Report of the Small Business Advocacy Review Panel on the OSHA
Draft Proposed Standard for Occupational Exposure to Beryllium

TABLE OF CONTENTS

1. Introduction

2. Reasons Why Action by the Agency is Being Considered	p. 3	
3. Summary of Comments from Small Entity Representatives	p. 5	
4. Panel Findings and Recommendations	p. 20	
Appendix A: List of Panel Members and Staff Representatives		
Appendix B: List of Small Entity Representatives		
Appendix C: Written Comments Submitted by Small Entity Representatives		
Appendix D: Preliminary Initial Regulatory Flexibility Analysis		

p. 3

Report of the Small Business Advocacy Review Panel on the OSHA Draft Proposed Standard for Occupational Exposure to Beryllium

1. Introduction

This report has been developed by the Small Business Advocacy Review Panel (the Panel) for the OSHA draft proposed standard for Occupational Exposure to Beryllium. The Panel included representatives of the Occupational Safety and Health Administration (OSHA), the Office of the Solicitor of the Department of Labor, the Office of Advocacy within the Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. On November 15, 2007, the Panel Chairperson, Robert Burt of OSHA, convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*). A list of the panel members and staff representatives is included in Appendix A.

This report consists of four parts: This introduction is Part 1; Part 2 provides background information on the development of the draft proposed rule; Part 3 summarizes the oral and written comments received from the small entity representatives (SERs); and Part 4 presents the findings and recommendations of the Panel. A list of the SERs is included in Appendix B of this report, and a complete copy of the written comments submitted by the SERs is included as Appendix C. In addition, the principal document sent to the SERs, the Preliminary Initial Regulatory Flexibility Analysis, is included as Appendix D to this document.

2. Reasons Why Action by the Agency is Being Considered

Acute beryllium disease (ABD), chronic beryllium disease (CBD), and lung cancer are three distinct lung diseases that have generally been associated with occupational exposure to beryllium. ABD is a rapid onset form of chemical pneumonia from breathing high airborne concentrations (e.g., $100 \, \mu g/m^3$ and above) of soluble beryllium (e.g. beryllium sulfate or beryllium fluoride). ABD results in lung swelling, fever, and shortness of breath that could be fatal, if the exposure continues.

CBD is a hypersensitivity or allergic reaction to beryllium that leads to a chronic inflammatory disease of the lungs. Unlike ABD, it takes months to years after initial beryllium exposure before signs and symptoms of CBD occur. Removing the employee from the beryllium source does not always lead to recovery. In some cases, CBD continues to progress following removal from beryllium exposure. CBD is not a chemical pneumonitis but an immune-mediated granulomatous lung disease. For CBD to

occur, an employee must first become sensitized (i.e., become allergic) to beryllium. Once an employee is sensitized, inhaled beryllium that deposits and persists in the lung may trigger a cell-mediated immune response (i.e., hypersensitivity reaction) that results in the formation of a type of lung scarring known as a granuloma. The granuloma consists of a localized mass of immune and inflammatory cells that have formed around a beryllium particle lodged in the interstitum of the lung. Over time, the granulomas spread and can lead to chronic cough, shortness of breath (especially upon exertion), fatigue, abnormal pulmonary function, and lung fibrosis. While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys.

Some studies demonstrate that sensitization and CBD cases have occurred in workplaces that use a wide range of beryllium compounds, including several beryllium salts, refined beryllium metal, beryllium oxide, and beryllium alloys. While water-soluble and water-insoluble beryllium compounds have the potential to cause sensitization, it has been suggested that CBD is the result of occupational exposure to beryllium oxide and other water-insoluble berylliums rather than exposure to water-soluble beryllium or beryllium ores. However, there are inadequate data, at this time, on employees selectively exposed to specific beryllium compounds to eliminate a potential CBD concern for any particular form of this metal. Regardless of the type of beryllium compound, for CBD to occur, the inhaled beryllium must contain particulates that are small enough to reach the bronchoalveolar region of the lung where the disease takes place.

Inhalation of respirable beryllium may be only one of several factors that determine whether an employee becomes sensitized to beryllium. It has been shown by some studies that employees with genes that code for specific protein molecules on the surface of their immune cells are at greater risk of becoming sensitized to beryllium and developing CBD. Some recent research suggests that skin exposure to small beryllium particles or beryllium-containing solutions may also lead to sensitization. These additional risk factors may explain why some individuals with seemingly brief, low-level exposure to airborne beryllium become sensitized while others with long-term, high exposures do not. Some studies suggest that even though employees sensitized to beryllium do not exhibit clinical symptoms, their immune function is altered such that inhalation to previously safe levels of beryllium can now trigger serious lung disease.

Several epidemiological cohort studies have reported excess lung cancer mortality among employees employed in U.S. beryllium production and processing plants during the 1930s to 1960s. OSHA has preliminarily determined that the weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens. Other scientific organizations, such as the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.

3. Summary of SER Comments

Based on oral and written comments from SERs, the industries represented by them could roughly be separated into two groups—one with relatively high airborne exposures and one with low exposures. The "high exposure" group had processes or operations that resulted in exposures near the lowest permissible exposure limit (PEL) option (0.1 micrograms) with occasional samples above that level. SERs in this high exposure group also performed almost daily work with beryllium materials, and beryllium-related work was a significant part of their revenues. SERs in industries in the "low" exposure group had processes that rarely, if ever, resulted in exposures near the lowest PEL option or only processed beryllium materials occasionally.

SERs in the high exposure group were manufacturers of precision metals, precious metal recycling, dental alloy, and medical optics. These SERs had beryllium programs to protect employees and control exposures. Employees received training in the hazards and proper handling of beryllium and the companies performed exposure monitoring. Several also had comprehensive medical surveillance programs. One of these SERs with over 200 employees made precision parts from beryllium metal and high-content alloy and had considerable engineering controls, a medical surveillance program (including the BeLPT), and performed considerable exposure monitoring. A SER in the recycling industry also reported that they had programs for beryllium, including respirator use, ventilation controls, exposure monitoring, and showers and change rooms for employees. A SER who makes beryllium alloy and has foundry operations for casting products reported that the company had a program with all of the provisions addressed in the draft standard. Three SERs currently offer employees the BeLPT and a fourth had tried the BeLPT in the 1990s, but abandoned the test when problems with the test results occurred.

