10 Laboratory Security

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10.A INTRODUCTION

The world has become more security conscious, and that awareness extends to laboratories. New guidelines and approaches, driven by legislation and regulation—to say nothing of common sense—are promulgated every year. A laboratory security system is put in place to mitigate a number of risks and is complementary to existing laboratory security policies. In very broad terms, laboratory safety keeps people safe from chemicals, and laboratory security keeps chemicals safe from people. This chapter is intended to provide the reader with an overview of laboratory security concerns and to raise awareness of the issue. Risks to laboratory security include

- theft or diversion of chemicals, biologicals, and radioactive or proprietary materials (such materials could be stolen from the laboratory, diverted or intercepted in transit between supplier and laboratory, at a loading dock, or at a stockroom, and then sold or used, directly or as precursors, in weapons or manufacture of illicit substances);
- theft or diversion of mission-critical or high-value equipment;
- threats from activist groups;
- intentional release of, or exposure to, hazardous materials;
- sabotage or vandalism of chemicals or high-value equipment;
- loss or release of sensitive information; and
- rogue work or unauthorized laboratory experimentation.

The type and extent of the security system needed depend on several factors, including

- known and recognized threats gleaned from the experience of other laboratories, institutions, or firms;
- history of theft, sabotage, vandalism, or violence directed at or near the laboratory, institution, or firm;
- presence of valuable or desirable materials, equipment, technology, or information;
- intelligence regarding groups or individuals who pose a general threat to the discipline or a specific threat to the institution;
- regulatory requirements or guidance;
- concerns regarding information security; and
- the culture and mission of the institution.

A good laboratory security system should, among other things, increase overall safety for laboratory personnel and the public, improve emergency preparedness by assisting with preplanning, and lower the organization’s liability.

10.B SECURITY BASICS

There are four integrated domains to consider when improving security of a facility:

- physical or architectural security—doors, walls, fences, locks, barriers, controlled roof access, and cables and locks on equipment;
- electronic security—access control systems, alarm systems, password protection procedures, and video surveillance systems;
- operational security—sign-in sheets or logs, control of keys and access cards, authorization procedures, background checks, and security guards; and
- information security—passwords, backup systems, shredding of sensitive information.

These domains are complementary, and each should be considered when devising security protocols. Any security system should incorporate redundancy to prevent failure in the event of power loss or other environmental changes. Security systems should help

- detect a security breach, or a potential security breach, including intrusion or theft;
- delay criminal activity by imposing multiple layered barriers of increasing stringency or “hardening” in the form of personnel and access controls; and
- respond to a security breach or an attempt to breach security.

10.B.1 Physical and Electronic Security

There are many systems available for physical and electronic laboratory security. The choice and implementation depends on the level of security needed and resources available. The following sections provide some examples, although new technologies are always under development.

The concept of concentric circles of protection, as shown in Figure 10.1, is useful when considering a laboratory’s physical security. Physical and electronic security begins at the perimeter of the building and becomes increasingly more stringent as one moves toward the interior area (e.g., at the intervention zone), where sensitive material, equipment, or technology reside. Note that although physical measures are
implemented in the intervention zones, electronic and operational security measures are implemented only under certain conditions, depending on need.

10.B.1.1 Door Locks

Within a laboratory, perhaps the most obvious form of security is the door lock. There are many choices available, including

- Traditional locks with regular keys (which are subject to duplication, loss, theft, and failure to return after access) should no longer be utilized in areas where dual-use materials are located.
- Traditional locks with keys marked “Do Not Duplicate” have the same drawbacks as above, but may be less likely to be duplicated.
- Cipher locks with an alpha or numeric keypad may be vulnerable to thieves who are able to deduce the access code from the appearance of the keys. Access codes should be changed from the factory default when the lock is installed.
- High-security cores are difficult to break into and to duplicate.
- Card access (dip locks) traditionally have data-logging capabilities that allow those with access to security records to identify which cards were used to gain access.
- Card access (swipe cards). These provide a transaction record and can be programmed for different levels and times of access.
- Key fobs or card access (proximity card readers) have the same benefits as swipe cards, but there is no requirement to place the card physically in the reader.
- Biometric readers offer a high level of security but are expensive and require more intensive maintenance.

Each of these systems requires training, management, and maintenance, whether it is a key inventory system or controls for card access. Of course, the system is only as effective as the users allow it to be. Users should be trained to not hold doors open for others, and that everyone needs to use their key to pass through an access point. Unauthorized personnel should not be allowed to enter the laboratory, and if there is any question, laboratory personnel should be instructed to call security for guidance. The organization should ensure that there is a program in place to collect keys or revoke card access to the laboratory before a person leaves the workplace.
10.B.1.2 Video Surveillance

Video surveillance systems are often used to supplement locks for documenting access and may be continuously monitored by security personnel. Recordings of relevant video may be reviewed after an incident.

When implementing a video surveillance system, document the purpose and ensure that personnel understand the objectives. Video surveillance may be used to

- prevent crime by recognizing unusual activity in real time, which requires staff dedicated to watching the camera output and is most effective when the presence of individuals alone is suspicious;
- validate entry authorization by verifying the identity of the worker; and
- verify identity of unauthorized personnel after unauthorized access.

Video surveillance cameras should be located to provide a clear image of people in the area, particularly those entering or exiting. They are not as useful in the work area itself unless suspicious behavior is obvious.

If video is recorded, a system of storage and documentation is needed. Establish the duration of recording retention, the media used, and the need for permanent archiving. Create a procedure to quickly find, maintain, and duplicate critical recordings if an incident occurs.

No matter the objective of the video surveillance system, it is crucial to establish a policy and procedure for using it and for reviewing recordings. Involve human resources and legal personnel in the policy-making process. For example, if the video surveillance system is designed to record unauthorized entry, it may not be allowable by the institution to use it to track worker productivity. Clarify under what circumstances the information may be viewed, and by whom.

10.B.1.3 Other Systems

There are many other methods of implementing physical and electronic security, ranging from simple to sophisticated, which can be employed for crime deterrence, recognition, or investigation. A few examples include

- glass-break alarms for windows and doors,
- intrusion alarms,
- hardware to prevent tampering with window and/or door locks,
- lighting of areas where people may enter a secure area,
- bushes and other barriers to reduce visibility of sensitive areas from outside the building,
- locks on roof access doors,
- walls that extend from the floor to the structural ceiling,
- tamper-resistant door jambs,
- blinds on windows,
- locks and cables on equipment to prevent easy removal,
- badges or other forms of identification, and
- sign-in logs.

10.B.2 Operational Security

Operational security is responsible for the people within the laboratory. A security system is only as strong as the individuals who support it, and thus, among the goals of an operational security system are to increase awareness of security risks and protocols, to provide authorization for people who need access to a given area or material, and to provide security training.

Though far from comprehensive, elements of operational security include

- screening full- and part-time personnel before providing access to sensitive materials or information;
- providing ID badges;
- working to increase the situational awareness of laboratory personnel (e.g., knowing who is in the laboratory, identifying suspicious activity);
- encouraging the reporting of suspicious behavior, theft, or vandalism;
- restricting off-hour access to laboratories;
- providing entry logs at building and laboratory access points; and
- inspecting and inventorying materials removed from the laboratory.

10.B.3 Information Security

Information and data security can be as critical as security of equipment and materials. Loss of data and computer systems from sabotage, viruses, or other means can be devastating for a laboratory.

The issue of dual use applies to information as well as laboratory materials. Over the years, several examples of cybersecurity breaches have led to loss of sensitive information. A detailed description of a laboratory procedure may find its way into the public domain, creating a new resource for those with illicit intentions, or simply depriving the researchers of recognition for their work.

Most institutions and firms have information security policies and procedures and information technology support staff who can help implement security systems. Laboratory managers and personnel should be familiar with and follow their protocols.
10.B.3.1 Backup Systems

Develop and institute a plan for backing up data on a regular basis with backup media off-site, in fire-safe storage, or at a central facility (e.g., the institution’s information technology facility).

10.B.3.2 Confidential or Sensitive Information

Assess the type of data produced by the laboratory, department, or group. Laboratories that possess chemicals of interest (COI) and are covered by the Chemical Facilities Anti-Terrorism Standards (CFATS) are subject to U.S. Department of Homeland Security (DHS) requirements for Chemical-terrorism Vulnerability Information (CVI). CVI may not be openly shared. It includes data and results from an inventory assessment called a Top-Screen (see section 10.E.4.2), the facility’s DHS Security Vulnerability Assessment and Site Security Plan (e.g., procedures and physical safeguards), as well as training and incident records, and drill information.

Other data may fit into the following categories:

- public, shared freely with anyone;
- internal, shared freely within the institution;
- department, shared only within the department;
- laboratory, shared only in the laboratory; or
- confidential,\(^1\) shared only with those directly involved with the data or on a need-to-know basis.

If the laboratory produces private, sensitive, or proprietary data,

- Provide training to those with access to this information, stressing the importance of confidentiality. Review any procedures for releasing such information outside the laboratory or group.
- Consider a written and signed confidentiality agreement for those with access to such information.
- Keep passwords confidential. Do not store or write them in an obvious place.
- Change passwords routinely.
- Safeguard keys, access cards, or other physical security tools.
- Before discarding materials that contain sensitive information, render them unusable by shredding them, or by erasing magnetic tape.

Many services and programs are available to protect data from viruses and similar threats as well as high levels of security. Refer to the institution’s information technology group or an outside consultant.

10.C SYSTEMS INTEGRATION

Since events such as the attacks on the World Trade Center, institutions and firms have steadily improved their security systems for personal as well as institutional protection. They have incorporated more rigorous planning, staffing, training, and command systems and have implemented emergency communications protocols, drills, background checks, card access systems, video surveillance, and other measures. What’s more, many colleges and universities, to say nothing of commercial institutions, have engaged their own sworn and armed on-site police force.

Security is not new, at least for some laboratories. For years, secure management of controlled substances and denatured alcohol has been required by law; however, global events have raised the stakes for these laboratories as well as for those that were not previously concerned about security. It is not enough to implement a laboratory security system; it is imperative that such a system protect the laboratory and also be compatible, consistent, and integrated smoothly with the overarching systems in the institution. The institution is responsible for the general security atmosphere, and laboratory systems focus on residual and specialized security risks.

Moreover, the security plan should identify protocols, policies, and responsible parties, clearly delineating response to security issues. This includes coordination of institution and laboratory personnel and coordination of internal and external responders, including local police and fire departments.

