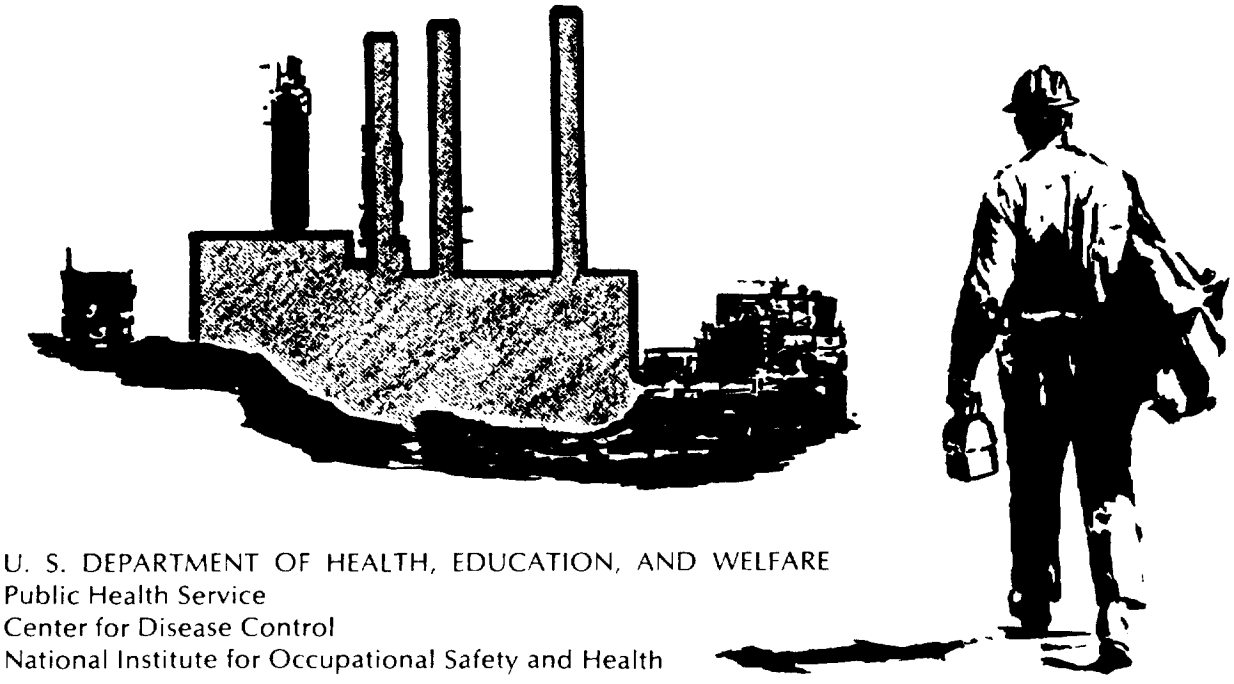
NIOSH

CRITERIA FOR A
RECOMMENDED STANDARD....

OCCUPATIONAL
EXPOSURE TO

o-TOLIDINE



U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
National Institute for Occupational Safety and Health

criteria for a recommended standard....

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DISCLAIMER

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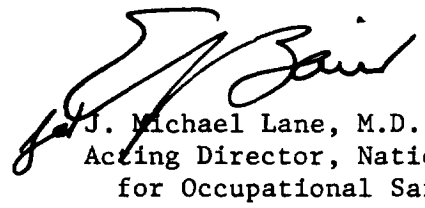
PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and provide for the safety of workers occupationally exposed to an ever-increasing number of potential hazards. The National Institute for Occupational Safety and Health (NIOSH) evaluates all available research data and criteria and recommends standards for occupational exposure. The Secretary of Labor will weigh these recommendations along with other considerations, such as feasibility and means of implementation, in promulgating regulatory standards.

NIOSH will periodically review the recommended standards to ensure continuing protection of workers and will make successive reports as new research and epidemiologic studies are completed and as sampling and analytical methods are developed.

The contributions to this document on o-tolidine by NIOSH staff, other Federal agencies or departments, the review consultants, the reviewers selected by the Society of Toxicology, and Robert B. O'Connor, M.D., NIOSH consultant in occupational medicine, are gratefully acknowledged.

The views expressed and conclusions reached in this document, together with the recommendations for a standard, are those of NIOSH. They are not necessarily those of the consultants, the reviewers selected by professional societies, or other Federal agencies. However, all comments, whether or not incorporated, have been sent with the criteria document to the Occupational Safety and Health Administration for its consideration in setting the standard. The review consultants and the Federal agencies which received the document for review appear on pages v and vi.



