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The OSHA's chemical occupational exposure standard for laboratories is an outgrowth of the previously issued Hazard Communication Standard. The standard relieves laboratories from complying with general industry standards but does require compliance with specific guidelines. The heart of the standard is the creation of a Chemical Hygiene Plan (CHP) in every laboratory. The CHP addresses major issues such as safety equipment and procedures, work practices and training, the designation of a chemical hygiene officer, and the provision of medical consultation and examination for affected employees. This new standard, in effect as of 31 January, 1991, presents yet another regulatory challenge to laboratory managers but also will ensure a safer work environment for laboratory workers.

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The OSHA hazardous chemical occupational exposure standard for laboratories

A new management regulation to ensure employee health

David A. Armbruster

OSHA's chemical occupational exposure standard for laboratories is an outgrowth of the previously issued Hazard Communication Standard. The standard relieves laboratories from complying with general industry standards but does require compliance with specific laboratory guidelines. The heart of the standard is the creation of a Chemical Hygiene Plan (CHP). The CHP addresses major issues such as safety equipment and procedures, work practices, training, the designation of a chemical hygiene officer, and the provision of medical consultation and examination for affected employees. This new standard, in full effect as of January 31, 1991, presents yet another regulatory challenge to laboratory managers but also ensures a safer environment for laboratory workers.

Introduction

Regulating the handling, control, and disposal of hazardous chemicals is a front page issue for both the nation and the clinical laboratory field. The Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) regulations have affected most, if not all, clinical laboratories. The issue of hazardous waste disposal in clinical laboratories, as promulgated by the EPA in the Code of Federal Regulations (CFR), was previously discussed in this journal (1).

In 1983, OSHA issued a chemical Hazard Communication Standard that applied to manufacturing operations in general industry. In 1987, this standard (29 CFR 1910.1210) was revised and expanded to include all workplaces, including laboratories. In the January 31, 1990 issue of the *Federal Register*, OSHA published a new standard addressing occupational exposure to hazardous chemicals found specifically in the laboratory setting (2).

This standard, codified as 29 CFR 1910.1450, recognized that laboratories differ from industrial operations in their use and handling of chemicals and that it is impractical to lump laboratories and manufacturing facilities together for the purpose of regulating these activities. A major provision of the new standard is the creation and implementation of a Chemical Hygiene Plan (CHP) for every laboratory. For the standard in general, the effective implementation date was May 1, 1990; for the CHP, OSHA mandated an implementation date of January 31, 1991.

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OSHA's own estimate is that 87% of the nation's laboratories are subject to the standard, including approximately 7,100 hospital laboratories and 7,600 independent clinical laboratories. In total, the standard affects approximately 934,000 employees in 34,214 laboratories. OSHA projects that the total annual cost of compliance for hospital laboratories will be (in 1987 dollars) about \$567,891 (or \$80 per laboratory) and about \$2,146,805 (or \$283 per facility) for independent practice laboratories. According to OSHA: "Such costs would not adversely affect the competitive status of the entities in any of the laboratory categories" (2).

These estimates seem optimistically low, but even if the cost of compliance is minimal, a greater concern to laboratory managers may be the potential cost of noncompliance. OSHA inspectors may present themselves at a facility as a result of an employee complaint or in the course of a special emphasis inspection. The inspector observes work practices firsthand. As a result of the inspection, citations and penalties may be issued. Whether easily affordable or not, clinical laboratorians have no choice but to familiarize themselves with the requirements and to adhere to them, including creating and implementing a CHP, because compliance is a management responsibility.

This article reviews the major components of the standard and provides interpretive comments to demonstrate its specific impact on clinical laboratories.

Background

The standard was issued under the authority of the Secretary of Labor, as OSHA is an office of the Department of Labor, and is intended to encourage employees and employers to reduce the number of occupational safety and health hazards in the workplace. Keep in mind that this regulation grew out of a concern for safe working conditions for all employees in the nation, regardless of the size, location, or nature of the workplace. OSHA has long been involved in regulating exposure to hazardous chemicals, but usually with an eye to industrial situations. Interested parties raised objections to the agency because the existing rules were not always relevant to laboratories, which by nature are not very similar to large manufacturing facilities.

In July 1986, OSHA proposed to create a standard entitled "Occupational Exposure to Toxic Substances in Laboratories" to redress the shortcomings of existing regulations. The current standard was developed by incorporating comments from many interested

parties—both individuals and organizations—who responded to OSHA's request for feedback.

Guided by Supreme Court interpretations, OSHA sought to enact the most protective regulations possible to eliminate significant health risks within the constraints of technological and economical feasibility. OSHA believes that the hazardous substances used in laboratories pose a significant risk requiring this type of standard and, as an example, cites the danger of xylene exposure to histotechnologists in anatomic pathology laboratories. In contrast to industrial settings where a single toxic substance may be used in large quantities, OSHA does recognize that laboratories are more likely to use multiple hazardous substances in small amounts. Under this standard, OSHA generally classifies laboratories as academic, clinical, or industrial.