10.D DUAL-USE HAZARD OF LABORATORY MATERIALS

In addition to inadvertent misuse of chemicals, it is apparent that chemicals can also be misused intentionally, for example, as precursors of illicit narcotics. Much of the recent focus on security in research and teaching laboratories pertains to “dual use” materials. Dual-use or multiple-use materials are materials that have both a bona fide use in scientific research and education, but

\(^1\)The term “confidential” may have special meaning for some operations and funding resources. Use care in choosing terminology for sensitive information. In the event of an inspection by a government agency or association providing information or funding, there may be expectations related to the use of these terms. Classified information is often defined further as confidential, secret, or top secret.
also can be used for criminal or terrorist activities. For example, common chemical substances that are easily removed from the laboratory without notice or readily purchased, such as acetone and hydrogen peroxide, can be converted to highly explosive or otherwise hazardous products. Although certain dual-use materials can be obtained from hair salons, hardware stores, and the like, laboratories are also a source, and security should be considered.

Dual-use biological agents include live pathogens and biological toxins that have a realistic potential to be used for terrorism (e.g., anthrax). There are national as well as international regulations to address the risk of dual use, such as import and export controls. Firms and institutions may wish to integrate their facility dual-use controls with both levels of regulation.

Terrorist Web sites have suggested that their operatives can pose as students to gain access to university laboratories and remove hazardous chemical, biological, or radiological agents. However, meaningful quantities of some dual-use chemicals can also be found outside the laboratory in situations that are less secure than laboratories. As a result, the acquisition and dual use of laboratory chemicals is a real possibility, especially utilizing chemicals that can pose a high risk in relatively small laboratory quantities.

Although there is no comprehensive list of dual-use chemicals, DHS has developed a list of COI because of concern about dual use. (See section 10.E.4.2 for more information.) In addition to known warfare agents, such as nitrogen mustard and sarin (which are difficult to acquire or synthesize in makeshift laboratories), more common laboratory reagents, such as ammonia, chlorine, phosgene, cyanogen chloride, sodium cyanide, and sodium azide are considered dual-use compounds. These substances can cause human injury—either directly or after acidification—that is relatively resistant to medical treatment (Shea and Gottron, 2004), and therefore could be sought by terrorists gaining access to laboratory facilities. Alternatively, a research laboratory could be used for the illicit synthesis of terror substances.

Objective evaluation of the utility of a given chemical to terrorists might underestimate the true risk posed by malicious intent. For example, osmium tetroxide, which is highly toxic in pure solid form and in solution, has been judged to be a poor choice for terrorists because of its high cost, its rapid evaporation, and the fact that an explosion would convert it to harmless products. Nonetheless, osmium tetroxide poisoning was suspected to be the intended means of a thwarted terror attack in the vicinity of London, England (Kosal, 2006). One cannot assume terrorists will follow the same logical path or practical considerations as an individual who is trained in laboratory sciences.

10.E LABORATORY SECURITY REQUIREMENTS

For most laboratories, there are a few general security requirements; however, most security measures are based on an assessment of the vulnerabilities and needs of an individual laboratory or institution. For some materials or operations, regulations or strict guidance documents specify the type or level of security.

10.E.1 Biological Materials and Infectious Agents

Certain biological agents, including viruses, bacteria, fungi, and their genetic elements, are considered dual-use materials because of their potential for use by terrorists to harm human health. Biological materials pose a unique problem because these materials can replicate; thus, theft of even small amounts is significant.

In the United States, these dual-use biological materials are called Select Agents and Toxins, and their laboratory use is regulated by the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS). Individuals planning to use Select Agents and Toxins are required to perform a security risk assessment (i.e., a detailed background check) to determine whether they are permitted to work with the materials. There are additional requirements for laboratory security, and the CDC or APHIS will conduct periodic inspections to assess compliance.

In addition, federal guidance from the National Institutes of Health (NIH) addresses the management of dual-use risks from gene synthesis, synthetic biology, and certain experiments. The publication Biosafety in Microbiology and Biomedical Laboratories (BMBL; HHS/CDC/NIH, 2007a) includes guidance for selectivity of biological materials, based on a risk assessment method described in the document. For institutions that receive NIH funding, compliance with the BMBL is a grant requirement for recombinant DNA research.

10.E.2 Research Animals

Animal research is the focus of numerous animal rights organizations, including some that have engaged in malicious behavior. Vivarium security is critical for the safety of animals and researchers. The Association for Assessment and Accreditation of Laboratory Animal Care International provides guid-
ance for security of laboratory animals and research facilities.

10.E.3 Radioactive Materials and Radiation-Producing Equipment

In most laboratories, the quantity, isotope, and characteristics of radioactive materials used for research or teaching do not pose a serious dual-use risk. However, any radioactive materials can be perceived as a risk by the community.

In the United States, use of radioactive materials is regulated by the U.S. Nuclear Regulatory Commission (USNRC) or USNRC-authorized state agencies. Compulsory guidelines for security are included in the requirements for licensing and use of these materials. Specific USNRC security requirements typically vary depending on the risk of the material.

10.E.4 Chemicals

Chemical security is garnering increasing attention from regulators. Most regulations that require specific security measures are aimed at facilities with large stores of materials—such as production facilities—rather than laboratory-scale quantities. However, federal, state, and local regulatory agencies are increasingly applying standards to chemical laboratories.

10.E.4.1 Drug Enforcement Agency Chemicals

Illicit drugs and their precursors pose a theft risk because of their resale (street) value. The U.S. Drug Enforcement Agency (DEA) has strict rules about procurement, inventory, use, disposal, and security of these chemicals. A person using materials regulated by DEA must obtain a user license or work under the direction of a person with such a license. The materials must be secured, with the level of security needed dependent on the classification of the material.

Laboratories in which DEA-regulated materials are used must keep an inventory log that documents the quantity and date that any amount of material is removed, as well as a signature or other record to identify who removed the material. Once a DEA-regulated material has expired or is ready for disposal, it must be either destroyed or returned to the manufacturer or distributor. Destruction must render the material unusable and unidentifiable as the original agent and must be done by a person designated by the licensed user and witnessed by at least two people, one of whom, preferably, is a law enforcement officer. The destroyed materials must be disposed of in accordance with applicable laws (see Chapter 9 for disposal details).

10.E.4.2 DHS Chemicals of Interest (COI)

DHS has promulgated regulations that apply to chemical facilities, including laboratories, with the purpose of keeping dual-use chemicals out of the possession and control of terrorists. The Chemical Facility Anti-Terrorism Standards are concerned with the following types of chemicals:

- EPA Risk Management Plan chemicals,
- highly toxic gases,
- chemical weapons convention chemicals,
- explosives, and
- precursors of the above chemicals.

In the DHS process for determination of risk, all laboratory facilities are expected to survey their entire facility (including nonlaboratory areas) for the presence of COI and compare their inventory to the threshold screening quantities established in the standard. If the facility meets or exceeds the threshold quantity for any chemical of interest, the facility must report the inventory by completing an assessment document called “Top-Screen.”

Upon receiving a completed Top-Screen, the facility is required to conduct a security vulnerability assessment. There are four risk tiers, with tier 1 for facilities posing the greatest risk and tier 4 posing the least risk. Based on the results of the assessment and the risk tier, the facility is expected to develop and implement an approved site security plan. There are also requirements for information security and training provisions under this rule.

As of the time of publication, DHS was continuing to develop rules and guidance for chemical facilities, including laboratories.

10.F SECURITY VULNERABILITY ASSESSMENT

Whether or not the security of a laboratory material is regulated by a government agency, it is prudent to assess risk. A security vulnerability assessment (SVA) is used to catalog potential security risks to the laboratory and the magnitude of possible threats. It begins with a walk-through of the laboratory, building, and building perimeter, and includes discussion with laboratory staff pertaining to the chemicals, equipment, procedures, and data that they use or produce. The SVA process will also assess the adequacy of the systems
already in place and help determine the security planning needs for the laboratory, building, or department.

There are a number of ways to conduct an SVA. DHS has developed an SVA protocol for higher risk facilities, which may include laboratories if threshold amounts of COI are present. Completion of this SVA is mandatory for facilities that DHS has classified into a risk tier (see section 10.E.4.2). The DHS SVA is available on its Web site for use by any facility, even those not regulated by DHS.

Many states have adopted SVAs for their critical infrastructure, which often includes colleges, universities, and other facilities with research or pilot laboratories. Several professional organizations have also developed SVA checklists, such as the one by the American Chemical Society Committee on Chemical Safety, which is available on the CD that accompanies this book.

The following is a partial list of issues to review as part of an SVA:

- existing threats, based on the history of the institution (e.g., theft of laboratory materials, sabotage, data security breaches, protests);
- the attractiveness of the institution as a target, and the potential impact of an incident;
- chemicals, biological agents, radioactive materials, or other laboratory equipment or materials with dual-use potential (see section 10.D);
- sensitive data or computerized systems;
- animal care facilities;
- infrastructure vulnerabilities (e.g., accessible power lines, poor lighting);
- security systems in place (e.g., access control, cameras, intrusion detection);
- access controls for laboratory personnel (e.g., background checks, authorization procedures, badges, key controls, escorted access);
- institutional procedures and culture (e.g., tailgating, open laboratories, no questioning of visitors);
- security plans in place; and
- training and awareness of laboratory personnel.

Where the perceived risk is high, institutions should consider contracting a laboratory security consultant to conduct the SVA with input and feedback from security, safety, and laboratory staff.

10.G DUAL-USE SECURITY

When assessing security needs, determine whether laboratories possess materials, equipment, or technologies that have the potential for dual use, such as Select Agents or COI. Whether or not security regulations apply, take prudent steps to reduce the risk of theft or use for terrorist activity.

- Maintain inventory records of dual-use materials.
- Limit the number of laboratory personnel who have access to dual-use agents.
- Provide easy access to a means of emergency communication, in case of a security breach or a threat from within or outside. Consider adding repeaters, or bidirectional signal amplifiers, so that someone with a cell phone can make an emergency phone call from within the secure area.
- Periodically and carefully review laboratory access controls to areas where dual-use agents are used or stored.
- Maintain a log of who has gained access to areas where dual-use materials are used or stored.
- Develop a formal policy prohibiting use of laboratory facilities or materials without the consent of the principal investigator or laboratory supervisor.
- Monitor and authorize specific use of these materials.
- Remain alert and aware of the possibility of removal of any chemicals for illicit purposes. Report such activity to the head of security.
- Train all laboratory personnel who have access to these substances, including a discussion of the security risks of dual-use materials.