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The Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, had primary responsibility for the development of the criteria and recommended standard for o-tolidine. Herbert L. Venable of this Division served as criteria manager. SRI International developed the basic information for consideration by NIOSH staff and consultants under contract CDC-99-74-31.

The Division review of this document was provided by Douglas L. Smith, Ph.D. (Chairman), Keith H. Jacobson, Ph.D., and Frank L. Mitchell, D.O., with Larry K. Lowry, Ph.D. (Division of Behavioral and Biological Sciences) and Charles C. Hassett, Ph.D.

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Environmental Protection Agency
  Office of Deputy Assistant Administrator
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I. RECOMMENDATIONS FOR AN o-TOLIDINE STANDARD

NIOSH recommends that employee exposure to o-tolidine in the workplace be controlled by adherence to the following sections. The recommended standard is designed to protect the health and provide for the safety of employees for up to a 10-hour workshift, 40-hour workweek, over a working lifetime. Compliance with all sections of the recommended standard should prevent adverse effects of o-tolidine on the health of employees and provide for their safety. The standard is measurable by techniques that are reproducible and available to industry and government agencies. The employer should regard the recommended workplace environmental limit as a maximum limit for exposure and should make every effort to keep the exposure as low as is technically feasible. Sufficient technology exists to permit compliance with the recommended standard. The criteria and standard will be subject to review and revision as necessary.

o-Tolidine is widely used in the dye industry. It is also used in analytical chemistry procedures, including tests for chlorine in water, and in medical laboratory tests for sugar or occult blood. The biologic dye, trypan blue, contains the o-tolidine moiety. Animals exposed to o-tolidine have developed cancers at various sites, and results of bacterial tests indicate that o-tolidine may be mutagenic. Damage to mammalian DNA metabolism has also been reported. o-Tolidine is readily absorbed through the skin, and nasal irritation has been reported in humans exposed to it.

The term "o-tolidine" refers to various physical forms of the compound and its salts. Synonyms for o-tolidine include 3,3-dimethylbenzidine, 4,4-diamino-3,3-dimethylbiphenyl, diorthotoluidine, diaminoditolyl, azoic diazo reagent, gold diazo reagent, nitro coupling reagent, direct blue 63, fast blue R base, and benzo fast blue R. "Occupational exposure to o-tolidine" is defined as work in any place in which o-tolidine is produced, stored, used, packaged, or distributed. If o-tolidine is handled or stored only in intact, sealed containers, (eg, during shipment), adherence to the following sections, except for Sections 3, 5(a), 6(g), and 8(a), is not required. This recommended standard does not apply to users of test tapes or test kits containing o-tolidine. Employees shall avoid skin contact with o-tolidine, since skin absorption can be a significant source of exposure.

Section 1 - Environmental (Workplace Air)

(a) Concentration

Occupational exposure to o-tolidine shall be controlled so that employees are not exposed at a concentration greater than 20 micrograms per cubic meter of air (μg/cu m), determined as a ceiling concentration in a 1-hour sampling period. Skin contact with o-tolidine shall be avoided.

(b) Sampling and Analysis

Procedures for the collection and analysis of environmental samples shall be as provided in Appendix I or by any methods shown to be at least equivalent in precision, accuracy, and sensitivity to the methods specified.

Section 2 - Medical

Medical surveillance shall be made available as outlined below to all employees occupationally exposed to o-tolidine.

(a) Preplacement medical examinations shall include at least:

(1) Comprehensive medical and work histories with special emphasis directed towards the urinary tract.

(2) Comprehensive physical examination to include urinalysis with a microscopic examination of cells in urine. If the urinalysis is judged to be abnormal, a reexamination shall be performed. If the abnormal finding is confirmed, a comprehensive urologic evaluation should follow.

(3) A judgment of the worker's ability to use positive pressure respirators.

(b) Periodic examinations shall be made available at least annually to employees occupationally exposed to o-tolidine. Quarterly urine examinations are recommended. These examinations shall include at least:

(1) Interim medical and work histories.

(2) Comprehensive physical examination as described in (a)(2).

(c) Pertinent medical records shall be maintained for all employees exposed to o-tolidine in the workplace. Such records shall be kept for at least 30 years after the last occupational exposure to o-tolidine. Records of environmental exposures applicable to an employee shall be included in the employee's medical records. These records shall be made available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and of the employee or former employee.