The other group of SERs had exposures that were very low relative to even the lowest PEL option. SERs in this group were from precision machining industries, bushing and bearing producers, metal stampers of low-content copper-beryllium alloy, and dental labs. (An abrasive blasting SER could have significant exposures when using coal slag, but employees are always wearing an air-supplied abrasive blasting respirator required by OSHA standards.) Each of these SERs reported very low exposures and did not have beryllium programs. Most provided some training in the hazards of beryllium to employees and may prohibit some high-exposure processes like grinding, but did not have engineering controls, provide respiratory protection, or perform exposure monitoring. If they provided physicals or other medical surveillance, they did not provide or require the BeLPT. Some SERs in the precision metal industries only had occasional work with beryllium alloy. For some stampers beryllium alloy was an important part of their business, but their machinery was automated and enclosed, and the metal was bathed in oil/coolant; thus, employers in the industry believed that their exposures were very low. SERs in this low exposure group were clearly aware of the hazards of beryllium, but reported that until now did not believe that their exposure levels constituted much risk for their employees. For example, many SERs in the low exposure

group noted that there had been no cases of disease related to beryllium reported throughout their industry.

All SERs reported very low exposures in their establishments and industries--relative to the proposed PELs, and far below the current PEL--based either on their own exposure sampling, published reports, or industry-wide knowledge. The SER that was most extensively involved in processing beryllium reported average exposures below the lowest PEL option of 0.1 micrograms per cubic meter. This SER and another had internal PELs of 0.2 with action levels of 0.1 micrograms. Only two SERs reported that they had occasional samples measuring at or above 0.2 micrograms. As a consequence, unlike most OSHA health standards where the challenge to employers is achieving a PEL far below current exposures and the subsequent cost of engineering controls, many SERs viewed the impact of a beryllium standard on their establishments mainly via the ancillary provisions (e.g., showers, change rooms, housekeeping, etc.).

The SERs said their concerns about the impact of the ancillary provisions, discussed individually below, stemmed from two sources: 1) costs of ancillary provisions that were significant for SERs in some industries; and 2) more importantly, creating considerable uncertainty in other areas. These additional areas of uncertainties or risks included: creating fear among current or prospective customers and employees about using beryllium-based products or working with beryllium; possible litigation in the event that an employee is found to be sensitized to beryllium; impacts on the cost of company health or workers' compensation insurance; and, most importantly, losing customers to foreign manufacturers if the standard resulted either in significant cost increases or regulatory or management burden. In short, in a globally competitive market, many SERs were concerned that out-of-pocket costs or other effects of regulatory burdens would result in loss of beryllium-related business. In some industries, such a dental labs and dental alloy production, SERs were worried about losing domestic demand as well, because consumers would be afraid to use their products.

Provisions of the Standard

Definitions

Many SERs were concerned that key terms or phrases, lacking a definition in this section, triggered various ancillary provisions of the standard. The phrase "subject to routine contact with beryllium powders, dusts, or contact with contaminated surfaces" immediately raised questions to SERs of not only of what would constitute "routine" contact, but more importantly: "What is a "contaminated surface?" If OSHA did provide a clear definition of "contaminated," either in plain English or by a quantifiable measure, how would employers easily determine whether a surface was contaminated with beryllium—or just other substances? Similarly in paragraph (f) Methods of Compliance, the requirement for a written exposure control plan is triggered, in part, by the phrase "potential for significant skin contact." What would constitute "significant skin contact?"

Three ancillary provisions [(h) Protective Clothing, (i) Hygiene Areas, and (j) Medical Surveillance] are triggered by the action level or by "skin exposure from routine handling of beryllium powders or dusts or contact with contaminated surfaces." As one SER wrote:

OSHA should remove contact with contaminated surface language from the rule: I am concerned that this provision, which is a trigger for medical surveillance, the use of PPE [actually protective clothing and equipment], the installation of change rooms and showers, was problematic and vague and should be removed from the standard. (Goulding)

SERs did not provide definitions of these terms, but proposed alternative triggers for ancillary provisions.

Scope and application

Many SERs supported exemptions of their industry for various reasons: significant costs of the standard and potentially upsetting events or conditions among employees, customers, and the market for their products. Alternatively, some proposed that OSHA regulate high- and low-exposure industries differently, or regulate by the content of beryllium in the materials that are processed. Another suggested alternative was to apply a regulation by process (i.e., based on type of manufacturing), which is really a variant of the previously suggested approaches.

A number of SERs said that OSHA lacked evidence of beryllium disease in their industry, or even exposure. SERs from the stamping industry, for example, said that they had never heard of a case of beryllium-related disease associated with their industry. They suggested that OSHA should prove the existence of the hazard in each industry prior to regulating. One SER noted that although there were 40,000 employed over many years in his industry, a few cases of beryllium disease was insufficient justification for a standard that would impose significant costs and might disrupt the industry. One SER recommended a PEL-only standard, obviating the need for industries with low exposures, and presumably low risk, to comply with ancillary provisions.

Permissible Exposure Limits (PELs) and engineering controls

There was little discussion of the PELs. As noted above, most SERs have low exposures, although some SERs have not performed any exposure monitoring and rely on industry knowledge about exposures in operations. However, since several of the ancillary provisions of the standard are triggered by exposures above an action level, which is

usually one-half the PEL, there was concern voiced by SERs about that aspect of the impact of the PEL. If the PEL was set as low as 0.1 micrograms, then SERs in some industries would have to engage in compliance actions to satisfy requirements of the ancillary provisions triggered by the still lower action level. A number of SERs in their written comments suggested amending the draft standard to trigger some ancillary provisions on the standard's PEL rather than an action level (Harder, Gallet, Morgan). The ancillary provisions proposed for this alternative are initial exposure monitoring, written exposure control plan, and medical surveillance. SERs did not voice concern about meeting the airborne PELs under consideration. For example, one SER stated that:

...our concerns would escalate depending on how low the final PEL would be...we are operating with an internal PEL of $0.2 \,\mu\text{g/m}^3$ or ALARA (as low as reasonably achievable with an action level of $0.1 \,\mu\text{g/m}^3$. (Bradford)

None of the SERs commented on how alternative exposure metrics (e.g., number of particles versus mass, etc.) might impact their business.

Several SERs reported the use of considerable engineering controls. Most of the precision metal SERs reported some use of ventilation although most lathes and other machines are enclosed and work is performed under a flow of oil or coolant that limits or restricts any airborne exposures. A SER whose 200+ employees are involved daily in producing precision metal parts from high content beryllium reported extensive controls, including ventilation and enclosure of processes. Stampers' machines are automated and enclosed with metal strip bathed in oil/coolant at the stamping area. A SER who manufactures dental alloy reported that some operations are performed in enclosed and automated operations, some cutting and grinding is performed as wet operations with ventilation, and one grinding operation relied on ventilation to control dust. A SER from a dental lab said that the primary engineering control is to use ventilation when grinding is performed. All SERs reported exposure levels at or below the lowest PELs under consideration, and there was no discussion of the SERs' inability to achieve low exposure levels.

