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Guidelines for Biosafety Laboratory Competency

CDC and the Association of Public Health Laboratories

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Guidelines for Biosafety Laboratory Competency
CDC and the Association of Public Health Laboratories

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Summary

These guidelines for biosafety laboratory competency outline the essential skills, knowledge, and abilities required for working with biologic agents at the three highest biosafety levels (BSLs) (levels 2, 3, and 4). The competencies are tiered to a worker's experience at three levels: entry level, midlevel (experienced), and senior level (supervisory or managerial positions). These guidelines were developed on behalf of CDC and the Association of Public Health Laboratories (APHL) by an expert panel comprising 27 experts representing state and federal public health laboratories, private sector clinical and research laboratories, and academic centers. They were then reviewed by approximately 300 practitioners representing the relevant fields. The guidelines are intended for laboratorians working with hazardous biologic agents, obtained from either samples or specimens that are maintained and manipulated in clinical, environmental, public health, academic, and research laboratories.

Introduction

Biosafety laboratories must ensure adequate safety conditions to avoid potential hazards associated with the handling of biologic materials, the manipulation of genomes, the creation of synthetic organisms, and the spread of multidrug-resistant bacteria, and threats of biologic terrorism. These guidelines define the essential competencies needed by laboratory personnel to work safely with biologic materials and other hazards that might be found in a biologic laboratory (e.g., those related to research animals, chemicals, radiologic materials, and the physical environment).

A successful laboratory safety program encompasses a continuous process of hazard recognition, risk assessment, and hazard mitigation. The risk for exposures, laboratory-acquired infections, and the unintended release of research or clinical materials to the environment should ultimately be reduced by ensuring the competency of laboratorians at all levels.

Competencies are measurable and include not only knowledge, skills, and abilities but also judgment and self-criticism (*1*,*2*). The establishment of competencies is the essential first step in developing training. Although the 2006 Pandemic All-Hazards Preparedness Act (PAHPA) legislation required the development of competency-based training curricula (*3*), an extensive national and international library search identified no existing set of competencies for laboratory biosafety to guide this development. This gap spurred the effort to develop such a set of competencies.

Purpose

The primary purpose of these guidelines is to establish the behaviors and knowledge that laboratory workers at all levels should have to work safely with biologic materials. Other key issues addressed are the need for a well-designed workspace, knowledge of specific biologic agents and toxins, quality laboratory management practices, and an overall safety culture. This document provides essential competencies for incorporation into safety programs by laboratories that use biologic materials. These guidelines are designed for laboratorians practicing in the United States but also might have applicability for an international audience.

The material in this supplement originated in a multiagency, multisector workgroup that was sponsored by the Laboratory Science, Policy, and Practice Office, May Chu, PhD, Director, Office of Surveillance, Epidemiology and Laboratory Services, Stephen B. Thacker, MD, Director, and the Office of Safety, Health, and Environment, CDC, Paul J. Meechan, PhD, Director.
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Background

Several circumstances led to the development of biosafety competencies for practicing laboratorians. In 2006, PAHPA called for the assessment, development, delivery, and evaluation of competency-based training for biosafety in high containment laboratories (*3*). In 2008, CDC convened the Blue Ribbon Panel for issues of Clinical Laboratory Safety to address incidence of laboratory-acquired infection (*4*). Also in 2008, a Trans-Federal Task Force (*5*) was convened for federal agencies with laboratories to address biosafety and biosecurity in working with agents that pose a significant public health threat, whether they arise from nature, accidental exposure, or deliberate terrorist attacks. These efforts underscored the need to develop competency guidelines for laboratory biosafety.

Methodology

In early 2009, a CDC Steering Committee, comprising CDC's Associate Directors for Laboratory Science and representatives from the Office of Workforce and Career Development, met to discuss the need for development of core competencies for laboratorians to work safely in all levels of biosafety containment. The CDC Steering committee recommended that the Association of Public Health Laboratories (APHL) lead this effort and identified those agencies and groups that should be involved. Each group or agency identified was invited to nominate a representative to participate in an expert panel to define biosafety competencies for laboratory workers. To ensure inclusiveness, CDC and APHL selected as members of this panel* practitioners representing all levels of biosafety practice† from federal and state public health, government-funded research, military, private clinical, reference, and academic laboratories as well as experts in biosafety and competency development.

The expert panel working group was guided by the previous development of applied epidemiology competencies that used the framework developed by the Council on Linkages between Academia and Public Health Practice (COL) (*6*–*8*). A 3-day meeting of the expert panel in June 2009 initiated the work, which was carried out by subgroups that focused on developing competencies based on level of expertise (entry, mid, senior, and management) and biosafety level (BSL-2, BSL-3, and BSL- 4).

To ensure that terminology was as consistent and widely understood as possible, a Blooms' taxonomy of educational objective terms was used (*1*). A draft document was developed and shared among the group. Subgroups continued to work via teleconference and WebEx (Cisco Systems, San Jose, California) document review to determine content and context of competencies and subcompetencies for presentation to the larger panel. A first complete draft of three sets of competencies, one for each biosafety level, for four tiers of practice (entry, mid, senior, and management) was submitted for review to the CDC Steering Committee in October 2009. Upon recommendation from the CDC Steering Committee and other reviewers, the expert panel decided to reorganize the competencies from the COL framework to that presented in the biosafety guide developed by CDC and the National Institutes of Health (Biosafety in Microbiological and Biomedical Laboratories, 5th edition [BMBL]) (*9*). This decision was made to facilitate the use of the competencies by practicing laboratorians.

