Chapter 15

Safety in the Biotechnology Workplace

Introduction

Safeguarding employees in the workplace is a fundamental responsibility of all companies. In the biotechnology industry, safety problems are different from those common to other industries, for example, the construction industry. Employees in biotechnology companies would not normally be exposed to the elements or to dangerous machinery, such as rotary saws, power hammers, and earthmovers, but on the other hand may be exposed to more subtle dangers, such as working with biohazardous, toxic, or carcinogenic substances. Acute as well as long-term exposure to hazardous chemicals and to potential carcinogens are of great concern. To this end, state and federal legislation has been passed to protect employees from hazardous materials in the workplace and, as a result, safety apparel such as safety glasses, face and ear protection, respirators, gloves, acid-resistant aprons, and safety overalls are standardly used. In addition, biological containment hoods and chemical fume hoods that vent to the outside of the building, as well as biological hoods that have multiple filter systems for recirculating air in the laboratory are now common equipment in the workplace.

Health and Surveillance Programs

It is not unusual for employees in biotechnology, pharmaceutical, and chemical companies to work with or come in contact with hazardous materials or pathogenic organisms. Over the past decade, consensus standards have been developed to indicate or require occasional or continual medical surveillance for employees who are at risk because of exposure to such hazards as carcinogenic chemicals, highly infectious microorganisms, oncogenic viruses, and recombinant DNA products. One of the first federal documents describing medical screening before job assignment and during work was the OSHA Carcinogen Stan-

M. G. Pappas, *The Biotech Business Handbook*

dard (Federal Regulation 39:3756–3797, 1974). Since then, other standards have been implemented to protect laboratory and other personnel from on-the-job hazards. Companies benefit from such standards because the consensus standards identify individuals who are unsuitable to perform certain work, make employees aware of job-associated hazards, and thus reduce accidents, ensure that individuals working with infectious organisms are vaccinated, and reduce the insurance costs associated with protecting the health and well being of employees.

Once the potential for exposure of employees to hazardous chemicals, organisms, and radioactive materials has been assessed by the company Safety Officer and other members of the Safety Committee, personnel can be chosen who should participate in surveillance programs. There are a number of hazard categories that require employee surveillance. These categories include scientists and other personnel working with infectious organisms, chemicals known or suspected to be carcinogenic, mutagenic, or teratogenic, pathogens known or suspected to be oncogenic or teratogenic, and animals with infectious diseases.

Medical surveillance programs normally include employee medical histories, work exposure information, physical examinations, supplemental medical procedures, such as chest X-rays, electrocardiograms, and tuberculin tests, clinical laboratory tests, such as blood chemistries, hematology, and urinalysis procedures, and special treatments for personnel working with animals or hazardous microorganisms, such as immunizations. Personnel who are not immune to diseases likely to be encountered in the workplace should be vaccinated or should receive booster shots. All individuals should be monitored periodically and blood, urine, or saliva specimens should be taken for laboratory tests.

Laboratory Accidents

Medical and laboratory personnel are generally at an increased risk for infections because of the nature of their work. Many laboratory research workers and clinical personnel come in contact with large numbers and types of infectious organisms as part of their daily work. Accidental exposure can occur at many times, such as during the inoculation, growth, transfer, and harvesting of microorganisms grown in agars, broths, or tissue cultures, or during the handling and processing of blood, serum, and other potentially infectious body fluids. Pathogenic microorganisms can enter the body through the conjunctiva, nose, mouth, and through both unbroken and broken skin. It is important to note that in laboratory-acquired infections, the pathogen may not enter the body in the same manner as it is transmitted in nature. Knowing when an accident has occurred is very important in reducing laboratory-acquired infections. Sometimes an incident becomes apparent to the individual performing a task. Examples include being bitten by an infected laboratory animal, dropping a culture container, spilling media, causing a tissue-culture aerosol, or suffering a needle prick. Immediate steps can then be taken to clean up the area or treat the individual. In other cases, the accident may not be apparent. This includes creating microaerosols or touching containers whose outer surfaces are contaminated. In rare cases,