The SERs (with the exception of an abrasive blasting and coating employer using coal slags--for which substitutes were said to cost more) said that it was not easy to substitute for beryllium in their products. For dental labs, there is a substitute alloy, but the SERs reported that it is inferior to nickel-beryllium alloy. The beryllium alloy is springy and adjustable compared to the alternative. One SER said he produces spring seals for sprinkler heads for which no other material will work. SERs in precision metal industries say that their work is driven by what their customers demand. Beryllium is a superior product because of its strength and lightness and is used in many components in the aerospace industry, such as wing flaps, landing gear, and brakes. Similarly, stampers produce what customers demand. Copper-beryllium alloy is the superior product for electrical connectors needed in airplanes and many computer and other electronic components. For some components, beryllium-copper has unique properties, such as for miniature parts. A SER producing medical optics said that his company had to produce what customers specify, and beryllium-containing components are required in medical

optics applications. A SER who makes bearings reported that there were no alternatives to copper-beryllium that he knew of, as the alloy makes the strongest non-ferrous bearing material. A SER involved in abrasive blasting said that there were substitute media to coal slags, but, as noted above, they cost more.

Exposure Assessment

Five of the SERs said that they currently perform exposure monitoring. SERs who make products from materials with a high content of beryllium as an important part of their business performed considerable sampling. Some of the precision product manufacturers with less beryllium or low-content alloy performed some sampling, while SERs from the parts stamping industry had not performed any sampling—and neither had the SER from the abrasive blasting and coating industry. A SER from a precious metal recovery and recycling employer also perform sampling for beryllium as well as other hazards such as lead and cadmium.

SERs from industries with current very low exposures expressed frustration with the requirement for exposure monitoring as an initial assessment. For example, in the metal stamping industries where parts are now produced by enclosed, automated machines, the beryllium-copper strip is continually washed with a metal working fluid, or oil. SERs said that there is little chance of airborne beryllium being generated. One SER suggested that data generated by the industry should be permitted to substitute for every employer performing exposure monitoring. Several stampers noted that they do not permit or perform any grinding of alloy. With their current processes, there is no reason to believe they generate dangerous levels of beryllium. Another SER suggested that OSHA bear the burden of characterizing exposures in affected industries. If there were no problems found, then OSHA should not require employers to bear the cost of taking samples. Instead OSHA should regulate by classifying industries into separate categories with their own required provisions. As one SER put it, he was not against exposure monitoring, but OSHA should only require it where it is needed.

Regulated Areas

A few of the SERs reported that they currently isolate or segregate processes in some fashion in their beryllium operations. However, most do not. For example, SERs from the stamping industry generally described their current facilities as large, open spaces with machinery spaced throughout and with very high ceilings. Currently, work with beryllium-copper alloy may be performed on different automated stamping machines around the plant, and occasionally they move machines around the plant floor to help productivity. Some SERS said that it might be possible to segregate operations with

beryllium alloy, while others said they would not be able to. Regulated areas are triggered by the PEL in the draft standard, and generally SERs were not as concerned about its impact on their operations as other ancillary provisions. Several acknowledged that it might be possible to restrict certain areas to machines to perform stamping work. A SER from the recycling industry noted that their employees already wear respirators around hot metal or melting operations or any other operations with high exposures. SERs from the precision metal products industry described their processing of beryllium as very well controlled in enclosed lathes or forming machines. In addition, for several SERs, processes with beryllium-contained materials was only occasional, frequently as part of a larger order. They said it would be impractical to isolate specific areas or machines to beryllium work in such a case.

Methods of Compliance

Several SERs reported that they currently had a beryllium program. These SERs were ones with relatively high exposures and regular or daily processing of beryllium materials. SERs did not voice opposition to the provision in the standard; however, several suggested that OSHA base the written program on the standard's PEL rather than an action level or potential skin exposures.

Respiratory Protection

Several SERs provide respiratory protection for employees in some operations. A SER with abrasive blasting operations always provides the required air-supplied respirator. A SER in the recycling industry reported use of respirators at all facilities, with use mandatory in some operations. Another SER with major, daily work in making high-content beryllium parts reported use of respirators where necessary, based on an internal occupational exposure limit of 0.2 micrograms, including maintenance operations and cleaning baghouses. Another SER with foundry operations reported use of respirators for certain grinding operations on castings, used in addition to ventilation on the process. Abrasive blasting operations with coal slag, like other abrasive media, are performed with employees in air-supplied respirators and in protective clothing from head to toe, one SER reported. Other SERs in industries with very low exposures did not report any use of respirators. There was no written comment from SERs on this provision in the draft standard.

Protective Work Clothing and Equipment

Several of the SERs provide work clothing for employees. For high-exposure jobs such as cleaning baghouses or maintenance some SERs reported use of Tyvek/disposable protective suits. A SER performing abrasive blasting provides clothing and equipment to completely cover employees engaged in blasting operations, whatever the blasting media used. SERs' main concern with this provision was that it was triggered by the terms "skin exposure" and "contaminated surfaces," which are vague and left undefined in the draft standard

Hygiene Areas

Several SERs provide showers and change rooms at their facilities, but did not require employees to shower since their exposures were low. A number of SERs in low exposure industries said that they do not have showers and change rooms currently and that they did not have unused space within their facilities to build them. Again, SERs objected to triggering this provision on "anticipated skin exposure...or contact with contaminated surfaces."

Housekeeping

Almost all SERs reported that they perform housekeeping in some fashion. A precision metal shop reported that they sweep and then wet mop. A maker of beryllium-copper bushings reported that they do the same and also vacuum. A bearing maker reported that operators dry sweep their own work areas and floors are washed with scrubbing machines once a week. One SER working with pure beryllium metal and alloys on a daily basis said that they clean floors and machines daily. Floors are wet mopped and vacuumed; baghouses are cleaned twice a year; machines are vacuumed. But rafters and air-handling equipment are not cleaned frequently. A SER from the metal stamping industry said that small businesses do not have the resources to clean their entire production area every day. Some SERs in the stamping industry said that employees generally clean machines at the end of the day or after a production run with vacuums. The company provides respirators for this. Another stamper reported employees vacuuming their machines while wearing Tyvek clothing. As with other ancillary provisions, the SERs objected to the trigger for housekeeping provisions rather than the other provision of this paragraph. Several asked: "What is a contaminated surface?" "What is a surface?" "Does that include rafters and other surfaces high above the work areas, work surfaces such as benches, or just machinery?"