In January 2010, a second meeting of a subset of the expert panel was held to revise the competencies on the basis of the BMBL framework for review by the entire expert panel. In March 2010, after reviewing all the documents, the full panel met and decided to combine the management and senior levels because the competencies were similar. The panel also determined that, although the risks and controls are different, competencies are essentially the same across all biosafety levels, allowing one competency statement to be applied in various ways across the entire field. Thus, the final draft provided for national review included a single set of competencies for use at all BSL levels at three tiers of laboratory practice: entry level, midlevel, and senior level.

Validation Process

The structured process included ample opportunity for national input from practicing and academic laboratorians to comment on the laboratory biosafety competencies. This process included the development of a survey tool (SurveyMonkey.com, Palo Alto, California) designed to collect opinion regarding the competencies as stated and to solicit comments and suggested revisions from respondents. The survey was publicized for several weeks via the working group members, professional association electronic distribution lists, and APHL's website. The survey tool was released in April 2010 and was available for comment for 6 weeks. A total of 274 responses were received from laboratorians representing all biosafety levels and types of laboratories (Table 1). In addition, several organizations, including NIH and ABSA, convened internal review committees to provide comment. These groups submitted a single survey response accompanied by recommended revisions.

* A list of the members of the expert panel appears on page 23.

† Organizations and agencies included the American Association for Laboratory Animal Science (AALAS), American Biological Safety Association (ABSA), American Clinical Laboratory Association, American Society of Microbiology, Association of Public Health Laboratories, Eagleson Institute, Emory University, Frontline Foundation, Food and Drug Administration, Georgia State University, National Institutes of Health, Occupational Safety and Health Administration, University of Texas Medical Branch, U.S. Department of Agriculture, and U.S. Department of Defense.

TABLE 1. Number and percentage of survey respondents, by selected demographic characteristics — Biosafety Level (BSL) Competency Survey, United States, 2010

Characteristic	No.	(%)
Job classification		
Entry-level laboratorian	6	(2)
Mid-level laboratorian	32	(12)
Senior-level laboratorian	133	(49)
Biosafety professional	103	(38)
BSL level		
BSL-2	158	(58)
BSL-3	95	(35)
BSL-4	21	(8)
Domain of practice		
Local or state public health	59	(22)
Federal agency	63	(23)
Clinical	35	(13)
Academic research	98	(36)
Private	27	(10)
Other	26	(10)

All comments were collated and reviewed by a panel member who summarized for the entire panel. The summary of comments included basic demographic information regarding survey respondents, including domain of practice (e.g., academic, public health, and clinical) as well as information on the competencies which received the most and the fewest comments (Table 2). In addition, the summary report included agreement by skill domain and subdomain areas of the competencies. In June 2010, the expert panel met to review and address recommendations and concerns cited by the national survey respondents. Overall ≥88% of the respondents agreed with the draft competencies as written. Comments and suggested revisions by the <12% of reviewers who expressed some disagreement with the draft document were collated and discussed. When issues with the draft document stemmed from an apparent lack of clarity in the document, the competencies were modified to be clearer. Concerns that were considered substantive and those that were shared by multiple reviewers were given top priority. These competencies were revised to address the reviewers' concerns. In addition, after response from the laboratory community, changes were made to the domain structure, consolidating some domains and making slight modifications in others. Because ≥88% of the respondents to the initial draft agreed with the competencies as written, and the competencies with substantive or frequent comments were clarified or modified, the panel decided not to repeat the survey process with the revised competencies.

TABLE 2. Percentage of domain responses — Biosafety Level (BSL) Competency Survey, United States, 2010

Three skill domains with fewest comments	Approval %
Hazard controls: engineering controls — equipment (primary barriers)	93
Emergency preparedness and response: emergency response drills and exercises	91
Emergency preparedness and response: exposure prevention and hazard mitigation	89

Three skill domains with most comments	Approval %
Potential hazards: biologic materials	76
Hazard controls: decontamination and laboratory waste management	76
Potential hazards: radiologic materials	78

Agreement by domain	Agreement %
Potential hazards	
General	85
Research animals	85
Biologic materials	76
Chemical materials	85
Radiologic materials	78
Physical environment	80
Hazard controls	
Personal protective equipment (primary barriers)	88
Engineering controls — equipment (primary barriers)	93
Facilities — (secondary barrier) BSL-2 & BSL-3	84
Decontamination and laboratory waste management	76
Administrative controls	
Hazard communication and signage	86
Guideline and regulation compliance	84
Safety program management	82
Medical surveillance	86
Risk assessment	87
Risk associated with laboratory procedures	88
Emergency preparedness and response	
Emergencies and incident response	88
Exposure prevention and hazard mitigation	89
Emergency response drills and exercises	91

Guiding Principles

Culture of Safety

No regulation or guideline can ensure safe practices. Individual and organizational attitudes regarding safety will influence all aspects of safe practice, including willingness to report concerns, response to incidents, and communication of risk. Each organization should strive to develop a culture of safety that is open and nonpunitive, encourages questions, and is willing to be self-critical. Persons and organizations must be committed to safety, be aware of risks, behave in ways that enhance safety, and be adaptable. Scientists understand that practices should be refined as observations are made, hypotheses tested, findings published, and technical progress achieved. The same holds true for safety in the laboratory, which should evolve as experience is gained and as laboratory

activities change. As laboratorians gain more knowledge over time concerning how to recognize and control hazards, the level of risk that is considered acceptable should become smaller, with the goal of moving continuously to eliminate or reduce risk to the lowest reasonably achievable level.

Laboratorians have both the responsibility to report concerns to management and the right to express concerns without fear of reprisal. Similarly, management has the responsibility to address concerns raised from any direction. A continuous process of hazard recognition, risk assessment, and hazard mitigation practices ensures that management and laboratory workers alike are aware of the issues and work together to maintain the highest standard of safety (*10,11*).