Table 15.1
Sources of Infections Acquired in the Laboratory Setting*

Event	*Examples*
Accident	Aspirating fluid through a pipet, bite or scratch from a laboratory animal, or the bite of an exoparasite (flea, louse, or tick), infection from processing infected patient specimen (blood, tissue, serum, semen, or spinal fluid), spills or splashes of nutrient broths and culture fluids, needle punctures, sharp laboratory objects, and broken glassware
Aerosol	Airborne bacterial, fungal, or viral microdroplets atomized during laboratory procedures that can remain airborne for extended periods of time and be carried great distances via ventilation systems, centrifugation, opening lyophilized vials or other containers, pipeting, and vortexing suspensions or solutions at high speed
Animals	Bites or scratches from infected laboratory animals, mice, rats, gerbils, cats, dogs, monkeys, or chimpanzees, bites from blood-sucking arthropod parasites on the animals that may carry pathogenic bacteria, protozoan parasites, rickettsia, or viruses
Arthropods/Insects	Bites from infected blood-sucking insects (phlebotomine sandflies, tsetse flies, mosquitoes, triatome [reduviid] bugs, or arthropods [chiggers, fleas, lice, mites, soft- or hard-bodied ticks]), all of which may carry pathogenic bacteria, protozoan parasites, rickettsia, or viruses
Clinical specimens	Accidental inoculation, splashing in the face or eyes, or onto hands or clothing of pathogens found in patient tissue specimens and body fluids, of such pathogens as hepatitis B and C viruses, HIV-1 and HIV-2, HTLV-2, monkey B virus, etc.
Ingestion	Accidental ingestion through mouth-pipeting, eating, or drinking in the laboratory of food products that may come in contact with infectious agents through storage in refrigerators or contact with laboratory benches. Also, ingestion by smoking in the laboratory
Intentional	Premeditated infection of one's own self (suicide) or others through ingestion of pathogens, such as tubercle bacilli, and other infectious bacteria and viruses

*From: How laboratory infections are acquired. (Chapter 2) in: *Laboratory-Acquired Infections.* by C. H. Collins. Butterworth, Boston, 1983, pp. 27–35.

deliberate self-infection and premeditated infection of others can occur. The most common sources of laboratory-acquired infections are listed in Table 15.1.

Surveys have given health officials a general idea of the numbers and types of infections that occur in research and clinical laboratories. Data acquired from gen-

eral surveys of laboratories have provided more relevant information than special surveys or studies performed on commercial, common-source outbreaks, such as restaurants and childcare providers, which are typically handled by state health authorities, or by the Centers for Disease Control. A significant study into actual laboratory-acquired infections was conducted by Sulkin and Pike in 1951. These researchers mailed questionnaires to several thousand laboratories nationwide. Commercial biological laboratories, state and local health departments, hospitals, medical and veterinary schools, teaching institutions, and government laboratories were included in the survey.

Of 1342 laboratory infections, 69 distinct infecting microorganisms were identified, including bacteria, *Chlamydia*, fungi, parasites, and viruses. In this early study, the majority of infections were caused by bacteria, but though deaths resulted from infection by pathogens within each group, the majority of deaths (4.5%) resulted from viral infections.

In later years, additional data from foreign countries was added to the growing data from the United States, and in 1976, Pike reported a total of 3921 cases of laboratory-acquired infections with 164 deaths (4.1%). Interestingly, the distinct kinds of infecting organisms had increased from 69 to 164. Bacterial and viral infections were the most common infections acquired, and the death rates were not significantly different (4.1% for bacteria versus 5.1% for viruses). Although *Chlamydia* infections were relatively rare, they resulted in a higher percentage of deaths (*see* Table 15.2).

Although the numbers of laboratory-acquired infections were impressive, they did not account for the true numbers of infections in each group, which were likely much higher. This was probably the result of a number of factors, including a lack of response to questionnaires by some laboratories, the difficulty in distinguishing natural infections from those acquired at the workplace, simply missing many actual infections, and possibly even underreporting cases on purpose. Still, the large numbers reported in the Pike study demonstrated that infections occurred in many kinds of laboratories. An investigation of the types of laboratories in which they were found revealed that the majority of infections with pathogens occurred in research laboratories (58.5%), followed by diagnostic laboratories (17.3%), biological-products-manufacturing laboratories (3.4%), and teaching laboratories (2.7%). Not surprisingly, the greatest number of laboratory-acquired infections in large laboratories occurred in the microbiology department (31.9%), which typically analyzes a variety of patient specimens for the presence and identification of pathogenic bacteria, fungi, parasites, and viruses.