As appropriate, address these steps in the SVA and ensure that the security plans adequately provide for the issues these steps address.

10.H SECURITY PLANS

The SVA findings provide a list of risks, needs, and options for improvement (i.e., materials and laboratories in need of security measures beyond a lock and key). There is no template that can apply to every laboratory security plan, because several factors make each organization unique, including building architecture, building use (e.g., mixed use with classrooms, offices, or meeting rooms), organizational culture, and so on.

DHS provides guidance on the planning process in its Risk-Based Performance Standard for chemical security. These guidelines were prepared for dual-use materials that pose high or unusual risks. Recognizing that facilities need “the flexibility to choose the most cost-effective method for achieving a satisfactory level of security based on their risk profile” (DHS, 2008), this guidance provides an outline of elements that should be considered for any laboratory security plan:

- Identify the leadership structure for security issues.
- Secure the assets identified in the vulnerability assessment in a manner that prevents access by unauthorized individuals.
• Deter cyber sabotage, including unauthorized on-site or remote access to critical process controls.
• Prevent diversion using secure shipping, receiving, and storage of target materials.
• Detect theft or diversion of target materials through inventory controls.
• Establish a process for personnel surety, such as background checks, of laboratory personnel, visitors, and others with access to the laboratory.
• Screen and control access to the facility using identification badges, electronic access controls, and security personnel. Check individuals to ensure individuals do not bring harmful materials into the laboratory.
• Train laboratory personnel on the security measures, response, and importance of compliance with security procedures.
• Deter and delay a security breach through the use of multiple security layers and the physical security measures discussed below. Deterrents add time between the detection of a breach and the successful act (i.e., theft or release), which allows more time for responders to prevent the act.
• Monitor (detect) the security of those assets, such that a security breach would be noticed, and (for high-risk materials) would prompt an immediate response by laboratory or security personnel.
• Maintain monitoring, communication, and warning systems.
• Develop and implement response plans for security breaches, and exercise those plans.
• Investigate and track reports of security-related incidents. Document the incident reports, including findings and mitigation.
• Report significant incidents involving chemical security to local law enforcement.
• Maintain records of compliance with the security plan.
• Establish information-sharing and communication networks with associations and government agencies that regularly evaluate and categorize threats relevant to the laboratory or laboratory personnel. Develop a multilevel security plan that identifies appropriate security processes, procedures, and systems for normal security operations and increasing levels of security for periods of higher risk.

DHS also recommends that security plans address the security of the site perimeter and institute vehicle checks. These elements may be appropriate where laboratories are located within an industrial facility, but may be impractical at a medical, research, or educational facility.

Background checks are important for individuals working with dual-use or high-security materials, but it can be challenging to make them complete and accurate. Criminal background checks sometimes include only local crimes, rather than those committed in other areas, or vice versa. However, potential problems can be identified by noting gaps in job history and verifying employment and education background information provided by the applicant. It is often very difficult to get good background information for people who have lived, worked, or been educated in a foreign country.

### 10.H.1 Levels of Security

When developing a security plan, it is important to establish levels of security that correspond to the security needs of a particular laboratory or portion of a laboratory. These needs will also be influenced by the mission of the organization. For example, in many universities, research laboratories are housed in the same building as instructional classrooms. In those cases, strong access controls to the building are not practical, and would likely cause consternation on campus. Establishing security levels facilitates the review of security needs for a laboratory, ensures consistency in the application of security principles, and integrates the specific measures described above.

The following is one example of a management system for laboratory security, which illustrates how an institution or firm might set three security levels based on operations and materials.

**10.H.1.1 Normal (Security Level 1)**

In this example, a laboratory characterized as Security Level 1 (see Table 10.1) poses low risk for extraordinary chemical, biological, or radioactive hazards. Loss to theft, malicious pranks, or sabotage would have minimal impact to operations, health, or safety.

**10.H.1.2 Elevated (Security Level 2)**

A laboratory characterized as Security Level 2 (see Table 10.2) poses moderate risk for potential chemical, biological, or radioactive hazards. The laboratory may contain equipment or material that could be misused or threaten the public. Loss to theft, malicious pranks, or sabotage would have moderately serious health

<table>
<thead>
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<th>Physical</th>
<th>Operational</th>
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<tbody>
<tr>
<td>• Lockable doors and windows</td>
<td>• Lock doors when not occupied</td>
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<td></td>
<td>• Ensure all laboratory personnel receive security awareness training</td>
</tr>
<tr>
<td></td>
<td>• Control access to keys, use judgment in providing keys to visitors</td>
</tr>
</tbody>
</table>
and safety impact, and be detrimental to the research programs and the reputation of the institution.

10.H.1.3 High (Security Level 3)

A laboratory characterized as Security Level 3 (see Table 10.3) in this example can pose serious or potentially lethal biological, chemical, or radioactive risks to students, employees, or the environment. Equipment or material loss to theft, malicious pranks, or sabotage would have serious health and safety impacts and consequences to the research programs, the facilities, and the reputation of the institution.

10.H.2 Managing Security

As noted above, any security plan, no matter what level of security is needed, should identify a person or group responsible for the overall plan. The person or group managing the program should have at least basic security knowledge, understand the risks and vulnerabilities, and should be provided sufficient resources, responsibility, and authority.

10.H.3 Training

Security should be an integral part of the laboratory safety program. Ensure all personnel are trained in security issues, in addition to safety issues. Although safety and security are two different things, there are many overlaps between measures used to increase security and those used to increase safety, including

- minimizing the use of hazardous and precursor chemicals, which reduces health, safety, and potential security risks;
- minimizing the supply of hazardous materials on-site;
- restricting access to only those who need to use the material and understand the hazards from both a chemical standpoint and a security standpoint; and
- knowing what to do in an emergency or security breach, and how to recognize threats.

Ensure that all personnel understand the security measures in place and how to use them. No matter how complex a system may be, the weakest link tends to be personnel. For example, even the best access control system may not prevent laboratory personnel from granting an unauthorized individual access to a sensitive area.
## 11
### Safety Laws and Standards Pertinent to Laboratories

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There are a number of federal, state, and local laws, regulations, ordinances, and standards that pertain to the laboratory activities and conditions that affect the environment, health, and safety. These are reviewed briefly in this chapter. For safety laws and standards described in detail elsewhere in this book, this chapter will refer to that section.

Laws, rules, regulations, and ordinances are created and enforced by federal, state, and local governments. International regulations apply to air and marine transport of laboratory materials. Safety standards and codes are created by nongovernmental bodies, but are important to know because they may be required by a law (by reference), as condition of occupancy, by your insurance company, by an accrediting body, or as a widely accepted industry standard. In some cases, following a safety guideline is a condition of receiving a research grant.

Please note that this chapter is not meant to be a compliance guide. This chapter only provides an overview of certain laws. Further, this chapter mostly focuses on federal requirements. State and local requirements may be more stringent, so be sure to check to determine the specific rules that apply.

11.A.1 Making Safety Laws and Their Rationale

Organizations that handle chemicals in laboratories should participate in the regulatory process so that regulators will understand the impact that proposed rules can have on the laboratory environment. The best way to provide input to this process is through dialogue with the regulators, which can take place directly or in collaboration with the institution’s environmental health and safety (EHS) or governmental relations office. Also, professional associations, such as the American Chemical Society (ACS), the American Industrial Hygiene Association (AIHA), the American Conference of Governmental Industrial Hygienists (ACGIH), and the American Institute of Chemical Engineers (AIChE), as well as trade associations such as the American Chemistry Council (ACC) and the Campus Health Safety and Environmental Management Association (CHSEMA), regularly comment on proposed regulations, especially proposed federal regulations (which, by law, require solicitation of comment from interested parties). Participation in the regulatory process through such groups is encouraged.

A brief description of the federal legislative and regulatory processes may be helpful. Laws are a product of legislative activity. Legislation is usually proposed by senators and representatives to achieve a desired result, for example, improved employee safety or environmental protection. Proposed laws are often known by their Senate or House file numbers, for example, S.xxx or H.R.xxx. Copies of proposed laws can be obtained by visiting thomas.loc.gov, the Web site for the legislative search engine at the Library of Congress, or by requesting them from local offices of House or Senate members. Sponsors of proposed legislation are open to comment from the public. Once a law is passed, it is known by its Public Law number, for example, P.L. 94-580, Resource Conservation and Recovery Act (RCRA). It is published in the United States Code and is referenced by title and section number; 42 USC § 6901 et seq. is the citation for RCRA.

When a law is passed, it is assigned to an administrative unit (agency or department) for development of rules and regulations that will implement the purpose of the legislation. The major federal agencies involved in regulation of laboratory chemicals are the U.S. Occupational Safety and Health Administration (OSHA), the U.S. Environmental Protection Agency (EPA), the U.S. Drug Enforcement Agency, the U.S. Department of Homeland Security (DHS), and the U.S. Department of Transportation (DOT). Proposed regulations are published in the Federal Register, a daily publication of federal agency activities. Typically, a public comment period and perhaps public hearings are specified, during which all affected parties have an opportunity to present their support for or concerns with the regulations as proposed. This is the second significant opportunity for involvement in the regulatory process. Final rules are published in the Federal Register and in the Code of Federal Regulations (CFR), which is updated annually to include all changes during the previous year. Rules in the CFR are referenced by title and part number; for example, 40 CFR Parts 260–272 is the citation for RCRA’s hazardous waste rules.

It is helpful to understand the rationale that underlies EHS laws and regulations. These laws reflect congressional, state, and local legislative concerns about worker safety, human health, and the environment, and enjoy strong public support.

Regulations and compliance with them is complicated by the fact that it is a virtual impossibility for EHS regulators to weigh every risk precisely. To attempt chemical-by-chemical regulation of the thousands of known, and unknown, chemicals would be so onerous and time-consuming as to leave many serious hazards unregulated. Consequently, regulators attempt to strike a balance by regulating classes of hazards and risks.

Those managing and working in laboratories should also recognize that violation of EHS laws and regulations not only may pose unnecessary risks to those in the laboratory and the surrounding community, but
also can result in significant civil penalties (at publication of this book, some laws allow maximum fines of more than $30,000 per day per violation), as well as criminal penalties. Violations can erode community confidence in an institution’s seriousness of purpose in safeguarding the environment and complying with the law. Prudent practice requires not only scientific prudence, but also prudent behavior in terms of preventing the risks of noncompliance, adverse publicity, and damage to public trust and an institution’s community support.