Scope

Although these guidelines address many hazards that might be encountered in a laboratory, they cannot be the sole resource used to develop a safety program. Similarly, if a laboratory does not use certain identified hazards (e.g., animals or radiologic materials), then those competencies will not be applicable. Ensuring that an effective safety culture exists in an organization requires the structuring of several components covered in this document. These include facilities, protocols, engineering controls, personal protective equipment, knowledge of risks being handled (agent- or toxin-specific), communications and signage, decontamination and waste management. The value of these guidelines is that they serve as a resource tool for education and training, which is the most effective way to build a safety culture.

Many laboratory-associated activities (e.g., shipping, animal housing, and manufacturing) were not included in this document. Depending on the nature of the work, these activities might be included when assessing safety competencies. A primary resource regarding safe use of biologic materials used across many fields is BMBL (*9*), which defines biosafety levels and describes safe practices, engineering, and controls for each biosafety level. The four domains specified in the following guidelines reflect the pattern established in the BMBL.

Broad Application

Biologic science is applicable to a wide range of activities. Biologic materials are used in private and government-supported research, clinical settings, academic and research institutions, diagnostic and drug development, animal science, agricultural development, and many adjunct areas, including nanotechnology and biochemistry. The competencies described in this document are broad enough to be considered for use in developing laboratory safety criteria in all fields that use biologic materials, but the guidelines are not intended to be all-inclusive. Federal, state, local, and institutional regulations, policies, and guidelines that address safety and security concerns also should be consulted while developing a site-specific safety program.

Competencies and Skill Domains

A competency is a measurable, documentable factor that involves not only skills that can be taught and developed but also the judgment and ability to recognize the limitations of the work environment and one's own skills and the skills of others in the laboratory. The verbs selected for each level of competency follow Bloom's Taxonomy (*1*), a standard construction for competency development, wherever appropriate. The verbs used correlate to an increasing level of skill, judgment, and responsibility at each of the three professional levels of practitioners. The specialized terms used in this document have been defined (Appendix A). Competencies are not tasks; however, a list of tasks can be developed by using these competencies as a guideline. The overall framework for the competency guidelines comprises four skill domains that follow the pattern established in BMBL: potential hazards, hazard controls, administrative controls, and emergency response and preparedness (Box); these competencies are outlined in detail (Appendix B).

BOX. Competency domains framework

Domain I:	**Potential hazards**
	Biologic materials
	Research animals
	Chemical materials
	Radiologic materials
	Physical environment
Domain II:	**Hazard controls**
	Personal protective equipment
	Engineering controls – equipment (primary barriers)
	Engineering controls – facility (secondary barriers)
	Decontamination and waste control management
Domain III:	**Administrative controls**
	Hazard communication and signage
	Guidelines and regulatory compliance
	Safety program management
	Occupational health – medical surveillance
	Risk management
Domain IV:	**Emergency preparedness and response**
	Emergencies and incident response
	Exposure prevention and hazard mitigation
	Emergency response – exercises and drills

Continuum of the Competencies

The competencies should be viewed as a matrix of varying levels of responsibility that are based on experience and risk. Novices to the field begin at the entry level but should have the education and experience appropriate to understand and apply the principles of biologic safety relevant to their field of work. As a person gains experience, he or she might advance to a midlevel position and eventually to a senior-level position within a specific biosafety level. Depending on the size, scope, and mission of the organization, titles and roles can vary (Table 3).

Risks associated with each biosafety level increase from BSL-2 through BSL-4 (*9*), and each increased level requires additional practices and engineering controls to mitigate those risks. Therefore, a laboratorian who is competent to work at a senior level with BSL-2 agents must begin again at the entry level to build competencies when starting to work with BSL-3 agents, and similarly for starting to work with BSL-4 agents. The amount of time required to become competent in each domain at each biosafety level will vary widely depending on the scope of the work and a person's knowledge, skills, abilities, opportunity for experience, and judgment.

Collaboration

Laboratory safety is a collaborative effort that, to be successful, should include participation of all persons involved. The appropriate breadth of collaboration depends on the hazards in use in a given laboratory. Internal groups necessary for collaboration might include human resources, facility engineering, occupational and environmental health and safety, biosafety, security, occupational medicine, risk management, and emergency preparedness personnel. External collaborators should include first responders (e.g., fire, police, and emergency medical personnel) and hospitals or other health-care facilities that receive patients.

Regularly soliciting input from laboratorians who work directly with biologic materials is critical. Often laboratorians recommend possible work changes that might increase safety directly or indirectly through developing more efficient methods. Ideally, an organization can assess and implement these practices while keeping documentation current.

Intended Use

These guidelines define the expected essential competencies for working safely with biologic and other hazardous laboratory materials. Laboratory personnel can use this information to enhance their existing comprehensive safety programs. Each organization must tailor its comprehensive safety program to address the organization's specific needs and use all available resources. Different organizations might find different uses for these guidelines, depending on their structure and guidelines already in existence. The application of these guidelines will vary widely depending on the field (e.g., agriculture, industry, research, academia, military, health-care, clinical, or professional organizations). Their intended use will also vary by category of user, which might include the following persons and responsibilities:

- practitioners
  - — assess current skills and establish goals,
  - — plan training and educational needs,
  - — meet biosafety competencies relevant to each step of an advancing career path
- employers
  - — develop training plans for employees,
  - — establish the safety portions of position descriptions and job qualifications,
  - — assess the capability of an organization to operate safely with biologic materials;
- educators in sciences and safety
  - — develop coursework to meet the needs of biologic laboratory safety
  - — incorporate the elements of these competencies into existing curricula (*5*).

These guidelines should be read in full before beginning to apply their contents. The competency development and review process indicated that words often have different meanings to persons in different fields and minimizing the overlap between the sections of the document and other regulatory and guidance documents requires a comprehensive effort. Unless otherwise noted, the definitions of the terms used in this report (Appendix A) were created by the working group or represent nuances or modifications to compiled online dictionaries or BMBL.