Agents that have recently been identified as posing the greatest risk of infection to laboratory personnel include HIV-1 and HIV-2, hepatitis B virus, *Mycobacterium tuberculosis*, and *Shigella spp.*; those posing a high risk include *Brucella spp.*, *Coccidioides immitis*, *Coxiella burnetii*, *Leptospira interrogans* serovars, *Rickettsia spp.*, and *Salmonella spp.*

OSHA

Because many job related injuries and illnesses have historically gone unreported, a need was seen to establish guidelines for

Table 15.2
Documented Laboratory-Acquired Infections*

Disease agent	*Number of cases*	*Number of deaths*	*Deaths (%) of total*
Bacteria	1669	69	4.1
Viruses	1049	54	5.1
Rickettsia	575	23	4.0
Fungi	353	5	1.4
Chlamydia	128	10	7.8
Parasites	115	2	1.7
Agent not specified	34	1	2.9
Grand total	3921	164	4.1

*From: How laboratory infections are acquired. (Chapter 2) in: *Laboratory-Acquired Infections.* by C.H. Collins. Butterworth, Boston, 1983, pp. 7–8.

safety in the workplace and to develop quantitative data based on actual occurrences of injuries, laboratory infections, or illnesses. In 1970, the Occupational Safety and Health Administration (OSHA) was formed to meet these needs for all workers.

Under OSHA and approved state regulations, all employers must meet record-keeping requirements and comply with applicable annual reports on accidents. Companies with ten or fewer employees are exempt from the regulations. Illnesses or injuries that cause an employee to die or that result in the hospitalization of five or more employees must be reported to OSHA or an approved state agency within 48 hours of the occurrence. Reports may be made by telephone or by telegram. An occupational injury that results in loss of consciousness, medical treatment other than standard first-aid, lost work days, job reassignment, or employment termination must be reported. An occupational illness is not defined in the same way as an occupational injury, since it is the result of hazardous factors that are found at the work site. These include infectious bacteria, viruses, and parasites, carcinogens, poisons, toxic fumes, and toxic agents, such as research chemicals and solutions. It should be noted that OSHA-recordable accidents and illnesses represent only a fraction of the total mishaps that typically occur in the laboratory.

Exposures to Hazardous Chemicals in the Laboratory

A new OSHA standard on exposures of employees to hazardous chemicals in the laboratory setting was enacted on May 1, 1990. Entitled OSHA's Standard on Exposure to Hazardous Chemicals in Laboratories, the new regulation now affects about one million laboratory workers in all laborato-

ries, including research and quality control labs. Whereas earlier regulations, such as the OSHA Hazard Communication Standard, dealt mainly with providing a comprehensive, single document containing pertinent information regarding hazardous substances that normally is found only in many different sources, this important standard gives employees who come in contact with hazardous chemicals on a routine basis or by accidental exposure the right to medical examinations. The standard allowed biotechnology and other firms affected by the regulations until January 31, 1991 to establish and implement their own Chemical Hygiene Plans (CHP), which must include the appointment of a laboratory coordinator to oversee the plan, and protocols for the following: (1) safe handling and use of chemicals; (2) informing personnel regarding the potential adverse effects of chemicals being used; (3) assuring acceptable air quality in the facility, and; (4) the medical examination of employees at routine intervals and after accidental exposure to hazardous materials. The laboratory coordinator is also responsible for approving any changes in procedures developed for chemical handling and use. The failure of biotechnology companies to comply with the new OSHA regulations can lead to government actions and fines.

Emergency Equipment

Easy access to emergency equipment provides employee security as well as minimizing facility and employee medical insurance costs for the biotechnology company. Examples of necessary emergency equipment include water sprinklers, fire hoses attached to in-house water mains, portable fire extinguishers for various classes of fires, fire blankets, emergency showers, eye wash stations, and first-aid kits.

Proper storage of potentially flammable substances and caustic materials is also very important. Specially constructed storage cabinets that meet OSHA safety requirements and National Fire Protection Association guidelines (NFPA No. 30) are used to store ethanol and other flammable liquids. These are generally painted yellow for identification purposes and are manufactured with removable ports on either side to allow the escape of potentially harmful vapors through vents to the outside of the building. Reinforced cabinets for corrosives, such as acids and bases, are also required, and these are generally painted blue to identify them during an emergency. Explosion-proof laboratory refrigerators for storing potentially explosive solutions, such as those containing ether, are available.