11.A.2 OSHA and Laboratories

It is important to understand the relationships between the regulations and standards that mediate laboratory activities. The OSHA Laboratory Standard (Occupational Exposure to Hazardous Chemicals in Laboratories, 29 CFR § 1910.1450) is the primary regulation, but laboratory personnel and EHS staff should understand its relationship to the hazard communication standard. In addition, the general duty clause is often invoked, and OSHA standards not written specifically for laboratories may also apply. Laboratory personnel also need to know the relationship between OSHA’s permissible exposure limits (PELS), ACGIH threshold limit values (TLVs), and the National Institute of Occupational Safety and Health (NIOSH) recommended exposure limits (RELS).

11.A.2.1 OSHA Enforcement and State OSHA Laws

Enforcement of OSHA standards (such as the Laboratory Standard), may be a shared responsibility of the federal government and of state occupational safety and health programs. Under Section 18 of the Occupational Safety and Health Act, individual states may be authorized by federal OSHA to administer the act if they adopt a plan for development and enforcement of standards that is at least as effective as the federal standards. These states are known as “state-plan” states. In states that do not administer their own occupational safety and health programs, federal OSHA is the regulator, covering all nonpublic employers. State-plan states have generally included public employees in their regulatory approach. What this means is that a given institution may be subject to (1) the federal Laboratory Standard, enforced by federal OSHA; (2) a state laboratory standard, enforced by state OSHA; or (3) if a public institution is not subject to OSHA regulation, state public institution health and safety regulations enforced by a state agency. The EHS office at each institution should have a copy of the applicable standard.

11.A.2.2 The General Duty Clause and “Nonlaboratory” OSHA Standards

Another important point to understand about OSHA and laboratories is that although the Laboratory Standard supersedes existing OSHA health standards, other OSHA rules on topics not specifically addressed in the standard remain applicable. The so-called general duty clause of the Occupational Safety and Health Act, which requires an employer to “furnish to each of his employees . . . a place of employment . . . free from recognized hazards that are likely to cause death or serious physical harm . . .” and requires an employee to “comply with occupational safety and health standards and all rules . . . issued pursuant to this chapter which are applicable to his own actions and conduct” continues to be applicable and, indeed, is one of the most commonly cited sections in cases of alleged OSHA violations.

11.A.2.3 Laboratory Standard Versus Hazard Communication Standard

As noted above, the Laboratory Standard is intended, with limited exceptions, to be the primary OSHA standard governing employees who routinely work in laboratories. The Hazard Communication Standard, on the other hand, applies to all nonlaboratory operations “where chemicals are either used, distributed or are produced for use or distribution.”

The obvious difficulty is that workers in maintenance shops, even if in a laboratory building, would be covered by the Hazard Communication Standard, not the Laboratory Standard. The requirements of the Hazard Communication Standard are, in certain respects, more demanding than those of the Laboratory Standard. For example, the Hazard Communication Standard requires that each container of hazardous chemicals used by the employee be labeled clearly with the identity of the chemical and appropriate hazard warnings, whereas the Laboratory Standard requires only that employers “ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.”

The Hazard Communication Standard further requires that copies of material safety data sheets (MSDSs) for each hazardous chemical be readily accessible to employees, whereas the Laboratory Standard requires only that employers “maintain MSDSs that are received with incoming shipments, and ensure that they are readily accessible. . . .”

Custodial and maintenance staff who service the laboratory continue to be governed by the Hazard Communication Standard and other OSHA standards, which set forth the information, training, and health
and safety protections required to be provided to non-laboratory employees.

Many organizations, faced with the difficulty of designing EHS programs that meet both the requirements of the Laboratory Standard and the requirements of the Hazard Communication Standard, have opted to follow the requirements of the Hazard Communication Standard for all workplaces, laboratory and nonlaboratory, while additionally adopting and implementing the Chemical Hygiene Plan requirements of the Laboratory Standard as they apply to laboratories. Careful comparison of the two standards should be made when designing an EHS program.

11.A.2.4 PELs, TLVs, and RELs

OSHA has developed PELs for chemicals. These are enforceable regulatory limits for the air concentration of individual substances to which a worker may be exposed. Many PELs are based on TLVs, which are nonregulatory exposure limits prepared by ACGIH using existing published, peer-reviewed scientific literature. Quoting the TLV booklet (ACGIH, 2009), “The TLVs . . . represent conditions under which ACGIH believes that nearly all workers may be repeatedly exposed without adverse health effects. They are not fine lines between safe and dangerous exposures, nor are they a relative index of toxicology.” PELs and TLVs are average concentrations for a normal 8-hour workday and a 40-hour workweek. This time-weighted average (TWA) approach to evaluating airborne contaminant exposure means that some periods of the day may have higher or lower exposures than others, reflecting the variability in most work with chemicals.

For a small number of compounds, both OSHA and ACGIH have also established a short-term exposure limit (STEL), a concentration considered safe for no more than four 15-minute periods a day. STELs are published only for compounds where toxic effects have been reported from high-level, short-duration exposures in humans or animals. In addition, both groups have also established ceiling limits for some compounds (indicated by a “C” preceding the TLV or PEL value). The ceiling limit is the concentration that should not be exceeded during any time portion of exposure. For compounds that include neither a STEL nor a C notation, a limit on the upper level of exposure should still be imposed. According to the TLV booklet, “Excursions in worker exposure levels may exceed 3 times the TLV-TWA for no more than a total of 30 minutes during a work day, and under no circumstances should they exceed 5 times the TLV-TWA, provided that the TLV-TWA is not exceeded.”

The action level (AL) is an OSHA regulatory concept applied to only a few substances. The AL is also an exposure limit for airborne concentration (lower than its associated PEL) that, if exceeded, requires certain additional protective measures to be implemented, such as additional confirmatory exposure monitoring, training, or medical surveillance. Although personal exposures in research laboratory environments are generally controlled well below all of these limits by the use of local exhaust devices and room air change rates, laboratories working with any of the chemicals covered by an OSHA substance-specific standard must be aware of the applicable regulatory provisions and implement them.

RELs are additional exposure values that are developed by the National Institute for Occupational Safety and Health (NIOSH). Like TLVs, RELs are not legal standards but are science-based recommendations that do not need to take into account feasibility, financial impact, or other consequences of their use. As a result, RELs and TLVs are generally more conservative (i.e., lower, more protective) than OSHA’s limits.

11.A.3 Understanding Other Laboratory Safety Requirements

These rules are vast, complex, and intricate in their details and interrelationships. As noted above, the application and specifics of federal laws vary from state to state, local jurisdictions, and among federal regulatory agency regional offices. Further, there is a great variety of state and local laws, and so requirements depend on the laboratory’s location. State and local laws are not covered here, and so specific requirements may vary from the general information provided here. Where available, an EHS officer who is familiar with the details of these rules can act as a resource for scientists. Smaller organizations can seek advice directly from their counsel, insurance provider, regulatory agencies, EHS professionals at other organizations, or consultants.

Table 11.1 lists safety laws that pertain to laboratories, along with their associated regulations. This table is not comprehensive. As noted previously, a detailed explanation of these requirements, and all the nonregulatory safety standards that apply to laboratories, is beyond the scope of this book. Laboratory safety standards that are among the most relevant are those published by the American Industrial Hygiene Association, American National Standards Institute (ANSI; e.g., laboratory decommissioning standard), Clinical and Laboratory Standards Institute (e.g., clinical laboratory waste management), College of American Pathologists, International Association for Assessment and Accreditation of Laboratory Animal Care, and the National Council on Radiation Protection and Measurement (e.g., radiation exposure, waste manage-
### TABLE 11.1  Federal Safety Laws and Regulations That Pertain to Laboratories