TABLE 3. Roles of biosafety laboratory personnel, by field and level — Biosafety Level Competency Survey, United States, 2010

Field	Entry level	Midlevel	Senior level
Academia or research	Technician, research associate, or specialist	Principal investigator, laboratory manager, postdoctoral student, or senior or staff scientist	Principal investigator or branch or division manager
Clinical setting	Laboratory scientist or medical technologist	Chief/lead scientist or medical technologist, laboratory specialist, or laboratory manager	Laboratory manager, chief technologist, or hospital or clinic director

Dissemination

CDC and APHL intend to disseminate these guidelines broadly throughout a variety of professional organizations and newsletters, including, but not limited to, scientific, educational, safety, and public health. The competencies will be presented at meetings of public health practitioners and biologic safety professionals (e.g., ABSA). The guidelines also will be maintained on CDC's website (http://www.cdc.gov) and on APHL's website (http://www.aphl.org).

Conclusion

These guidelines outline the essential expectations for behaviors and knowledge of laboratory workers necessary to work safely with biologic materials at all levels of the profession in the life sciences. The development of these guidelines is a first step toward defining comprehensive safety competencies in biologic laboratories. These guidelines reflect a range of past experiences and will be reviewed periodically and refined as additional experience is gained. The guidelines can be used as a resource to develop educational goals, training standards, safety assessments, professional development, and certification. Every organization using these competencies should regularly review and improve its practices and documents with an eye toward continual reduction of the risks involved in working with biologic and other hazardous laboratory materials. Training is not limited to the initial instruction received at the start of a laboratory worker's employment but is continuous and refreshed periodically. Some professions or organizations that were contributors to these guidelines, including AALAS and the Council of State and Territorial Epidemiologists, also have addressed biologic safety practices (*12,13*).

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APPENDIX A

Terms Used in These Guidelines

Administrative controls: changes in work procedures such as written safety policies, work practices, rules, supervision, schedules, and training with the goal of reducing the duration, frequency, and severity of exposures to hazardous materials or situations (*1*).

Aerosolization: the generation of liquid droplets or particles, 5 microns in diameter or less, that can be inhaled and retained in the lungs.

ALARA (as low as reasonably achievable): the terminology used most often in relation to radiation exposure levels, designating a work principle or philosophy intended to protect the worker from unnecessary exposure to workplace hazards. This practice involves using or modifying a procedure or workplace element to reduce or eliminate the degree of exposure when reasonable and economically feasible to do so.

Barriers: any method used to separate workers, the outside community, and the environment from any hazardous material utilized; can include primary or secondary barriers.

Biohazardous materials: infectious agents or hazardous biologic materials that present a risk or potential risk to the health of humans, animals, or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA, organisms and viruses infectious to humans, animals, or plants (e.g., parasites, viruses, bacteria, fungi, prions, and rickettsia), and biologically active agents (e.g., toxins, allergens, and venoms) that can cause disease in other living organisms or cause significant impact to the environment or community.

Biologic agents: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), infectious substance or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance capable of causing death, disease, or other biologic malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment (*2*).

Biologic materials: Any biologically derived materials or materials that contain biologic species, including bacteria, viruses, microorganisms, genetically modified organisms or microorganisms, or prions, including but not limited to cellular lines, DNA materials, tissues, organs, body fluids, biologic agents and toxins, allergens and cultured cells. Biologic materials are not necessarily pathogenic or hazardous.

Biologic waste: any biohazardous or nonbiohazardous waste containing biologic material, including but not limited to blood and blood products, clinical specimens, pathological waste, animal carcasses and soiled bedding, cultures and stocks of microbial materials, sharps and other items that have been in contact with biohazardous materials, biotechnology byproduct effluents designated for disposal, and laboratory supplies, plastics, or glassware that have been in contact with biologic materials.

Biosafety manual: a laboratory manual developed and implemented by the employer that outlines procedures, equipment, personal protective equipment, and work practices that are capable of protecting employees from the health hazards presented by hazardous biologic materials used in that particular workplace.

Biosafety records: records that are retained as required by regulatory and institutional policies for documentation of employee training, medical surveillance, equipment maintenance and certification, accidents and exposure, inspections and audits, and inventories for chemical and other hazardous agents.

Biosecurity: the system to prevent unauthorized entry to laboratory areas, access to dangerous pathogens, or the unwarranted or accidental release of materials to the outside environment.

Biosecurity manual: laboratory manual that provides practical guidance related to the overall security of personnel reliability and the containment of biologic agents and toxins in the laboratory setting.

Biosurety: An integrated approach to the management of potentially hazardous materials and activities. This includes health, safety, security, environmental protection, emergency management, and community relations concerning activities involving potentially etiologic biological materials and select agents, recombinant DNA, genetic research, and environmental bioremediation (*3*).

Chemical hygiene plan: a written program developed and implemented by the employer that outlines procedures, equipment, personal protective equipment, and work practices that are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace and that complies with Occupational Safety and Health Administration (OSHA) regulations (*4*).

Chemical materials: substances with a distinct molecular composition that are produced by or used in chemical processes. Chemicals can be present in the laboratory as solids, liquids, mists, vapors, or gases.

Compressed gas: any gas or mixture of gases exerting in a container, at a pressure exceeding 40.6 psia at 20° C. Also refers to liquefied and dissolved gases meeting the criteria (*5*).

Containment: methods used to shield or protect personnel, the immediate work environment, and the community from exposure to hazardous, radiologic, chemical, or biologic materials.

Decontamination: The removing of chemical, biologic, or radiologic contamination from, or the neutralizing of it on, a person, object, or area (*6*).

