances, as well as to provide appropriate hazard warnings. This provision simply directs the employer's attention to longstanding labeling requirements of the HCS. When employers and employees are aware of the presence of Cr(VI) and its potential hazards, appropriate measures can be implemented to protect employees. The alternative of leaving those who handle these items in ignorance of the presence of Cr(VI) discounts the very real possibility that adverse health effects may occur if proper precautions are not taken. Other OSHA health standards, such as those for lead (29 CFR 1910.1025), asbestos (29 CFR 1910.1001), cadmium (29 CFR 1910.1027), and bloodborne pathogens (29 CFR 1910.1030) include similar labeling requirements.

The final rule requires that the employer clean, launder, repair and replace protective clothing as needed to ensure that the effectiveness of the clothing and equipment is maintained. This provision is necessary to ensure that clothing and equipment continue to serve their intended purpose of protecting workers. This also prevents unnecessary exposures outside the workplace from employees taking contaminated clothing and equipment home for cleaning.

In keeping with the performance-orientation of the final rule, OSHA does not specify how often clothing and equipment must be cleaned, repaired or replaced. The Agency believes that appropriate time intervals may vary widely based on the types of clothing and equipment used, Cr(VI) exposures, and other circumstances in the workplace. The obligation of the employer, as always, is to keep the clothing and equipment in the condition necessary to perform its protective functions.

Removal of Cr(VI) from protective clothing and equipment by blowing, shaking, or any other means which disperses Cr(VI) in the air is prohibited. Such actions would result in increased risk to employees from unnecessary exposure to airborne Cr(VI) as well as possible dermal contact.

The standard requires that the employer inform any person who launders or cleans protective clothing or equipment contaminated with Cr(VI) of the potentially harmful effects of exposure to Cr(VI), and the need to launder or clean contaminated clothing and equipment in a manner that effectively prevents skin or eye contact with Cr(VI) or the release of airborne Cr(VI) in excess of the PEL. As with the provision reminding employers of their obligation for labeling under the HCS, this requirement is intended to ensure that persons who clean or launder Cr(VI)-contaminated items are aware of the associated hazards so they can take appropriate protective measures. Where laundry or cleaning services are performed by third parties, the information transmitted need not be extensive to accomplish this goal. Appropriate hazard warnings, as required on labels by the HCS, will be sufficient to indicate the potentially harmful effects of exposure to Cr(VI). In addition, the language used in this provision (i.e., the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with Cr(VI) and effectively prevents the release of airborne Cr(VI) in excess of the PEL) could be put on a label, thereby fulfilling the requirements of the provision. The employer is not expected to specify particular work practices that third parties must follow to accomplish these objectives.

(i) Hygiene Areas and Practices

Paragraph (i) of the final rule (paragraph (h) for construction and shipyards) requires employers to provide hygiene facilities and to assure employee compliance with basic hygiene practices that serve to minimize exposure to Cr(VI). The rule includes requirements for change rooms and washing facilities, ensuring that Cr(VI) exposure in eating and drinking areas is minimized, and a prohibition on certain practices that may contribute to Cr(VI) exposure. OSHA believes that strict compliance with these provisions will substantially reduce employee exposure to Cr(VI).

Several of these provisions are presently required under other OSHA standards. For example, OSHA's current standard addressing sanitation in general industry (29 CFR 1910.141) requires that whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing shall be provided.

The sanitation standard also includes provisions for washing facilities, and prohibits storage or consumption of food or beverages in any area exposed to a toxic material. Similar provisions are in place for construction (29 CFR 1926.51). The hygiene provisions of this paragraph are intended to augment the requirements established under these other standards with additional provisions applicable specifically to Cr(VI) exposure.

In workplaces where employees must change their clothes to use protective clothing and equipment, OSHA believes it is essential to have change rooms with separate storage facilities for street and work clothing to prevent contamination of employees' street clothes. This provision will minimize employee exposure to Cr(VI) after the work shift ends, because it reduces the duration of time they may be exposed to contaminated work clothes. Potential exposure resulting from contamination of the homes or cars of employees is also avoided. Change rooms also provide employees with privacy while changing their clothes. OSHA intends the requirement for change rooms to apply to all covered workplaces where employees must change their clothes (i.e., take off their street clothes) to use protective clothing and equipment. In those situations where removal of street clothes is not necessary (e.g., in a workplace where only gloves are used as protective clothing), change rooms are not required.

This provision reiterates the current requirements for change rooms found in 29 CFR 1910.141(e) (for general industry and shipyards) and 29 CFR 1926.51(i) (for construction). Several commenters appeared to interpret this provision to indicate a new obligation for employers to provide change rooms that were not previously required (Tr. 557–558, 923–924, 1702, Exs. 38–205; 38–218; 38–233). The Agency's intent in including this provision in the final rule is to provide a consolidated reference of certain requirements for employers, rather than to establish new and different requirements for change rooms. Change rooms that meet the requirements of 29 CFR 1910.141(e) or 29 CFR 1926.51(i) fulfill the change room requirements of this final Cr(VI) rule.

Paragraph (i)(3) (paragraph (h)(3) of the construction and shipyard standards) contains requirements for washing facilities. The employer must provide readily accessible washing facilities capable of removing Cr(VI) from the skin and ensure that affected employees use these facilities when necessary. Also, the employer must ensure that employees who have skin contact with Cr(VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. The value and importance of washing facilities was recognized and supported by a number of commenters (Tr. 1457, Exs. 38–244; 39–40; 39–41; 40–10–2; 47–26).

Washing reduces exposure by diminishing the period of time that Cr(VI) is in contact with the skin. Although use of appropriate protective clothing and equipment is intended to prevent hazardous skin and eye contact with Cr(VI) from occurring, OSHA realizes that in some circumstances these exposures will occur. For example, a worker who wears gloves to protect against hand contact with Cr(VI) may inadvertently touch his face with the contaminated glove during the course of the day. The intent of this provision is to have employees wash in order to mitigate the adverse effects when skin and eye contact does occur. At a minimum, employees are to wash their hands and faces at the end of the shift because washing is needed to remove any residual Cr(VI) contamination. Likewise, washing prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics or using the toilet also protects against further Cr(VI) exposure.

The requirements of the final rule for washing facilities are consistent with existing requirements for washing facilities found in 29 CFR 1910.141(d) (for general industry and shipyards) and 29 CFR 1926.51(f) (for construction). One commenter believed the requirement for washing facilities to be ‘‘vague and subject to interpretation’’ (Ex. 38–233). OSHA disagrees. The existing requirements contain sufficient detail to guide any employer in setting up his or her washing facilities. Washing facilities that meet the requirements of 29 CFR 1910.141(d) or 29 CFR 1926.51(f) are sufficient to meet these requirements in this final Cr(VI) rule. In addition, both washing facility requirements address the traditional stationary workplace and worksites that are temporary or serviced by mobile crews. Because these requirements already apply to workplaces covered by the Cr(VI) rule, interpretation of a requirement for washing facilities should not be an issue; the facilities should already be provided. Because several comments on the proposal indicated apparent non-compliance with existing requirements (e.g., Tr. 1241–1242, 1453–1454), the final rule reiterates these requirements for washing facilities in order to clarify the issue and to educate employers and provide a comprehensive reference of requirements. In addition, the final Cr(VI) rule supplements the general requirements for provision of washing facilities with relatively simple, common-sense requirements that the facilities be used when appropriate to minimize Cr(VI) exposures.

OSHA has not included a requirement for shower facilities in the final rule. In the preamble to the proposed rule, the Agency requested comment on the issue of whether or not provisions for showers should be included in a final Cr(VI) standard. Some comments supported shower requirements (Exs. 39–71; 40–10–2). NIOSH, for example, indicated a preference for showers after anything more than limited, minor contact with Cr(VI) (Ex. 40–10–2). Other commenters did not believe showers were necessary (Exs. 38–267; 39–52; 39–19; 39–48; 39–40; 39–47; 38–235; 38–244; 38–220; 39–60; 38–214; 38–228; 39–20). OSHA agrees with the latter group that a requirement for showers is not reasonably necessary in the final Cr(VI) rule.

OSHA expects that hazardous skin and eye exposures will occur infrequently with the proper use of appropriate protective clothing and equipment. In these situations, the Agency believes that washing facilities will generally be sufficient to allow employees to remove any Cr(VI) contamination that may occur. Showers may in some situations be an appropriate industrial hygiene control measure. Wayne Pigment Corporation, for example, indicated that showers are currently used in its facility (Ex. 38–204). However, OSHA does not believe that showers are necessary in all circumstances, and has therefore not included a requirement for showers in the final rule.

To minimize the possibility of food contamination and to reduce the likelihood of additional exposure to Cr(VI) through inhalation or ingestion, OSHA believes it is imperative that employees have a clean place to eat. Where the employer chooses to allow employees to eat at the worksite, the final rule requires the employer to ensure that eating and drinking areas and surfaces are maintained as free as practicable of Cr(VI). Employers also are required to assure that employees do not enter eating or drinking areas wearing protective clothing, unless the protective clothing is properly cleaned beforehand. This is to further minimize the possibility of contamination and reduce the likelihood of additional Cr(VI) exposure from contaminated food or beverages. Employers are given discretion to choose any method for removing surface Cr(VI) from clothing and equipment that does not disperse the dust into the air or onto the employee's body. For example, if a worker is wearing coveralls for protection against Cr(VI) exposure, thorough HEPA vacuuming of the coveralls could be performed prior to entry into a lunchroom.

The employer is not required to provide eating and drinking facilities to employees. Employers may allow employees to consume food or beverages on or off the worksite. However, where the employer chooses to allow employees to consume food or beverages at a worksite where Cr(VI) is present, OSHA intends for the employees to be protected from Cr(VI) exposures in these areas. To this end OSHA is requiring the employer to ensure that eating and drinking areas are as free as practicable of Cr(VI). These provisions are consistent with the current requirements addressing consumption of food and beverages in the workplace found at 29 CFR 1910.141(g) and (h) (for general industry and shipyards) and 29 CFR 1926.51(g) (for construction).

Paragraph (i)(5) (paragraph (h)(5) in the construction and shipyard standards) specifies certain activities that are prohibited. These activities include eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas, or in areas where skin or eye contact with Cr(VI) occurs. Products associated with these activities, such as food and beverages, cannot be carried or stored in these areas. Because the construction and shipyard standards do not include requirements for regulated areas, reference to regulated areas is omitted in the regulatory text for these standards. This provision in the final standard is necessary and appropriate to protect employees from additional sources of exposure to Cr(VI) not necessary to job performance.

(j) Housekeeping

The final standard includes housekeeping provisions that require general industry employers to maintain surfaces as free as practicable of Cr(VI), promptly clean Cr(VI) spills and leaks, use appropriate cleaning methods, and properly dispose of Cr(VI)-contaminated waste. These provisions are important because they minimize additional sources of exposure that engineering controls generally are not designed to address. Good housekeeping is a cost effective way to control employee exposures by removing accumulated Cr(VI) that can become entrained by physical disturbances or air currents and carried into an employee's breathing zone, thereby increasing employee exposure. Contact with contaminated surfaces may also result in dermal exposure to Cr(VI). The final provisions are generally consistent with housekeeping requirements for general industry in other OSHA standards, such as those for cadmium (29 CFR 1910.1027) and lead (29 CFR 1910.1025).

Cr(VI) deposited on ledges, equipment, floors, and other surfaces should be removed as soon as practicable, to prevent it from becoming airborne and to minimize the likelihood that skin contact will occur. When Cr(VI) is released into the workplace as a result of a leak or spill, the standard requires the employer to promptly clean up the spill. Measures for clean-up of liquids should provide for the rapid containment of the leak or spill to minimize potential exposures. Clean-up procedures for dusts must not disperse the dust into the workplace air. These work practices aid in minimizing the number of employees exposed, as well as the extent of any potential Cr(VI) exposure.

The standard requires that, where possible, surfaces contaminated with Cr(VI) be cleaned by vacuuming or other methods that minimize the likelihood of Cr(VI) exposure. OSHA believes vacuuming to be a reliable method of cleaning surfaces on which dust accumulates, but other effective methods may be used. These methods may include wet methods, such as wet sweeping or use of wet scrubbers. Dry shoveling, dry sweeping, and dry brushing are permitted only if the employer can show that vacuuming or other methods that are usually as efficient as vacuuming have been tried and found not to be effective under the particular circumstances in the workplace. The standard also requires that vacuum cleaners be equipped with HEPA filters to prevent the dispersal of Cr(VI) into the workplace.

Paragraph (j)(2)(ii) of the final rule differs somewhat from the proposal in that it differentiates between wet and dry cleaning methods, indicating that *dry* shoveling, sweeping, and brushing can be used only where the employer shows that HEPA-vacuuming or other methods that minimize the likelihood of exposure to Cr(VI) had been tried and found not to be effective. The North American Insulation Manufacturers Association (NAIMA) requested that OSHA recognize wet sweeping as an acceptable alternative to HEPA-filtered vacuuming (Exs. 38–228–1, p. 21; 47–30, p. 40). The Color Pigments Manufacturers Association (CPMA) also argued that wet cleaning methods may be more efficient and produce lower exposures than dry vacuuming (Ex. 38–205, p. 60). OSHA agrees that wet methods can serve to minimize exposure to Cr(VI), and has modified the language of the provision to allow wet methods to be permitted.

The use of compressed air for cleaning is only allowed when used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air, or when no alternative cleaning method is feasible. This provision is intended to prevent the dispersal of Cr(VI) into the workplace. The United Auto Workers, International Brotherhood of Teamsters and the Building Construction Trades Department, AFL–CIO supported restrictions on the use of compressed air as a means of minimizing employee exposures to Cr(VI)(Exs. 39–73–2, p. 20; 38–199–1, pp. 41, 46; 38–219–1, p.24).

An allowance for use of compressed air when no alternative method is feasible was not included in the proposal. This provision was added in response to arguments by NAIMA that, in some circumstances, no other cleaning method was available. Specifically, NAIMA indicated that during furnace rebuilds, tight spaces and hard to reach crevices can only be effectively cleaned with compressed air (Ex. 38–228–1, p. 21). In an active furnace area, it was contended that extreme heat limits use of methods such as vacuuming (Tr. 1207, Ex. 47–30–1, p. 40). Other examples were also cited (Ex. 47–30–1, p. 40).