Section 3 - Labeling and Posting

All warning signs shall be printed both in English and in the predominant language of non-English-reading employees. Workers who cannot read the language used on labels or warning signs shall receive information regarding hazardous areas and shall be informed of the instructions printed on labels and signs.

All containers of o-tolidine shall be labeled and all areas where o-tolidine is stored, handled, used, produced, or distributed shall be posted in accordance with the following subsections.

(a) Containers of o-tolidine shall bear the following label in addition to, or in combination with, labels required by other statutes, regulations, or ordinances:

O-TOLIDINE
DANGER
CANCER SUSPECT AGENT
CAN BE ABSORBED THROUGH SKIN

Use only with adequate ventilation.
Handle with gloves resistant to o-tolidine.
Wash from skin immediately.

(b) The following warning sign shall be posted in readily visible locations at or near entrances to areas in which o-tolidine is stored, handled, used, produced, or distributed:

WARNING--HAZARDOUS AREA
O-TOLIDINE
CANCER SUSPECT AGENT
CAN BE ABSORBED THROUGH SKIN
AUTHORIZED PERSONNEL ONLY

Section 4 - Personal Protective Equipment and Clothing

Employers shall use engineering controls and safe work practices to keep exposure to o-tolidine as low as possible and to minimize skin contact. When necessary, these shall be supplemented by the use of personal protective equipment. All employees entering the regulated area shall be equipped with clean work clothing (long-sleeved shirts, trousers, underwear, and footwear) and with the necessary protective equipment. Full-body protection with appropriate head covering and air supply shall be used in weighing and charging operations in which there is occupational exposure to o-tolidine. At no time shall protective equipment be stored in the regulated area.

(a) Respirators may be used only:

(1) During the time necessary to install and test the required engineering controls.

(2) During nonroutine operations or maintenance and repair activities in which brief exposure to o-tolidine dust or vapor may occur.

(b) Respirators permitted or required by paragraph (a) of this section shall be supplied-air or self-contained positive-pressure respirators with full facepiece and shall comply with the standards jointly approved by NIOSH and the Mining Safety and Health Administration as specified in 30 CFR 11. All respiratory protective devices should be worn with full-body clothing resistant to penetration by o-tolidine. Employers shall provide respiratory protection for employees and shall establish and enforce a respiratory protection program meeting the requirements of 29 CFR 1910.134 and shall ensure that employees use the respiratory protective equipment when necessary.

(c) Employers shall ensure that respirators are properly cleaned and maintained. They shall also ensure that employees know the location of respirators assigned to them, how to use them, and how to test respirators for leaks, proper operation, and proper fit.

(d) Respirators shall be easily accessible. If respirators for more than one purpose are present, employees shall be taught to recognize the proper one.

Section 5 - Informing Employees of Hazards from o-Tolidine

(a) Employees who work in areas in which o-tolidine is stored, handled, used, produced, or distributed shall be informed at the beginning of their assignment and at least annually thereafter of the hazards of exposure to o-tolidine, including the information that o-tolidine is believed capable of causing cancer, that it can be absorbed through the skin, mouth, and respiratory tract, and that it may cause kidney damage. Employees shall also be informed of the value of continued periodic medical examinations. Information shall also be provided on the specific nature of the operation that could result in exposure and on how to recognize and evaluate conditions and situations that may result in the release of o-tolidine. The employer shall also inform the employees about cleanup, decontamination, and emergency procedures and their role in these activities. Employers shall post this information in the workplace and shall keep it on file, readily accessible to employees.

(b) Employers shall institute a continuing education program, conducted at least annually by persons qualified by experience or training, for employees whose jobs may involve occupational exposure to o-tolidine to ensure that all such employees have current knowledge of job hazards; relevant maintenance, cleanup, and decontamination methods; and proper respirator use. The instruction program shall include a description of the environmental and medical surveillance procedures and of the advantages to the employee of participating in these procedures. As a minimum, instruction shall include the information in Appendix III.

(c) Required information shall be recorded on the "Material Safety Data Sheet" shown in Appendix III or on a similar form approved by the Occupational

Safety and Health Administration, US Department of Labor, and kept on file, readily accessible to employees at all places of employment where there is occupational exposure to o-tolidine.

Section 6 - Work Practices

(a) Emergency Procedures

For all work areas in which emergencies involving o-tolidine may occur, employers shall ensure that employees are properly trained and follow the procedures specified below and any others appropriate for the specific operation or process.

(1) All employees involved in the emergency who may have had skin contact with o-tolidine shall wash affected parts promptly and thoroughly.