Disinfection: the process of reducing or eliminating microorganisms from a surface or space.

Emergency equipment: items used in communication and response to an emergency or incident event. Examples include fire extinguishers, telephones, eye washes, spill clean-up supplies, or fire alarms.

Engineering controls: refers to methods to remove a hazard or place a protective barrier between the worker and the workplace hazard, which usually involves building design elements and specialized equipment.

Ergonomic: Interactions between humans and their total working environment plus stresses related to such environmental elements as atmosphere, heat, light, and sound as well as all tools and equipment of the workplace. The scientific study of or design of equipment and work tasks and their relation to or fit with the operator (*1*).

Exposure control plan: a written program developed and implemented by the employer that outlines procedures, engineering controls, personal protective equipment, work practices, and other methods that are capable of protecting employees from exposure to bloodborne pathogens and that complies with OSHA requirements (*7*).

Exposure prevention and hazard mitigation: a process that involves evaluating the incident response procedures to ensure that actions taken during the response do not result in hazardous exposures.

Guidelines and regulatory compliance: safety information and required practices from federal (e.g., U.S. Department of Health and Human Services, Environmental Protection Agency, and OSHA), state, and local regulatory sources, and guidelines (nonregulatory) from agencies, councils, associations, institutes, societies, and acts (e.g., Association of Assessment and Accreditation of Laboratory Animal Care, National Fire Protection Association, or Clinical Laboratory Improvement Amendments).

Hazard communication: a written program that identifies the process for ensuring that information concerning hazards is transmitted appropriately to personnel, to include, but not be limited to, use of signage, symbols, container labels, material safety data sheets, and other written sources describing hazards of a material or space.

Hazard control: methods used to eliminate or reduce the potential for exposures to a hazard.

Incident: an unexpected event that causes or has the potential to cause loss, injury, illness, unsafe conditions, or disruptions to normal procedures.

Incident response plan: a written program that identifies how personnel should react to incidents and other emergencies at their facility.

Institutional safety committees: committees comprising a cross-section of staff with the goal of establishing or monitoring work practices to ensure worker safety, compliance, and awareness with regard to a specific or general workplace hazard. Examples include such local committees as the safety committee, radiation safety committee, institutional animal care and use committee, institutional biosafety committee, chemical safety committee, institution review board, and environmental programs advisory board.

Inventory records: records that track the quantity, form, location, and disposition of any biologic, chemical, or radiologic material in use, stored, or disposed of in a laboratory.

Isotope: one of two or more atomic species of an element differing in atomic weight, but having the same atomic number. Each contains the same number of protons but a different number of neutrons (e.g., uranium 238 and uranium 235).

Laboratory animal allergy (LAA): condition that might develop when susceptible persons are exposed to allergens produced by laboratory animals. LAA is most associated with exposure to fur, saliva, and urine of rats, mice, guinea pigs, and rabbits.

Laboratory emergencies: serious situations or occurrences in the laboratory that happen unexpectedly and demand immediate action.

Laboratory waste management practices: written procedures that describe sterilization, decontamination, and disinfection practices and how the different waste streams (e.g., biologic, chemical, or radiologic) generated in the laboratory will be handled to comply with regulatory and institutional requirements.

Material safety data sheet (MSDS): a fact sheet summarizing information regarding material identification for a chemical product or mixture, including hazardous ingredients; health, physical, and fire hazards; first aid; chemical reactivities and incompatibilities; spill, leak, and disposal procedures; and protective measures required for safe handling and storage.

Medical surveillance program: the ongoing, systematic collection of health data that signal either biomarkers of exposure or early signs of adverse health outcomes from known biologic materials and toxicants in persons working with those

materials. Includes a program for preemployment screening, ongoing monitoring, and postexposure management.

Mitigate: to correct identified deficiencies and to make a hazard less severe. This includes corrective actions taken as a result of an inspection or audit, or after an incident.

Nonionizing radiation: electromagnetic radiation that does not cause ionization (i.e., does not remove an electron completely from an atom or molecule). Examples include ultraviolet, laser, infrared, microwave, and radio waves.

Nonroutine samples/specimens: samples or specimens received that normally are not handled by the facility and might include materials that potentially pose a greater or different hazard than encountered normally.

Personal protective equipment (PPE): items worn by laboratory workers to prevent direct exposure to hazardous materials, including gloves, gowns, aprons, coats, containment suits, shoe covers, eye and face shields, respirators, and masks.

Personnel training program: the required training and follow-up evaluation to ensure that staff are capable of performing their duties in accordance with the institution's safety program. A comprehensive training program should include such areas as biosafety, biosecurity, hazardous waste management, emergency response, sample and specimen receipt and accessioning, specimen packaging and shipping, testing procedures, and hazard communication.

Physical environment: location where work is performed. Also includes the associated equipment, materials, air, and other objects.

Physical hazards: unsafe conditions in the workplace that can cause injury or illness. Examples include, but are not limited to, ergonomic concerns, exposure to hot and cold, electricity, compressed gas cylinders, noises, and sharps.

Prions: a transmissible agent that can cause neurodegenerative disease in humans and animals. Having no genetic material, a prion is a protein that normally is harmless. In a process that is not fully understood, the prion folds into an abnormal shape that also can cause other normal prions to fold into abnormal shapes.

Primary barriers: specialized laboratory equipment with engineering controls designed to protect against exposure to hazardous laboratory materials, including, but not limited to, biologic safety cabinets, chemical fume hoods, enclosed containers, bench shields, animal cages, and engineered sharps injury-protection devices (e.g., safety needles, safety scalpels, and sharps containers).

Radiation safety manual: a laboratory manual that details how the laboratory handles, stores, and disposes of radioactive material in a safe manner according to its user license with the Nuclear Regulatory Commission.