Although OSHA agrees that in certain circumstances no alternative to use of compressed air may be feasible, the Agency anticipates that these circumstances will be extremely limited. The vast majority of operations are expected to use preferred methods, such as HEPA-vacuuming, to remove Cr(VI) contamination from workplace surfaces. Where compressed air is used without a ventilation system designed to capture the dust cloud created, the employer must be able to demonstrate that no alternative cleaning method is feasible.

Cleaning equipment is to be handled in a manner that minimizes the reentry of Cr(VI) into the workplace. For example, cleaning and maintenance of HEPA-filtered vacuum equipment must be done carefully to avoid exposures to Cr(VI). Filters need to be changed as appropriate and the contents of bags disposed of properly to avoid unnecessary Cr(VI) exposures.

The final rule requires that items contaminated with Cr(VI) and consigned for disposal be collected and disposed of in sealed impermeable bags or other closed impermeable containers. This provision is intended to prevent dispersal of Cr(VI) into the air or dermal contact with Cr(VI)-contaminated items during the disposal process.

Some commenters expressed concern about the proposed provision, indicating that sealed, impermeable bags are impractical for large, heavy items such as refractory brick (Tr. 1215–1216, Exs. 38–228–1, p. 22; 47–30, pp. 39–40; 47–32). OSHA intends this provision to be performance-oriented, to allow use of any container so long as that container prevents release of or contact with Cr(VI). Sealed barrels could be used to serve this purpose. Other methods, such as palletizing items and wrapping the pallet in plastic so as to create an impermeable barrier between workers and the Cr(VI)-contaminated waste, scrap or debris would also be acceptable.

OSHA proposed that bags or containers of waste, scrap, debris, and other materials contaminated with Cr(VI) that are consigned for disposal be labeled, and included specific language in paragraph (l) of the proposed standard to be included on labels. The purpose of this provision was to inform individuals who handle these items of the potential hazards involved. OSHA has retained this requirement in the final rule, but has modified the provision to require labeling in accordance with the Agency's Hazard Communication Standard (HCS)(29 CFR 1910.1200). As discussed with regard to paragraph (l), OSHA believes that it is critically important that employees be made aware of the hazards associated with potential Cr(VI) exposures. By alerting employers and employees who are involved in disposal to the potential hazards of Cr(VI) exposure, they will be better able to implement protective measures. However, the Agency has determined that the information required on labels by the HCS, including the chemical identity and appropriate hazard warnings, is sufficient to make employees aware of potential Cr(VI) hazards. The specific language for labels included in paragraph (l) of the proposal, and the reference to that language in this provision, have therefore been deleted from the final rule. Reference to the HCS has been added to ensure that employers are aware of their obligations under the HCS for labeling of containers containing Cr(VI) contaminated waste.

No housekeeping requirements are included in the final rule for construction or shipyards. OSHA has determined that the housekeeping provisions in the general industry standard are not appropriate for these sectors because of the difficulties of complying with such requirements in construction and shipyard environments.

OSHA's decision not to include housekeeping requirements in these industries was supported by a number of commenters (Exs. 38–214, p. 21; 38–244, p. 13; 39–19; 39–20, p. 23; 39–60; 40–1–2, p. 33). The AFL–CIO, on the other hand, argued that housekeeping requirements should apply to construction and shipyard workplaces as well as those in general industry (Ex. 47–28, p. 7). The AFL–CIO maintained that housekeeping requirements are important measures for protecting worker health, and noted that housekeeping requirements have been included in previous OSHA health standards covering construction and shipyards (Ex. 47–28, p. 7). However in the previous rulemakings that covered substantial numbers of construction and shipyard workers, such as lead in construction (29 CFR 1926.62) and asbestos in construction (29 CFR 1926.1101) and shipyards (29 CFR 1915.1001), OSHA did not find housekeeping provisions to present the difficulties anticipated with regard to Cr(VI) that are discussed below. OSHA believes these standards address operations that are generally more amenable to housekeeping measures. For example, the standards for asbestos in construction and shipyards include requirements for the use of dropcloths and barriers to prevent the migration of asbestos from many areas where asbestos removal operations are performed. These requirements simplify compliance with housekeeping provisions by confining asbestos contamination in many cases to discrete and easily identified areas. Similarly, lead operations in construction are often enclosed to prevent environmental contamination, easing the burden of complying with housekeeping requirements.

In previous rulemakings, the issue of excluding these industries was not specifically raised for comment; here three pertinent questions were included in the proposal and a record developed. In addition to two general questions on modifications to the standards that would better account for the workplace conditions in construction and shipyards while still providing appropriate protection (Questions 31 and 32), the Agency specifically requested information on its preliminary determination that housekeeping requirements would likely be difficult to implement in construction and shipyard environments (69 FR 59310, 59311). OSHA received a number of comments in response and, although there was not general agreement among them, sufficient information was presented to allow OSHA to make its conclusions.

OSHA has concluded that there are compelling reasons to exclude specific requirements for housekeeping for construction and shipyard worksites in this final rule. In construction and shipyard settings, operations involving Cr(VI) exposure are often of short duration, commonly performed outdoors under variable environmental conditions, and in locations that vary from day to day or even hour to hour within a shift. Under these circumstances, it is often difficult to distinguish Cr(VI)-contaminated dusts from other dirt and dusts commonly found at the worksite (Ex. 39–19). Welding operations present particular problems in construction and shipyards. Welding is the predominant source of Cr(VI) exposures in these sectors (*see* section VIII). Due to the small particle size of the fumes generated, welding operations may result in the deposition of Cr(VI) over wide areas when the welding is performed outdoors. In addition, the deposition may be highly dependent on environmental conditions (e.g., wind direction and speed).

These deposited fumes may not be visible to the naked eye, and they can become intermingled with other dusts commonly found on construction and shipyard worksites so that they are unrecognizable. Therefore, it is unreasonable to believe that employers will be able to consistently and accurately identify Cr(VI)-contamination at construction and shipyard worksites, or distinguish Cr(VI)-contaminated dusts from soil or other dusts found at the worksite. For example, if a pipe fitter welds a section of stainless steel pipe outdoors over open ground, it is unclear how large an area, if any, would need to be cleaned. In addition, as noted above, construction and shipyard operations are often of relatively short duration, and work is often performed at non-fixed workstations or worksites. These changes in workplace conditions add to the difficulty of complying with the specific housekeeping requirements set forth in the final rule for general industry.

The housekeeping measures that apply to general industry are also impractical on many construction and shipyard worksites. HEPA-filtered vacuums would likely gather disproportionately large volumes of non-Cr(IV) dust and debris relative to the volume of Cr(VI) captured, particularly on open ground. This would result in the continued need to unclog or replace filters designed for the collection of fine particulates. Wet or dry sweeping would be unlikely to produce better results. Disposal of waste, scrap, and debris would be subject to similar difficulties. For these reasons, OSHA has concluded that housekeeping requirements are highly impracticable for control of Cr(VI) exposures in construction and shipyard workplaces and therefore has not included housekeeping requirements for these industry sectors.

Several commenters expressed the view that many activities in general industry workplaces are similar to those in construction and shipyard workplaces, and therefore these activities, or general industry as a whole, should not be subject to housekeeping requirements either (Exs. 38–203; 39–47; 39–51, p. 15; 39–56; 40–1–2). Some argued that housekeeping requirements are inappropriate for welding and cutting operations (Exs. 38–203; 38–254; 39–47; 39–48; 39–56, 40–1–2). Some commenters claimed that regardless of whether welding is performed in construction or general industry, the quantity of settled fume is insignificant and difficult to identify for housekeeping purposes (Ex. 38–203; 38–254; 39–47; 39–48; 39–56, 40–1–2). Others claimed that steel mills, rolling mills, and forging operations generate substantial amounts of dusts that do not contain Cr(VI) (Ex. 38–233, p. 40). These employers argued that they could not comply with housekeeping requirements because they would be unable to identify Cr(VI)-contaminated dusts or keep the facility entirely dust-free (Ex. 38–233, p. 41). Edison Electric Institute (EEI) alleged that coal-burning power plants would face similar difficulties with fly ash (Tr. 436, Ex. 40–1–2, pp. 15–16). ORC Worldwide noted that many general industry work operations take place in dusty outdoor environments (Ex. 39–51, p. 15).

OSHA has concluded that the housekeeping requirements of the final rule for general industry are reasonable and appropriate. A large proportion of the workers covered by the general industry standard are exposed in operations other than welding. In these operations, Cr(VI) contamination is generally more easily identified, and housekeeping measures are more practical and effective. Moreover, in general industry, welding operations are usually performed in controlled environments where Cr(VI) contamination can be identified and cleaned up consistent with the requirements of the housekeeping provisions.

The Agency recognizes that in some cases general industry work operations and work environments may be comparable to those found in construction and shipyards. However, certain work conditions and factors commonly present in construction and shipyard environments differ from those typically found in general industry. Construction and shipyard tasks are often relatively short in duration; operations are commonly performed outdoors, sometimes under adverse environmental conditions (*e.g.*, wind, rain); and work is often performed at non-fixed workstations or work sites (Exs. 39–19; 39–60; 38–214). Collectively, these factors make compliance with the specific housekeeping requirements of the final rule impractical for typical construction and shipyard operations. OSHA has thus made a finding, based on the rulemaking record, that for the majority of construction and shipyard settings, compliance with housekeeping provisions is impracticable. In contrast, OSHA believes that compliance with these housekeeping requirements usually does not involve the same practical difficulties in general industry operations. For the reasons discussed above, OSHA has determined that it is appropriate to include housekeeping requirements in the final rule for general industry. Moreover, paragraph (j)(1)(i) of the final rule only requires surfaces to be maintained free of the accumulation of Cr(VI) ''as practicable''. Thus, the final rule gives sufficient flexibility for the few general industry situations where the housekeeping provisions are particularly difficult to implement.

Also, construction and shipyard employers will still need to comply with the general housekeeping requirements found at 29 CFR 1926.25 (for construction) for 29 CFR 1915.91 (for shipyards). These standards include general provision for keeping workplaces clear of debris, but do not contain the more specific requirements found in the Cr(VI) standard for general industry (*e.g.*, the obligation to use preferred cleaning methods).

EEI also cited the Administrative Law Judge (ALJ) decision in *Cincinnati Gas & Elec. Co. Beckjord Station,* 2002 CCH OSHD P32,622 (No. 01–711)(ALJ), *aff'd on other grounds,* 21 BNA OSHC 1057 (2005), that ''the general industry housekeeping standard, 29 CFR 1910.22(a), does not apply to coal-fired power plants' (Ex. 39–52, p. 13). This is not correct. The ALJ did not hold that the general housekeeping standard, 29 CFR 1910.22(a), categorically does not apply to coal-fired power plants; rather, the ALJ found that the Secretary could not cite an employer under the housekeeping standard at 1910.22 *for an explosion hazard* caused by the accumulation of combustible coal dust because this type of explosion hazard is specifically addressed by 1910.269(v)(11) of the Electric Power Generation, Transmission, and Distribution standard. In affirming the decision for different reasons, the Occupational Safety and Health Review Commission would not '' * * * exclude the possibility that the Secretary could make * * * a showing'' that the general housekeeping standard would not be preempted even with respect to an explosion hazard by virtue of that standard providing meaningful protection beyond that afforded by the specific standard. The Commission concluded, however, that the record before it was not sufficient to make such a finding. *Cincinnati Gas & Elec. Co.*, 21 BNA OSHC 1057, 1058 (No.01–0711, 2005). Regardless, the housekeeping requirements in this section do not protect against explosion hazards; they protect workers from exposure to a toxic chemical and known carcinogen and therefore would not be preempted by 1910.269(v)(11).

EEI also claimed that the proposed housekeeping requirements conflict with the requirements under 1910.269(v)(11) of the Electric Power Generation, Transmission, and Distribution standard (Ex. 39–52, p. 22). OSHA does not foresee such a conflict because an employer can comply with both standards. Section 1910.269(v)(11) requires controlling ignition sources to abate the explosion hazard, which does not conflict with the housekeeping provisions of this section that require all surfaces to be kept as free as practicable from accumulation of Cr(VI). The housekeeping provisions of this section are intended to minimize worker exposure to Cr(VI), and nothing suggests that controlling ignition sources would limit exposures. Thus, the housekeeping provisions in this standard are necessary to protect workers.

EEI also believed that housekeeping requirements would conflict with OSHA's standard addressing occupational exposure to inorganic arsenic, 29 CFR 1910.1018 (Exs. 39–52, p. 22; 47–25, p. 10). OSHA does not foresee a conflict between the housekeeping provisions of this rule and those of the arsenic rule. When housekeeping is performed in environments where provisions of both standards apply, the employer may choose methods that comply with both requirements. For example, the arsenic standard prohibits use of compressed air for cleaning, while this rule allows use of compressed air for cleaning in extremely limited circumstances; the arsenic rule does not require HEPA filters on vacuums used for cleaning, while this rule does. Where both standards apply, the employer could comply by avoiding the use of compressed air for cleaning and using HEPA-filtered vacuums.

(k) Medical Surveillance

Paragraph (k) of the final standard (paragraph (i) for construction and shipyards) sets forth requirements for the provision of medical surveillance for employees in general industry, construction and shipyards. This paragraph specifies which employees are to be offered medical surveillance and at what times. It also specifies the content of required examinations and material to be provided to and obtained from the licensed health care professional administering the program.

The purpose of medical surveillance for Cr(VI) is, where reasonably possible, to determine if an individual can be exposed to the Cr(VI) present in his or her workplace without experiencing adverse health effects; to identify Cr(VI)-related adverse health effects so that appropriate intervention measures can be taken; and to determine the employee's fitness to use personal protective equipment such as respirators. This final standard is consistent with Section 6(b)(7) of the OSH Act which requires that, where appropriate, medical surveillance programs be included in OSHA health standards to aid in determining whether the health of workers is adversely affected by exposure to toxic substances. Almost all other OSHA health standards have also included medical surveillance requirements.

The final standard requires that each employer covered by this rule make medical surveillance available at no cost, and at a reasonable time and place, for all employees meeting the requirements of this paragraph. As in previous OSHA standards, this final standard is intended to encourage participation by requiring that medical examinations be provided by the employer without cost to employees (also required by section 6(b)(7) of the Act), and at a reasonable time and place. If participation requires travel away from the worksite, the employer would be required to bear the cost. Employees would have to be paid for time spent taking medical examinations, including travel time.