Scope and applicability

Originally, OSHA proposed to exempt certain laboratories (*e.g.*, veterinary, dental, group medical practice) from the requirements of this standard. Individuals who commented on the standard when it was only a proposal, including representatives of the American Society of Clinical Pathologists (ASCP) and the College of American Pathologists (CAP), argued that employee protection afforded by this standard should not be limited by an arbitrary classification of laboratories. It was emphasized that, because of the varied nature of facilities bearing the title "laboratory," automatic exemptions based on a label used to categorize a particular class of laboratory were not appropriate.

After wrestling with the definition of "laboratory," OSHA concurred that the standard should apply to a wide spectrum of facilities. Although some laboratories might legitimately be excluded from regulation, none could be arbitrarily exempted simply because they belonged to a particular class of laboratory. "Laboratory," as defined by the standard, is a facility in which multiple chemical procedures are performed using relatively small quantities of hazardous chemicals on a nonproduction basis and using protective practices and equipment.

To further clarify the definition, "laboratory scale" is defined as work in which containers for hazardous chemicals are easily manipulated by one person. Laboratory scale excludes workplaces where commercial quantities of substances are handled. A facility that does not meet the criteria of a "laboratory" or that does not operate on a "laboratory scale" is still subject to OSHA regulations for general industry.

A "hazardous chemical" is a chemical for which there is statistically significant evidence that it may produce acute or chronic adverse health effects in exposed workers. Health hazards include carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents acting on the hematopoietic system, and agents that damage the lungs, skin, eyes, or mucous membranes.

The term "hazardous chemical" was specifically chosen to maintain consistency with OSHA's Hazard Communication Standard (29 CFR 1910.1210), which was issued in 1983 and revised in 1987. If a laboratory uses a chemical listed in OSHA's 29 CFR 1910, Subpart Z, it must comply with the permissible exposure limits (PELs) allowed for general industry in that document (3,4).

PELs have been established for 600 substances, but most clinical laboratories probably do not have a legitimate requirement to monitor PELs. The individual laboratory is responsible for determining what hazardous chemicals, if any, it uses; every chemical used is open to scrutiny. The National Institute for Occupational Safety and Health (NIOSH) has identified at least 319 hazardous chemicals used in hospitals that fit OSHA's definition (5). For clinical laboratories, the list of hazardous chemicals includes acetone, acetic acid, ethanol, formaldehyde, glutaraldehyde, isopropanol, methanol, toluene, xylene, and any common concentrated acid (HCl, HNO³, H²SO⁴) and base (NaOH, NH⁴OH).

Other key definitions

Other key definitions are provided by the standard. A "chemical hygiene officer" is an employee designated by the employer and qualified by training or experience to provide technical guidance in developing and implementing the provisions of the CHP. A chemical hygiene officer is required as part of the CHP. The CHP itself is a written program—developed and implemented by the employer—that prescribes procedures, equipment, and work practices to protect employees from health hazards presented by hazardous chemicals particular to a given workplace.

A "designated area" is a work area with select carcinogens, reproductive toxins, or substances with a high degree of toxicity. The designated area may be an entire laboratory or a limited area, such as a designated laboratory hood.

"Employee" is any individual employed in a laboratory who is potentially exposed to hazardous chemicals in the course of job performance. The definition

includes maintenance and custodial personnel who must enter a hazardous laboratory area but does not cover occasional visitors such as guests or sales personnel.

"Laboratory use of hazardous chemicals"

means:

- 1 activities that include chemical manipulations carried out on a laboratory scale
- 2 the use of multiple chemical procedures or multiple chemicals
- 3 procedures that are not part of a production process
- 4 the use of protective practices and equipment.

"Medical consultation" is a consultation between an employee and a licensed physician to determine if a medical examination or procedure is necessary after exposure to a hazardous chemical has taken place.

Chemical hygiene plan

The CHP must be readily available to employees, employee representatives, and to the Assistant Secretary of the Department of Labor. It must include the following:

- 1 standard operating procedures for using hazardous chemicals
- 2 criteria for determining and implementing control measures to reduce exposure to hazardous chemicals
- 3 a requirement to ensure proper functioning of fume hoods and other protective equipment
- 4 a provision for employee information and training
- 5 a provision for medical consultation and examination of exposed employees
- 6 designation of a chemical hygiene officer
- 7 a provision for additional employee protection for work with particularly hazardous substances
- 8 designation of specific operations that cannot be performed without prior approval from the employer.

Training pursuant to the CHP will be given at the time of an employee's initial work assignment, and refresher training will be given as determined by the employer. Specific training must include: detecting the occurrence of a hazardous chemical release, recognizing the physical and health hazards of chemicals in the work area, and learning protective measures.