Radiologic materials: radioisotopes, radioactive waste products, and chemical or biologic materials that have been modified to include radioisotope labels.

Radiologic monitoring devices: devices that provide a scientific determination of amount, rate, and distribution of radiation emitted from a source of ionizing radiation. An example is a Geiger counter.

Records management system: a paper or electronic system for tracking the creation, receipt, revision, and retention of laboratory records in accordance with applicable regulatory standards and guidelines and in accordance with any applicable quality assurance or quality control standard for the laboratory. Records can include, but are not limited to, audio and video recordings, photographs or other graphic images, and e-mail messages.

Research animals: animals used in the laboratory. When evaluating hazards of research animals, laboratorians should consider the risks inherent to the species itself, those associated with handling the animals (e.g., bites, scratches, and allergens), and the risks for handling the bedding and other associated waste products.

Respiratory protection program: a detailed plan describing the use of PPE to protect laboratory workers from respiratory exposure to hazardous materials. Includes the required respiratory protection devices to be used for various procedures and describes the required fit-testing procedure necessary before use of respirators. Must comply with OSHA regulations (*8*).

Risk assessment: a process to evaluate the probability and consequences of exposure to a given hazard, with the intent to reduce the risk by establishing the appropriate hazard controls to be used.

Routes of exposure: paths by which humans or other living organisms come into contact with a hazardous substance. Three routes of exposure are breathing (inhalation), eating or drinking (ingestion), and contact with skin (dermal absorption).

Safety manuals: collections of policies, procedures, and work practices intended for guidance in protection against identified and potential workplace hazards.

Safety program management: institutional general safety, biosafety, biosecurity, chemical, radiologic, and emergency-response programs and plans that all staff are required to follow to manage possible workplace hazards.

Sample: a material of nonbiologic origin (e.g., water or soil) submitted for analysis to an environmental or research laboratory. Samples might have the potential to contain biologic materials.

Secondary barriers: facility design and construction features to include, but not be limited to, directional air flow, entrance airlocks, controlled-access zones, HEPA-filtered exhaust air, facility controls, decontamination equipment, eyewash stations, protective showers, and sinks for hand washing.

Sharps: items capable of cutting or piercing human skin. Examples include hypodermic needles, syringes (with or without attached needles), Pasteur pipettes, scalpel blades, suture needles, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that have been in contact with infectious agents (e.g., used microscope slides and cover slips).

Specimen: biologic material such as blood or tissue submitted for analysis to a clinical, public health, or research laboratory.

Standard operating procedures: established procedures to be followed in carrying out a given operation or in a given situation. Development of procedures is based on prudent laboratory practices that conform to safety guidelines and regulatory requirements.

Standard operating procedures for emergency response: procedures developed to guide the response of personnel to specific emergency situations. These can include the facility emergency response plan, the chemical/biological spill response procedure, the continuity of operations plan, or the occupant emergency plan.

Sterilization: the use of physical or chemical methods to completely destroy or eliminate all forms of microbial life.

Universal precautions: guidelines recommended by CDC for reducing the risk for transmission of bloodborne and other pathogens in hospitals, laboratories, and other institutions in which workers are potentially exposed to human blood and body fluids. The precautions are designed to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals, laboratories, and other institutions to the workers in these facilities (*9*).

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APPENDIX B

Biosafety Laboratory Competency Guidelines

I. SKILL DOMAIN: POTENTIAL HAZARDS

Purpose statement: This skill domain is focused on the competencies involved with understanding the hazards in a given laboratory setting. The ability to recognize hazards is the first step in preventing occupational and environmental exposures. The five subdomains are biologic, chemical, and radiologic materials, research animals, and physical environment.

Biologic Materials

Entry level	Midlevel	Senior level
1. Describe the concept of biohazardous materials a. List biohazardous materials present in the laboratory	1. Distinguish biohazardous from nonhazardous materials a. Ensure that a comprehensive list of biohazardous materials is present in the laboratory	1. Ensure personnel's knowledge of biohazardous materials a. Ensure personnel have knowledge of biohazardous materials handled in the laboratory
2. Recognize potential hazards associated with biohazardous materials handled in the laboratory a. Describe association of infectious agents and toxins to disease b. Describe the virulence and pathogenicity of the organisms c. Describe the principal exposure routes of laboratory-acquired infections d. Recognize potential hazards of unknown/nonroutine samples	2. Explain the potential hazards associated with the biologic materials handled in the laboratory a. Ensure understanding of the association of infectious agents and toxins to human disease b. Same as entry level c. Same as entry level d. Mitigate hazards of unknown/nonroutine samples	2. Manage biohazardous materials a. Assess personnel's knowledge of infectious agents and toxin risk-group classifications b. Assess personnel's knowledge of the virulence and pathogenicity of the organisms handled in the laboratory c. Assess personnel's knowledge of the principal exposure routes of laboratory-acquired infections d. Manage mitigation of hazards of unknown/nonroutine samples
3. Utilize control measures and work practices with biologic materials a. Describe personal protective equipment (PPE) that should be used when handling biologic materials b. Describe work practices that reduce or control biologic exposure risks (e.g., practice universal precautions) c. Explain storage and handling requirements for biologic materials d. Recognize when biologic materials should be considered for transfer to a different type of hazard control (e.g., should go from BSL-2 to BSL-3 facility and practices, or transfer from bench to the biological safety cabinet) e. Demonstrate response procedure after suspected exposure.	3. Ensure utilization of established hazard controls for biologic materials used in laboratory procedures a. Demonstrate correct use of PPE when handling these biologic materials b. Ensure implementation of work practices that reduce or control biologic exposure risks (e.g., compliance with universal precautions) c. Implement storage and handling requirements for biologic materials d. Implement procedures for appropriate transfer of biologic materials to a different type of hazard control e. Explain response procedure after suspected exposure	3. Establish hazard controls for biologic materials used in laboratory procedures a. Evaluate PPE that should be used when handling biologic materials b. Determine work practices that reduce or control biologic exposure risks (e.g., universal precautions) c. Formulate storage and handling requirements for biologic materials d. Evaluate laboratory's procedures for transfer of biologic materials that require a different type of hazard control e. Establish response procedure after suspected exposure
4. Recognize hazards associated with various procedures	4. Discuss hazards associated with various procedures	4. Assess procedures for hazardous components