Some commenters questioned the utility of medical surveillance at construction worksites and recommended that medical surveillance not be required in the final Cr(VI) standard covering construction. For example, several commenters representing construction employers noted a number of particular difficulties in providing medical surveillance on construction work sites such as the frequent movement of construction workers from job-to-job and from one employer to another and the difficulty in finding health care professionals familiar with signs and symptoms of Cr(VI) exposure (*e.g.*, Exs. 38–236; 38–244; 39–36; and 39–65). More specifically, the Associated Builders and Contractors (ABC) testified that ''no rationale exists showing such surveillance would likely show causation or would be feasible'' (Ex. 39–65), adding that it was not possible to demonstrate a cause and effect through exposure monitoring and medical surveillance (Tr. 1272–1277). Such impracticalities, they imply, would render medical surveillance in construction settings of little utility since one would not be able to determine if an exposure at a particular job site was responsible for the observed signs or symptoms.

OSHA continues to believe that despite the challenges posed by the changing nature of work and the mobility of construction workers, medical surveillance in construction settings serves an important role just as it does in general industry and shipyard settings. OSHA has included medical surveillance in other OSHA health standards where construction has been a primary industry impacted by those rules (*e.g.*, lead, asbestos and cadmium) and finds no reason why the Cr(VI) final standard should be an exception. OSHA disagrees that it will be difficult to find health care professionals with expertise in Cr(VI) toxicity. The major effects associated with Cr(VI) exposures include common ailments such as asthma and dermatitis that would not require any exceptional expertise in Cr(VI) per se. OSHA believes that it is important for health care professionals to be familiar with an employee's work duties and Cr(VI) exposures in order to aid them in addressing any reported signs or symptoms, and as discussed below requires important occupational information to be provided to the selected health care professional. As to ABC's concern about showing causality, OSHA does not believe that the inability to link a specific exposure to an individual worker's particular outcome is sufficient cause not to provide medical surveillance. Cr(VI) exposure, as discussed previously in the health effects section of this preamble, may cause non-malignant respiratory effects such as asthma, nasal ulcerations and perforations, as well as allergic and irritant contact dermatitis. The fact that an employer may not be able to identify the specific exposure that caused a particular observed effect does not negate the value of identifying such effects and making sure that the affected employee gets the proper medical attention. Moreover, by questioning the affected employee about his or her work practices and likely exposures, it may be possible to identify lapses in the employer's exposure control measures or the employee's work practices that contributed to the observed effect. Such information will help to prevent future adverse events for this employee as well as other employees at the worksite or perhaps even other construction job sites that have similar types of exposures and operations.

In the proposed standard, OSHA specified that medical surveillance be provided to those employees who are experiencing signs or symptoms of the adverse health effects associated with Cr(VI) exposure, or who are exposed in an emergency. In addition, OSHA proposed that general industry (but not construction or shipyard) employers be required to provide medical surveillance for all employees exposed to Cr(VI) at or above the PEL for 30 or more days a year.

OSHA received a variety of comments regarding the proposed triggers for determining which employees should be provided medical surveillance. Some commenters did not support the use of signs and symptoms to trigger medical surveillance, stating that OSHA had not provided any definition for what it meant by signs and symptoms and that symptoms associated with adverse Cr(VI) health effects such as asthma and dermatitis could also be caused by various other workplace chemicals, allergies, or sources outside the work environment (*e.g.*, Tr. 985–988; Exs. 38–124; 38–205; 47–16; 39–65). In particular, the Color Pigment Manufacturers Association (CPMA) voiced concern that employees could simply assert that a symptom had occurred and the employer, who has no medical expertise to determine if symptoms are a result of Cr(VI) exposure, would have no choice but to incur the cost of the medical examination even though that symptom may not have been the result of a workplace exposure (Ex. 38–205, p. 64). Another commenter suggested that OSHA use a narrow definition of adverse heath effects to avoid difficulties with commonplace health effects unrelated to Cr(VI) exposure (Ex. 39–20).

Others supported the use of signs and symptoms to trigger medical surveillance (*e.g.*, Exs. 39–20; 38–220; 39–51; 39–71; 39–19; 39–48; 47–26) but some objected to the sole use of signs and symptoms to trigger medical surveillance in construction and shipyard settings and felt that the same triggers required in general industry should be applied to construction and shipyard settings (*e.g.*, Exs. 38–199; 38–220; 39–51; 38–219; 40–10–2). Organization Resource Counselors noted that many workers are reluctant to report medical problems for a variety of reasons and if medical surveillance is solely dependent on workers reporting signs and symptoms to their employers, cases may go undetected until it is too late to take effective action (Ex. 39–51). NIOSH agreed and voiced concern that shifting the sole responsibility of medical surveillance to employees to report signs and symptoms of worker exposure, as they believed the proposal did, was a departure from long-established public health practice (Tr. 300–301; Ex. 40–10–2).

While supporting the need to include an airborne exposure trigger for routine medical surveillance, many commenters did not support OSHA's use of the PEL as the airborne trigger and argued that OSHA should use the action level as it has in most of its past health standards (*e.g.*, Tr. 1117–1118; Exs. 39–73; 39–71; 47–26; 47–23; 40–18–1; 38–199). NIOSH and the United Auto Workers (UAW) reasoned that given the remaining significant risk at the PEL, the action level would be a more appropriate trigger for medical surveillance (Exs. 40–10–2; 39–73). The UAW also recommended that OSHA remove from the medical surveillance provisions the 30 day exemption for exposures above the PEL, arguing that exposures of fewer than 30 days could contribute to kidney toxicity. Others advocated task-based or hazard assessment-based approaches, either in conjunction with other triggers or alone, for determining when employees should be offered medical surveillance (*e.g.*, Tr. 1442–1443; Exs. 38–199; 38–214; 40–10–2; 38–220). Such task-based or hazard-assessment approaches could be used, they argued, to identify high exposure or high risk operations where medical surveillance might be useful.

Several groups supported triggering medical surveillance after emergencies (*e.g.*, Exs. 40–10–2; 38–233; 38–219) while some questioned the value of offering medical surveillance after an emergency event given that a substance such as Cr(VI) presents chronic hazards (Exs. 39–19, 39–47, 40–1–2). Finally, while some groups were supportive of OSHA's proposal not to include eye and skin contact as a trigger for medical surveillance (Exs. 39–72–1, 38–233), NIOSH recommended that OSHA consider a dermal exposure trigger such as the one OSHA used for its final standard for methylenedianiline, where medical surveillance was triggered after dermal exposures of 15 days or more.

OSHA continues to believe, despite the comments offered, that the observation of signs and symptoms known to be caused by Cr(VI) exposure serves as a valuable complement to the use of airborne exposure triggers as a mechanism for initiating medical surveillance. Some employees may exhibit signs and symptoms of the adverse health effects associated with Cr(VI) exposure even when not exposed above a specified air limit for 30 or more days per year. These employees could be especially sensitive, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests. Therefore in the final rule OSHA has required that employees who experience signs or symptoms of the adverse health effects associated with Cr(VI) exposure be included in medical surveillance. OSHA recognizes that signs and symptoms associated with adverse health effects such as dermatitis, asthma, and skin ulcerations may be non-specific (*i.e.*, they may be caused by factors other than Cr(IV)). However, it is important to realize the context in which signs and symptoms are expected to be used in medical surveillance. Signs and symptoms are generally expected to be self-reported by employees and as such are not intended to serve as a means for diagnosing adverse health effects or determining their causality. Rather, they serve as a useful signal that an employee may be suffering from a Cr(VI) exposure-related health effect or are at the beginning stages of suffering a Cr(VI)-related adverse health effect. Once these signals are recognized, the employee can be referred to a PLHCP who can, with sufficient information about the employee's duties, potential exposures, and medical and work histories (as required by this standard and discussed later), make determinations about the Cr(VI)'related effects, provide medical treatment and recommend work restrictions where necessary. OSHA believes that employees can be trained, through the required hazard communication training, to identify signs and symptoms consistent with Cr(VI) toxicity such as blistering lesions, redness or itchiness of the skin's exposed areas, shortness of breath and wheezing that worsens at work, nose bleeds, and whistling during inspiration or expiration. Viewed in this context, OSHA believes that the inclusion of signs and symptoms is an important part of the overall medical surveillance program. Thus, the final standard would protect employees exposed to Cr(VI) in unusual circumstances even if they don't meet the other criteria for routine medical surveillance. OSHA acknowledges CPMA's concern that an employee can simply assert a symptom has occurred and the employer would be forced to provide medical surveillance and bear the cost. However, OSHA believes that the overriding concern should be that appropriate medical attention be provided for workers experiencing signs and symptoms of effects known to be caused by Cr(VI). By properly training employees about the signs and symptoms associated with Cr(VI) and providing appropriate work-related exposure information to the PHLCP, Cr(VI) work-related health effects can be distinguished from other non-occupational effects. Once identified as occupationally-related, many of these outcomes are likely to be subject to state worker compensation benefits and defray the employer's costs of providing medical surveillance. Under such a system, OSHA believes employees will be unlikely to abuse medical surveillance. Nevertheless, even the possibility that a few bad actors may act irresponsibly should not be reason to deny worker protection where it is appropriate to evaluate the employee's condition to determine if exposure to Cr(VI) is the cause of the condition, and to determine if protective measures are necessary. In addition, the Agency has found in past rulemakings that employees generally do not unnecessarily avail themselves of medical surveillance.

OSHA proposed that in construction and shipyard settings that signs and symptoms and exposure in emergencies be the sole criteria for determining which employees to provide with medical surveillance. In the proposal, only general industry employers were required to use an airborne trigger for initiating medical surveillance. OSHA is convinced by comments submitted to the record that it is important that the triggers for medical surveillance for all industries be the same. Specifically, OSHA agrees with NIOSH and ORC that having medical surveillance triggered only by signs and symptoms may miss important opportunities for detecting adverse effects that may go undetected by employees. For those reasons, OSHA believes it is appropriate to make the triggers and the medical surveillance provisions identical across the general industry, construction and shipyard standards. Even in situations where the performance-oriented option for exposure determination is used, OSHA believes that employers using historical or objective data to characterize airborne exposures will be able to effectively use that data to determine when to provide routine medical surveillance.

OSHA had originally proposed that the PEL be used to trigger medical surveillance. However, based on the comments received on this issue and the fact that the action level is now higher than the proposed PEL, OSHA agrees with those urging the action level be used to trigger medical surveillance. Given the remaining risk at the final PEL, it is more appropriate to use the action level as the trigger rather than the PEL. However, OSHA continues to believe that having a 30 day exposure requirement in conjunction with the action level is a reasonable approach for determining which employees to provide with medical surveillance. OSHA agrees with the UAW that Cr(VI) metabolizes differently than cadmium but notes that OSHA has included a similar 30 day exemption for other regulated substances that have different metabolic half-lives compared to cadmium (*e.g.*, methlyene chloride, 1,3-butadiene, ethylene oxide). OSHA disagrees with the UAW that Cr(VI) presents a kidney toxicity risk that necessitates medical surveillance for exposures less than 30 days above the action level. As discussed in the health effects section of this preamble, OSHA does not believe that the available scientific studies show a strong correlation between kidney dysfunction and Cr(VI) exposure. OSHA thus continues to believe the 30 day trigger is a reasonable benchmark to apply to Cr(VI) for focusing the provision of medical surveillance to capture effects that may be strongly influenced by repeated exposure. In cases where adverse effects occur among workers exposed less than 30 days over the action level, OSHA believes that these effects will generally present themselves as signs or symptoms that employees can be trained to observe and report. Such instances, as discussed above, are covered by this final rule.

While some commenters recommended that OSHA require a task-based or hazard-based approach for determining when to provide routine medical surveillance, OSHA believes that a trigger, based both on the action level and the number of days an employee is exposed to Cr(VI), is a reasonable and administratively convenient basis for providing medical surveillance benefits to Cr(VI)-exposed workers. In addition, it is consistent with previous OSHA standards. This final standard would not prohibit employers from augmenting their medical surveillance programs to include hazard or risk-based approaches where they feel it is helpful to identify employees who may benefit from medical surveillance. OSHA always encourages employers to go beyond the minimum requirements set forth in OSHA standards.

OSHA disagrees with commenters who question the value of requiring medical surveillance shortly after an emergency has occurred (Exs. 39–19; 39–47; 40–1–2). While there are chronic effects associated with Cr(VI) exposure, there are also short term effects such as skin ulcerations and dermatitis that might result from high exposures occurring during an emergency. Emergency situations (as defined in the standard) involve uncontrolled releases of Cr(VI), and OSHA believes the high exposures that may occur in these situations justify a requirement for medical surveillance. Thus, OSHA has made a final determination that medical surveillance must be made available to employees exposed in an emergency regardless of the airborne concentrations of Cr(VI) normally found in the workplace. This requirement for medical examinations after exposure in an emergency in the final rule is consistent with the provisions of several other OSHA health standards, including the standards for methylenedianiline (29 CFR 1910.1050), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

OSHA has also made a final determination not to include eye or skin contact as a basis for medical surveillance. NIOSH suggested that OSHA use a trigger similar to the one the Agency used in its standard on methylenedianiline (MDA; 29 CFR 1910.1050). However, it is important to note that, as discussed in the preamble for the final MDA standard, MDA is readily absorbed through the skin and contributes to the dose causing systemic effects from MDA (57 FR 35630, 8/10/92). The Agency estimated in the final MDA risk assessment that ‘‘a 20 fold increase in risk could be prevented by not allowing dermal exposure to MDA’’ (57 FR at 35648). Therefore, using a dermal component to trigger medical surveillance for MDA was deemed appropriate. This is not the case, however, for Cr(VI) which is not absorbed into the body but rather causes its effects by surface contact. Thus, OSHA believes that the MDA standard does not serve as a useful model for a dermal trigger for medical surveillance and is not appropriate in the final Cr(VI) standard. In addition, in previous OSHA standards where the substance being addressed also caused dermal irritation or sensitization (*e.g.*, formaldehyde; 29 CFR 1910.1048 and methylene chloride; 29 CFR 1910.1052), OSHA did not use skin or eye contact in itself with the substance to trigger medical surveillance. OSHA believes that compliance with the provisions for protective work clothing and equipment, hygiene areas and practices, and other protective measures will minimize the potential for adverse eye and skin effects. When such health effects occur, OSHA believes that trained employees will be able to detect these conditions, report them to their employer, and obtain medical assistance. In such situations, affected employees would be provided medical surveillance on the basis that they are experiencing signs or symptoms of Cr(VI)-related health effects.