Medical Surveillance

This was the most controversial part of the draft standard for most SERs and received the most comment. Three SERs whose daily operations have the potential for higher exposures to beryllium provide the BeLPT for the employees. One of these SERs with over 200 employees, has provided the BeLPT for many years, but noted they had stopped doing the test annually because it was expensive and found to be unnecessary by their medical advisers. They now offer the test every two years and have focused their physical exams more narrowly as well. In their written comments, the SER suggested permitting performance-based medical surveillance; that is, allowing affected employers to design and determine what tests were appropriate (Bradford). This SER has discontinued annual physicals, x-rays, and spirometry and instead perform symptombased exams. Annual physicals and BeLPTs "result in excess needless costs with no additional benefit to our employees" (Bradford). A dental alloy manufacturer also provides the BeLPT for employees who work in melting and other high exposure areas as well as other annual health evaluations (Howe). One SER in the precision metals industry reported that they had provided the BeLPT to employees, but discontinued its use in the 1990s when the test "resulted in false readings due to smoking or other factors." The remaining SERs do not provide the BeLPT for employees, and many also did not provide or require an annual physical.

During the teleconference calls, SERs objected to the medical surveillance requirement for many reasons. First, the test was described by SERs as "expensive." Secondly, several SERs referred to a published article that questioned the reliability and accuracy of the test. SERs in industries with very low exposures, no history of beryllium disease, or who only occasionally performed beryllium-related work said that they did not feel the test was necessary. Finally, SERs were worried that the BeLPT could have multiple impacts on their business. Several SERs noted that it could be more difficult hiring individuals if potential employees were afraid of working with beryllium, and that requiring a BeLPT before beginning work would increase that fear. One SER also thought current employees might be affected in a similar way. Workers' compensation insurance and health insurance premiums might be increased as a result of greater concern with beryllium risks.

Many SERs were worried about what they would be faced with if an employee tested positive. Legal action by the employee could cost \$150-250 thousand dollars, one SER suggested. Rising fear of beryllium use, besides scaring their own employees, could also drive customers away, customers who up until now did not have concerns about the safety of the products they were buying. SERs also objected to the "triggers" for providing the BeLPT in the draft standard: the action level; skin exposure from routine handling of beryllium powders and dusts; or contact with contaminated surfaces.

These reasons were repeated and expanded upon in written comments. For example, many SERs recommended removing the BeLPT entirely (McManus, Harder, Morgan) from the medical surveillance provisions. However, none of the SERs who currently provide the BeLPT recommended its elimination. SERs had additional criticisms of the

BeLPT on scientific or technical grounds in written comments: that the test methodology is not standardized among the labs performing it and new tests are currently being developed (Harder, Morgan). Another said that there were other deficiencies: test results have varied within labs and between labs; significant numbers of reversals from positive to negative occur from one test to the next; and there are published reports that 1 to 2 percent of the population may test positive without any known occupational beryllium exposure (Goulding).

This SER noted what he felt to be further weaknesses in the BeLPT to identify beryllium sensitization: removal from exposure after a positive result on the BeLPT does not result in "changes in the natural history of beryllium sensitization, sCBD [sub-clinical CBD], or cCBD [clinically observed CBD]"; "there is no evidence that treatment of clinical CBD changes the long-term outcome of the disease"; "Individuals testing positive to the BeBLPT [or BeLPT] have been unnecessarily treated with steroids"; that there has been "no formal analysis of the significant socio-economic impacts of the BeBLPT [BeLPT] when used for screening, monitoring, or surveillance"; and that the "BeBLPT [BeLPT] is a lagging measure and, as such, does nothing to protect workers who are currently exposed to beryllium..."(Goulding). The conclusion reached was that "multiple scientific studies and data sets have established beyond any question that the BeBLPT test is neither sensitive nor specific enough to be consistently reliable as an individual screening test."

Medical Removal Protection (MRP)

Although medical removal was not included in the draft standard, many SERs saw the issues of using the BeLPT as leading to the issues surrounding MRP and had considerable comment. One SER with over 200 employees in the precision machining industry had been testing employees with the BeLPT since 1995 and had 28-30 employees who had tested positive. This SER leaves choice up of future job placement to the affected individual. Some employees leave the company—and some of these have returned to work at the facility. About half have left and half have stayed. One important factor is that this SER reported that the facility is a high-wage employer in a rural area.

Most SERs opposed a provision for MRP. Many asked: "What would we do if we had an employee who was sensitized?" Several were aware of possible legal liability if the employee were fired, or that they might incur legal action against the company for the health outcome itself. Many SERs with low exposures apparently do not currently have to deal with other similar serious occupational health risks in their workplaces.

Communication and Training

Most SERs reported training their employees to some extent about the risks of beryllium, such as how employees can protect themselves and prohibiting some types of tasks (such

as grinding copper-beryllium alloy). SERs had little comment on this provision, with the exception that one SER in a written comment wrote that:

OSHA should remove the cancer warnings from signs and labels based on the most recent scientific evidence: OSHA did not seek comment on its intent to require products supplied by the SERs would have to be labeled with a cancer warning...such warnings would unnecessarily scare customers and employees. (Goulding)

Recordkeeping

SERs had no comment on the recordkeeping paragraph or costs or burden specifically.

Costs and Economic Impacts

A few SERs said that overall OSHA had underestimated the costs of the draft standard. "We feel that the costs involved in implementing all aspects of the standard (as written) are greatly under-estimated. Annual medical surveillance (involving BeLPTs) would be extremely costly. If we were forced to segregate our machining areas...or re-construct our changing rooms...we would involve a far greater expense than the estimates cited in the data provided" (Bradford). "OSHA's overall economic impact is significantly understated" (Goulding).

Most SERs focused their concerns about costs of meeting several ancillary provisions. There was only one comment on the costs estimated for meeting a PEL with engineering controls, although there was concern that a low PEL and resulting lower action level would trigger in costs of ancillary provisions. Reducing the PEL to the lower options would cause one SER to install "about \$30,000 worth of equipment to attempt to reduce Beryllium dust in our grinding operation and foundry. However, it is unknown if this approach will be effective, since we take significant precautions already" (Howe). Another SER who had a full beryllium program commented that the exposure assessment provision "will be costly for firms with less experience but who need to determine levels" (Bradford).

Many SERs said that the cost estimates for providing showers and change rooms were too low—one-half to two-thirds too low, according to one SER. Other SERS said the cost would be even higher as they did not have unused space in their facility for hygiene areas. This would make providing these facilities "unaffordable," said one SER. A SER in the abrasive blasting and coating industry said that the monthly cost of renting showers would be \$6,000.

Several SERs said the costs of medical surveillance were underestimated. In addition, some SERs thought that follow-up BeLPT were not included in the cost estimates and, more importantly, that a resulting case of sensitization would create new costs from litigation. Several of the written comments noted that the BeLPT was "expensive" (Harder, Morgan). Other SERs in low exposure industries were concerned about the amount of management resources that would be necessary to develop, implement, and sustain the many facets in the standard. "Management's time to review and implement the standard" was identified as a significant issue by one SER (Howe).