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<th>Purpose</th>
<th>Comments</th>
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<tr>
<td><strong>Regulation of Chemicals Used in Laboratories</strong></td>
<td></td>
<td></td>
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<tr>
<td>Occupational Safety and Health Act (OSHA)</td>
<td>29 USC § 651 et seq.</td>
<td>Worker protection</td>
<td></td>
</tr>
<tr>
<td>General duty clause</td>
<td>29 USC § 654(5)(a) and (b)</td>
<td>Assurance of workplace free from recognized hazards that are causing or likely to cause serious physical harm</td>
<td>Foundation enforceable requirement in absence of a specific standard</td>
</tr>
<tr>
<td>Occupational Exposure to Hazardous Chemicals in Laboratories (Laboratory Standard)</td>
<td>29 CFR § 1910.1450</td>
<td>Laboratory worker protection from exposure to hazardous chemicals</td>
<td>Requires a chemical hygiene plan. Title 29 rules are written and enforced by OSHA</td>
</tr>
<tr>
<td>Hazard Communication Standard</td>
<td>29 CFR § 1910.1200</td>
<td>General worker protection from chemical use</td>
<td>Requires labeling and material safety data sheets (MSDSs)</td>
</tr>
<tr>
<td>Air contaminants</td>
<td>29 CFR §§ 1910.1000–1910.1050</td>
<td>Standards for exposure to hazardous chemicals</td>
<td>See section 11.C.1 for chemical-specific regulations pertinent in laboratories</td>
</tr>
<tr>
<td>OSHA Respiratory Protection Standard</td>
<td>29 CFR § 1910.134</td>
<td>When respiratory protection is required; how to fit and use respirators; and medical review</td>
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<tr>
<td>Personal protective equipment</td>
<td>29 CFR §§ 1910.132–1910.138</td>
<td>Head, hand, foot, eye, face, and respiratory tract protection</td>
<td>See also American National Standards Institute standards</td>
</tr>
<tr>
<td>Control of hazardous energy (Lock out/Tag out)</td>
<td>29 CFR § 1910.147</td>
<td>Worker protection from electrical and other stored energy hazards</td>
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<tr>
<td>Machinery and machine guarding</td>
<td>29 CFR §§ 1910.211–1910.219</td>
<td>Worker protection from mechanical hazards</td>
<td></td>
</tr>
<tr>
<td>Controlled substances</td>
<td>21 CFR §§ 1300-1399</td>
<td>Requires licenses and controls for the purchase, use, and possession of controlled substances, illicit drugs, and certain drug precursors</td>
<td>Enforced by the Drug Enforcement Agency</td>
</tr>
<tr>
<td>Chemical Facility Anti-Terrorism Standards (CFATS) with Appendix</td>
<td>6 CFR Part 27</td>
<td>Establishes risk-based performance standards for the security of chemical facilities</td>
<td>Appendix A of the regulation contains list of chemicals of interest and their threshold quantities</td>
</tr>
<tr>
<td>Toxic Substances Control Act (TSCA)</td>
<td>40 CFR Part 761</td>
<td>Prohibition against PCBs in manufacturing, processing, distribution in commerce, and certain uses</td>
<td>Permits certain limited laboratory use of PCBs</td>
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<td>Polychlorinated biphenyls (PCBs)</td>
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<td>Permit and excise tax for purchase of 190- and 200-proof ethanol</td>
<td>27 CFR Part 211</td>
<td>Control of the sale of ethanol</td>
<td>Enforced by the U.S. Bureau of Alcohol, Tobacco, and Firearms</td>
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<td><strong>Regulation of Biohazards and Radioactive Material Used in Laboratories</strong></td>
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<td>Occupational exposure to bloodborne pathogens</td>
<td>29 CFR § 1910.1030</td>
<td>Worker protection from exposure to bloodborne pathogens</td>
<td>Select agents are biological agents that are a terror risk. Rules are administered by the U.S. Centers for Disease Control and Prevention and the U.S. Animal and Plant Health Inspection Service</td>
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<tr>
<td>Select agents and toxins</td>
<td>42 CFR Part 73</td>
<td>Establishes the requirements for possession, use, and transfer of select agents and toxins.</td>
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<td>Atomic Energy Act</td>
<td>42 USC § 2073 et seq.</td>
<td>Establish standards for protection against radiation hazards</td>
<td>See also OSHA, Ionizing Radiation</td>
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<td>42 USC § 5841 et seq.</td>
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<td>Standards for Protection Against Radiation; Licenses</td>
<td>10 CFR Part 20</td>
<td>Establish exposure limits and license conditions</td>
<td>Title 10 rules are written and enforced by Nuclear Regulatory Commission</td>
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<td></td>
<td>10 CFR Parts 30–35</td>
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<tr>
<td>Notices, Instructions, and Reports to Workers; Inspections</td>
<td>10 CFR Part 19</td>
<td>Workplace information that must be posted where radiation or radioactive materials are present</td>
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<td>Environmental Regulations Pertaining to Laboratories</td>
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<td>Resource Conservation and Recovery Act (RCRA)</td>
<td>42 USC § 6901 et seq.</td>
<td>Protection of human health and environment</td>
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<tr>
<td>Hazardous waste management</td>
<td>40 CFR Parts 260–272</td>
<td>“Cradle-to-grave” control of chemical waste</td>
<td>Subpart K of 40 CFR Part 262 is an opt-in rule specific to laboratories in academia. Title 40 rules are written and enforced by EPA</td>
</tr>
<tr>
<td>Clean Air Act (CAA)</td>
<td>42 USC § 7401 et seq.</td>
<td>Protection of air quality and human health</td>
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<tr>
<td>CAA Amendments of 1990</td>
<td>42 USC § 7409 et seq.</td>
<td>Expansion of air quality protection</td>
<td>Requires development of specific rules for laboratories</td>
</tr>
<tr>
<td>National Emission Standards for Hazardous Air Pollutants</td>
<td>40 CFR Part 82</td>
<td>Control of air pollutant emissions</td>
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<tr>
<td>Montreal Protocol for Protection of Stratospheric Ozone</td>
<td>40 CFR Part 82</td>
<td>Control of emission of ozone-depleting compounds</td>
<td>Severely limits use of certain chlorofluorocarbons</td>
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<tr>
<td>Federal Water Pollution Control Act</td>
<td>33 USC § 1251 et seq.</td>
<td>Improvement and protection of water quality</td>
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<tr>
<td>Criteria and standards for the National Pollutant Discharge Elimination System (NPDES)</td>
<td>40 CFR Part 125</td>
<td>Control of discharge to public waters</td>
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<tr>
<td>General pretreatment regulations for existing and new sources of pollution</td>
<td>40 CFR Part 403</td>
<td>Control of discharge of pollutants to public treatment works</td>
<td>Implemented by local sewer authorities</td>
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<tr>
<td>Shipping, Export, and Import of Laboratory Materials</td>
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<tr>
<td>Hazardous Materials Transportation Act</td>
<td>48 USC § 1801 et seq.</td>
<td>Control of movement of hazardous materials</td>
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</tr>
<tr>
<td>Hazardous material regulations</td>
<td>49 CFR Parts 100–199</td>
<td>Regulation of packaging, labeling, placarding, and transporting</td>
<td>Standards of the International Air Transport Agency apply to chemicals shipped by air. Title 49 rules are written and enforced by DOT.</td>
</tr>
<tr>
<td>Hazardous materials training requirements</td>
<td>49 CFR §§ 172.700–172.704</td>
<td>Assurance of training for all persons involved in transportation of hazardous materials</td>
<td>Also known as HM126F</td>
</tr>
<tr>
<td>TSCA</td>
<td>15 USC § 2601 et seq.</td>
<td>Requires testing and necessary restrictions on use of certain chemical substances</td>
<td>Collection and development of information on chemicals</td>
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<tr>
<td>Reporting and recordkeeping requirements</td>
<td>40 CFR Part 704</td>
<td>One provision exempts users of small quantities solely for research and development (R&amp;D)</td>
<td>Must follow R&amp;D exemption requirements</td>
</tr>
<tr>
<td>Significant adverse reaction</td>
<td>40 CFR Part 717</td>
<td>Record of new allegation that chemical substances or mixture caused significant adverse effect for health or the environment</td>
<td>TSCA § 8(c)</td>
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Prudent Practices in the Laboratory

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<th>Comments</th>
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<tr>
<td>Technically qualified individual (TQI)</td>
<td>40 CFR § 720.3(ee)</td>
<td>Definition of TQI by background; understanding of risks, responsibilities, and legal requirements</td>
<td>Follow TQI requirements with R&amp;D</td>
</tr>
<tr>
<td>TSCA exemption for R&amp;D</td>
<td>40 CFR § 720.36</td>
<td>Exemption for R&amp;D from PMN if chemical substance not on TSCA inventory or is manufactured or imported only in small quantities solely for R&amp;D</td>
<td>Follow R&amp;D exemption requirements including labeling and MSDS information</td>
</tr>
<tr>
<td>Exports of samples, chemicals, biologicals, other materials, and laboratory equipment</td>
<td>15 CFR Parts 730–774</td>
<td>Regulates shipments of certain chemicals and other research materials out the United States</td>
<td>These rules are administered by the U.S. Department of Commerce; other export regulations may apply</td>
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</tbody>
</table>

#### Regulation of Laboratory Injuries, Accidents, and Spills

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<th>Law or Regulation</th>
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<th>Purpose</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Recording and reporting occupational injuries and illnesses</td>
<td>29 CFR Part 1904</td>
<td>Standards for employee reporting and recordkeeping</td>
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</tr>
<tr>
<td>Employee emergency plans and fire prevention plans</td>
<td>29 CFR § 1910.38</td>
<td>Requirements for written emergency and fire prevention plans</td>
<td></td>
</tr>
<tr>
<td>Medical services and first aid</td>
<td>29 CFR § 1910.151</td>
<td>Provision of medical services, first-aid equipment, and facilities for quick drenching and flushing of eyes</td>
<td></td>
</tr>
<tr>
<td>Superfund Amendments and Reauthorization Act (SARA)</td>
<td>42 USC § 9601 et seq. 42 USC § 11000 et seq. 40 CFR Part 370 (§ 311–312) 40 CFR Part 372 (§ 313)</td>
<td>Planning for emergencies and reporting of hazardous materials</td>
<td>Title III, also known as Community Right-to-Know Act</td>
</tr>
<tr>
<td>Emergency planning and notification</td>
<td>40 CFR Part 355</td>
<td>Requirements for reporting of extremely hazardous materials and unplanned releases</td>
<td>Applies to all chemical users</td>
</tr>
<tr>
<td>Emergency planning and notification</td>
<td>40 CFR Part 355</td>
<td>Requirements for reporting of extremely hazardous materials and unplanned releases</td>
<td>Applies to all chemical users</td>
</tr>
<tr>
<td>Hazardous Waste Operations and Emergency Response</td>
<td>29 CFR § 1910.120 40 CFR Part 311</td>
<td>Worker protection during hazardous waste cleanup</td>
<td>Applies to state and local government employees not covered by OSHA</td>
</tr>
</tbody>
</table>

#### Other Laboratory Regulations and Standards

<table>
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<tr>
<th>Law or Regulation</th>
<th>Citation</th>
<th>Purpose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americans with Disabilities Act</td>
<td>28 CFR Part 36</td>
<td>Standards for making workplace accommodations for students and employees with disabilities</td>
<td></td>
</tr>
<tr>
<td>Access to employee exposure and medical records</td>
<td>29 CFR § 1910.20</td>
<td>Employee and privacy and other rights; employer responsibilities</td>
<td></td>
</tr>
<tr>
<td>Occupational noise exposure</td>
<td>29 CFR § 1910.95</td>
<td>Standards for noise, monitoring and medical surveillance</td>
<td></td>
</tr>
</tbody>
</table>

(See Chapter 10, section 10.E, for an explanation of laboratory security requirements.)

Two laws that have perhaps the most impact on laboratories are the Occupational Safety and Health Administration’s Occupational Exposure to Hazardous Chemicals in Laboratories (the OSHA Laboratory Standard) and RCRA, under which EPA regulates chemical hazardous waste. Because of its importance, the text of the OSHA Laboratory Standard is reprinted in Appendix A. Laboratory workers and managers should read and understand these regulations.

### 11.B Regulation of Laboratory Design and Construction

Laboratory design, construction, and renovation are regulated mainly by state and local laws that incorporate, by reference, generally accepted standard
practices set out in various uniform codes, such as the International Building Code (IBC), the International Fire Code (IFC), and the National Fire Protection Association standards. For laboratory buildings where hazardous chemicals are stored or used, detailed requirements usually cover spill control, drainage, containment, ventilation, emergency power, special controls for hazardous gases, fire prevention, and building height. Some localities have initiated regulations aimed at increasing efficiency and sustainability in building design. These may become more common in the future, and laboratory designers may wish to consider these issues when planning new construction.

Building and fire codes also apply after construction has been completed. These codes are typically enforced by the fire authority having jurisdiction—usually the local fire marshal. As explained in Chapter 6, sections 6.F.5 and 6.F.7 these codes describe how flammables, reagents, and gases must be stored, and limit their quantities in fire control areas.