The required medical surveillance must be performed by or under the supervision of a physician or other licensed health care professional (PLHCP). The Agency considers it appropriate to permit any health care professional to perform medical examinations and procedures provided under the standard when they are allowed by state law to do so. This provision provides flexibility to the employer, and reduces cost and compliance burdens. This requirement is consistent with the approach of other recent OSHA standards, such as those for methylene chloride (29 CFR 1910.1052), bloodborne pathogens (29 CFR 1910.1030), and respiratory protection (29 CFR 1910.134). OSHA received comments from 3M that asked the Agency to broaden its application of this provision to allow a PLHCP who is licensed in one state to be able to provide medical surveillance in other states where the employer has employees covered by the rule (Ex. 47–36). As discussed in detail previously in this summary and explanation section on paragraph (b) definitions, OSHA has made a final determination not to broaden the definition of a PHLCP. OSHA continues to believe that issues regarding a PHCLP's scope of legal practice reside most appropriately with state licensing boards.

In the proposed standard, OSHA also specified how frequently medical examinations were to be offered to those employees covered by the medical surveillance program. OSHA proposed that all employers be required to provide all covered employees with medical examinations whenever an employee shows signs or symptoms of Cr(VI) exposure; within 30 days after an emergency resulting in an uncontrolled release of Cr(VI); and within 30 days after a PLHCP's written medical opinion recommends an additional examination. In addition, employers in general industry were to provide covered employees with examinations within 30 days after initial assignment unless the employee has received a medical examination provided in accordance with the standard within the past 12 months; annually; and at the termination of employment, unless an examination has been given less than six months prior to the date of termination.

OSHA received few comments on the frequency of medical exams. Those offering comment focused on OSHA's proposed provision for annual medical exams. Some commenters reported that general medical surveillance programs were already being offered annually by some employers (Exs. 38–204; 39–71) implying that an annual requirement for Cr(VI) medical exams might not be that burdensome. NIOSH supported OSHA's general approach towards annual medical surveillance but also recommended that certain tests be done at earlier stages after an initial baseline assessment (*e.g.*, 3 months after an initial assessment for a spirometric test, 3 to 6 months after initial assessment for a chest X-ray) (Ex. 40–10–2). As discussed above, some commenters expressed concern with the requirement to provide exams within 30 days after an emergency (Exs. 39–19; 39–47; 40–1–2) and after employees report signs or symptoms (*e.g.*, Exs. 38–124; 38–205; 47–16; 39–65).

Having received no comments to the contrary, OSHA is maintaining its requirement for an initial medical exam within 30 days of assignment to a job with Cr(VI) exposure. The requirement that a medical examination be offered at the time of initial assignment is intended to achieve the objective of determining if an individual will be able to work in the job involving Cr(VI) exposure without adverse effects. It also serves the useful function of establishing a health baseline for future reference. Where an examination that complies with the requirements of the standard has been provided in the past 12 months, that previous examination would serve these purposes, and an additional examination would not be needed. In keeping with its final decision to have the triggers for providing medical surveillance consistent across general industry, construction and shipyard settings, OSHA is also expanding the requirement for initial medical exams to construction and shipyard settings.

Similarly, OSHA has made a final determination to expand the requirement for annual medical exams to construction and shipyard settings. OSHA believes that the provision of medical surveillance on an annual basis is an appropriate frequency for screening employees for Cr(VI)-related diseases. The main goal of periodic medical surveillance for workers is to detect adverse health effects at an early and potentially reversible stage. The requirement for annual examinations is consistent with other OSHA health standards, including those for cadmium (29 CFR 1910.1027), formaldehyde (29 CFR 1910.1048), and methylene chloride (29 CFR 1910.1052). Based on the Agency's experience, OSHA believes that annual medical surveillance would strike a reasonable balance between the need to diagnose health effects at an early stage, and the limited number of cases likely to be identified through surveillance.

Although NIOSH suggested that there are other more frequent intervals where tests such as spirometric examinations or X-rays might be useful, OSHA believes that the final Cr(VI) standard's requirement for employers to provide additional tests when recommended by the PLHCP is sufficient to address situations where additional procedures might be useful. OSHA continues to believe that a PLHCP is in the best position to recommend more frequent evaluations in order to follow developments in a worker's condition, or to allow for specialized evaluation. Therefore, OSHA is maintaining in the final standard, the requirement for the provision of medical examinations within 30 days after a PLHCP recommends additional testing.

OSHA is also retaining its requirements for medical examinations within 30 days after an emergency and whenever an employee shows signs or symptoms of the adverse health effects associated with Cr(VI) exposure. As discussed earlier in this section, OSHA believes that despite the non-specificity of some signs and symptoms associated with Cr(VI)-related effects, it is important to provide an opportunity for evaluation by a PHLCP after an employee reports signs or symptoms. The PHLCP can, with work and medical history information, make determinations as to whether an employee's reported signs and symptoms are associated with Cr(VI) exposure and recommend appropriate remedies. Also as discussed previously, OSHA believes that medical examinations after an emergency also serve an important role because of the nature of exposures likely to occur in an emergency event and thus retains this provision in the final standard.

Similar to OSHA's final determination to expand initial and annual medical examinations to construction and shipyard settings, OSHA is also extending the requirement for medical examination at the termination of employment to these sectors. The requirement that the employer offer a medical examination at the termination of employment is intended to assure that no employee terminates employment while carrying an active, but undiagnosed, disease. In situations where a previous examination, meeting the requirements of paragraph (k), (paragraph (i) for construction and shipyards) had been provided with 6 months prior to termination, that previous examination would suffice for this purpose.

In the proposed standard, OSHA specified that the examination to be provided by the PLHCP was to consist of a medical and work history; a physical examination of the skin and respiratory tract; and any additional tests considered appropriate by the PLHCP. Special emphasis was to be placed on the portions of the medical and work history focusing on Cr(VI) exposure, health effects associated with Cr(VI) exposure, and smoking. OSHA did not indicate specific tests that must be included in the medical examination. This was based on the Agency's belief that there were not any particular tests generally applicable to all employees covered by the medical surveillance requirements. Instead, the proposal required that determinations about the need for any additional tests be left to the discretion of the PLHCP.

While some commenters agreed that specific tests such as urine testing should not be included in the content of the required medical exam (Tr. 2330, Exs. 40–10–2; 38–220; 38–228; 38–235), others recommended that OSHA include spirometric evaluations, X-rays, and helical computerized tomography (CT) scans. For example, NIOSH recommended the addition of baseline and periodic spirometry and baseline chest X-rays, stating that these are commonly recommended by various occupational health organizations such as the American Thoracic Society and the American College of Occupational and Environmental Medicine and can be useful tools to exclude preexisting abnormalities when subsequent evaluations are conducted (Tr. 355–360, Ex. 40–10–2) The AFL–CIO and PACE recommended that OSHA consider adding a requirement for helical (CT) scans for the purpose of early lung cancer detection (Tr. 2309, 2317–2333, 2376–2381; Exs. 8–222; 39–71; 44–41.). Such tests, they stated, have been shown to effectively find early stage lung cancer that has been curable through surgical intervention. While PACE acknowledged that the helical CT scan is not yet accepted medical practice and should be contingent upon employee informed consent, they argued that the test can be used for high risk factors based on the results of lung function tests and chest X-rays. Others, however, supported OSHA's proposal that such tests be provided only when a licensed health care professional recommends that certain additional medical tests are necessary. (Exs. 38–203; 38–228; 39–47; 39–56; 39–60). CPMA cautioned that in the "current malpractice environment", a requirement for any additional examination deemed necessary by the PLHCP would result in licensed health care professionals ordering a battery of tests in order to prevent the possibility of malpractice claims, and the employer would be required to pay for them (Ex. 38–205).

OSHA acknowledges the value of many of the tests suggested by the various groups commenting on this issue. However, OSHA continues to believe that it is more effective to allow the PLHCP the flexibility to determine when such specific tests might be most useful rather than requiring them for all employees in the medical surveillance program on a routine basis. With the basic information gained from the required medical histories, work histories and a physical examination focusing on the skin and respiratory tract (the two main targets for Cr(VI) toxicity), the PLHCPs can use their medical expertise to best determine what, if any, additional testing is appropriate for any individual employee. This is especially true for tests such as the helical CT scan, which although promising, has not been generally proven to be appropriate on a routine basis. As pointed out by PACE, the helical CT can be effectively used after identifying high-risk factors. For these reasons, the final standard does not include any specific tests but rather includes a physical exam focusing on the skin and respiratory tract. The physical exam focuses on organs and systems known to be susceptible to Cr(VI) toxicity. The information obtained will allow the PLHCP to assess the employee's health status, identify adverse health effects related to Cr(VI) exposures, and determine if limitations should be placed on the employee's exposure to Cr(VI). The examining PLHCP then has the flexibility to determine any additional tests that might be appropriate for an individual employee.

The proposed standard required the employer to ensure the PLHCP has a copy of the standard, and to provide a description of the affected employee's former and current duties as they relate to Cr(VI) exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

OSHA received few comments regarding information to be supplied to the PLHCP. CPMA felt that providing the required information to the PLHCP would be burdensome and would be of little relevance to the medical professional and OSHA should instead require that employers only provide information as warranted by the health care professional (Ex. 38–205). Ameren Corporation also expressed concerns about the burden of providing results from previous examinations and suggested that information gained from the medical and work histories required by the Cr(VI) standard would suffice (Ex. 39–47).

OSHA disagrees. OSHA believes that making the required information available to the PLHCP will aid in the evaluation of the employee's health and have extreme relevance to the medical professional. Especially in the case where the PLHCP is evaluating the signs and symptoms of potential Cr(VI)-related health effects, information on the employee's exposures to Cr(VI), the employee's use of personal protective equipment and the results of previous examinations, where possible, will provide important information that can be used in conjunction with information gained from the required medical and work histories, in determining whether the observed symptoms are a result of Cr(VI) exposure. This information will also aid in the PLHCP's evaluation of the employee's health in relation to assigned duties and fitness to use personal protective equipment, when necessary. OSHA does not believe that providing such information to the PLHCP would be unduly burdensome. Much of this information is already being collected by the employer for other reasons and therefore the employer is not likely to have to expend additional energies in providing such information to the PLHCP. With regard to providing the PLHCP results of previous examinations, one commenter appears to believe that extraordinary efforts would be necessary to locate and provide such information to the PLHCP (Ex. 39–47). However, OSHA has made it explicit in this provision that it is only requiring those records that are currently within the control of the employer to be made available to the PLHCP. Given that they are in control of the employer, this information should not be overly burdensome to produce. For these reasons, OSHA is retaining the proposed provisions detailing information to be provided to the PLHCP in the final standard.

In addition to providing certain information to the PLHCP, the proposed standard also would have required employers to obtain from the examining PLHCP a written opinion containing the results of the medical examination with regard to Cr(VI) exposure, the PLHCP's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to Cr(VI), and any recommended limitations on the employee's exposure or use of personal protective equipment. The PLHCP would also need to state in the written opinion that these findings were explained to the employee.

Few comments were received regarding information to be provided to the employer by the PLHCP. The UAW argued that OSHA should prohibit the PLHCP from revealing any information to the employer, and that the written opinion should only go to the employee or the designated employee representative (Ex. 39–73–2, Tr. 793–795). Ameren Corporation objected to limiting the written opinion to only diagnoses related to Cr(VI) exposure and argued that the PLHCP will likely be evaluating exposure to other OSHA regulated substances such as lead, asbestos, cadmium and arsenic and it would be burdensome to have the PLHCP write separate opinions for each substance for any individual employee (Ex. 39–47). They suggested the following language: ''The PLHCP shall not reveal to the employer specific findings or diagnosis unrelated to exposure to occupational contaminants''.

The purpose of requiring the PLHCP to supply a written opinion to the employer is to provide the employer with a medical basis to aid in the determination of placement of employees and to assess the employee's ability to use protective clothing and equipment. If OSHA were to deny this information to the employer, as requested by the UAW, this would diminish one of the main benefits of the medical surveillance requirements of this standard. Employers must be aware of this information to effectively place employees and select appropriate protective equipment. Medical findings unrelated to Cr(VI) exposure, however, are not necessary information for the employer. Under the final standard, the PLHCP would not be allowed to include findings or diagnoses which are unrelated to Cr(VI) exposure in the written opinion provided to the employer. OSHA has included this provision to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertinent to Cr(VI) exposure. The employee would be informed directly by the PLHCP of all results of his or her medical examination, including conditions of non-occupational origin, but the employer would only receive information necessary to make decisions regarding employee placement and protective equipment selection relative to Cr(VI) exposures. OSHA recognizes that some employees who are exposed to Cr(VI) may also be exposed to other OSHA regulated substances where a written opinion is required (*e.g.*, exposures to lead chromate). It is not the Agency's intent to have the PLHCP write separate written opinions for an employee who is exposed to more than one OSHA regulated substance. If the employer has an ongoing medical surveillance program where a PLHCP is providing a written opinion on other OSHA regulated substances, the PLHCP can combine the written opinion for an individual employee for all covered substances. The intent of this requirement is to assure that personal medical information not necessary for making determinations about employee placement and selection of personal protective equipment is not shared with the employer. Sharing personal medical information unrelated to workplace Cr(VI) exposures is prohibited by the final standard. OSHA does not believe that it is necessary to change the language of this requirement as suggested by Ameren Corporation to convey this message.

The employer is also required to provide a copy of the PLHCP's written opinion to the employee within two weeks after receiving it, to ensure that the employee has been informed of the result of the examination in a timely manner. The employer must obtain the written opinion within 30 days of the examination; OSHA believes this will provide the PLHCP sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The requirement that the opinion be in written form is intended to ensure that employers and employees have the benefit of this information.

The proposed rule did not include a provision for medical removal protection (MRP) because OSHA made a preliminary determination that MRP was not reasonably necessary or appropriate for Cr(VI)-related health effects. The Supreme Court has held that OSHA does not have authority to adopt wage and benefit guarantee provisions unless it can make a finding that such a requirement is ''related to the achievement of a safe and healthful work environment.'' *American Textile Mfr. Inst., Inc.* v. *Donovan,* 452 U.S. 490, 538 (1981). Consistent with this decision, OSHA has taken the position that it ''must always ascertain that MRP is needed for health reasons'' before adopting provisions for medical removal wage and benefit protection (52 FR 34460, 34557 (Sept. 11, 1987)).

The need for MRP can vary from health standard to health standard and is dependent on the nature of the hazard, health effects, and medical surveillance program involved, and the record evidence obtained during each rulemaking. Although virtually every previous OSHA health standard includes provisions for medical surveillance, OSHA has found MRP necessary for only six of those standards. They are lead, 1910.1025; cadmium, 1910.1027; benzene, 1910.1028; formaldehyde, 1910.1048; methylenedianiline (MDA), 1910.1050; and methylene chloride, 1910.1052.