In addition, there are special containers for commercial transportation of hazardous substances (*see* Fig. 15.1). For example, acrolein is a flammable and potentially harmful liquid if absorbed through the skin. A small bottle of acrolein is typically packaged and shipped in the following manner. The bottle is placed in a labeled can containing vermiculite and sealed. The can is then put in a box, also containing vermiculite, which is sealed. The box is then sealed in a plastic-coated foil package that is heat-sealed, and then this package is placed in a larger, corrugated box with a certified bursting pressure of 600 pounds per square inch. Along with the customer's address and shipper's address, a flammable label is affixed

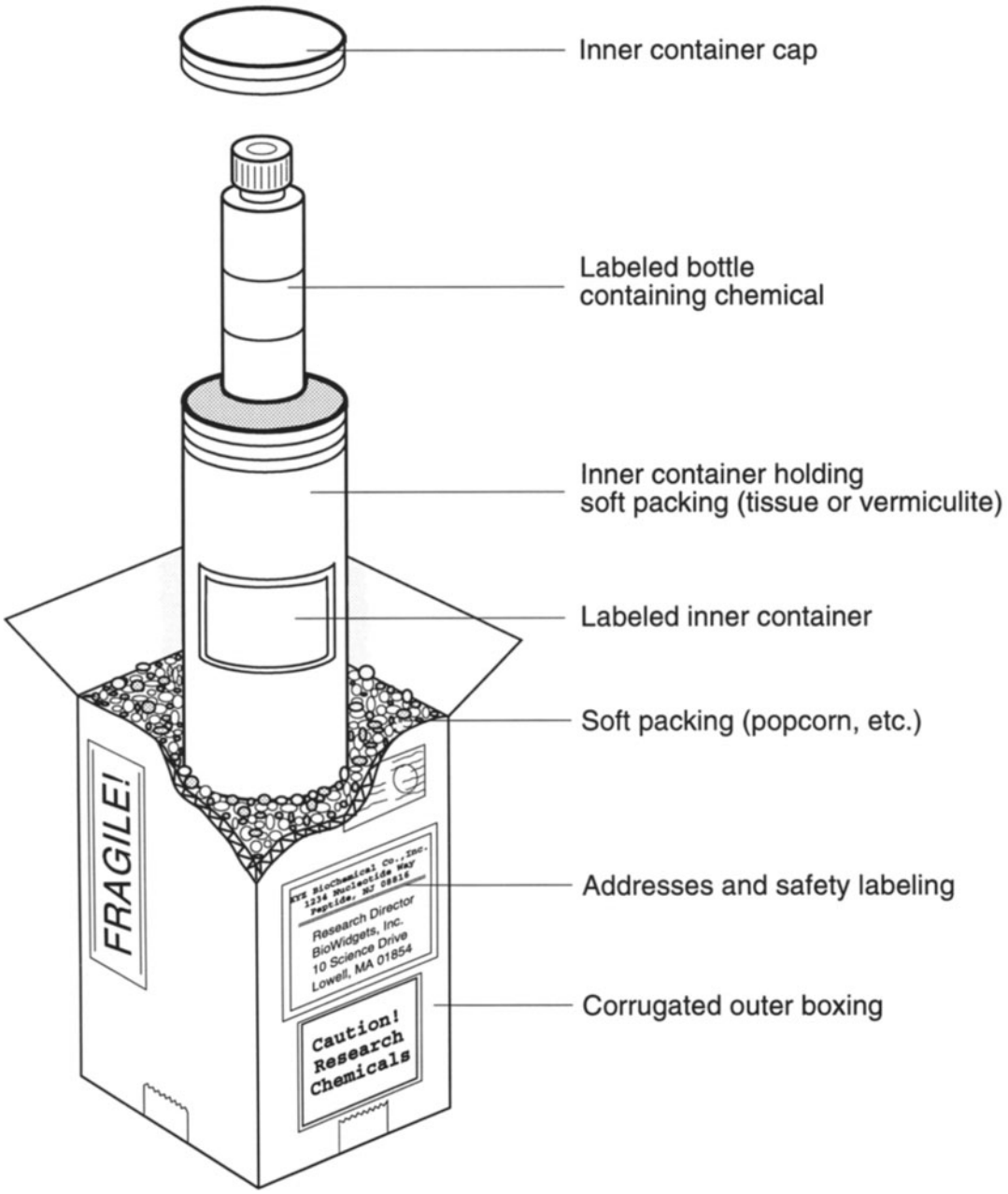

Figure 15.1. Safety packaging for shipping chemicals. The bottle is first placed in a soft absorbent material, such as tissue or vermiculite, then placed in a labeled, secondary covered container. This is then placed in boxing with acceptable strength specifications and surrounded with some form of soft packaging material, such as styrofoam "popcorn" or a similar material appropriate for interstate or international transportation. The outer packaging must have OSHA-approved labeling, complete addresses of recipient and sender, and postage.

to the outer box and a label stating that it cannot be shipped on passenger airplanes.