Research Animals

Entry level	Midlevel	Senior level
1. Describe inherent hazards associated with research animals a. Describe hazards associated with the animal species to be handled b. Describe hazards associated with experimentally infected animals	1. Identify inherent hazards associated with research animals a. Identify hazards associated with the animal species to be handled b. Assess hazards associated with experimentally infected animals	1. Assess the inherent hazards associated with research animals a. Assess hazards associated with the animal species to be handled b. Same as midlevel
2. Describe possible route of exposures to personnel in relation to the animal procedures used	2. Assess possible route of exposures to personnel in relation to the animal procedures used	2. Same as midlevel
3. Describe control measures and work practices to mitigate the risks associated with research animals and report on effectiveness to supervisors a. Adhere to occupational health requirements for treatment of exposures b. Adhere to animal facility's policies and procedures manual c. Describe PPE that should be used when handling animals d. Describe limits to control measures e. Example of a control measure: describe the Laboratory Animal Allergy (LAA) protocol i. Recognize signs and symptoms of animal allergens ii. Report suspected LAA to supervisor	3. Implement control measures and work practices to mitigate risks associated with research animals a. Same as entry level b. Ensure adherence to animal facility's policies and procedures manual c. Demonstrate proper use of PPE that should be used when handling animals d. Ensure limits to control measures are understood e. Example of a control measure: ensure implementation of the LAA protocol i. Same as entry level ii. Ensure reporting of suspected LAA to supervisor	3. Develop control measures and work practices to mitigate risks associated with research animals a. Ensure occupational health requirements for treatment of exposures are known and met b. Implement animal facility's policies and procedures manual c. Evaluate PPE that should be used when handling animals d. Establish limits to control measures e. Example of a control measure: establish the LAA protocol i. Same as entry level ii. Ensure reporting of suspected LAA to supervisor

Chemical Materials

Entry level	Midlevel	Senior level
1. Identify chemicals used in the laboratory	1. Ensure chemical inventory is complete	1. Establish chemical inventory
2. Describe hazards associated with chemicals used in laboratory procedures a. Explain the use of material safety data sheets (MSDS) and other sources of information regarding chemicals used in laboratory procedures b. Demonstrate ability to use MSDS and other sources to determine physical hazards, health hazards, and routes of exposures for chemicals c. State the hazard represented by the information on a chemical container's label	2. Explain hazards associated with chemicals used in the laboratory procedures a. Ensure MSDS are available for all chemicals used in the laboratory b. Ensure personnel can use MSDS and other sources to determine physical hazards, health hazards, and routes of exposures for chemicals c. Ensure chemical container labeling requirements are maintained and understood	2. Assess personnel's knowledge of hazards associated with chemicals used in laboratory procedures a. Ensure MSDS are available and kept updated for all chemicals used in the laboratory b. Same as midlevel c. Establish specific labeling practices to meet regulatory and institutional requirements
3. Recognize control measures and work practices to be used when working with chemicals a. Adhere to established work practices b. Describe personal protective equipment (PPE) needed when working with specific chemicals c. Describe engineering controls (e.g., chemical fume hood) needed when working with specific chemical d. Explain correct storage location for each chemical e. Demonstrate understanding of response protocols if exposure is suspected	3. Implement control measures and work practices to be used when working with chemicals a. Implement compliance with established work practices b. Explain how PPE selection provides protection from a specific chemical's hazards and routes of exposure c. Explain how engineering controls provide protection when working with specific chemicals d. Ensure chemicals are stored according to physical hazard properties e. Ensure prompt compliance with response protocols if exposure is suspected	3. Establish control measures and work practices to be used when working with chemicals a. Ensure compliance with established work practices b. Determine appropriate PPE needed when working with specific chemicals c. Determine appropriate engineering controls needed when working with specific chemicals d. Determine proper storage location for each chemical e. Establish response protocols for suspected exposures

Radiologic Materials

Entry level	Midlevel	Senior level
1. Identify radiologic materials used in the laboratory	1. Ensure list of radiologic materials used in the laboratory is complete	1. Establish inventory of radiologic materials used in the laboratory
2. Describe hazards associated with use of radiologic materials a. Describe sources of information regarding physical and health hazards (including routes of exposures) of radiologic materials b. Describe the meaning of information on the container labels	2. Explain hazards associated with use of radiologic materials a. Same as entry level b. Same as entry level	2. Assess hazards associated with use of radiologic materials (collaborate with radiation safety personnel, as needed) a. Ensure sources of information regarding physical and health hazards (including routes of exposures) to radiologic materials are available b. Ensure labeling information is understood
3. Recognize control measure and work practices to be used when working with radiologic materials a. Describe concept of ALARA (as low as reasonably achievable) b. Describe personal protective equipment (PPE) needed c. Describe engineering controls needed (e.g., bench shields) d. Demonstrate knowledge of proper storage requirements e. Describe inventory and survey requirements f. Describe training requirements	3. Implement control measure and work practices to be used when working with radiologic materials a. Implement ALARA practices b. Explain how PPE selection provides protection from radioactive hazards and routes of exposures c. Describe how special engineering controls (e.g., bench shields) provide protection d. Ensure radiologic materials are stored and secured according to regulations e. Same as entry level f. Demonstrate knowledge of training requirements	3. Establish control measure and work practices to be used when working with radiologic materials (collaborate with radiation safety personnel, as needed) a. Ensure compliance with ALARA b. Determine appropriate PPE selections on the basis of hazards and routes of exposure c. Determine appropriate engineering controls d. Establish correct and secure storage locations in compliance with regulations e. Establish inventory and survey requirements f. Develop laboratory-specific training requirements
4. Describe monitoring devices (e.g., Geiger counters and dosimetry badges)	4. Demonstrate proper operation and use of monitoring devices	4. Evaluate monitoring devices for suitability in detecting radioisotopes to be used (collaborate with radiation safety personnel, as needed)