Upon consideration of this rulemaking record, relevant court decisions, and the criteria OSHA has previously applied to determine when MRP is necessary, OSHA is unable to find that an MRP provision is reasonably necessary or appropriate for the Cr(VI) standard.

The purpose of the medical removal protection OSHA has included in some health standards is to assure employees they will not suffer wage or benefit loss if they are temporarily removed from further exposure as a result of findings made in the course of medical surveillance, and thereby to encourage the employees to participate in the medical surveillance program. As discussed below, OSHA has determined not to include MRP in the Cr(VI) standard for the principal reason that the agency does not anticipate that a significant number of employees will need to be temporarily removed from their jobs as a result of medical surveillance. In addition, the Cr(VI) standard's medical surveillance program is less dependent on employee action than the programs in some other health standards that include MRP, such as lead and formaldehyde, and other considerations that have led OSHA to use MRP in the past are inapplicable in the context of Cr(VI).

Most of the comments OSHA received regarding MRP were about the pros and cons of MRP provisions generally, and not about the specific need, or lack thereof, for MRP in the context of the proposed Cr(VI) standard. Some of the groups representing workers advocated the inclusion of MRP with provisions for multiple physician review on the basis that MRP is generally necessary to encourage worker participation in medical surveillance programs (Tr. 793–795, 803–806, 2314–2315, 2345, Exs. 38–219–1; 39–71; 39–73–2; 40–10–2; 40–19–1; 47–28;). Some comments came out against the need for MRP, suggesting, for example, that MRP was unnecessary in this standard because there are few instances in which temporary removal from Cr(VI) exposures would be beneficial. Those commenters noted the permanent nature of the adverse health effects of Cr(VI) exposure, such as allergic asthma, allergic dermatitis, and lung cancer (Tr. 629, Exs. 38–220–1; 39–228–1; 39–235; 39–19; 39–47; 40–1–2).

In its proposal, OSHA preliminarily concluded that MRP appeared unnecessary because it did not anticipate many circumstances in which employees would be removed from their jobs under the new standard. The Agency reasoned that an MRP provision was unnecessary because Cr(VI)-related health effects generally fall into one of two categories: either they are chronic conditions that temporary removal from exposure will not improve or remedy (*e.g.*, lung cancer, respiratory or dermal sensitization), or they are conditions that can be addressed through proper application of control measures and do not require removal from exposure (*e.g.*, irritant dermatitis). The evidence submitted during the rulemaking has led OSHA to conclude that its preliminary reasoning was correct and that for the reasons stated in the proposal there will be few, if any, instances where temporary removal from Cr(VI) exposures would improve employee health (Tr. 629, Exs. 38–220–1; 39–228–1; 39–235; 39–19; 39–47; 40–1–2)

OSHA has declined to adopt MRP provisions in other health standards under similar circumstances. In the final standard for Ethylene Oxide (EtO), for example, OSHA did not include MRP provisions, concluding that ''the effects of exposure to EtO are not highly reversible, as evidenced by the persistence of chromosomal aberrations after the cessation of exposure, and the record contains insufficient evidence to indicate that temporary removal would provide long-term employee health benefits'' (49 FR at 25788, 6/22/1984). Similarly, the more recent 1,3 butadiene standard, which primarily addresses irreversible effects such as cancer, does not include MRP provisions (61 FR 56746, 11/4/96).

OSHA expects that the overall number of medical removals under the new standard will be very low. OSHA recognizes that a small number of employees may be removed from their jobs due to the health effects of Cr(VI) exposure, but the health effects evidence suggests many of the Cr(VI)-related effects are permanent and thus any such removals are likely to be permanent, not temporary. OSHA has historically viewed MRP as a tool for dealing with temporary removals only, as reflected in the agency's decisions not to adopt MRP in the EtO and 1,3 butadiene standards discussed above. Workers' compensation is the appropriate remedy when permanent removal from exposures is required.

When the D.C. Circuit reviewed OSHA's initial decision not to include MRP in its formaldehyde standard, it remanded the case for OSHA to consider the appropriateness of MRP for permanently removed workers. *UAW* v. *Pendergrass*, 878 F.2d 389, 400 (D.C. Cir. 1989). OSHA ultimately decided to adopt an MRP provision for formaldehyde. However, the agency did not rely on a need to protect workers permanently unable to return to their jobs. Indeed, OSHA expressly rejected that rationale for MRP, noting that ''[t]he MRP provisions [were] not designed to cover employees * * * determined to be permanently sensitized to formaldehyde'' (see 57 FR 22290, 22295 (May 27, 1992)).

Permanent wage and benefit protection would be extremely costly and is far beyond the scope of the MRP programs OSHA has required. Given that MRP provides benefits only for a temporary period, it is logical that eligibility be limited to those who have only a temporary need for removal. (See, *e.g.*, 1910.1027(l)(12) (MRP benefits available for up to a maximum of eighteen (18) months); 1910.1028(i)(9) (capping MRP benefits at six (6) months); 1910.1052(j)(12) (MRP benefits limited to a maximum of six (6) months)). The purpose of MRP—to alleviate fear of economic loss—can only be fulfilled for employees who are concerned about being removed temporarily. An employee worried that he may be permanently removed from his job if he participates in medical surveillance is unlikely to be persuaded by the prospect of a few months protection. In addition, an important objective of MRP is to prevent permanent health effects from developing by facilitating employee removal from exposure at a point when the effects are reversible, and that objective has no application where the effects are already permanent.

The evidence in the record does not demonstrate that affected employees are unlikely to participate in medical surveillance absent wage and benefit protection. In fact, given the small number of removals anticipated under the new standard, any economic disincentive to participate would likely be minimal. In any event, the medical surveillance programs required under the new Cr(VI) standard are less dependent on employee action than are the medical surveillance programs required under some of OSHA's other health standards. For example, OSHA adopted an MRP provision in the formaldehyde standard because that standard ''does not provide for periodic medical examinations for employees exposed at or above the action level'' and instead relies on ''the completion of annual medical questionnaires, coupled with * * * employees' reports of signs and symptoms''—an approach completely dependent ''on a high degree of employee participation and cooperation'' (see 57 FR at 22293). Unlike under the formaldehyde standard, Cr(VI) medical surveillance programs are not entirely dependent on employee reports of signs and symptoms. The Cr(VI) standard requires regular medical examinations and mandates that those exams include an evaluation of the employee's skin and respiratory tract. OSHA expects that independent of any subjective symptoms that may or may not be reported by the employee, practitioners conducting these examinations can make necessary medical findings based on the required objective evaluations of the employee's physical condition.

In the lead standard, OSHA adopted an MRP provision in part due to evidence that employees were ''desperate * * * to avoid economic loss no matter what the consequences to * * * [their] health'' and were therefore using chelating agents to ''effect a rapid, short term reduction in blood lead levels.'' (see 43 FR 54354, 54446 (Nov. 21, 1978)). In that case ''[t]he success of periodic blood level biological monitoring depend[ed] * * * on workers refraining from efforts to alter their blood lead levels.'' *Id.* Unlike in the case of lead, OSHA is unaware of any steps employees can take to mask and prevent the detection of Cr(VI) related health effects. Therefore, OSHA is not concerned about economic considerations resulting in employees intentionally sabotaging their examinations in a way that would undermine the success of the required medical surveillance programs.

Other reasons OSHA has cited for needing to include MRP in its health standards are similarly inapplicable to Cr(VI). In lead, for example, OSHA explained that the new blood lead level removal criteria for the final lead standard were much more stringent than criteria currently being used by industry and therefore many more temporary removals would be expected under the new standard '' thereby increasing the utility of MRP (see 43 FR at 54445–54446). There is insufficient evidence in the Cr(VI) rulemaking record to indicate that this would be the case for Cr(VI). As stated above, OSHA anticipates few circumstances where medical removal will be needed. Furthermore, there are no criteria in the new standard that are likely to increase the small number of medical removals that may be occurring.

Finally, one reason OSHA adopted MRP in the lead standard was because it ''anticipate[d] that MRP w[ould] hasten the pace by which employers compl[ied] with the new lead standard'' (43 FR at 54450). OSHA reasoned that the greater the degree of noncompliance, the more employees would suffer health effects necessitating temporary medical removal and the more MRP costs the employer would be forced to incur. Thus, in that case OSHA thought that MRP would serve as an economic stimulus for employers to protect workers by complying with the standard. With respect to Cr(VI), however, there is no evidence in the record that employees suffering from the health effects of Cr(VI) exposure need to be removed from their jobs now—when the PEL and exposures are significantly higher than they will be under the new standard; OSHA therefore has no reason to believe that so many employees would need to be removed once the PEL is lowered that employers' concerns about the costs of MRP would induce more rapid compliance on the part of employers. In fact, as stated earlier, OSHA believes that the health effects of Cr(VI) exposures will result in only a small number of medical removals. MRP is thus unlikely to work as a financial compliance incentive in this case.

OSHA also notes that there are two health standards that provide limited medical removal protection under their requirements for respiratory protection. They are asbestos, 1910.1001(g)(2)(iii); and cotton dust, 1910.1043(f)(2)(ii). These standards require MRP when a medical determination is made that an employee who is required to wear a respirator is not medically able to wear the respirator and must be transferred to a position below the PEL where respiratory protection is not required. OSHA has determined that such a provision is unnecessary for the Cr(VI) standard because OSHA has since promulgated a revised respiratory protection standard that specifically deals with the problem of employees who are medically unable to wear negative pressure respirators (29 CFR 1910.134(e)(6)). The respirator standard addresses the problem, not through MRP, but by requiring the employer to provide a powered air-purifying respirator instead of a negative pressure respirator. In the Cr(VI) standard, OSHA requires employers to comply with the requirements of 1910.134, including medical evaluations required under that standard. As discussed earlier in the section of the preamble addressing respiratory protection, there was much support for referring all aspects of respiratory protection to OSHA's revised respiratory protection standard. OSHA sees no reason to supersede 1910.134 in the final Cr(VI) standard.

In sum, OSHA does not expect Cr(VI)-related health exposures to result in a large number of medical removals, either temporary or permanent, and because the record shows that any removals that do occur are likely to be permanent, OSHA concludes that the evidence does not support a finding that MRP is reasonably necessary or appropriate for the final Cr(VI) standard. This decision is based on the evidence obtained during this rulemaking, and is not intended to preclude OSHA from adopting MRP provisions in the future when it believes that such a provision would contribute to the well-being of employees.

(l) Communication of Hazards to Employees

Paragraph (l) of the final rule (paragraph (j) for construction and shipyards) sets forth requirements intended to ensure that the dangers of Cr(VI) exposure are communicated to employees in accordance with existing requirements of OSHA's Hazard

Communication standard (HCS) (29 CFR 1910.1200).

In the proposed standard, requirements for communication of hazards were designed to be substantively as consistent as possible with OSHA's existing HCS in order to avoid a duplicative administrative burden on employers who would need to comply with the requirements of both standards. However, despite this effort, a number of commenters expressed the view that OSHA's existing HCS requirements are sufficient, and that hazard communication provisions in this rule are not warranted (*e.g.*, Exs. 38–203; 38–244; 38–254; 39–19; 39–40; 39–47; 39–48; 39–51; 39–56; 39–64; 39–72–1; 40–1–2). The Color Pigments Manufacturers Association supported this position, adding that additional requirements only serve to increase the complexity of an already complex and lengthy standard (Ex. 38–205). The North American Insulation Manufacturers Association (NAIMA) claimed that additional requirements deprive employers of necessary discretion, conflict with efforts to streamline and simplify hazard communication requirements, and increase the burden on employers while providing no apparent benefit (Exs. 38–228; 47–30). Moreover, NAIMA added that relying on the HCS will, in time, have the added benefit of simplifying implementation of the Globally Harmonized System of Classification Labeling of Chemicals (GHS).

Several other commenters supported OSHA's proposed requirements for communication of hazards (*e.g.*, Exs. 38–199–1; 38–219–1; 40–10–2). For example, NIOSH considered that the general requirements of the HCS are useful for all workplace hazards, but Cr(VI)-specific requirements provide focused and enhanced protection of workers (Ex. 40–10–2). The Building and Construction Trades Department, AFL–CIO maintained that the information and training requirements contained in the standard allow employers to go to a single reference to ensure they are in compliance, helping employers understand their obligations and assisting compliance officers assess employer compliance (Ex. 38–219–1).

In viewing the comments submitted to the record, it is clear that there is widespread support for the communication of hazards to employees. OSHA continues to believe, as stated in the proposal, that informing employees of the hazards to which they are exposed and associated protective measures is essential to provide employees with the necessary understanding of the degree to which they themselves can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and in material safety data sheets. These written forms of communication will be successful and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects.

However, OSHA also continues to believe that it is important for the requirements for communicating Cr(VI) hazards to be consistent with the requirements in its existing HCS. To better assure this consistency, OSHA has made a final determination to remove items from the final rule that duplicate requirements in the HCS. While certain proposed items are not being retained in the final Cr(VI) standard, the obligations to provide communication and training on the issues addressed in these items are required by the HCS. Thus, their removal does not represent a lessening in worker protection. OSHA believes such streamlining will provide better consistency and reduce confusion between the communication of hazards obligations under the final Cr(VI) rule and the HCS. OSHA acknowledges the comments of the Building and Construction Trades Department who felt that retaining these items allows employers to go to a single reference to ensure they are in compliance. However, since OSHA requires the HCS to be followed and has not repeated that standard in its entirety in the Cr(VI) standard, employers would not be able to rely solely on the Cr(VI) standard as a single reference for complying with the HCS even if such elements were retained. Moreover, it is a very rare workplace that has only Cr(VI) and no other hazardous chemicals. Thus, the vast majority of employers would have to consult the HCS anyway.

OSHA has retained the proposed provisions requiring that employees be trained about the contents of the new Cr(VI) final rule and the purpose and description of the medical surveillance program required under the final Cr(VI) standard. The final standard also requires that the employer make a copy of the standard readily available to employees without cost. These elements are not required to be communicated by the HCS. However, OSHA believes that it is important for employees to be familiar with and have access to the final Cr(VI) standard and the employer's obligations to comply with it. Specifically, with regard to the purpose and description of the medical surveillance program, OSHA intends that employees be trained about the signs and symptoms of Cr(VI)-related adverse health effects. This information, in conjunction with the training on Cr(VI) hazards required by the HCS, will help to assure that employees are able to adequately report signs and symptoms of Cr(VI)-related adverse health effects in order to receive medical attention from a licensed health care professional (as required by the medical surveillance section of the final standard and previously discussed in the preamble).