In the laboratory, hazardous materials, such as bottles of acids, bases, or other caustics must also be transported in a safe manner. Therefore, special containers or buckets that are large enough to hold the entire contents of the bottle should breakage occur and that are resistant to the effects of spillage should be used when transporting the material. Carrying devices made of acid- and base-resistant materials, such as polypropylene, are commonly used in the laboratory and are commercially available from scientific equipment supply companies.

Material Safety Data Sheet (MSDS)

Companies that manufacture or distribute hazardous substances are required to make important safety information available to their customers. The Material Safety Data Sheet (MSDS) was developed by the US Department of Labor's Occupational Safety and Health Administration (OSHA) as an integral part of the Hazard Communication Standard, the so-called right-to-know regulation (*see* Table 15.3). The purpose of the form is to provide a single comprehensive document containing pertinent information regarding hazardous substances, data that normally can only be found in many different sources. Such information improves on-the-job safety by educating users of the potential safety and health hazards some chemicals pose. Information required in the MSDS include identifying the chemical or mixture, the name of the manufacturer or distributor and its location, toxicity hazards, health hazard data, including actions to take if exposed, fire and explosion hazard data, reactivity data, handling and storage precautions, cleanup procedures, and any additional important information.

Although the Hazard Communication Standard addressed the need for a document containing detailed information regarding hazardous substances, there is no mandatory form for the MSDS. Manufacturers need only include the required relevant information. However, OSHA has developed a form (OSHA Form 174) as a model for companies to base their documents on.

Most chemical manufacturers use the corporate letterhead to identify the company and routinely list the document's date of printing, and the corporate or emergency telephone numbers for assistance.

For purposes of illustrating actual information in an MSDS, a commonly used potentially hazardous chemical, 3,3'-diaminobenzidine tetrahydrochloride, commonly referred to as DAB, will be discussed. DAB is a precipitable, chromogenic substrate used in the development of diagnostics products in the biotechnology industry.

Identification:

The manufacturer or distributor identifies it by its common name and other synonyms, such as 3,3',4,4'-tetraaminobiphenyl tetrahydrochloride and normally its catalog number.

Toxicity Data:

Pertinent toxicity data, if available, is shown, such as the 50% lethal dose

Table 15.3
Components of the Material Safety Data Sheet

Section	*Information*
Manufacturer or distributor	Company name, address, and telephone number for further information or emergencies, date MSDS was prepared
Identity	Product chemical name, synonyms, OSHA permissible exposure limit, other safe exposure limits
Physical/chemical characteristics	Appearance (powder, liquid), color, and odor. Boiling point, melting point, vapor pressure, water solubility, specific gravity
Fire and explosion hazard data	Flash point, extinguishing procedures (water, CO_2, foam), special fire fighting procedures (respirators, special clothing), unusual fire or explosion hazards
Reactivity data	Substance stability, incompatibility with other chemicals, hazardous decomposition products, hazardous polymerization
Health hazard data	Acute effects (skin or respiratory irritation), chronic effects (potential carcinogen), proper first aid
Precautions for safe handling, use, and storage	Procedure for spills, proper waste disposal, appropriate safety clothing, proper storage (containers)

(LD_{50}) in milligrams per kilogram of body weight.

Health Hazard Data:

Health hazard data for DAB includes a description of how the substance can enter the body, lists acute exposure effects and chronic effects, and identifies first aid treatment. For example, DAB can exert harmful effects is swallowed, inhaled, or absorbed through the skin. It causes eye and skin irritation and can irritate the mucous membranes of the upper respiratory tract. Chronic effects include cancer. First aid after inhaling the substance is to remove the victim to fresh air, and if necessary, to provide artificial resuscitation. For eye contact, flushing the eyes with large volumes of water for at least 15 minutes is recommended. Skin contact requires washing the exposed area with large amounts of soap and water.

Physical Data:

Physical data include the appearance and odor, if any. In this example, it would be stated that DAB is a light brown powder.

Fire and Explosion Data:

Fire and explosion data indicate that in cases in which DAB is in a fire area or is actually burning, it can be extinguished using water, carbon dioxide,

dry chemical powder, or polymer foam. Firefighters are recommended to wear self-contained breathing apparatuses and protective clothing.

Reactivity Data:

In terms of reactivity with other substances, DAB is incompatible with strong oxidizing agents, such as hydrogen peroxide and periodate, and gives off dangerous combustion products including carbon dioxide and carbon monoxide, nitrogen oxides, and hydrogen chloride gas.

Spill or Leak Procedures:

If the substance is accidentally released or spilled, a self-contained respirator, gloves, and boots are required, and care should be taken not to raise dust. The waste DAB can be disposed of by dissolving it in a combustible solvent and burning it in a chemical incinerator equipped with an afterburner and scrubber.