In addition, OSHA standards affect some key laboratory design and construction issues, for example, eyewashes, safety showers, and special ventilation requirements. Other consensus standards prepared by organizations such as ANSI and the American Society of Heating, Refrigeration, and Air Conditioning Engineers are relevant to laboratory design. It is not uncommon for various codes and consensus standards to be incorporated into state or federal regulations.

### 11.C REGULATION OF CHEMICALS USED IN LABORATORIES

OSHA and EPA regulation of chemical use in laboratories is described below. The laboratory use of controlled substances, regulated by the U.S. Drug Enforcement Agency, is described in Chapter 10, section 10.E.4.1. Select agent toxins are regulated by the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS).

#### 11.C.1 OSHA Standards for Specific Chemicals

OSHA has developed comprehensive standards for several chemicals, which are listed in Table 11.2. To prevent exposure to personnel, these standards cover all aspects of the use of these chemicals. These standards are above those required by the Laboratory Standard and, in some cases, may require special signs, medical surveillance, and routine air monitoring of your workplace. For more information, see 29 CFR Part 1910 as well as in specific standards following section 1910.1000, such as the vinyl chloride standard, 29 CFR § 1910.1017, which prohibits direct contact with liquid vinyl chloride.

Other OSHA standards setting forth PELs apply to the extent that they require limiting exposures to below the PEL, and, where the PEL or AL is routinely exceeded, the Laboratory Standard’s provisions (described below) require exposure monitoring and medical surveillance (see Appendix A, sections (d) and (g)).

If you use these chemicals routinely, even for short periods of time, you should have your workplace evaluated by your EHS officer to ensure that your work practices and engineering controls are sufficient to keep your exposures below the OSHA-specified limits. Because of their common use in campus laboratories, the specific standards for formaldehyde (used as formalin for preservation of tissue samples), benzene, and ethylene oxide are of particular concern.

#### 11.C.2 The OSHA Laboratory Standard

In 1990, OSHA promulgated its Laboratory Standard (Occupational Exposure to Hazardous Chemicals in...
Laboratories, 29 CFR § 1910.1450; see Appendix A). In brief, the OSHA Laboratory Standard requires organizations to

1. Keep laboratory personnel exposures to chemicals below OSHA’s PELs.
2. Write a Chemical Hygiene Plan.
3. Designate a Chemical Hygiene Officer to implement the plan.
4. Train and inform new laboratory personnel of
   • the OSHA Laboratory Standard,
   • the Chemical Hygiene Plan and its details,
   • OSHA’s PELs,
   • the signs and symptoms of exposure to hazardous chemicals,
   • MSDSs,
   • *Prudent Practices in the Laboratory*,
   • methods to detect the presence of hazardous chemicals,
   • the physical and health hazards of the chemicals, and
   • measures to protect laboratory personnel from chemical hazards.
5. In certain circumstances, provide laboratory personnel access to medical consultations and examinations.
6. Keep labels of supplied chemicals intact.
7. Maintain the MSDSs for all your supplied chemicals.
8. For chemical substances developed in your laboratory, train laboratory personnel as described above.
9. Use respirators properly.

It is important to understand that the OSHA PELs and substance-specific standards do not include all hazardous chemicals. It is the laboratory manager’s responsibility under the Laboratory Standard and its general duty clause to apply scientific knowledge in safeguarding workers against risks, even though there may be no specifically applicable OSHA standard. In circumstances where exposure limits are exceeded or where work with particularly hazardous substances is conducted, laboratories must keep records of exposure monitoring and medical surveillance.

The Laboratory Standard refers to the National Research Council’s *Prudent Practices for Handling Hazardous Chemicals in Laboratories* (NRC, 1981) as “non-mandatory . . . guidance to assist employers in the development of the Chemical Hygiene Plan.”

One of the most common Laboratory Standard OSHA citations has been for failure to have a Chemical Hygiene Plan or for missing an element in the plan. Another commonly cited violation is failure to meet the employee information and training requirements of the Laboratory Standard.

11.C.2.1 The Chemical Hygiene Plan

The centerpiece of the Laboratory Standard is the Chemical Hygiene Plan. This is a written plan developed by employers. It has the following major elements:

- employee information and training about the hazards of chemicals in the work area, including how to detect their presence or release, work practices and how to use protective equipment, and emergency response procedures;
- circumstances under which a particular laboratory operation requires prior approval from the employer;
- standard operating procedures for work with hazardous chemicals;
- criteria for use of control measures, such as engineering controls or personal protection equipment;
- measures to ensure proper operation of fume hoods and other protective equipment;
- provisions for additional employee protection for work with “select carcinogens” (as defined in the Laboratory Standard) and for reproductive toxins or substances that have a high degree of acute toxicity;
- provisions for medical consultations and examinations for employees; and
- designation of a Chemical Hygiene Officer.

Section 2.B of Chapter 2 describes additional elements, not required by law, that may be added to a Chemical Hygiene Plan.

Some firms and institutions have developed a single generic Chemical Hygiene Plan for the entire organization. To be most effective, however, the plan should include detailed protections that are specific to each laboratory, project, experiment, procedure, and worker. Laboratory-specific plans allow considerable flexibility in achieving the performance-based goals of the Laboratory Standard. Model Chemical Hygiene Plans are available from your state OSHA consultation service or the American Chemical Society.

11.C.2.2 Particularly Hazardous Substances

There are special provisions in the Laboratory Standard regarding work with “particularly hazardous substances,” a term that includes “select carcinogens,”
“reproductive toxins,” and “substances with a high degree of acute toxicity.”

- **A select carcinogen** is defined in the standard as any substance (1) regulated by OSHA as a carcinogen; (2) listed as “known to be a carcinogen” in the *Report on Carcinogens* published by the National Toxicology Program (HHS/CDC/NTP, 1995); (3) listed under Group 1 (“carcinogenic to humans”) by the *International Agency for Research on Cancer (IARC)* Monographs; or (4) in certain cases, listed in either Group 2A or 2B by IARC or under the category “reasonably anticipated to be carcinogens” by NTP. A category (4) substance is considered a select carcinogen only if it causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria: (1) after inhalation exposure of 6 to 7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m³; (2) after repeated skin application of less than 300 mg/kg of body weight per week; or (3) after oral dosages of less than 50 mg/kg of body weight per day.

- **“Reproductive toxins”** are defined as those chemicals that affect reproductive capabilities, including chromosomal damage (mutations) and effects on fetuses (teratogenesis).

- **Chemicals with a “high degree of acute toxicity”** are highly toxic noncarcinogenic or highly volatile toxic materials that may be fatal or cause damage to target organs as a result of a single exposure or exposures of short duration. Examples include hydrogen sulfide, nitrogen dioxide, hydrogen cyanide, and methylmercury.

Although “select carcinogens” are specifically identified through reference to other publications, “reproductive toxins” and chemicals with a “high degree of acute toxicity” are not specified further, which has made it difficult to apply these categories. Some organizations have chosen to adopt the OSHA Hazard Communication Standard definition of “highly toxic” (LD₅₀ < 50 mg/kg oral dose) as a workable definition of high degree of acute toxicity. There is little agreement on how to determine reproductive toxins.

The OSHA-mandated special provisions for work with carcinogens, reproductive toxins, and substances that have a high degree of acute toxicity include consideration of “designated areas,” use of containment devices, special handling of contaminated waste, and decontamination procedures. The OSHA requirement is for evaluation, assessment, and implementation of these special controls, when appropriate. These special provisions are to be included in the Chemical Hygiene Plan.

### 11.C.3 Chemical Facility Anti-Terrorism Standards

In 2007, Congress authorized DHS to “establish risk-based performance standards for security chemical facilities.” In response, DHS issued the Chemical Facility Anti-Terrorism Standards (CFATS). According to the agency, the standards identify high-risk facilities based on the likelihood of an attack, the consequences of an attack, and the threat of an attack based on the intent and capability of an adversary. The standards are concerned with

- EPA Risk Management Plan chemicals,
- highly toxic gases,
- chemical weapons convention chemicals, and
- explosives.

The specific “Chemicals of Interest” are listed in Appendix A of the CFATS rule. (See Chapter 10, section 10.E.4.2 for examples.) The standard applies to any institution that meets or exceeds the threshold quantity established for these chemicals. All facilities, including those with laboratories, are expected to survey their site for the presence of the chemicals of interest and compare the inventory to the threshold screening quantities established in Appendix A of the standard. If the facility meets or exceeds the threshold quantity for any chemical of interest, the facility must report the inventory to DHS.

On the basis of the report, chemical facilities are categorized into risk-based tiers. Each facility is assigned a tier ranging from tier 1 (highest risk) to tier 4 (lowest risk). Facilities that fall into risk tiers 1–3 must prepare a security vulnerability assessment (SVA) to identify facility security vulnerabilities, and develop and implement site security plans. Should a facility fall into tier 4, circumstances may allow for submission of alternate security programs in lieu of an SVA, a site security plan, or both.

For more information about SVAs and CFATS, see Chapter 10, sections 10.F and 10.E.4.2.

### 11.C.4 Regulations Covering Polychlorinated Biphenyls (PCBs)

Regulations pursuant to the Toxic Substances Control Act (TSCA) apply to the use of PCBs and monochlorobiphenyls in laboratories. Although the rules except the use of “small quantities for research and development” and use “as an immersion oil in microscopy,”
researchers contemplating work with PCBs (including environmental studies with PCB-contaminated media) should consult their institution’s EHS officer because of the stringency of these regulations.

11.D REGULATION OF BIOHAZARDS AND RADIOACTIVE MATERIALS USED IN LABORATORIES

As explained in Chapter 4, sections 4.H, and Chapter 6, section 6.E.2, most radioactive materials that are used in laboratories are regulated by the U.S. Nuclear Regulatory Commission (USNRC). Rules most pertinent to laboratories are in Title 10 of the Code of Federal Regulations, Parts 20 and 30. The USNRC licenses the use of radioactive materials. Many institutions and firms obtain a broadscope license from the NRC, which provides flexibility but requires an institutional Radiation Safety Officer and Radiation Safety Committee.

As explained in Chapter 4, section 4.G, and Chapter 6, section 6.E.1, the most widely accepted standards for using biohazards in laboratories can be found in Biosafety in Microbiological and Biomedical Laboratories (BMBL; HHS/CDC/NIH, 2007a). The Foreword explains that, “the BMBL remains an advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories, from a biosafety perspective and is not intended as a regulatory document.” However, many accrediting bodies, grant-making organizations, and state regulators expect laboratories that use biohazards to adhere to the BMBL.