Although SERs were concerned about the costs of some provisions, they were more concerned about how either those costs or the effect of unknown events or uncertainties might affect them through the markets for their products. The prime example of this worry was stated by a SER who produced dental alloy:

The OSHA Hazard Information Bulletin (HIB 02-04-19) issued in 2002 caused CMP Industries LLC to lose at least \$600,000 of income over the 5-year period 2002-2006 (Attachment 4). The loss represented about 28% of income over this time period. Our workforce was reduced as a result. (Howe)

While this reported loss of profit was due to a sudden drop in demand, other SERs were afraid that costs and regulatory burden would result in a loss of market to foreign competitors. SERs in the stamping and metal forming industries repeatedly referred to the competition they face from China, India, and other Asian countries. SERs were worried that their customers might also come under the regulation and search for alternatives or out-of-country sources to meet their needs without the burden of U.S. regulations.

Certainly if they need the product as part of the offering, the probable path would be to move their manufacturing process to a low cost, unregulated location, such as China. Certainly most of the electronic connector companies already have facilities in China and export back to the US in the way of finished goods...The regulation as proposed will help continue that trend. (Goulding)

And:

The position of Small Business and all of U.S. manufacturing is very tenuous at this moment. It is imperative that regulatory agencies like OSHA understand that well intentioned rulings can materially affect the cost of doing business and exacerbate manufacturing's ongoing problem of competing on [a] global basis. (Harder, Morgan)

Similarly, a SER in the dental lab industry said that increased costs and regulatory burden could result in the partial dentures, for example, being shipped to off-shore countries for manufacture, which has already begun to occur.

SERs reported that they are also concerned about pressures on their business arising from unexpected and uncertainty from other sources. For example, greater difficulty in hiring and retaining employees or a sensitized individual suing the company or filing for disability. The increasing recognition of hazards in the workplace from beryllium could result in higher workers' compensation or health insurance premiums. A single case of sensitization or medical removal could involve the company in litigation which could cripple a small company. In written comments SERs argued more forcefully for measures that would exempt or effectively shield companies in their industry from having to comply with the ancillary provisions of the draft standard.

One SER stated that "U.S. industry is under attack. We must focus on so many regulations and other problems. We will try to resist any more costs." The other SERs participating on the conference call agreed.

Another SER said he was already being pressured by his customers to move his operations to China to be closer to them.

Duplicative and overlapping regulations

SERs did not comment on the draft standard's duplicating or overlapping with other regulations.

Regulatory alternatives

SERs in low-exposure industries (stamping, some precision machining SERs, dental labs, bearing and bushing manufacturers, occasional work with beryllium) generally endorsed one of several regulatory alternatives that would reduce their burden and involvement with a beryllium standard:

- Exempt low exposure industries.
- Regulate high- and low-exposure industries differently—or high- and low-beryllium content industries differently.

SERs stated that these approaches were justified because of the lack of evidence of risk—or absence of beryllium-caused disease—in their industries. Additional costs, regulatory burden, or fear on the part of employees and customers put them on the cusp of losing their business to foreign producers and competition.

OSHA should exempt stamping and machining processes that do not generate small particulate from all these requirements. (Morgan, Harder)

Brush-Wellman's website contains information regarding air sampling conducted at metal stamping facilities...all of results from this air sampling were below 0.2 [micrograms per cubic meter]. (Morgan)

...the dental laboratory industry should be excluded from these regulations...the industry is a very low risk for beryllium-related illnesses...the economic benefit to the dental laboratory industry will not outweigh the detriment. (Howe)

Two more suggestions by SERs in low-exposure industries were also offered to shield them from "expensive" compliance with a standard they perceive to be unnecessary:

- Trigger ancillary provisions on the PEL, without reference to eye or skin exposure and surface contamination, or
- Promulgate a PEL-only standard.

These approaches, although not as sweeping as an exemption in the scope or industry-by-industry regulation, would allow employers with low exposures to avoid the complication of meeting the ancillary provisions, which they believe are unnecessary. "OSHA should remove contact with contaminated surfaces language from the rule" (Harder). Several SERs said that there was, besides the vagueness of the trigger terms and too high costs for some ancillary provisions, a lack of scientific evidence between skin contact and sensitization, particularly with insoluble forms of beryllium or beryllium compounds (Harder, Morgan, Bradford).

With regard to medical surveillance, almost all SERs recommended the same solution:

• Eliminate the BeLPT from medical surveillance.

Providing the BeLPT to employees creates the most uncertainty and is seen by SERs to be fraught with risk. Many SERs asked, "What would we do if an employee tested positive?" The SERs in the low exposure industries were not deeply involved in other sources of occupational health risk in their facilities. SERs that do intensive work with beryllium and have full programs apparently are more accustomed to handling all of the difficult and costly issues with beryllium—as well as other occupational hazards such as lead and cadmium. Whereas in the teleconference calls SERs in low-exposure industries objected to the triggers and were concerned about the possible results of a sensitized employee (as well as providing the BeLPT at all), in their written comments they proposed to delete the test from the standard. SERs identified a variety of scientific and technical issues that they concluded made the BeLPT an unsound test for screening employees exposed to beryllium, in addition to the test's cost.

• Utilize performance-based medical surveillance.

One SER with years of experience in medical surveillance of more than 200 employees had made considerable changes to their program since the 1990s. This SER recommended a performance-based medical surveillance program. The SER noted that annual general physicals and BeLPTs are expensive and unnecessary. The company has

tailored and focused its resources more narrowly on beryllium-related tests, symptoms, and exams. The company still provides the BeLPT to employees.

• Do not include medical removal protection

SERs made the following comments:

There should be no medical removal requirement in the standard. Since there is no medical evidence proving that removing a beryllium sensitized individual from a beryllium environment will change the outcome of their medical condition....This [MRP] could potentially involve litigation issues because of ADA violations and wrongful discharge claims. (Bradford)

The potential for mandatory or individual-requested medical removal is an item that is particularly troubling to Metech International. If a worker has an initial positive test and is notified, the resulting consequences can vary significantly. Some workers may have a retest that indicates negative results and work without any contention. Others may express the desire to leave their work area or the company even after a second test is negative. Individuals may have residual psychological doubt. Some may seek a disability claim after receiving confirmation of a second positive BeLPT or pursue legal action against the company. (McManus)

Mandatory removal certainly has even more consequences since most small companies do not have permanent alternate work assignments. The likelihood of disability or legal claims would become a greater issue with a mandatory removal provision. Even one moderate-sized claim under worker's compensation would cause increased premiums and potentially impact the entire industry-sector group. (McManus)

• Eliminate skin contact and surface contamination triggers for ancillary provisions.