(2) Persons essential to emergency operations shall have the approved protective clothing and respirators, as specified in Section 4, readily available.

(3) Procedures shall be prepared for maintenance or cleanup and decontamination of areas where leaks or discharges of o-tolidine have occurred. Employees not essential to emergency operations shall be evacuated from the affected areas during emergencies. Perimeters of these areas shall be delineated, posted, and secured.

(4) Only personnel properly trained in emergency procedures and protected against the attendant hazards shall clean up and decontaminate spills and control and repair leaks. After cleanup and decontamination, protective clothing and equipment shall be decontaminated and removed and the employee required to shower.

(5) Emergency telephone numbers shall be prominently posted.

(b) Engineering Controls

Engineering controls shall be used to prevent the inhalation of, and to minimize skin contact with, o-tolidine by controlling the amount of o-tolidine that is emitted into the air and, indirectly, the amount present in the work area through settling. The most effective control measure is enclosure of unit operations and processes. For small operations, glove boxes or laboratory hoods may constitute sufficient enclosure. Local exhaust ventilation may also be effective when used at the source of o-tolidine emission.

Ventilation systems shall be inspected for corrosion, subjected to regular preventive maintenance, and cleaned at least every 6 months to ensure their effectiveness. The effectiveness of the system shall be verified by airflow measurement at least annually and a log showing the results of annual

inspections shall be kept. Exhaust ventilation systems shall discharge to the outside air through an appropriate filtering device and shall conform to applicable local, state, and Federal regulations. Contaminated exhaust air shall not be recirculated or discharged to other work areas, either regulated or unregulated.

Enclosures, exhaust hoods, and ductwork shall have pressure-failure alarms and shall be kept in good repair so that design airflows are maintained. Airflow at each hood shall be measured at least quarterly, but monthly measurements are recommended. Continuous airflow indicators, such as water or oil manometers properly mounted at the juncture of fume hood and duct throat (marked to indicate acceptable airflow), are recommended. A log showing design airflow and the results of quarterly inspections shall be kept and may be used in place of the annual inspection log of the ventilation system.

(c) Regulated Areas

Regulated areas shall be established and maintained where o-tolidine is manufactured, used, processed, or repackaged. Access to these areas shall be limited to authorized persons. This requirement for regulated areas includes the manufacturing and processing of o-tolidine test tapes and test kits, but it does not apply to the use of such tapes or kits for testing applications (such as for water analysis for chlorine or for measurement of occult blood) if skin contact with o-tolidine is avoided. An entry roster shall be kept of employees entering regulated areas. Toilets shall be located in regulated areas for use of employees in these areas and shall be separate from other toilet facilities.

(1) Access to the regulated area shall be limited to employees having assigned duties there.

(2) A daily entry roster shall be kept of all employees entering the regulated area and of their length of stay.

(3) Employees working in regulated areas shall wash their face, neck, hands, and forearms each time they leave the regulated area. Washing facilities shall be provided at each exit. Employees working in regulated areas shall wash their hands and forearms before and after using the toilet.

(4) Employees engaged in operations in which o-tolidine is transferred, charged, or discharged, or which involve using a laboratory-type hood, opening a closed system, or repackaging, shall be provided with gloves and aprons or coveralls or with full-body protective suits resistant to penetration by o-tolidine.

(5) As a backup precaution, employees using glove boxes to handle o-tolidine shall wash their hands and arms on completion of the assigned task.

(6) When employees use protective clothing and equipment, they shall remove it and leave it at the exit before they leave the regulated area; the

employees shall then wash their hands, forearms, face, and neck to remove accumulated o-tolidine before they enter nonregulated areas.

(d) Clean Room

A clean room shall be established and maintained that is free of o-tolidine contamination and that contains locker facilities.

(1) Shower facilities shall separate the clean room from the regulated area.

(2) The clean room shall be kept under positive pressure relative to the regulated area.

(3) Signs meeting the requirements of Section 3 shall be posted at the doorway separating the clean room and regulated area. Instructions informing employees of the procedures for entering and leaving the regulated area shall also be posted.

(4) Employees assigned to the regulated area shall change into clean work clothing (long-sleeved shirts, trousers, underwear, and footwear) each day before entering the regulated area. The necessary protective clothing and equipment shall also be put on at this time.

(5) At the end of each workday, protective clothing, work clothing, and protective equipment shall be removed and placed in clearly labeled containers located in the regulated area. The employee shall then proceed to the shower facility and shower and shampoo before entering the clean room to put on street clothing.