Like the HCS, OSHA intends that the required training be performance-oriented. The standard lists the subjects, in addition to those that are already covered by the HCS, that must be addressed in training, but not the specific ways that this is to be accomplished. Hands-on training, videotapes, slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program in each specific workplace.

OSHA believes that the employer is in the best position to determine how the training can most effectively be accomplished. The Agency has therefore laid out the objectives to be met to ensure that employees are made aware of the hazards associated with Cr(VI) in their workplace and how they can help to protect themselves. The specifics regarding how this is to be achieved are left up to the employer.

The communication of hazards elements proposed, but not included the final rule, are requirements for:

- Warning signs for regulated areas;
- Warning labels for Cr(VI)-contaminated work clothing and equipment and Cr(VI) wastes and debris;
- Employees to be provided training and training records;
- Initial training;
- Training that is understandable;
- Certain topics for training; and
- Additional training.

As discussed below, OSHA believes that these requirements either duplicate or are inconsistent with requirements in the HCS and are therefore not necessary in the final Cr(VI) standard.

Under the proposed standards, OSHA included requirements for specific language on signs and labels (e.g.,

DANGER; CHROMIUM (VI); CANCER HAZARD; CAN DAMAGE SKIN, EYES, NASAL PASSAGES, AND LUNGS; AUTHORIZED PERSONNEL ONLY; RESPIRATORS MAY BE REQUIRED IN THIS AREA.) OSHA is deleting the requirement for specific language on signs for regulated areas and on labels for containers of contaminated clothing and equipment and containers of Cr(VI) contaminated waste and debris consigned for disposal. By deleting these requirements OSHA is only deleting requirements for special signage. As discussed earlier in this preamble for paragraph (e), regulated areas, OSHA maintains in the final Cr(VI) standard requirements that regulated areas in general industry be demarcated but allows them to be demarcated in any manner that adequately establishes and alerts employees of the boundaries of the regulated area. OSHA believes that it is not necessary to require a prescribed sign in order to adequately demarcate a regulated area. Any manner of demarcation may suffice to achieve this goal. Similarly, OSHA has removed the requirements for specific language for warning labels. As discussed earlier in this preamble for paragraph (h), protective clothing and equipment (paragraph (g) for construction and shipyards) and paragraph (j), housekeeping, labels are still required for containers of Cr(VI)-contaminated work clothing and equipment and containers of Cr(VI) waste and debris. However, instead of specific mandated signage, OSHA is only requiring that those containers be labeled in accordance with OSHA's HCS. OSHA believes this achieves the same primary goal while providing flexibility for the employer. Moreover, as pointed out by the NAIMA, prescribed language may interfere with hazard communication harmonization under the GHS (Ex. 38–228).

In the proposed rule, OSHA required that training be provided for all employees who are exposed to airborne Cr(VI) or who have eye or skin contact with Cr(VI), that employers maintain a record of that training, and that the training be provided at the time of initial assignment to a job with potential exposure to Cr(IV). OSHA believes that these issues are already adequately addressed by the HCS. For example, paragraph (c) of the HCS defines employee as a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Such a definition would encompass those employees who are exposed to airborne Cr(VI) or who have skin or eye contact with Cr(VI). In addition, paragraph (e)(1) of the HCS requires that employers develop and implement a written hazard communication program that provides for employee training. Finally, paragraph (h)(1) of the HCS requires that employers provide training at the time of initial assignment.

The HCS does not require training records to be kept. OSHA finds no evidence in this record to support requiring training records in the final Cr(VI) standard or to justify this inconsistency with the HCS. This issue is discussed in further detail later in this preamble under paragraph (m), recordkeeping.

The proposed standard required that the employer provide training that is understandable to the employee. Because the HCS requires training to be ''comprehensible'' to employees (see 4/10/88 letter of interpretation; *http://www.osha.gov/pls/ oshaweb/owadisp.show_ document?p_table=INTERPRETATIONS&p_id=19651),* OSHA does not believe it is necessary to include this provision in the final Cr(VI) standard. Nevertheless, OSHA emphasizes that in order for the training to be effective, the employer must ensure that it is provided in a manner that the employee is able to understand. Employees have varying educational levels, literacy, and language skills, and the training must be presented in a language and at a level of understanding that accounts for these differences in order to meet the requirement that individuals being trained understand the specified elements. This may mean, for example, providing materials, instruction, or assistance in Spanish rather than English if the workers being trained are Spanish-speaking and do not understand English. The employer is not required to provide training in the employee's preferred language if the employee understands both languages; as long as the employee is able to understand the language used, the intent of the standard will be met.

OSHA has also removed certain elements addressing topics to be covered under employee information and training. OSHA believes that the HCS requires training on such items. The items removed address: the health hazards associated with Cr(VI) exposure; the location, manner of use and release of Cr(VI); engineering controls and work practices associated with the employee's job assignment; the purpose, selection and use of respirators and protective clothing; emergency procedures; and measures employees can take to protect themselves. Paragraphs (h)(2)(ii) and (h)(3)(ii-iii) of the HCS cover these topic areas. Therefore, OSHA believes that removing these elements from the final Cr(VI) standard neither removes any employer training requirements nor diminishes worker protection.

OSHA has also removed the proposed element for training employees on their rights to access records under 29 CFR 1910.1020(g). Such information on employees' rights is already required to be transmitted to employees under paragraph (g)(1) of OSHA's Access to Employee Medical and Exposure Records standard, 29 CFR 1910.1020. Therefore, OSHA sees no need to duplicate that requirement in the final Cr(VI) standard.

Finally, OSHA has removed elements addressing additional training. The proposed rule would have required that additional training be provided when necessary to ensure that each employee maintains an understanding of the safe use and handling of Cr(VI) and when workplace changes result in an increase in employee exposures. While the HCS does not have a provision requiring periodic retraining, it has been interpreted to require that employees ''must be aware of the hazards to which they are exposed . . . and know and follow appropriate work practice'' (see OSHA Compliance Directive, CPL 2–2.38D, Inspection Procedures for the Hazard Communication Standard) OSHA believes that since employees are required to be aware of the hazards to which they are exposed, this would mandate that as new exposures occur because of changes in the workplace employees must be made aware of them. Similarly, it would mandate additional training as necessary to maintain employees' understanding of the safe use and handling of Cr(VI) as this is critically linked to their awareness of hazards to which they are exposed.

In summary, although OSHA has removed a number of items under the communication of hazards in the final rule, the training obligations imposed by this final standard have not meaningfully changed. OSHA has only removed those items that are duplicative or inconsistent with the HCS, while retaining items not covered by the HCS that the Agency believes are necessary to ensure employees understand this final Cr(VI) standard and thereby protect employee health.

(m) Recordkeeping

Paragraph (m) of the final rule (paragraph (k) for construction and shipyards) requires employers to maintain exposure and medical surveillance records. OSHA proposed a requirement for employers to maintain records of employees' Cr(VI)-related training. This requirement has not been included in the final rule. As indicated in the discussion of paragraph (l) of the standard, OSHA believes that the provisions of the Agency's Hazard Communication standard (HCS) provide appropriate and sufficient requirements for training employees who are potentially exposed to Cr(VI). The HCS does not require retention of training records, and the addition of such a requirement in this rule would involve substantial additional paperwork burdens for employers. OSHA believes that the performance-oriented requirements of the HCS, along with the requirements of paragraph (l) that employees be able to demonstrate knowledge of both the Cr(VI) standard and the medical surveillance program it requires, will be sufficient to ensure that employees are adequately trained with regard to Cr(VI) hazards and protective measures. The absence of a requirement for retention of training records is also consistent with OSHA's two most recent substance-specific health standards, addressing exposure to methylene chloride (29 CFR 1910.1052) and 1,3 butadiene (29 CFR 1910.1051).

Relatively few comments addressed the proposed recordkeeping requirements. However, the final rule's requirements for maintenance of exposure records have been modified to reflect changes to paragraph (d) of this section addressing exposure determination. Specifically, requirements for maintaining exposure data have been added to the construction and shipyard standards. The requirements for retention of medical surveillance records are unchanged from the proposal.

The final recordkeeping requirements are in accordance with section 8(c) of the OSH Act, which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries and illnesses. The recordkeeping provisions are also consistent with OSHA's access to employee exposure and medical records rule (29 CFR 1910.1020).

Where the employer performs air monitoring to determine employee Cr(VI) exposures, records must be kept that identify the monitored employee and all other employees whose exposure the monitoring represents, and accurately reflect those exposures. The employer is required to keep records for each exposure measurement taken. Specifically, records must include the following information: The date of measurement for each sample taken; the operation involving exposure to Cr(VI) that was monitored; sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective equipment used; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

The final rule allows employers the option of relying on historical monitoring data or objective data to determine employee exposures to Cr(VI) where appropriate. Historical monitoring data are Cr(VI) monitoring results obtained prior to the effective date of the standard that were obtained during work operations conducted under workplace conditions closely resembling the employer's current operations. Objective data are information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to Cr(VI) associated with a particular product or material or a specific process, operation, or activity. Use of historical monitoring data and objective data under this final rule is described in greater detail in the discussion of paragraph (d) above addressing exposure determination.

Where historical monitoring data are relied upon to meet the exposure determination requirements of this standard, records of these data must be maintained. The records of historical monitoring data must demonstrate that the data were obtained using a method sufficiently accurate to be allowed under paragraph (d)(5) of the standard. The records must also show that the work being performed, the Cr(VI)-containing material being handled, and the environmental conditions at the time the historical monitoring data were obtained are the same as those on the job for which exposure is being determined. Other data relevant to operations, materials, processing, or employee exposures must also be included in records.

Where objective data are used to satisfy the exposure determination requirement, the employer must establish and maintain an accurate record of the objective data upon which he or she relied. This record must include: The chromium-containing material in question; the source of the objective data; the testing protocol and results of testing, or analysis of the material for the release of chromium (VI); a description of the process, operation, or activity involved and how the data support the determination; and other data relevant to the process, operation, activity, material, or employee exposures.

Since historical monitoring data and objective data may be used to exempt the employer from provisions of the standard or provide a basis for selection of respirators, it is critical that this determination be carefully documented. Reliance on historical monitoring data and objective data is intended to provide the same degree of assurance that employee exposures have been correctly characterized as air monitoring would, and records must demonstrate a reasonable basis for the exposure determination.

These records are also available to employees so that they can examine the determination made by the employer and assure themselves they are being protected by the employer. Moreover, compliance with the requirement to maintain records of exposure data enables the employer to easily show at least for the duration of the retention of records that the exposure determination was accurate and conducted in an appropriate manner.

In addition to records relating to employee exposures to Cr(VI), the employer must establish and maintain an accurate medical surveillance record for each employee subject to the medical surveillance requirements of the standard. OSHA believes that medical records, like exposure records, are necessary and appropriate for the protection of employee health, the enforcement of the standard, and to the development of information regarding the causes and prevention of occupational illnesses. Good medical records, including the record of the examination at termination of employment, are important to the employee in that this information will assist the employee and his or her PLHCP in making the best health care decisions. Medical records are necessary for the proper evaluation of the employee's health. The employer will benefit from knowing when his or her employees have Cr(VI) health related problems. The employer can then act to address workplace conditions that have been associated with Cr(VI) exposure. Finally the records can be useful to the Agency and others in enumerating illnesses and deaths attributable to Cr(VI), in evaluating compliance programs, and in assessing the efficacy of the standard.

Medical surveillance records are required to include the following information: The name, social security number, and job classification of the employee; a copy of the PLHCP's written opinions; and a copy of the information provided to the PLHCP. This information includes the employee's duties as they relate to Cr(VI) exposure, Cr(VI) exposure levels, and descriptions of personal protective equipment used by the employee (see paragraph (k)(4) in general industry, paragraph (i)(4) in shipyards and construction).

Several commenters expressed the view that requiring a copy of the information provided to the PLHCP would entail creating and maintaining an unnecessary duplicate copy of medical records (e.g., Exs. 38–203; 38–254; 39–47; 39–56). OSHA believes it is important for the employer to maintain medical records, even if duplicate information is maintained by the PLHCP. As mentioned previously, this information is useful in evaluating health outcomes, and retention by the employer ensures that complete records are available from a single source even if different PLHCPs provide examinations.

OSHA does not intend for this provision to be interpreted to require an employer to maintain multiple copies of records. If records of previous medical exams are within the control of the employer, that record is sufficient and does not need to be reproduced. For instance, where an employer maintains a record of medical exams provided to an employee, a duplicate record does not need to be created in order to fulfill recordkeeping requirements for a copy of the information provided to the PLHCP.

The final rule requires that exposure monitoring and medical surveillance records include the employee's social security number. The Color Pigments Manufacturers Association suggested that an employee identification number be permitted in lieu of a social security number (Ex. 38–205). OSHA examined alternative forms of identification in Phase II of the Agency's Standards Improvement Project (70 FR 1112 (1/5/05)) and did not take any action in that rulemaking concerning the use of social security numbers, indicating that further investigation was required.

For purposes of this rule, OSHA does not believe that alternative forms of identification, such as employee identification numbers, represent an acceptable alternative to social security numbers. The Agency understands the privacy concerns raised by this requirement. However, social security numbers have much wider application, and are correlated to employee identity in many other types of records. Social security numbers are therefore a more useful tool since each number is unique to an individual for a lifetime and does not change as an employee changes employers. This requirement is consistent with previous OSHA substance-specific health standards.

The final rule also incorporates the requirement that employers maintain and provide access to records in accordance with OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020). The medical and exposure records standard requires that exposure records be kept for at least 30 years and that medical records be kept for the duration of employment plus thirty years. It is necessary to keep these records for extended periods because of the long latency period commonly associated with cancer. Cancer often cannot be detected until 20 or more years after first exposure. The extended record retention period is therefore needed because causality of disease in employees is assisted by, and in some cases can only be made by, having present and past exposure data as well as the results of present and past medical examinations.

(n) Dates

Paragraph (n) of the standard (paragraph (l) for construction and shipyards) establishes start-up dates for requirements of the standard. OSHA has extended the effective date from that proposed and provided more time for employers to comply with most provisions of the final rule, based on information submitted to the record indicating that compliance may require additional time (*e.g.*, Exs. 39–19; 39–40; 39–47; 38–202; 38–205; 47–32; 38–233). The dates included in this final rule are also based on the Agency's experience with other standards concerning the amount of time required for employers to comply with similar requirements.