Objections and criticisms to these triggers have been noted above. Substitution of the PEL alone as a trigger was suggested by several SERs. Several SERs (Harder, Morgan, Gallet) provided written revisions of the draft regulatory text, largely changing the triggers, for the following paragraphs: (d) Exposure Assessment; (f) Methods of Compliance; (i) Hygiene Areas and Practices; (k) Medical Surveillance; and (l) Communication of Beryllium Hazards to Employees.

The linkage of surface contamination and skin exposure to dusts and powders with resulting requirements of the proposed standard is too vague. The terms "contaminated surfaces" and "potential skin contact" may be interpreted in a number of different ways. Metech International does not believe that contact with surfaces should have any medical surveillance implications. (McManus)

Continued concern a standard is construed with a vague reference to contaminated surfaces triggering additional monitoring, medical surveillance, use of PPE, and the installation of change rooms and showers. Justification for surface cleanliness standard in form of wipe test was not presented. (Orr)

OSHA should remove eye and skin contact with contaminated surfaces language from the Draft Proposed Standard. Given that there are no studies that have found that skin contact with insoluble forms of beryllium (beryllium metal, beryllium oxide, beryllium containing alloys) can cause beryllium sensitization or CBD, we strongly object to this language in the proposed draft standard that eye and skin contact with contaminated surfaces triggers a number of unnecessary actions including workplace assessments, development of a written exposure control plan, protective equipment, installation of change rooms, lockers and showers, medical surveillance and training. (Morgan, Harder)

Although many SERs favor eliminating these triggers altogether, clearly all SERs would prefer that if they are employed in some manner that they be made clear in terms of what or how employers are to comply with these provisions.

• Better define housekeeping.

OSHA should provide clearly defined criteria for housekeeping. Define "contamination" or specify what housekeeping measures are sufficient.

• Provide guidelines for each industry to follow.

If OSHA's goal is to protect dental laboratory technicians from the potential hazard of working with beryllium-containing alloys, then I would recommend producing an educational DVD that fairly represents the findings of accurate research...and show—in detail—how to take precautions in a dental lab to stay safe...We feel strongly that OSHA should take a "carrot" approach to this issue, rather than [a] stick approach which will simply diminish the quality of dental care, eliminate US jobs and impair the financial operations of CMP industries." (Howe)

4. Panel Findings and Recommendations

Costs and economic impacts

Cost of engineering controls

One SER (a dental alloy manufacturer) reported that the company would need additional engineering controls to reach lower PEL options. This SER estimated that \$30,000 worth of additional controls would be necessary to control exposure for six foundry workers, who also perform some grinding operations wearing respirators. Most SERs do not conduct sampling, so they do know how much it would cost to achieve the lower PEL options. However, they believe, based on industry information, that their exposures are very low. An abrasive blasting company said that substituting for coal slag to meet a low PEL, if required, would result in higher costs because substitute media are more expensive. One SER suggested that a PEL of 1.0 micrograms would be reasonable, with an action level of 0.5 micrograms. This SER felt that this level would be protective, but would reduce the financial impact on the beryllium industry as a whole

The Panel recommends that OSHA evaluate carefully the costs and technological feasibility of engineering controls at all PEL options, especially those at the lowest levels.

Costs of exposure assessment

Five SERs perform exposure monitoring and the remaining SERs have never sampled. SERs in very low exposure industries, or who only perform beryllium work occasionally, did not express an opinion about the costs of monitoring or OSHA's estimated costs. One SER, who takes about 1,000 samples per year, thought that "[initial] exposure assessment would be costly for firms with less experience who need to determine levels." One SER with 55 production employees sampled every other year at a cost of \$1,500.

The Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations with exposures far below the PEL. The Panel also recommends that OSHA consider explaining more clearly how employers may use "objective data" to estimate exposures. Although the draft proposal contains a provision allowing employers to initially estimate exposures using "objective data" (e.g., data showing that the action level is unlikely to be exceeded for the kinds of process or operations an employer has), the SERs did not appear to have fully understood how this alternative may be used. The

Panel recommends that OSHA consider providing some type of guidance to describe how to use objective data to estimate exposures in lieu of conducting personal sampling. Using objective data could provide significant regulatory relief to several industries where airborne exposures are currently reported by SERs to be well below even the lowest PEL option. In particular, since several ancillary provisions, which may have significant costs for small entities may be triggered by the PEL or an action level, OSHA should consider encouraging and simplifying the development of objective data from a variety of sources.

Costs of regulated areas

Several SERs said that the costs of isolating beryllium operations with exposures above a PEL could be quite expensive. Some SERs said that segregating processes with beryllium could be achieved, but it would affect productivity to some extent because, in this case, metal stampers move production orders around the floor to different machines and sometimes also move the machines.

The Panel notes that the regulated area provision in the draft standard only applies where exposure exceeds the PEL and does not require employers to either segregate all beryllium work together or isolate such work from other work areas. Since among all the SERs only one may have a process with typical, or average, exposures over the lowest PEL option, the provision for regulated areas seems at present to have virtually no impact on industries represented by the SERs. The Panel recommends that OSHA revisit its analysis of the costs of regulated areas if a very low PEL is proposed.

Costs of hygiene areas

A number of SERs stated that OSHA's costs for hygiene areas were significantly underestimated. Comment was directed at the cost of building and installing showers and change rooms, rather than the time allowance for employees to shower and change. Several said that their plants had no room for change rooms or showers and that this provision would make compliance "unaffordable." Several SERs—those with more intense involvement with beryllium—have showers and change rooms, but not all required employees to use them.

In the draft rule this provision is triggered by "anticipated skin exposure from routine handling of beryllium powders and dusts or contact with contaminated surfaces." SERs' concerns centered on the lack of definition of terms in that phrase, so they felt virtually any employer with beryllium on the premises could be affected and have to comply. As in other parts of the draft standard, SERs questioned the necessity of hygiene areas if their industry had very low exposures and no history of beryllium disease.

The Panel recommends that OSHA revisit its cost model for hygiene areas to reflect SERs' comments that estimated costs are too low and more carefully consider the opportunity costs of using space for hygiene areas where SERs report they have no unused space in their physical plant for them. The Panel also recommends that OSHA consider more clearly defining the triggers (skin exposure and contaminated surfaces) for the hygiene areas provisions. In addition, the Panel recommends that OSHA consider alternative requirements for hygiene areas dependent on airborne exposure levels or types of processes. Such alternatives might include, for example, hand washing facilities in lieu of showers in particular cases or different hygiene area triggers where exposure levels are very low.