(e) Decontamination

Good housekeeping practices shall be observed to prevent contamination of areas and equipment with o-tolidine solids, solutions, and aerosols. The regulated area shall be washed thoroughly at the end of each shift to prevent such contamination.

Solids or solutions containing o-tolidine shall be removed from work areas by vacuum cleaning with a specially designated vacuum cleaner or by other methods, including wet methods, that do not increase the concentration of airborne o-tolidine. No dry sweeping, blowing by compressed air, or any method of dust removal that increases the concentration of airborne o-tolidine shall be allowed. After cleanup, the area shall be decontaminated and washed with water.

(f) Laundering

The employer shall provide for the daily decontamination and laundering of used work clothing. Clothing should be washed with soap or other detergent and water. Precautions shall be taken to protect personnel who handle and

launder soiled clothing. These employees shall be advised of the hazards of, and means of preventing, exposure to o-tolidine. If an outside laundry facility is used, the launderers shall be advised of the hazards and proper procedures involved in handling contaminated work clothing. Contaminated clothing that is to be transported to an outside laundry facility shall be placed in sealed containers.

(g) Storage

Storage areas shall be isolated, well ventilated, and fire-resistant. Containers of o-tolidine shall be tightly closed and stored safely away from strong oxidizing materials and corrosive liquids and gases, heat, explosives, and gases under pressure to minimize the possibility of accidental breakage or spills.

(h) Maintenance

Lines and fittings that may carry o-tolidine shall be made of materials resistant to penetration of o-tolidine and shall be inspected frequently for corrosion and leaks. All o-tolidine equipment, including valves, fittings, and connections, shall be checked for tightness and kept in good working order. Such inspections shall be made immediately after new connections are made and after o-tolidine is introduced. Repairs and adjustments shall be made promptly.

(i) Entry into Confined Spaces

Entry into confined spaces, such as tanks, pits, and process vessels, that have contained o-tolidine shall be controlled by a permit system. Permits shall be signed by an authorized employer representative, certifying that preparation of the confined space, precautionary measures, and personal protective equipment are adequate and that prescribed procedures will be followed.

(1) All lines shall be disconnected or blocked while a vessel is being cleaned. All valves or pumps leading to and from the vessel shall be locked out or tagged out.

(2) The vessel shall be either washed with water and purged with air or purged with nitrogen and then with air.

(3) The vessel shall then be checked by trained personnel for fire or explosion hazard, airborne o-tolidine, possible oxygen deficiency, and concentrations of other likely contaminants, to assure that no danger exists.

(4) If a respirator is necessary, a self-contained breathing apparatus as specified in Section 4 of this chapter shall be provided to the employee.

(5) Each employee entering the vessel shall be equipped with appropriate respiratory protection, a harness, and a lifeline. At least one

other person equipped with appropriate respiratory protection, harness, and lifeline shall watch at all times from the outside. At least one more person shall be available to assist in an emergency. Mechanical ventilation shall be provided continuously when workers are inside the vessel.

(j) Disposal

Waste material contaminated with o-tolidine and containers of o-tolidine shall be disposed of in a manner not hazardous to employees. The disposal method shall conform to applicable local, state, and Federal regulations and shall not constitute a hazard to the surrounding population or environment. Waste water shall be flushed to holding basins for decontamination.

Section 7 - Sanitation

(a) The pertinent requirements for plant sanitation, stated in 29 CFR 1910.141, shall be complied with. The subsections entitled General (a), Toilet Facilities (c), Washing Facilities (d), Change Rooms (e), and Consumption of Food and Beverages on the Premises (g) are especially relevant to o-tolidine.

(b) Washing facilities, conveniently located and near the exit, shall be provided to employees in the regulated area. Locker room facilities, including showers, shall be located outside the regulated area.

(c) Preparing, storing, dispensing (including that done through vending machines), or eating food shall be prohibited in regulated areas.

(d) Smoking shall be prohibited in regulated areas.

Section 8 - Monitoring and Recordkeeping Requirements

(a) Industrial Hygiene Surveys

Each employer who has a place of employment in which o-tolidine is stored, produced, processed, or otherwise handled shall determine by an industrial hygiene survey the areas in which occupational exposure to o-tolidine occurs. Records of these surveys shall be retained until the next survey has been completed. For areas where an employer concludes that there is no occupational exposure to o-tolidine, the records shall show the basis for this conclusion. Surveys shall be repeated at least annually and within 14 days after any process change likely to result in occupational exposure to o-tolidine.