Handling and Storage Precautions:

Not surprisingly, the MSDS recommends wearing safety goggles, rubber gloves, and approved respirators, since it is an irritant and can enter the body through the mouth, eyes, and skin. In addition, the material should be used only in a fume hood and the container should be kept tightly closed and stored in a cool dry place.

Disclaimer:

Some companies also include a disclaimer in their MSDS stating that the information is correct to the best of its knowledge, that they assume no liability for any damage resulting from handling or contact with the hazardous substance, and that the MSDS does not purport to be all inclusive.

Electronic MSDS

There are also electronic forms available that can be valuable to biotechnology or related companies using large numbers of chemicals. The electronic MSDS satisfies OSHA requirements, allows fast access to documents, and greatly reduces filing and storage problems.

In order to reduce the costs associated with the MSDS, most companies make it a policy to provide the required information the first time the hazardous substance is purchased. If significant changes in the information occurs, then updated MSDS forms are provided by the manufacturer or distributor with subsequent purchases.

MSDS Information on Product Labels

Information regarding material safety can be found on labels of chemicals and reagents. For example, Fisher Scientific has produced a ChemAlert™ guide and condensed MSDS section on the label of each chemical sold by the company. The label contains handy information, such as hazard codes established by the National Fire Protection Association (NFPA). These hazards are color-coded and numerically rated (0–4) to correspond to the degree of danger the chemical or reagent presents. Health, flammability, and reactivity hazards are presented, as are special warnings. In addition, storage codes are provided to distinguish the chemical as a flammable,

corrosive, oxidizing agent, or as a toxic substance. The labels were designed to comply with the OSHA Hazard Communication Standard (29 CFR 1910.1200) dealing with the proper labeling of hazardous material.

Hazardous and Toxic Waste Regulations

The federal and state governments have recognized the serious health threat that hazardous wastes imposes upon the environment we live in. Many states have created regulations to protect the quality of their air and water resources, and have consolidated and strengthened their surveillance and enforcement capabilities for hazardous and solid waste treatment and disposal. Many states developed their environmental laws based upon the federal governments Environmental Protection Agency (EPA) guidelines and modified their environmental regulations based upon a number of factors, including changes implemented by the federal government, by other states, and by learning of new technological developments for improving the environment or treating wastes. Cost considerations are also taken into account. Regulations that are promulgated or revised go through a set pattern of proposal, review and comment, consideration, and reproposal before being formally adopted. Businesses may affect the regulatory procedure by petitioning the state agency to adopt a regulation or to challenge the validity of standing regulations in court. Invalidation of regulations is achieved by proving that the regulation conflicts with the United States Constitution or the state constitution, exceeds the statutory authority, or was adopted in violation of statutory procedures.

Medical Waste

Disposal of medical industry waste has become an important part of state regulation of biotechnology companies, as well as other companies, government agencies, hospitals, and clinics. This is mainly the result of increasing public awareness through the news media of specific cases of infectious materials being mishandled and disposed of improperly and the threat of being infected with HIV and other infectious agents by these materials. These materials, termed "special medical wastes," must be identified, packaged, segregated from other wastes, manifested, and transported to treatment or disposal facilities under regulations developed by the state. Regulations vary from state to state, as do definitions of what constitutes medical waste. However, for the most part, special medical waste includes solid wastes comprised of human and animal tissues and organs, blood and blood components, such as whole blood, serum, plasma, platelets and leukocytes, blood-soiled articles, contaminated laboratory materials such as latex gloves, paper products such as absorbent towels, pipets and pipet tips, test tubes, microtiter plates, microscope slides, and microbiological laboratory waste, such as tissue culture flasks, Petri dishes, hollow-fiber cell culture cartridges and filters, and syringes, needles, and other surgical instruments, loosely defined as "sharps," that are capable of puncturing human skin. Once special medical wastes are rendered noninfectious by treatments prescribed in the regula-

tions, the waste generally can be disposed of by incineration, or in landfills like other common waste. By far, incineration is the method of choice for disposing of large amounts of waste, such as the above mentioned items, laboratory animal carcasses, animal bedding, and so on. Incineration of medical and other wastes typically requires preapproval from local and state pollution control boards, and the issuance of necessary permits. The outcome of complete incineration is ash, which is an innocuous end-product. In addition, ash production significantly reduces the waste volume that would otherwise go to landfills.