Costs of housekeeping

Most SERs reported that they currently have significant daily housekeeping activities, including wet mopping, vacuuming, and sweeping of machines and areas around machines. Some SERs said that employees wear Tyvek clothing and respirators while performing housekeeping tasks. Other SERs said that PPE and respirators were available but employees were not required to use them while performing housekeeping. Some of these SERs said that after hearing from the other SERs they would now require employees to use those protections during housekeeping. Finally, some SERs said they did not provide any PPE or respirators for housekeeping activities.

OSHA based its estimates of costs on each affected employee who works with beryllium spending 15 minutes per day in clean up. SERs said they were unable to comment on the estimated costs of this requirement because of what they saw as the vagueness of the requirement that cleaning is needed to ensure that "all surfaces are maintained as free as practicable of accumulations of beryllium..." SERs questioned whether "all surfaces" include walls, rafters, ceilings, etc., or just machines and work benches. SERs also said the provision did not specify how often cleaning must be done or what constitutes "clean." One SER commented that "small businesses do not have the resources to completely clean their facilities every day."

The Panel recommends that OSHA consider clearly explaining the purpose of the housekeeping provision and describing what affected employers must do to achieve it. For example, OSHA should consider explaining more specifically what surfaces need to be cleaned and how frequently they need to be cleaned. The Panel recommends that the Agency consider providing guidance in some form so that employers understand what they must do. The Panel also recommends that once the requirements are clarified that the Agency re-analyze its cost estimates.

Costs of medical surveillance

Some SERs currently provide medical surveillance (such as physical exams) for employees exposed to beryllium, but most do not. Similarly, some SERs currently provide or in the past have provided the BeLPT test, but most do not. One SER—who advocates a performance-based medical surveillance program—reduced the frequency of physicals and the BeLPT to every other year and reduced the scope of the exams to beryllium-related symptoms

Many SERs described the requirement for the BeLPT as "expensive." However, none of the SERs, including those who provide the BeLPT for their employees currently, commented that OSHA's estimate of the cost was in error or reported a different cost for the test (OSHA estimated that the annual cost of medical surveillance per affected employee was \$460, including physicals). Some SERs questioned whether OSHA's cost estimates accounted for retests in the event of positive results or transportation to where the test could be taken. One SER who provides BeLPTs to employees said that an annual test "would result in needless costs with no additional benefit to employees." This SER has provided the BeLPT every two years since 1995. The SERs were also very concerned about the potential costs of an employee having a positive test in terms of legal liability, disability claims and workers' compensation, life insurance, repercussion among current and future employees, etc.

There is a second parameter besides the costs of each test that determines the total costs of the BeLPT: the number of employees who must be tested. In the draft standard, medical surveillance is triggered by airborne exposure above the action level or skin exposure from routine handling of beryllium powders and dusts or contact with contaminated surfaces. Some SERs felt this was not a clear delineation of when medical surveillance is required, and many concluded under the proposed triggers that many employees would have to be provided with the test. In OSHA's cost model, the Agency estimated that all production employees in "high exposure" industries would be provided the BeLPT under the draft standard, but many fewer employees would be offered the test in industries with low exposures. SERs clearly were concerned that the terms in the triggering phrase were vague and subjected them to providing the BeLPT to many if not most employees.

The Panel recommends that OSHA consider more clearly defining the trigger mechanisms for medical surveillance and also consider additional or alternative triggers-such as limiting the BeLPT to a narrower range of exposure scenarios and reducing the frequency of BeLPT tests and physical exams. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.

Medical removal protection (MRP)

A provision for MRP was not in the draft proposed standard provided to the SERs, but it was one of the alternatives discussed in the PIRFA. A cost estimate was provided (about \$6,000 per affected employee [sensitized] per year). All SERs who commented on a possible MRP provision opposed it. They feared that mandatory removal could involve companies in litigation over disability or the Americans with Disabilities Act violations, SERs said. Many of the SERS said they do not have permanent alternate work assignments. Although the likelihood of an employee having a positive test was low among most SERs, the potentially very costly consequences of even one case was daunting to them.

The one SER who had employees who had been sensitized leaves the decision about the job up to the employee. About one-half of the SER's employees who had been sensitized to beryllium had left the company, but some later returned to the company.

The Panel recommends that OSHA consider that small entities may lack the flexibility and resources to provide alternative jobs to employees who test positive for the BeLPT, and whether MRP achieves its intended purpose given the course of beryllium disease. The Panel also recommends that if MRP is implemented, that its effects on the viability of very small firms with a sensitized employee be considered carefully.

Economic impacts and economic feasibility

The greatest concern of most SERs was for the potential loss of their product market either to foreign competitors, as in the case of the precision machining industry and metal stamping industries, or to a collapse of domestic demand due to spreading fear of beryllium itself (for example, dental alloy manufacturing and dental labs). SERs were concerned that fear of beryllium materials could spread to their customers, leading them to seek substitutes, even if those substitutes are inferior to beryllium-containing products. Many SERs were also concerned about possible significant costs of the ancillary provisions themselves. For example, some SERs said their limited physical plants made it impossible or unaffordable to install showers and changing rooms for some SERs. Another area of concern was both the cost and unknown outcomes with the BeLPT. SERs were concerned that a single sensitized employee could result in very high costs of legal action associated with disability, workers' compensation premiums, and so forth. As mentioned above, one SER suggested a PEL of 1.0 micrograms would be reasonable while relieving the economic pressures on most the beryllium industries.

The Panel recommends that the Agency, in evaluating the economic feasibility of a potential regulation consider not only the impacts of estimated costs on affected establishments, but also the effects of the possible outcomes cited by SERs: loss of market demand, the loss of market to foreign competitors, and of U.S. production being

moved abroad by U.S. firms. The Panel also recommends that OSHA consider the potential burdens on small businesses of dealing with employees who have a positive test from the BeLPT. OSHA may wish to address this issue by examining the experience of small businesses that currently provide the BeLPT test.

Provisions of the proposed rule

Scope and application

SERs in several industries wanted OSHA to exempt them from the standard, including dental alloy manufacturing, metal stamping, dental labs, and others having very low exposures to beryllium. They argued that exposures are very low and that there have been no cases of beryllium-related disease (in the case of dental labs, there have been a few known cases of CBD among an estimated 40,000 dental lab technicians). The SERs contended that a costly standard is unnecessary where risk is so low. Other SERs said that OSHA should first show that there is a risk to their industry or regulate on an industry-by-industry basis, or according to the percentage of beryllium in the materials used.