Select agents are regulated by CDC and the Department of Agriculture’s APHIS.

11.E ENVIRONMENTAL REGULATIONS PERTAINING TO LABORATORIES

Federal and state environmental regulations apply to laboratory waste, air emissions, and discharges to the sewer. Of these, EPA’s rules for chemical hazardous waste may be the most demanding.

11.E.1 Management of Chemical Hazardous Waste

Chapter 8 covers the regulation of chemical hazardous waste in laboratories, while this section covers the regulation of that waste at an institutional level.

RCRA, EPA is given great responsibilities in promulgating detailed regulations governing the generation, transport, treatment, storage, and disposal of hazardous (chemical) waste. RCRA and EPA regulations apply to laboratories that use chemicals.

11.E.1.1 Definitions and Types of Hazardous Waste Generators

A generator is any firm or institution whose processes and actions create hazardous waste. There are three categories of generator:

1. Large-quantity generators are those whose facilities generate 1,000 kg or more per month (about four 55-gal drums of hazardous waste) or over 1 kg of “acutely hazardous waste” per month. By this measure, most large research organizations, including the larger universities, are large-quantity generators.

2. Generators of more than 100 but less than 1,000 kg of hazardous waste per month, and less than 1 kg of “acutely hazardous waste” per month (and accumulate less than 1 kg at any one time). This category may not accumulate more than 6,000 kg at any one time.

3. Conditionally exempt small-quantity generators of 100 kg or less of hazardous waste per month and less than 1 kg of “acutely hazardous waste.” The special requirements applicable to conditionally exempt small-quantity generators can be found in 40 CFR § 261.5.

11.E.1.2 Implications of EPA’s Definition of On-Site

Federal and state definitions of on-site have bearing on the generation category of each site, and how laboratory hazardous waste is transported and managed. This is particularly important for firms, colleges, universities, and other organizations that are transected by public roads.

“Individual generation site” is defined by RCRA regulation as a contiguous site at or on which hazardous waste is generated. A firm or institution located in one geographic area may be viewed as a single generator with a single EPA generator identification number or, if it is transected by public roads, may be viewed as multiple generator sites requiring multiple EPA generator identification numbers. Multisite facilities are required to have separate EPA identification numbers for each site.

Note that each individual laboratory generating waste is not itself a RCRA “generator,” but instead is part of the “generator” site. Each laboratory therefore
must comply with the requirements applicable to the site’s generator category.

RCRA defines “on-site,” as “the same or geographically contiguous property which may be divided by public or private right-of-way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along [emphasis added] the right-of-way.”

The significance of this definition is that, with one exception, hazardous waste that is being transported on public roads can be sent only to a permitted treatment, storage, and disposal facility (TSDF). The exception [in 40 CFR § 262.20 (f)] explains that this restriction does “not apply to the transport of hazardous wastes on a public or private right-of-way within or along the border of contiguous property under the control of the same person, even if such contiguous property is divided by a public or private right-of-way.”

In all other cases, hazardous waste cannot be transported on public roads to an unpermitted holding facility, even if the public road and the receiving location are within the boundaries of an institution.

11.E.1.3 Minimum Requirements for Generators

Generators must obtain an EPA identification number, prepare the waste for transport, follow accumulation and storage requirements, manifest hazardous waste, and adhere to detailed record-keeping and reporting requirements. At most firms and institutions, hazardous waste is shipped off-site, treated, stored, and disposed of at commercial EPA-permitted TSDFs. Note that generators producing more than 1 kg in a calendar month of “acute hazardous waste” (see above) are subject to full regulation under RCRA as a large-quantity generator.

Although conditionally exempt small-quantity generators are partially exempt from these requirements, they must still

- identify their waste to determine whether it is hazardous,
- not accumulate more than 1,000 kg of hazardous waste, and
- ensure that the waste is sent to a permitted TSDF or a recycling facility.

Note that state laws may differ. For example, some states regulate all generators of hazardous waste with no exemptions, and some states regulate chemical wastes that are not included in RCRA (e.g., used oil, as hazardous waste).

See Chapter 8, section 8.B.4 for a detailed explanation of hazardous waste collection and storage requirements.

11.E.1.4 RCRA Waste Minimization Requirements

Generators are required to certify on the manifest accompanying off-site shipment of waste that they have a waste minimization program. Guidelines for a waste minimization program are available from EPA. By signing the manifest, the generator is certifying the following:

**Large-Quantity Generators:** “I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable and I have selected the practicable method of treatment, storage, or disposal currently available to me which minimizes the present and future threat to human health and the environment.”

**Small-Quantity Generators:** “I have made a good faith effort to minimize my waste generation and select the best waste management method that is available to me and that I can afford.”

11.E.1.5 Transportation of Chemicals and Hazardous Waste

For organizations whose laboratory operations are at a single site, transportation within that site is not regulated, as long as that transport involves no travel along public ways. Most organizations, however, have developed policies for on-site transport covering labeling, segregation of incompatibles, containment and double containment, and other necessary safeguards to prevent accidental release to the environment or injury to persons during transportation.

As with hazardous materials, off-site transportation of hazardous waste is regulated by DOT in accordance with the Hazardous Materials Transportation Uniform Safety Act. These regulations apply not only to those who actually transport, but also to those who initiate or receive hazardous waste shipments. DOT regulations applicable to transport of laboratory chemicals include those governing packaging, labeling, marking, placarding, and reporting of discharges. Those who prepare hazardous materials for transportation must also meet certain training requirements.

Under the DOT Materials of Trade exception, facilities may transport their own chemicals to another facility owned by the same organization under certain conditions. This exemption also applies to transport for the purpose of chemical demonstrations, such as at a local high school or as part of a special event. All chemicals must be properly packaged in DOT-specification containers. Hazardous waste may not be transported as a Material of Trade.

As explained in Chapter 8, section 8.B.7, EPA’s RCRA rules include additional requirements for transporta-

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2From 40 CFR § 262.27(a).
tion of hazardous waste. Detail of the many requirements for transporting hazardous waste is beyond the scope of this book.

11.E.2 Management of Radioactive and Biohazardous Waste

Disposal of low-level radioactive waste from laboratories is governed by USNRC rules in Title 10 of the Code of Federal Regulations, Parts 20 and 30, as well as conditions specified in institutional licenses. Short-half-life radwaste is typically held for decay in storage, and then disposed of without regard to its radioactivity.

Federal laws that regulate laboratory biohazardous and infectious waste are limited. Most important are the OSHA bloodborne pathogen standard, DOT rules for transporting biomedical waste, and EPA medical waste incineration rules. The OSHA bloodborne pathogen standard addresses the collection and management of needles, blades, and other sharps. Most states regulate the treatment and disposal of laboratory biohazardous waste; consult your state laws for specific requirements.

11.E.3 Discharges to the Sewer

Contact your local publicly owned treatment works (POTW) for rules on discharges to the sanitary sewer. Your POTW is the best source for information about limits and prohibitions for the discharge of laboratory wastewaters that contain chemicals, biologicals, or radioactive materials. Federal rules exist that pertain to the discharge of hazardous waste and radioactive materials, but those limits are usually incorporated in POTW ordinances.

11.E.4 Air Emissions from Laboratories

The Clean Air Act (CAA) regulates emissions into the air. Laboratories should be aware of the regulations that control stratospheric-ozone-depleting substances. The list of such substances can be found in 40 CFR Part 82, Appendixes A and B to Subpart A. The list includes as “Class I” substances most common freons, carbon tetrachloride, and methyl chloroform.

Under the CAA, EPA also sets national emission standards for hazardous air pollutants (NESHAPs). NESHAPs for radionuclides and sterilants have been established, and these may apply to some laboratories. EPA has not established emission standards for volatile organic compounds or other emissions from laboratory operations, nor has EPA established a special source category for research or laboratory facilities. However, some states have set emission limits that apply to laboratories, or require permits for laboratory hoods. Check with your state environmental agency to determine if there are specific air emission requirements for your laboratory.

11.F SHIPPING, EXPORT, AND IMPORT OF LABORATORY MATERIALS

Shipping, export, and import laws strictly regulate the domestic and international transport of an extensive list of laboratory materials, including many chemicals, vaccines, genetic elements, microbiological agents, radioactive materials, and a wide array of research equipment, technologies, and supplies. Many items that are not perceived to be particularly hazardous, valuable, or uncommon are nevertheless subject to export control laws and shipping regulations. Export and import laws may require special licenses or permits prior to leaving or entering the United States.

Regulated activities include conveying laboratory materials via

- shipments and mailings using the U.S. Post Office and other mail couriers;
- receiving or sending regulated materials by any method of transport;
- shipments to (exporting) or from (importing) a foreign country;
- transporting any amount of regulated material in a commercial aircraft, whether on your person or in carry-on luggage or checked luggage.

The many laws for shipping laboratory materials are described below, including regulations from the U.S. Department of Commerce (DOC), DOT, and EPA. Although these rules are described individually, please note that several regulations often apply to a single shipment.

In addition to these requirements, your institution may have entered into a Material Transfer Agreement, which controls any transfer of the research materials from your institution to another.

See Chapter 5, section 5.F for practical, nonlegal information about shipping laboratory materials.

11.F.1 General Shipping Regulations

Regulations on the transportation of hazardous materials are aimed at ensuring that the public and the workers in the transportation chain are protected from exposure to potentially hazardous materials being transported. Protection is achieved through the following requirements:
• rigorous packaging that will withstand rough handling and contain all liquid material within the package without leakage to the outside,
• appropriate labeling of the package to alert the workers in the transportation chain to the hazardous contents within,
• documentation of the hazardous contents within the package and emergency contact information in the event of an emergency with the package, and
• training of workers in the transportation chain to familiarize them with the hazardous contents so as to be able to respond to emergency situations.

DOT is the national authority that regulates the shipment and transport of hazardous material. DOT regulations governing hazardous materials transport are detailed in Title 49 of the Code of Federal Regulations, Parts 171–178.

Technical Instructions for the Safe Transport of Dangerous Goods by Air, published by the International Civil Aviation Organization (ICAO), are the legally binding international regulations. Annually, the International Air Transport Association (IATA) publishes Dangerous Goods Regulations (DGR) that incorporates the ICAO provisions and may add further restrictions. The ICAO rules apply on all international flights. For national flights (i.e., flights within one country), national civil aviation authorities apply national legislation. This is normally based on the ICAO provisions, but may incorporate variations. State and operator variations are published in the ICAO Technical Instructions and in the IATA DGR.