Biotechnology companies, like other generators of medical wastes, must comply with state, and sometimes also local, regulations, regarding proper handling and disposal. Generally, the regulations include defining who are generators and what precisely are their responsibilities. The responsibilities include determining which wastes generated by the company fall under the regulations, and then performing on-site treatment of the waste followed by proper disposal, or labeling, packaging, and shipping of special medical waste for proper treatment and disposal elsewhere.

On-Site Treatment

Regulated on-site treatment of wastes includes disinfection of laboratory materials with bleach, or the autoclaving of solid medical wastes for a specified time period and temperature, or both.

Depending upon the regulations, some medical waste producers may be exempt from required manifesting documentation and shipping procedures. The usual requirement deals with low-level generators of waste who fall below a certain level per unit time. However, the medical waste must still be properly identified, packaged, and segregated from other types of wastes prior to disposal according to state regulations.

Hazardous Waste

Substances that convey toxic, lethal, or other injurious effects or that cause sublethal alterations to plant, animal, or aquatic life, or that may injure humans or persist in the environment, are termed hazardous wastes. Hazardous wastes include the low-level nuclear wastes that are generated in the biotechnology industry. State laws may differ from federal regulations, such as the Resource Conservation and Recovery Act (RCRA), in the categorization of hazardous wastes. For example, polychlorinated biphenyls (PCBs) are controlled in the state of Maryland at two categories of concentration, namely 50–500 ppm (Maryland toxic) and above 500 ppm as acutely hazardous waste. PCBs are not regulated under the RCRA, but are regulated under the Toxic Substances Control Act (TSCA) by the EPA.

Many biotechnology firms perform research or clinical activities that generate low-level radioactive wastes. Such procedures include radioimmunoassays (^{125}I), DNA hybridization assays (^{32}P), cytotoxicity assays, and genetic research (^{3}H). If radioactivity levels are very low, some states allow disposal of mildly radioactive solutions down laboratory sinks with large volumes of water, which "infinitely dilutes" the waste materials in the discharge.

Inspections

States ensure that regulated companies (given permits) are complying with environmental laws by performing inspections. Normally, inspectors visit facilities during regular business hours and request to inspect the premises. In the event that the company refuses inspection, the inspectors usually obtain a search warrant. However, refusal may not be allowed, since some permits contain a consent to inspection. If the company's facilities are not entered, but the facilities are inspected from the public area, warrants are not necessary.

A broad range of information may be requested by inspectors. This includes copies of previous inspection reports, records, and files, regulatory compliance reports, and waste control systems data. If advance warning is given to the biotechnology company, then it is advisable to prepare in advance for the inspection by assembling documents and making sure that an appropriate company representative (e.g., the Safety Officer, Laboratory Coordinator, or equivalent employee) is present for the entire inspection. The designated company representative should define the limits of the inspection. This allows the inspection to proceed smoothly and prevents random movement of the inspectors into restricted areas. After each inspection the state representative completes an inspection report that usually contains checklists and comments, and gives a copy to the company representative. It is appropriate and worthwhile to request an exit conference with the inspector to discuss findings of the visit. A confirming letter or memorandum should be made of the meeting and of a copy of the inspection findings.

Drug-Free Workplace

In order to reduce the adverse affects of substance abuse on the job, the Drug-Free Workplace Act of 1988 (PL 100-690) was enacted. The law establishes policy requirements for employers receiving government contracts as a means of reducing drug-related accidents and thus improving employee safety as well as the quality of goods made for the government. Basically, the law requires that companies applying for or performing DHHS contracts must publish a statement notifying all employees that unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the contractor's workplace and that violations of the policy will result in appropriate personnel actions, from temporary suspension without pay up to and including employee termination. In addition, the contractor must establish a drug-free awareness program and make employees aware of any drug abuse assistance or rehabilitation programs offered locally or by the company. Each employee must receive a copy of the contract and agree to abide by the terms of the Drug-Free Workplace policy as a requirement of continued employment on government contracts. Any conviction under criminal drug statutes resulting from a violation at the workplace must be made known to the employer no later than 5 days after the conviction, and the employer has 30 days from such notification to impose personnel actions or remedial measures on the employee.

It is important to note that biotechnology companies receiving federal SBIR grant or contract money must also establish and abide by the directives of the Drug-Free Workplace Act in order to receive funding.

Equipment

Equipment such as biosafety hoods, clean rooms, and positive pressure rooms must be monitored to ensure that their performance meets state and local guidelines. Stickers are affixed to the biosafety hoods stating the date the equipment was checked, the types of filters replaced, and by whom. Fire hoses, fire extinguishers, and other safety equipment must also be periodically checked for proper function and the results documented. Such services are typically commercially available for a moderate fee.