Other items that must be specifically covered by the plan are: PELs for regulated substances, signs and symptoms of exposure to such substances, and the location and availability of Material Safety Data Sheets

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(MSDSs). Whether a single CHP will suffice for all laboratories operating within an establishment is left to the discretion of the facility. The options include: a separate CHP for each laboratory; a broad, generic CHP modified specifically for each laboratory; or an all-inclusive CHP.

Medical consultation/ examination

Employers must provide medical consultation to at-risk employees whenever an employee develops signs or symptoms of exposure to a hazardous chemical; when exposure monitoring reveals hazardous chemical concentrations routinely above the action level or PEL; or whenever an event such as a spill, leak, or explosion takes place and increases the likelihood of exposure.

A licensed physician will perform or supervise the medical consultation and, if necessary, the examination, without cost to the employee or loss of pay and at a reasonable time and place. Many laboratories may be able to arrange with a resident physician (pathologist or other hospital-based physician) to provide this service. All laboratories must provide this service and be able to document its availability.

The employer must also provide the physician with pertinent information about the hazardous chemical(s). The physician is required to give the employer a written opinion stating the results of the examination, any medical condition that increases the employee's risk if exposed to a hazardous chemical, recommendations for any further medical follow-up, and a statement that the employee has been informed of all the preceding information. Employers must maintain a record of exposure monitoring (if performed, as required by 29 CFR 1910, Subpart Z) and of any medical consultations/examinations that have taken place for each employee.

The National Research Council's (NRC) recommendations for chemical hygiene in laboratories is included as Appendix A to the standard. Adherence to the NRC recommendations is not mandatory; rather, the recommendations are provided as a guide and a logical starting point for developing a CHP. The five pages of recommendations cover the major subject areas appropriate for a CHP and can certainly serve as the backbone for a clinical laboratory CHP; naturally, the CHP must be customized for each specific facility. Finally, a list of other references potentially useful to laboratories for preparation of the CHP is included as Appendix B to the standard.

When implementing a CHP and complying

with this standard, laboratory managers should determine if any state programs, conducted in concert with OSHA, exist. State regulations must be as stringent as OSHA requirements, but they can be even more restrictive.

Conclusion

Unfortunately, new federal regulatory requirements are not always welcomed by the laboratory management community (or many other communities, for that matter)—if for no other reason than because they imply additional effort and work and an adverse consequence should regulators determine that a facility is in noncompliance. On the positive side, the goal of this new standard is to safeguard the health and well-being of laboratory workers. The welfare of our personnel is a top priority for all of us in laboratory management, and if the new OSHA regulation helps us to take care of our most important resource—our people—then it should be viewed as a welcome addition.

It is hoped that many facilities will find that most of the elements necessary for compliance with the hazardous chemical exposure standard are already in place in existing safety/chemical safety programs. For example, the employee training required (physical and health hazards of chemicals, detection of chemical release, protective measures) by the CHP may already be provided by a laboratory's training program.

The Clinical Laboratory Management Association (CLMA) has been quick to recognize the impact of this new standard on the field and to provide education and guidance to laboratory managers. On June 20, 1990, CLMA produced a videoconference entitled "Laboratory Safety and OSHA Compliance." Videotapes of this presentation are available from the CLMA Executive Office.

CLMA also publishes "A Model Chemical Hygiene Plan for Laboratories," written by CLMA member Terry Jo Gile (6). Gile's model plan succinctly lays out a workable general CHP approach for laboratories, covering all major elements and providing concrete examples of a formal policy statement, standard operating procedures, medical consultation/examination procedures, and duties of the chemical hygiene officer. This publication is certainly worthwhile for laboratories beginning the compliance process.

Hazardous chemicals are generally well controlled and contained in modern clinical laboratories. Nevertheless, it is imperative to recognize the real personnel threat that they pose. The OSHA chemical exposure standard regulates how this threat will be dealt

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Are You Prepared if OSHA Knocks at Your Door?

A Model Chemical Hygiene Plan for Laboratories

Terry Jo Gile, assistant administrative director of laboratories,
Barnes Hospital, St. Louis, Missouri

Written by a national expert on OSHA hazard communication, this publication is designed to give labs a head start in implementing a chemical hygiene program. The topics discussed include:

- training
- standard operating procedures for handling lab chemicals
- personal protective equipment
- hazard identification
- responsibilities of the chemical hygiene officer and committee
- engineering controls for ventilation, fire extinguishers, drench showers, and exit routes
- contaminated waste removal and disposal
- record keeping
- glossary.

Prices (Effective April 15, 1991)

Printed Manual

CLMA members	\$30
Nonmembers	\$35

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The computer disk is an ASCII version of the publication on a 5 1/4" floppy disk, making it easy for you to prepare your institution's chemical hygiene plan for OSHA. Just open the document in your word processor, adapt as necessary, and print it. Because you do not have to input the entire document, the computer disk *saves you hours of time!*

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with in laboratories. Laboratory managers should institute CHPs and comply with the standard to foster a safe environment for all laboratory workers. ❁

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