11.F.2 EPA Requirements for Chemical Export and Import

TSCA, administered by EPA, was established to ensure that the human health and environmental effects of chemical substances are identified and properly controlled prior to placing these materials into commerce. Chemical substances regulated by TSCA include, “Any organic or inorganic substances of a particular molecular identity including any combination of such substances occurring, in whole or in part, as a result of chemical reaction or occurring in nature and any element or uncombined radical.” Chemical substances not regulated or excluded by TSCA include pesticides regulated by the Federal Insecticide, Fungicide, and Rodenticide Act; tobacco and tobacco products regulated by the Bureau of Alcohol, Tobacco, Firearms, and Explosives; radioactive materials regulated by the USNRC; and foods, food additives, drugs, and cosmetics or devices regulated by the Food and Drug Administration.

11.F.2.1 TSCA Research and Development Exemption

TSCA includes a “Research and Development (R&D) Exemption” which greatly reduces requirements for laboratories, but does not eliminate them. Under the R&D Exemption, laboratory chemicals are exempted from many TSCA requirements if they are

• imported, manufactured, or used in small quantities (“not greater than reasonably necessary for such (R&D) purposes”); and
• solely for purposes of noncommercial scientific experimentation, analysis, or research, and
• under the supervision of a technically qualified individual.

To maintain this exemption status, laboratories engaged in R&D must keep records of allegations of adverse reactions and discovery of substantial risk. Also, chemical imports need to be certified in writing, and certain chemical exports require notification of the receiving countries.

11.F.2.2 TSCA Record-Keeping Requirements for R&D Laboratories

For R&D laboratories, TSCA is primarily an administrative, records-intensive program. Establish a TSCA compliance file to log significant adverse effects, file reports of substantial risks, and document imports and exports.

Under TSCA § 8(c), laboratories are required to keep records of allegations of significant adverse effects from R&D chemicals. For example, laboratories must create and maintain records of allegations of, for example, a skin rash, allergic reaction, or respiratory effect that may be attributable to exposure to an R&D chemical.

Laboratories must also document the discovery of any significant risks to human health or the environment potentially associated with R&D substances. Include this report in your TSCA compliance file.

Your file should also contain TSCA import and export certifications, as described below. Copies of the written notifications provided (i.e., the letter, the MSDS, and copies of all labels affixed to sample containers) should be maintained in a file for 5 years.

11.F.2.3 Chemical Exports from R&D Laboratories

Laboratories must complete and send to EPA a TSCA Export Notification Form prior to the exportation of chemical substances listed in the EPA’s Chemicals on Reporting Rule (CORR) Database. Sample forms, the CORR Database, and EPA submission instructions
are available via the Web (search for “TSCA Export Certification Form,” “EPA CORR Database” and “EPA TSCA Exports”). Copies of this form must be kept in lab records for 3 years.

An export notification is not required for R&D chemicals not listed in the CORR Database.

11.F.2.4 TSCA Requirements for Other Chemical Shipments

For shipments of R&D chemicals to locations within the United States, TSCA requires that laboratories

- Label the containers, shipping containers, and shipping papers with “This material is not listed on the TSCA Inventory. It should be used for research and development purposes only under the direct supervision of a technically qualified individual.”
- Prepare and include an MSDS for the substance. This MSDS should evaluate and communicate risks of the substance. On the “composition, information on ingredients,” section of the MSDS, indicate, “This material is for R&D evaluation only. It can only be used for R&D evaluations until PMN review by EPA is completed. If this material is used in plants or non-R&D locations for R&D evaluation, its use must be supervised by a technically qualified individual. Review all sections of this MSDS prior to use.” Alternatively, this information may be included on the shipment form.

If an R&D-exempt chemical is transferred to a pilot plant or manufacturing plant, see EPA rules for the additional requirements.

11.F.2.5 Chemical Imports from R&D Laboratories

Laboratories must complete the TSCA Import Certification Form for all R&D samples and chemicals received from a foreign country. There are no exceptions to this requirement.

Sample forms are available via the Web (search for “TSCA Import Certification Form”), chemical supply vendors, or customs brokers. Unless the imported chemical is excluded (see above), check “Positive Certification” on the Form. Provide this form to the mail or express delivery service or customs broker prior to the import date. Keep a copy in your TSCA compliance file for 3 years.

11.F.2.6 Nanomaterials Under TSCA

In January 2008, EPA issued “TSCA Inventory Status of Nanoscale Substances—General Approach,” which describes the agency’s perspective on whether nanomaterials are required to be registered under TSCA. EPA uses “molecular identity” to determine if a chemical substance is new. Substances are said to have different molecular identities if they

- have different molecular formulas,
- have the same molecular formulas but different atom connectivities,
- have the same molecular formulas and atom connectivities but different spatial arrangements of atoms,
- have the same types of atoms but have different crystal lattices,
- are different allotropes of the same element, or
- have different isotopes of the same elements.

Differences in physical characteristics such as particle size and shape are not considered part of a substance’s molecular identity. Thus, EPA states, “a nanoscale substance that has the same molecular identity as a substance listed on the TSCA Inventory . . . is considered an existing chemical, i.e., the nanoscale and non-nanoscale forms are considered the same chemical substances because they have the same molecular identity” (EPA, 2008).

Regulatory controls on nanomaterials will likely change as the field develops, and it is important for researchers and organizations to monitor this area. To assist with future regulatory questions regarding nanomaterials, EPA has created the Nanoscale Materials Stewardship Program. Those who work with nanomaterials should also be aware of international efforts through the International Organization for Standardization and others to develop standards, testing, health and safety practices, etc. and may affect future regulations.

11.F.3 Requirements for Biological Export and Import

Laboratories that export or import infectious substances, related biological substances, and/or materials that may contain infectious substances should be aware of the following regulatory programs:

- Infectious Substance (human pathogens) Import Permit Program (U.S. Department of Health and Human Services, U.S. Public Health Service, CDC, 42 CFR Part 71);
• Animal Pathogens and Related Biological Materials Import Permit Program (USDA APHIS);
• Importing a Plant Pathogen or Plant Product (USDA/APHIS Plant Protection and Quarantine PPQ, 7 CFR Part 330); and

11.F.4 Other Export Regulations

Scientists who ship or carry a research material oversees may be subject to the export licensing requirements of DOC.

DOC’s Export Administration Regulations (EAR) require licenses for the export of a wide variety of research materials. These materials (including chemicals and laboratory equipment) are classified and assigned an Export Control Classification Number. (On the Web, search “ECCN List” for examples of regulated exports.)

The type of material, the destination, and the proposed recipient are all subject to approval by the DOC Bureau of Industry and Security, who issues (or may deny) the license. If any of these elements (material, destination, and recipient) are under the control of the EAR, then an export license will be required.

11.G LABORATORY ACCIDENTS, SPILLS, RELEASES, AND INCIDENTS

Chapter 3 describes laboratory emergency planning and response. This section describes legal requirements for incidents that may occur in a laboratory.

11.G.1 Laboratory Injuries and Illnesses

Immediately report all laboratory injuries and illnesses to your firm or institution’s appropriate office (e.g., Workers’ Compensation, Risk Management, EHS), even if consultation with a medical professional is not deemed necessary. OSHA requires tracking and reporting of workplace injuries and accidents. State workers’ compensation laws detail procedures, provisions, employer responsibilities, and employee rights when dealing with workplace injuries and medical care. Your EHS officer should also be informed of any near misses, spills, releases, accidents, and incidents so that they can be investigated and safety problems are corrected.

OSHA standards and workers’ compensation laws apply only to “employees” of laboratory facilities. Unpaid students are not employees within the scope of the Occupational Safety and Health Act, but both moral and legal considerations suggest that colleges and universities provide the same protections to students as are provided to all employees regularly working in the laboratory.

11.G.2 Planning for Chemical Emergencies

Title III of the Superfund Amendments and Reauthorization Act (SARA Title III) was passed in 1986 to facilitate planning for chemical emergencies. One provision of the law requires that any institution with an EPA-listed “extremely hazardous substance” on-site in greater than its “threshold planning quantities” must notify emergency response authorities. The quantity limits are based on the total quantity of the hazardous chemical present at the facility rather than in an individual laboratory.

SARA Title III also requires facilities that use hazardous chemicals to submit copies of the MSDSs used in their operations and report inventories of hazardous chemicals. Research and clinical laboratories are exempt from these requirements because the law defines “hazardous chemical” to exclude any chemical, “to the extent it is used in a research laboratory or hospital or other medical facility under the direct supervision of a technically qualified individual.” Note that some states require chemical inventories or release notification for laboratories regardless of SARA exemptions.

11.G.3 Notification Requirements for Spills, Releases, and Other Emergencies

SARA Title III also requires that accidental releases be reported to emergency planning authorities. This emergency notification requirement applies to all facilities, including research laboratories, hospitals, and other medical facilities. A firm or institution must notify state and community authorities in the event of a release into the environment of a “hazardous substance” or an “extremely hazardous substance” in excess of EPA-established “reportable quantities.”

Also be sure to determine the additional emergency reporting requirements of your state and locale.

11.G.4 Emergency Training and Response

OSHA’s standard for hazardous waste operations and emergency response (29 CFR § 1910.120) establishes criteria for training, worker protection, and cleanup of spills and releases to the environment. This standard is an excellent reference for planning your response to laboratory spills and releases. This standard must be followed by spill response contractors and fire departments when they respond to a laboratory emergency involving hazardous materials.

In most cases, however, the immediate, simple
cleanup of a spill by laboratory staff is not subject to this requirement. According to 29 CFR § 1910.120(a)(3), “Responses to incidental releases of hazardous substances where the substance can be absorbed, neutralized, or otherwise controlled at the time of release by employees in the immediate release area, or by maintenance personnel are not considered to be emergency responses within the scope of this standard.” That section goes on to say, “Responses to releases of hazardous substances where there is no potential safety or health hazard (i.e., fire, explosion, or chemical exposure) are not considered to be emergency responses.”

It is important that facilities have a clear understanding of the circumstances under which employees are expected to respond to incidents, and train employees to be able to identify the difference between a routine incidental release and an emergency requiring outside assistance.

OSHA’s bloodborne pathogen standard describes the necessary precautions for cleaning a spill of human blood or body fluids.