The standard will become effective on May 30, 2006. This date is 90 days from the date of publication in the **Federal Register**. The proposed standard had provided that the final rule would become effective 60 days after publication in the **Federal Register**. The extension of the interval between the publication date and the effective date of the standard is in response to comments indicating that some employers will need more time to comply than the proposed rule would have allowed (e.g., Exs. 38–214; 38–218; 38–220; 38–235; 38–254; 39–19; 39–40; 39–47; 39–48; 39–56; 39–60; 40–1–2).

The Agency sets the effective date to allow sufficient time for employers to obtain the standard, read and understand its requirements, and undertake the necessary planning and preparation for compliance. Section 6(b)(4) of the OSH Act provides that the effective date of a standard may be delayed for up to 90 days from the date of publication in the **Federal Register**. Given the concerns expressed by commenters, OSHA's interest in having employers implement effective compliance efforts, and the minimal effect of the additional 30 day delay, the Agency has decided that it is appropriate to set the effective date at 90 days from publication, rather than at 60 days.

The dates for employer compliance with obligations of the final rule have also been extended from those proposed. Special provision has been made to account for the needs of small businesses in meeting the requirements of the new standards. OSHA proposed a requirement that all employers comply with provisions of the final rule (except those for engineering controls) 90 days after the effective date. The final rule requires employers with 20 or more employees to comply with most requirements 180 days after the effective date. Employers with 19 or fewer employees must comply with most requirements of the final rule one year after the effective date. This extension is intended to allow employers sufficient time to complete initial exposure assessments, establish regulated areas where required, obtain appropriate protective work clothing and equipment, and comply with other provisions of the rule. Several commenters expressed concerns that 90 days did not allow sufficient time for employers to come into compliance with these provisions (e.g., Exs. 39–19; 39–40; 39–47; 39–48; 39–51; 39–56; 39–60; 40–1–2). ORC Worldwide expressed this opinion, stating:

> OSHA's proposal that all obligations of the standard except the engineering control requirement would be fulfilled within 90 days after its effective date is not enough time for the industries that have not determined their Cr(VI) sources and characterized their exposures to complete those tasks and be in compliance. Many are large companies with extensive operations, and finding all potential Cr(VI) sources will take time. Once these sources are identified, the task of characterizing exposures will require additional time. OSHA should allow a start-up date that is at least six months from the effective date (Ex. 39–51).

The Society for the Plastics Industry (SPI) concurred with the view that 90 days was an insufficient amount of time for employers to come into compliance with the rule, claiming in particular that employers who do not currently have respiratory protection programs in place will require more than 90 days to develop a respiratory protection program, obtain respirators, conduct medical evaluations and fit testing, and provide training. SPI advocated allowing 180 days after the effective date before respirator use would be required (Ex. 38–218).

The potential difficulties faced by small businesses in meeting the requirements of the rule were also noted by SPI and others, who urged OSHA to allow additional time for employers to comply with the requirements of the final rule (Exs. 38–218, pp. 34–35; 38–233, pp. 33–34). SPI stated:

> * * * small employers should receive more time to meet the requirements of the new rule when it becomes effective. Many small employers in the plastics industry do not have the resources to provide respirators and implement respirator programs, exposure monitoring, training and education programs, provide other forms of protective work clothing and PPE, install warning signs and regulated areas, and implement medical surveillance programs all within 90 days of the effective date of the new rule (Ex. 38–218, p. 35).

OSHA believes these concerns regarding the proposed compliance timetable are reasonable, so the Agency is providing additional time in order to give employers the ability to comply with these obligations. Given the large number of small employers covered by the requirements, and the special problems of many of those employers in identifying and implementing appropriate control measures, OSHA has decided to permit these employers a longer time period in which to comply with most requirements of the standard. OSHA has chosen to specify employment of 19 or fewer employers as the threshold size for allowing additional time for compliance under the final rule. The Agency believes this is a reasonable threshold, and is consistent with the threshold applied for similar requirements in the Methylene Chloride standard (29 CFR 1910.1052). OSHA believes the extended compliance times will allow affected employers sufficient time to comply with the requirements of the standard.

In the proposal, OSHA indicated that change rooms would be required no later than one year after the effective date of the standard. As explained in the discussion of paragraph (i), this standard does not impose new requirements for change rooms beyond those found in 29 CFR 1910.141(e) (for general industry and shipyards) and 29 CFR 1926.51(i) (for construction). Therefore, because change rooms should already be established, no effective date is necessary and reference to change rooms in this paragraph has been deleted to avoid potential confusion.

Feasible engineering controls must be in place within four years after the effective date. This is to ensure that employers are provided sufficient time to complete the process of designing, obtaining, and installing the necessary control equipment. This represents an extension of two years beyond that proposed for engineering controls. Several commenters contended that substantially more time was needed to implement engineering controls than had been proposed (e.g., Exs. 38–202; 38–204; 38–205; 38–228–1; 38–233; 39–49; 39–51; 47–32). For example, Engelhard Corporation indicated that OSHA had underestimated the complexity involved in meeting the requirements of the standard, such as testing of new equipment, obtaining building permits for process changes, and air permit changes (Ex. 38–202). Steel industry representatives argued that, in addition to time needed to install adequate engineering controls, additional time should be provided for the steel industry and other significantly affected industries to absorb the costs associated with compliance (Ex. 38–233).

OSHA agrees that additional time may be needed to come into full compliance with the engineering control requirements of the final rule. In particular, the Agency is aware that in some cases employers may be required to reevaluate modified ventilation systems for compliance with regulations governing discharges of Cr(VI) into the environment (e.g., EPA's Emission Standards for Hazardous Air Pollutants (NESHAP) regulations (40 CFR 63)). OSHA has taken into consideration the need of many affected employers to coordinate their OSHA compliance efforts with their other regulatory compliance obligations. The Agency believes it appropriate to allow sufficient time for modification and reevaluation of ventilation systems to generally be accomplished during normal permitting cycles in order to lessen the impact of the standard.

Other employers who may also need additional time for implementing engineering controls include employers with certain electroplating operations and welding operations. For example, in electroplating there are new fume suppressant technologies that can be used to reduce airborne exposures created in electroplating baths. However, some of these technologies have not been fully tested in the variety of electroplating operations that exist and employers must be careful in applying this technology for a particular operation so that the fume suppressant does not adversely affect the quality of the item being electroplated. Additional time for implementing such an engineering control would allow employers to gain experience with this technology and learn more effective ways to control exposures for their particular plating operations.

In addition, as discussed previously in this preamble, many welders will be able to reduce Cr(VI) exposures by switching from shielded metal arc welding (SMAW) to gas metal arc welding (GMAW). This switch is not a simple matter. The employer must first research conditions where such a switch might be possible taking into account the configuration of the areas where the welding might take place, the substrate to be welded and the desired quality of the weld. Since specifications for the desired weld are important, tests of the new welding technique may be necessary to make sure those specifications are met. Additionally, extra time is likely to be needed to buy the necessary equipment and train the employees who will be required to perform the new welding method. The final rule thus allows four years from the effective date for employers to institute engineering controls to comply with the standard. During the period in which employers are implementing these controls, respirators may be used to comply with the new PEL.

The extension of the compliance deadline for implementation of engineering controls will allow those firms that need extensive engineering controls time to adequately plan for and implement these controls. This modification will thus help to ensure adequate protection for workers. OSHA also believes that the extension will have the ancillary benefit of limiting the economic impact of the rule by allowing employers additional time to plan for and absorb the costs associated with compliance. Based on its review of the rulemaking record, the Agency has reached the conclusion that employers will be able to implement engineering controls within the time frame established in the final rule.

Appendices

OSHA did not include appendices in the proposed standard. While some of OSHA's previous standards have included non-mandatory appendices on topics such as the hazards associated with the regulated substance, health screening considerations, and sampling and analytical methods, OSHA made a preliminary determination that topics typically included in appendices could be better addressed with guidance materials.

Various commenters supported guidance materials in conjunction with the standard (Tr. 1307, 1308, 1309–1312, Exs. 38–214, p. 24; 38–220–1, p. 35; 39–20, p. 26; 39–60). One commenter noted the utility of OSHA's compliance assistance tools and preferred the accessibility of those guidance documents and e-tools to appendices (Ex. 39–60). Others, however, felt that including appendices as a part of the standard would make them more directly available for review and determining actions (Tr. 1099–1100, Exs. 38–218, p. 35; 39–19; 39–60; 40–1–2).

After consideration of these comments, OSHA has made a final determination not to include non-mandatory appendices in the Cr(VI) final rule. First, many of the appendices OSHA has included in the past such as sampling and analytical methods and respiratory protection fit-testing procedures are already readily available. For example, fit-testing procedures are an appendix to the respiratory protection standard (29 CFR 1910.134), and employers using respirators to comply with OSHA PELs must consult that standard. OSHA's analytical methods are also available through OSHA's website. Secondly, OSHA believes that guidance materials in the form of compliance assistance and outreach tools are a more flexible means for disseminating current information to employees and employers than appendices due to the fixed nature of an appendix as a part of the promulgated standard. For example, OSHA analytical methods are often updated and thus an appendix with such a method included might easily become outdated. Appendices on medical surveillance guidance could also become outdated as advancements in medical science occur. Guidance documents separate from the standard, however, could be more easily updated. Finally, guidance materials can be disseminated in several ways and take several forms. OSHA's experience with its outreach and compliance assistance tools has shown these methods are very effective in disseminating information and are well received by both employers and employees. Thus, the final Cr(VI) standard will not contain appendices, but OSHA will issue compliance assistance information to cover areas useful to the implementation of this final rule.

XVI. Authority and Signature

This document was prepared under the direction of Jonathan L. Snare, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The Agency issues the final sections under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); section 41, the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2002 (67 FR 65008); and 29 CFR Part 1911.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

Signed at Washington, DC., this 16th day of February, 2006.

Jonathan L. Snare,

Acting Assistant Secretary of Labor.

XVII. Final Standards

■ Chapter XVII of Title 29 of the Code of Federal Regulations is to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

■ 1. The authority citation for Subpart Z of Part 1910 is revised to read as follows:

Authority: Sections 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657: Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z–1, Z–2, and Z–3 but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553 but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029 and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

■ 2–3. In § 1910.1000:

■ a. Table Z-1 is amended by revising "tert-Butyl chromate (as CrO_3)"; by removing "Chromic acid and chromates (as CrO_3)"; and by adding "Chromium (VI) compounds" and new footnote 5;

■ b. Table Z–2, the entry "Chromic acid and chromates (Z37.7–1971)" is revised, and a new footnote "c" is added.

The revisions and additions read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1.—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm(a) [1]	mg/m^3 (b)[1]	Skin designation
* * * * * * *				
tert-Butyl chromate (as CrO_3); see 1910.1026.	1189–85–1			
* * * * * * *				
Chromium (VI) compounds; See 1910.1026[5].				
* * * * * * *				

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[5] See Table Z–2 for the exposure limits for any operations or sectors where the exposure limits in § 1910.1026 are stayed or are otherwise not in effect."

TABLE Z–2

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift	
			Concentration	Maximum duration
* * * * * * *				
Chromic acid and chromates (Z37.7–1971) (as CrO_3)[c].	....	1 mg/10m³.		
* * * * * * *				

[c] This standard applies to any operations or sectors for which the Hexavalent Chromium standard, 1910.1026, is stayed or otherwise is not in effect.”

* * * * *

■ 4. A new Section 1910.1026 is added, to read as follows:

§ 1910.1026 Chromium (VI).

(a) *Scope.* (1) This standard applies to occupational exposures to chromium (VI) in all forms and compounds in general industry, except:

(2) Exposures that occur in the application of pesticides regulated by the Environmental Protection Agency or another Federal government agency (*e.g.*, the treatment of wood with preservatives);

(3) Exposures to portland cement; or

(4) Where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of chromium (VI) in concentrations at or above 0.5 μg/m³ as an 8-hour time-weighted average (TWA) under any expected conditions of use.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne chromium (VI) of 2.5 micrograms per cubic meter of air (2.5 μg/m³) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing monodispersed particles of 0.3 micrometers in diameter or larger.

Historical monitoring data means data from chromium (VI) monitoring conducted prior to May 30, 2006, obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to chromium (VI) associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (k) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of chromium (VI) exceeds, or can reasonably be expected to exceed, the PEL.

This section means this § 1910.1026 chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 5 micrograms per cubic meter of air (5 μg/m³), calculated as an 8-hour time-weighted average (TWA).

(d) *Exposure determination.* (1) *General.* Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure for each employee exposed to chromium (VI). This determination shall be made in accordance with either paragraph (d)(2) or paragraph (d)(3) of this section.

(2) *Scheduled monitoring option.* (i) The employer shall perform initial monitoring to determine the 8-hour TWA exposure for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift, for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest chromium (VI) exposures.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months.

(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months.

(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to chromium (VI), or when the employer has any reason to believe that new or additional exposures have occurred.

(3) *Performance-oriented option.* The employer shall determine the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data, historical monitoring data, or objective data sufficient to accurately characterize employee exposure to chromium (VI).

(4) *Employee notification of determination results.* (i) Where the exposure determination indicates that employee exposure exceeds the PEL, within 15 working days the employer shall either post the results in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing of the results.

(ii) Whenever the exposure determination indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(5) *Accuracy of measurement.* Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (+/− 25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to chromium (VI).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of chromium (VI) is, or can reasonably be expected to be, in excess of the PEL.

(2) *Demarcation.* The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees of the boundaries of the regulated area.

(3) *Access.* The employer shall limit access to regulated areas to:

(i) Persons authorized by the employer and required by work duties to be present in the regulated area;

(ii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; or

(iii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (f)(1)(ii) and paragraph (f)(1)(iii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(ii) Where painting of aircraft or large aircraft parts is performed in the aerospace industry, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below 25 $\mu g/m^3$ unless the employer can demonstrate that such controls are not feasible. The employer shall supplement such engineering and work practice controls with the use of respiratory protection that complies with the requirements of paragraph (g) of this section to achieve the PEL.

(iii) Where the employer can demonstrate that a process or task does not result in any employee exposure to chromium (VI) above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(i) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1910.141. Eating and drinking areas provided by the employer shall also be in conformance with § 1910.141.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, or in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(j) *Housekeeping.* (1) *General.* The employer shall ensure that:

(i) All surfaces are maintained as free as practicable of accumulations of chromium (VI).

(ii) All spills and releases of chromium (VI) containing material are cleaned up promptly.

(2) *Cleaning methods.* (i) The employer shall ensure that surfaces contaminated with chromium (VI) are cleaned by HEPA-filter vacuuming or other methods that minimize the likelihood of exposure to chromium (VI).