Summary

Employee safety is a vital responsibility of all laboratories. Because of the many potential biohazardous and toxic materials routinely used in research, clinical, and quality control laboratories, federal legislation has been enacted detailing procedures to be followed for laboratory safety, air quality, and medical examinations and treatment. Such OSHA standards emerge from an evolving process and undoubtedly still more standards will be modified or issued in the future. Though it is the responsibility of the management of biotechnology and other companies and organizations to ensure that safety equipment, literature, and procedures are available, functional, and in place, it is the responsibility of all employees to use the safety equipment when necessary and to follow approved procedures in a disciplined manner.

Pertinent Reading

Articles

Anonymous. 1981. Legal liability. in: *Better Science Through Safety*. (Eds., J.A. Gerlovich and G.E. Downs) Iowa State University Press, Ames.

Biosafety in Microbiological and Biomedical Laboratories. HHS Publication No. (CDC) 84-8395, US Government Printing Office, Washington, DC, 1984.

Collection, transport and receipt of infectious materials (chap. 7). in: *Laboratory-Acquired Infections.* by C.H. Collins. Butterworth, Boston, 1983, pp. 140–147.

How laboratory infections are acquired (chap. 2). in: *Laboratory-Acquired Infections.* by C.H. Collins. Butterworth, Boston, 1983, pp. 27–35.

Manning, C.R. 1991. Chemical exposure control in laboratories. *Am. Clin. Lab.* **10**:20–21.

Occupational Exposure to Bloodborne Pathogens; Final Rule. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, December 6, 1991.

Pike, R.M. 1979. Laboratory associated infections: Incidence, fatalities, causes and prevention. *Ann. Rev. Microbiol.* **33**:41–66.

Wilson, C.N. and P.W. Cavnar. 1992. The economic impact of OSHA's proposed rule on occupational exposure to bloodborne pathogens. *Lab. Med.* **23:** 29–32.

Books

AIDS/HIV Reference Guide for Medical Professionals (3rd ed.). (Eds., D.M. Shin and J. Avers). CIRID at UCLA, Los Angeles, CA, Regents of the University of California, 1988.

Biosafety in the Laboratory. Prudent Practices for the Handling and Disposal of Infectious Materials. Committee on Hazardous Biological Substances in the

Laboratory, Board on Chemical Sciences and Technology, Commission on Physical Sciences, Mathematics, and Resources, and the National Research Council. National Academy Press, Washington, DC, 1989.

CRC Handbook of Laboratory Safety (3rd ed.). (Ed., A.K. Furr). CRC Press, Boca Raton, FL, 1989.

Exposure to Hazardous Chemicals in Laboratories. OSHA Regulation 1910. 1450, Office of the Federal Register, 1100 L Street, NW, Washington, DC.

The Foundations of Laboratory Safety: A Guide for the Biomedical Laboratory. by S.R. Rayburn. Springer Verlag, New York, 1990.

Guide for Safety in the Chemical Laboratory (2nd ed.). Manufacturing Chemist's Association, Safety and Fire Protection Committee. van Nostrand-Reinhold, New York, 1972.

How To Comply with the OSHA Hazard Communication Standard. A Complete Guide to Compliance with OSHA Worker Right-To-Know Regulations. by D.J. Young. Van Nostrand-Reinhold, New York, 1989.

Improving Safety in the Chemical Laboratory: A Practical Guide (2nd ed.). by J.A. Young. Wiley, New York, 1991.

Laboratory-Acquired Infections: History, Incidence, Causes and Prevention. by C.H. Collins. Butterworth, Boston, 1983.

Laboratory Safety: Principles and Practices. (Eds., B.M. Miller, D.H.M. Groschel, J.H. Richardson, D. Vesley, J.R. Songer, R.D. Housewright, and W.E. Barkley) American Society for Microbiology, Washington, DC, 1986.

Maryland Guide to Environmental Law (in cooperation with the Maryland Department of the Environment). Piper and Marbury, Maryland Chamber of Commerce, 1989.

National Institutes of Health Biohazards Safety Guide. US Dept. of Health, Education and Welfare, US Government Printing Office, Washington, DC, 1974.

Prudent Practices For Handling Hazardous Chemicals In Laboratories. National Research Council. National Academy Press, Washington, DC, 1981.

The Sigma-Aldrich Library of Chemical Safety Data (2nd ed.). (Ed., R.E. Lenga). Sigma-Aldrich, Milwaukee, WI, 1988.

Techniques of Safety Management (2nd ed.). by D. Peterson. McGraw-Hill, New York, 1978.