(b) Personal Monitoring

If it has been determined that occupational exposure to o-tolidine occurs, the employer shall institute environmental monitoring.

(1) A program of personal monitoring shall be instituted to identify and measure, or permit calculation of, the exposure of each employee. Source and area monitoring may be used to supplement personal monitoring.

(2) In all personal monitoring, samples representative of exposure in the breathing zone of the employee shall be collected.

(3) For each determination of the concentration of o-tolidine, a sufficient number of samples shall be taken to characterize the employee's work and production schedules, location, or duties, and changes in production schedules shall be considered in deciding when samples are to be collected.

(4) Each operation in each regulated area shall be sampled at least once every 6 months while o-tolidine is produced or handled. For intermittent operations, ie, those lasting less than 6 months, at least one monitoring regimen shall be conducted during each operation period and monitoring should coincide with the periods of maximum potential exposure to o-tolidine during these intermittent operations.

If an employee is found to be exposed to o-tolidine at concentrations exceeding the recommended ceiling limit, the exposure of that employee shall be measured at least once every week, control measures shall be initiated, and the employee shall be notified of the exposure and of the control measures being implemented. Such monitoring shall continue until two consecutive determinations, at least 1 week apart, indicate that control measures are effective in that the employee's exposure no longer exceeds the recommended occupational exposure limit; routine semiannual monitoring may then be resumed.

(c) Recordkeeping

Records of environmental monitoring and other pertinent records shall be kept for at least 30 years after the employee's last occupational exposure to the o-tolidine. Records of environmental monitoring shall include an identification of the employee being monitored, duties and job locations within the worksite, time and dates of sampling and analysis, sampling and analytical methods used and available evidence of their precision and accuracy, the number, duration, and results of samples taken, environmental concentrations determined from these samples, and the type of personal protective equipment used by the employee. Entry rosters of authorized persons who enter regulated areas shall also be retained for at least 30 years. Environmental monitoring records and entry rosters shall be made available to designated representatives of the Secretary of Labor and of the Secretary of Health, Education, and Welfare. Employees shall have access to data on their environmental exposures. Medical records shall be made available to the designated medical representatives of the Secretary of Labor, of the Secretary of Health, Education, and Welfare, of the employer, and of the employee or former employee.

II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon that were prepared to meet the need for preventing disease or injury arising from occupational exposure to o-tolidine. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "develop criteria dealing with toxic materials and harmful physical agents and substances which will describe...exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

After reviewing data and consulting with others, NIOSH formalized a system for the development of criteria on which standards can be established to protect the health and to provide for the safety of workers from exposure to hazardous chemical and physical agents. The criteria and recommended standard should enable management and labor to develop better engineering controls and more healthful work practices, and simply complying with the recommended standard should not be the final goal.

These criteria for a standard for o-tolidine are part of a continuing series of criteria developed by NIOSH. The proposed standard applies to the processing, manufacture, storage, handling, and use of o-tolidine. The standard was not designed for the population-at-large, and any extrapolation beyond occupational exposures is not warranted. It is intended to protect against injury to health from o-tolidine, be measurable by techniques that are valid, reproducible, and available to industry and governmental agencies, and be attainable with existing technology.

o-Tolidine is widely used in small quantities in chromatography and other analytical chemistry techniques, including water test kits for chlorine, and in biologic stains. It has been used as a direct dye for textiles but is most commonly used as an intermediate from which other dyes are made. It may be used as a precursor or as a curing agent in the manufacture of urethane resins. The use of o-tolidine in the United States is expected to decline.

Absorption of o-tolidine through the intact skin and from the respiratory and gastrointestinal tracts has been reported. Cancer and kidney damage have been reported in animals exposed to o-tolidine alone at high doses. Bacterial tests of mutagenicity and mammalian tests of DNA damage further support the findings of mammalian carcinogenicity. Furthermore, o-tolidine resembles benzidine, a known human carcinogen, in chemical structure, physical properties, and metabolism and excretion. o-Tolidine is, therefore, judged to pose a risk of cancer in workers. The recommended standard for occupational exposure to o-tolidine is based on keeping exposure at the lowest possible level through engineering controls and work practices. The recommended sampling and analytical methods have been evaluated for benzidine and are expected to be useful for o-tolidine.

The development of the recommended standard for occupational exposure to o-tolidine has revealed the need for additional data in several areas, especially on the effects of long-term occupational exposure to o-tolidine in the absence of other aromatic amines, possible carcinogenic, teratogenic, or mutagenic effects, and possible kidney damage.