(ii) Dry shoveling, dry sweeping, and dry brushing may be used only where HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure to chromium (VI) have been tried and found not to be effective.

(iii) The employer shall not allow compressed air to be used to remove chromium (VI) from any surface unless:

(A) The compressed air is used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air; or

(B) No alternative method is feasible.

(iv) The employer shall ensure that cleaning equipment is handled in a manner that minimizes the reentry of chromium (VI) into the workplace.

(3) *Disposal.* The employer shall ensure that:

(i) Waste, scrap, debris, and any other materials contaminated with chromium (VI) and consigned for disposal are collected and disposed of in sealed, impermeable bags or other closed, impermeable containers.

(ii) Bags or containers of waste, scrap, debris, and any other materials contaminated with chromium (VI) that are consigned for disposal are labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200.

(k) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Who are or may be occupationally exposed to chromium (VI) at or above the action level for 30 or more days a year;

(B) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(C) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Within 30 days after initial assignment, unless the employee has received a chromium (VI) related medical examination that meets the requirements of this paragraph within the last twelve months;

(ii) Annually;

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination;

(iv) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(v) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(vi) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (k) of this section was less than six months prior to the date of termination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(l) *Communication of chromium (VI) hazards to employees.*

(1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall comply with the following requirements.

(2) *Employee information and training.* (i) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The contents of this section; and

(B) The purpose and a description of the medical surveillance program required by paragraph (k) of this section.

(ii) The employer shall make a copy of this section readily available without cost to all affected employees.

(m) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to chromium (VI) that is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and the results of samples taken;

(E) Type of personal protective equipment, such as respirators worn; and

(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Historical monitoring data.* (i) Where the employer has relied on historical monitoring data to determine exposure to chromium (VI), the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.

(ii) The record shall include information that reflects the following conditions:

(A) The data were collected using methods that meet the accuracy requirements of paragraph (d)(5) of this section;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;

(C) The characteristics of the chromium (VI) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The chromium containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);

(D) A description of the process, operation, or activity and how the data support the determination; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(4) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (k) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(n) *Dates.* (1) For employers with 20 or more employees, all obligations of this section, except engineering controls required by paragraph (f) of this section, commence November 27, 2006.

(2) For employers with 19 or fewer employees, all obligations of this section, except engineering controls required by paragraph (f) of this section, commence May 30, 2007.

(3) For all employers, engineering controls required by paragraph (f) of this section shall be implemented no later than May 31, 2010.

PART 1915—[AMENDED]

■ 5. The authority citation for 29 CFR part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017) or 5–2002 (67 FR 65008), as applicable.

Sections 1915.120, 1915.152 and 1915.1026 also issued under 29 CFR part 1911.

Section 1915.1001 also issued under 5 U.S.C. 553. 1915.1000 Air contaminants.

* * * * *

■ 6. In § 1915.1000, Table Z, the entries for ''tert-Butyl chromate (as CrO_3)'', and ''Chromic acid and chromates (as CrO_3)'' are revised to read as follows:

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z.—SHIPYARDS

Substance	CAS No.[d]	ppm[a*]	mg/m3[b*]	Skin designation
* * * * * * *				
tert-Butyl chromate (as CrO_3); see 1915.1026[n]. 1	1189–85–1			
* * * * * * *				
Chromium (VI) Compounds; see 1915.1026[o].				
* * * * * * *				
* * * * * * *				
* * * * * * *				

[3] Use Asbestos Limit § 1915.1001.

[*] The PELS are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25° C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

[n] If the exposure limit in 1915.1026 is stayed or is not otherwise in effect, the TLV is a ceiling of 0.1 µg/m^3 (as CrO_3).

[o] If the exposure limit in 1915.1026 is stayed or is otherwise not in effect, the TLV is 0.1 µg/m^3 (as CrO_3) as an 8-hour TWA.

■ 7. A new § 1915.1026 is added, to read as follows:

§ 1915.1026 Chromium (VI).

(a) *Scope.* (1) This standard applies to occupational exposures to chromium (VI) in all forms and compounds in shipyards, marine terminals, and longshoring, except:

(2) Exposures that occur in the application of pesticides regulated by the Environmental Protection Agency or another Federal government agency (e.g., the treatment of wood with preservatives);

(3) Exposures to portland cement; or

(4) Where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of chromium (VI) in concentrations at or above 0.5 µg/m^3 as an 8-hour time-weighted average (TWA) under any expected conditions of use.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne chromium (VI) of 2.5 micrograms per cubic meter of air (2.5 µg/m^3) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Historical monitoring data means data from chromium (VI) monitoring conducted prior to May 30, 2006, obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to chromium (VI) associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (i) of this section.

This section means this § 1915.1026 chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 5 micrograms per cubic meter of air (5 µg/m^3), calculated as an 8-hour time-weighted average (TWA).

(d) *Exposure determination.* (1) *General.* Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure for each employee exposed to chromium (VI). This determination shall be made in accordance with either paragraph (d)(2) or paragraph (d)(3) of this section.

(2) *Scheduled monitoring option.* (i) The employer shall perform initial monitoring to determine the 8-hour TWA exposure for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift, for each job classification, in each work area. Where an employer does representative

sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest chromium (VI) exposures.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months.

(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months.

(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to chromium (VI), or when the employer has any reason to believe that new or additional exposures have occurred.

(3) *Performance-oriented option.* The employer shall determine the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data, historical monitoring data, or objective data sufficient to accurately characterize employee exposure to chromium (VI).

(4) *Employee notification of determination results.* (i) Where the exposure determination indicates that employee exposure exceeds the PEL, as soon as possible but not more than 5 working days later the employer shall either post the results in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing of the results.

(ii) Whenever the exposure determination indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(5) *Accuracy of measurement.* Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (+/−25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to chromium (VI).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(e) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (e)(1)(ii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this section.

(ii) Where the employer can demonstrate that a process or task does not result in any employee exposure to chromium (VI) above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(f) *Respiratory protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(g) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(h) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1915.97. Eating and drinking areas provided by the employer shall also be in conformance with § 1915.97.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(i) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Who are or may be occupationally exposed to chromium (VI) at or above the action level for 30 or more days a year;

(B) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(C) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Within 30 days after initial assignment, unless the employee has received a chromium (VI) related medical examination that meets the requirements of this paragraph within the last twelve months;

(ii) Annually;

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination;

(iv) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(v) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(vi) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (i) of this section was less than six months prior to the date of termination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(j) *Communication of chromium (VI) hazards to employees.* (1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall comply with the following requirements.

(2) *Employee information and training.* (i) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The contents of this section; and

(B) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.

(ii) The employer shall make a copy of this section readily available without cost to all affected employees.

(k) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to chromium (VI) that is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and the results of samples taken;

(E) Type of personal protective equipment, such as respirators worn; and

(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Historical monitoring data.* (i) Where the employer has relied on historical monitoring data to determine exposure to chromium (VI), the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.

(ii) The record shall include information that reflects the following conditions:

(A) The data were collected using methods that meet the accuracy requirements of paragraph (d)(5) of this section;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;

(C) The characteristics of the chromium (VI) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The chromium containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);

(D) A description of the process, operation, or activity and how the data support the determination; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(4) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (i) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (i)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(l) *Dates.* (1) For employers with 20 or more employees, all obligations of this section, except engineering controls required by paragraph (e) of this section, commence November 27, 2006.

(2) For employers with 19 or fewer employees, all obligations of this section, except engineering controls required by paragraph (e) of this section, commence May 30, 2007.

(3) For all employers, engineering controls required by paragraph (e) of this section shall be implemented no later than May 31, 2010.

PART 1917—[AMENDED]

■ 8. The authority citation for 29 CFR Part 1917 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Section 1917.28 also issued under 5 U.S.C. 553.

Section 1917.29 also issued under Sec.29, Hazardous Materials Transportation Uniform Safety Act of 1990 (49 U.S.C. 1801–1819 and 5 U.S.C. 553).

■ 9. New paragraphs (a)(2)(xiii)(E) and (b) are added to § 1917.1, to read as follows:

§ 1917.1 Scope and applicability.

(a) * * *

(2) * * *

(xiii) * * *

(E) Hexavalent chromium § 1910.1026 (See § 1915.1026)

* * * * *

(b) Section 1915.1026 applies to any occupational exposures to hexavalent chromium in workplaces covered by this Part.

PART 1918—[AMENDED]

■ 10. The authority citation for 29 CFR part 1918 is revised to read as follows:

Authority: Sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Secretary of Labor's Order Nos. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736); 6–96 (62 FR 111) or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Section 1918.90 also issued under 5 U.S.C. 553

Section 1918.100 also issued under Sec. 29, Hazardous Materials Transportation Uniform Safety Act of 1990 (49 U.S.C. 1801–1819 and 5 U.S.C. 553).

■ 11. New paragraphs (b)(9)(v) and (c) are added to § 1918.1 to read as follows:

§ 1918.1 Scope and application.

* * * * *

(b) * * *

(9) * * *

(v) Hexavalent chromium § 1910.1026 (See § 1915.1026)

* * * * *

(c) Section 1915.1026 applies to any occupational exposures to hexavalent chromium in workplaces covered by this part.

PART 1926—[AMENDED]

Subpart D—[Amended]

■ 12. The authority citation for subpart D of 29 CFR part 1926 is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657);5 U.S.C. 553; Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

■ 13. In Appendix A to § 1926.55, the entries for ''tert-Butyl chromate (as CrO_3)'' and ''Chromic acid and chromates (as CrO_3)'' are revised to read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

APPENDIX A TO § 1926.55.—1970 AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS' THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS

[Threshold limit values of airborne contaminants for construction]

Substance	CAS No.[d]	ppm[a]	mg/m^3 [b]	Skin designation
* * * * * * *				
tert-Butyl chromate (as CrO_3); see 1926.1126[n].	1189–85–1			
* * * * * * *				
Chromium (VI) Compounds; See 1926.1126[o].				
* * * * * * *				

* * * * * * *

[3] Use Asbestos Limit § 1915.1001

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25° C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

[n] If the exposure limit in 1926.1026 is stayed or is not otherwise in effect, the TLV is a ceiling of 0.1 mg/m^3 (as CrO_3).

[o] If the exposure limit in 1926.1026 is stayed or is not otherwise in effect, the TLV is 0.1 mg/m^3 (as CrO_3) as an 8-hour TWA.

Subpart Z—[Amended]

■ 14. The authority citation for subpart Z of 29 CFR part 1926 is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); Sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017) or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Sections 1926.1101 and 1926.1127 also issued under 5 U.S.C. 553.

Section 1926.1102 not issued under 29 U. S. C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

■ 16. A new section 1926.1126 is added to subpart Z of 29 CFR part 1926 to read as follows:

§ 1926.1126 Chromium (VI).

(a) *Scope.* (1) This standard applies to occupational exposures to chromium (VI) in all forms and compounds in construction, except:

(2) Exposures that occur in the application of pesticides regulated by the Environmental Protection Agency or another Federal government agency (*e.g.*, the treatment of wood with preservatives);

(3) Exposures to portland cement; or

(4) Where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of chromium (VI) in concentrations at or above 0.5 $\mu g/m^3$ as an 8-hour time-weighted average (TWA) under any expected conditions of use.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne chromium (VI) of 2.5 micrograms per cubic meter of air (2.5 $\mu g/m^3$) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Historical monitoring data means data from chromium (VI) monitoring conducted prior to May 30, 2006, obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to chromium (VI) associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (i) of this section.

This section means this § 1926.1126 chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 5 micrograms per cubic meter of air (5 $\mu g/m^3$), calculated as an 8-hour time-weighted average (TWA).

(d) *Exposure determination.* (1) *General.* Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure for each employee exposed to chromium (VI). This determination shall be made in accordance with either paragraph (d)(2) or paragraph (d)(3) of this section.

(2) *Scheduled monitoring option.* (i) The employer shall perform initial monitoring to determine the 8-hour TWA exposure for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift, for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest chromium (VI) exposures.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months.

(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months.

(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to chromium (VI), or when the employer has any reason to believe that new or additional exposures have occurred.

(3) *Performance-oriented option.* The employer shall determine the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data, historical monitoring data, or objective data sufficient to accurately characterize employee exposure to chromium (VI).

(4) *Employee notification of determination results.* (i) Where the exposure determination indicates that employee exposure exceeds the PEL, as soon as possible but not more than 5 working days later the employer shall either post the results in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing of the results.

(ii) Whenever the exposure determination indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(5) *Accuracy of measurement.* Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (±25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to chromium (VI).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(e) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (e)(1)(ii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this section.

(ii) Where the employer can demonstrate that a process or task does not result in any employee exposure to chromium (VI) above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(f) *Respiratory protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(g) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard

Communication Standard, 29 CFR 1910.1200.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(h) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1926.51 Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1926.51. Eating and drinking areas provided by the employer shall also be in conformance with § 1926.51.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(i) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Who are or may be occupationally exposed to chromium (VI) at or above the action level for 30 or more days a year;

(B) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(C) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Within 30 days after initial assignment, unless the employee has received a chromium (VI) related medical examination that meets the requirements of this paragraph within the last twelve months;

(ii) Annually;

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination;

(iv) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(v) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(vi) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (i) of this section was less than six months prior to the date of termination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(j) *Communication of chromium (VI) hazards to employees.* (1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall comply with the following requirements.

(2) *Employee information and training.* (i) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The contents of this section; and

(B) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.

(ii) The employer shall make a copy of this section readily available without cost to all affected employees.

(k) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to chromium (VI) that is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and the results of samples taken;

(E) Type of personal protective equipment, such as respirators worn; and

(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Historical monitoring data.* (i) Where the employer has relied on historical monitoring data to determine exposure to chromium (VI), the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.

(ii) The record shall include information that reflects the following conditions:

(A) The data were collected using methods that meet the accuracy requirements of paragraph (d)(5) of this section;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;

(C) The characteristics of the chromium (VI) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The chromium containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);

(D) A description of the process, operation, or activity and how the data support the determination; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(4) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (i) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (i)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(l) *Dates.* (1) For employers with 20 or more employees, all obligations of this section, except engineering controls required by paragraph (e) of this section, commence November 27, 2006.

(2) For employers with 19 or fewer employees, all obligations of this section, except engineering controls required by paragraph (e) of this section, commence May 30, 2007.

(3) For all employers, engineering controls required by paragraph (e) of this section shall be implemented no later than May 31, 2010.

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