The Panel recommends that OSHA consider seeking ways of minimizing costs for small businesses where the exposure levels may be very low. Clarifying the use of objective data, in particular, may allow industries and establishments with very low exposures to reduce their costs and involvement with many provisions of a standard. The Panel also recommends that the Agency consider tiering the application of ancillary provisions of the standard according to exposure levels and consider a more limited or narrowed scope of industries.

The PEL

One SER questioned the appropriateness of identifying beryllium as a carcinogen, which would require appropriate labels on products. The SER said that concern about beryllium causing cancer is an artifact of twenty years ago when exposures were ten times as high as today. In addition, a SER stated that beryllium sensitization was not a material impairment of health and that OSHA should not regulate based on that health effect.

The Panel recommends that OSHA provide an explanation and analysis for all health outcomes (and their scientific basis) upon which it is regulating employee exposure to beryllium. The Panel also recommends that OSHA consider to what extent a very low PEL (and lower action level) may result in increased costs of ancillary provisions to small entities (without affecting airborne employee exposures). Since in the draft proposal the PEL and action level are critical triggers, the Panel recommends that OSHA consider

alternate action levels, including an action level set at the PEL, if a very low PEL is proposed.

<u>Triggers for ancillary provisions—methods of compliance, hygiene areas, protective clothing, medical surveillance, housekeeping</u>

SERs objected to the lack of definition in the triggers of ancillary provisions (i.e., "anticipated skin exposure from routine handling of beryllium powders and dusts or contact with contaminated surfaces"). They also questioned whether there was science or health data that linked skin exposure to sensitization and CBD. More specifically, some challenged whether insoluble beryllium forms had been linked to sensitization and disease via the skin. If not, the SERs said that triggers based on the premise should be removed from the proposed standard.

The Panel recommends that OSHA consider more clearly and thoroughly defining the triggers for ancillary provisions, particularly the skin exposure trigger. In addition, the Panel recommends that OSHA clearly explain the basis and need for small entities to comply with ancillary provisions. The Panel also recommends that OSHA consider narrowing the trigger related to skin and contamination to capture only those situations where surfaces and surface dust may contain beryllium in a concentration that is significant enough to pose any risk—or limiting the application of the trigger for some ancillary provisions.

Exposure assessment

Several SERs said that OSHA should first assume the burden of describing the exposure level in each industry rather than employers doing so. Others said that the Agency should accept exposure determinations made on an industry-wide basis, especially where exposures were far below the PEL options under consideration.

As noted above, the Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations or processes with exposures far below the PEL. The use of objective data is a principal method for industries with low exposures to satisfy compliance with a proposed standard. The Panel recommends that OSHA consider providing some guidance to small entities in the use of objective data.

Medical surveillance

The most critical issue for SERs concerning medical surveillance is the BeLPT test. Several SERs said that the BeLPT had many scientific and technical flaws. Those SERs criticized the BeLPT as inaccurate and unreliable, not performed in a standard way between labs, and that reversals of test findings occur over time. In addition, SERs said that new tests are being developed that may prove superior and that "background" positive results may occur to individuals who have no occupational exposure to be beryllium. SERs also questioned the value of the test since removal of employees from exposure may not affect the course of disease. Some SERs questioned whether the test was appropriate with a trigger of skin exposure and said sensitization via the skin has not been proven scientifically, particularly so of skin exposure to insoluble forms of beryllium.

The Panel recommends that OSHA consider more fully evaluating whether the BeLPT is suitable as a test for beryllium sensitization in an OSHA standard and respond to the points raised by the SERs about its efficacy. In addition, the Agency should consider the availability of other tests under development for detecting beryllium sensitization and not limit either employers' choices or new science and technology in this area. Finally, the Panel recommends that OSHA re-consider the trigger for medical surveillance where exposures are low and consider if there are appropriate alternatives.

Overlapping and duplicative regulations

SERs did not identify any concerns with overlapping or duplicative regulations by other governmental agencies.

Significant alternatives

The Panel recommends that OSHA carefully consider and solicit comment on the following alternatives:

• Seeking ways of minimizing costs to low risk processes and operations: OSHA should consider alternatives for minimizing costs to industries, operations, or processes that have low exposures. Such alternatives may include, but not be limited to: encouraging the use of objective data by such mechanisms as providing guidance for objective data; assuring that triggers for skin exposure and surface contamination are clear and do not pull in low risk operations; providing guidance on least-cost ways for low risk facilities to determine what provisions of the standard they need to comply with; and considering ways to limit the scope of

the standard if it can be ascertained that certain processes do not represent a significant risk.

- PEL only standard: One SER recommended a PEL only standard. This would protect employees from airborne exposure risks while relieving the beryllium industry of the cost of the ancillary provisions. The Panel recommends that OSHA, consistent with its statutory obligations, analyze this alternative.
- Alternative triggers for ancillary provisions: The Panel recommends that OSHA clarify and consider eliminating or narrowing the triggers for ancillary provisions associated with skin exposure or contamination. In addition, the Panel recommends that OSHA should consider tiering ancillary provisions dependent on exposure rather than have these provisions all take effect with the same trigger. If OSHA does rely on a trigger related to skin exposure, OSHA should thoroughly explain and justify this approach based on an analysis of the scientific or research literature that shows a risk of sensitization via exposure to skin. If OSHA adopts a relatively low PEL, OSHA should consider the effects of alternative airborne action levels in pulling in many low risk facilities that may be unlikely to exceed the PEL--and consider using only the PEL as a trigger at very low levels.
- Revise the medical surveillance provisions, including eliminating the BeLPT: The BeLPT was the most common complaint from SERs. The Panel recommends that OSHA carefully examine the value of the BeLPT and consider whether it should be a requirement of a medical surveillance program. The Panel recommends that OSHA present the scientific evidence that supports the use of the BeLPT as several SERs were doubtful of its reliability. The Panel recommends that OSHA also consider reducing the frequency of physicals and the BeLPT, if these provisions are included in a proposal. The Panel recommends that OSHA also consider a performance-based medical surveillance program, permitting employers in consultation with physicians and health experts to develop appropriate tests and their frequency.
- No medical removal protection (MRP): OSHA's draft proposed standard did not include any provision for medical removal protection, but OSHA did ask the SERs to comment on MRP as a possibility. Based on the SER comments, the Panel recommends that if OSHA includes an MRP provision, the agency provide a thorough analysis of why such a provision is needed, what it might accomplish, and what its full costs and economic impacts on those small businesses that need to use it might be.
- Drop or limit the provision for regulated areas: SERs with very low exposure levels or only occasional work with beryllium questioned the need for separating

areas of work by exposure level. Segregating machines or operations, SERs said, would affect productivity and flexibility. Until the health risks of beryllium are known in their industries, SERs challenged the need for regulated areas.