Physical Environment

Entry level	Midlevel	Senior level
1. Describe physical hazards in the laboratory (including, but not limited to): a. Describe proper use and disposal of laboratory sharps b. Describe hazards associated with compressed gases, pressure, and vacuum c. Describe hazards associated with temperature extremes d. Describe hazards associated with specific instruments and equipment e. Describe ergonomic hazards f. Describe nonionizing radiation (e.g., UV light, lasers) g. Describe slips, trips, and fall hazards	1. Explain physical hazards present in the laboratory (including, but not limited to): a. Explain proper use and disposal of laboratory sharps b. Explain hazards associated with compressed gases, pressure, and vacuum c. Explain hazards associated with temperature extremes d. Explain hazards associated with specific instruments and equipment e. Explain ergonomic hazards f. Explain nonionizing radiation (e.g., UV light and lasers) g. Explain slips, trips, and fall hazards	1. Ensure identification of physical hazards present in the laboratory a. Establish correct use and disposal of laboratory sharps b. Identify hazards associated with compressed gases, pressure, and vacuum c. Identify hazards associated with temperature extremes d. Identify hazards associated with specific instruments and equipment e. Identify ergonomic hazards f. Identify nonionizing radiation (e.g., UV light and lasers) g. Identify slips, trips, and fall hazards
2. Describe control measures and work practices to be used when physical hazards are present	2. Implement control measures and work practices to be used when working with physically hazardous materials	2. Establish control measures and work practices to be used when working with physically hazardous materials (collaborate with safety professionals, as needed)

II. SKILL DOMAIN: HAZARD CONTROLS

Purpose statement: This skill domain provides guidance for development of competencies associated with the use of primary and secondary barriers to prevent exposure to hazardous materials as well as competencies related to decontamination and management of hazardous waste. Primary barriers include personal protective equipment and specialized laboratory equipment with engineering controls designed to protect against accidental exposures. Secondary barriers include actual design and construction features of the laboratory facility to prevent exposure both within and outside laboratory areas. Competencies for waste management include guidelines related to biologic, chemical, and radiologic hazardous, including decontamination, sterilization, and safe removal of potentially contaminated laboratory equipment.

Personal Protective Equipment (PPE) (Primary Barriers)

Entry level	Midlevel	Senior level
1. List PPE required for general laboratory entry a. Provide input about user preference regarding selection of required PPE b. Describe safety practices to be used in conjunction with PPE	1. Monitor availability of PPE for general laboratory entry a. Same as entry level b. Implement safety practices to be used in conjunction with PPE	1. Determine PPE required for general laboratory entry a. Ensure (with institutional professionals) that PPE meets regulatory standards and policies b. Ensure that appropriate safety practices are used in conjunction with PPE
2. Describe specific PPE to be used for each laboratory procedure a. Not applicable b. Participate in evaluation of new PPE c. Cite location of all required PPE	2. Demonstrate use of specific PPE required for each laboratory procedure a. Not applicable b. Same as entry level c. Demonstrate location of all required PPE	2. Determine procedures (with institutional professionals) for use of specific PPE a. Develop PPE hazard assessment to be reviewed and updated at least annually b. Evaluate regularly the availability of new PPE c. Ensure that location of all required PPE is clearly designated
3. Describe respiratory protection program	3. Implement respiratory protection program	3. Develop a respiratory protection program to include fit testing for all staff using respiratory protection devices
4. Perform correct use of PPE a. Demonstrate donning (placement) and doffing (removal) sequence for PPE b. Describe limitations of PPE c. Demonstrate cleaning, disinfection, and disposal procedures for PPE	4. Implement correct use of PPE a. Same as entry level b. Same as entry level c. Implement cleaning, disinfection, and disposal procedures for PPE	4. Ensure personnel's compliance with correct use of PPE a. Develop procedures for personnel to comply with PPE donning and doffing sequence b. Ensure personnel's knowledge of limitations of PPE c. Develop cleaning, disinfection, and disposal procedures for PPE
5. Assess integrity and functionality of all PPE in use a. Describe pre- and post-use inspection protocol for PPE b. Identify compromised PPE	5. Implement assessment procedures for integrity and functionality of all PPE in use a. Implement pre- and post-use inspection protocols for PPE b. Monitor personnel's ability to identify compromised PPE	5. Establish assessment procedures to maintain integrity and functionality of all PPE in use a. Establish pre- and post-use inspection protocols for PPE b. Assess personnel's ability to identify compromised PPE
6. Describe appropriate reporting and response to compromised PPE a. Not applicable	6. Implement appropriate reporting and response procedures to compromised PPE a. Not applicable	6. Develop procedures for appropriate reporting and response to compromised PPE a. Ensure personnel's knowledge of procedures for appropriate reporting and response to compromised PPE

Engineering Controls — Equipment (Primary Barriers)

Entry level	Midlevel	Senior level
1. Describe laboratory equipment used with engineering controls to contain hazardous materials	1. Monitor availability of laboratory equipment with engineering controls used to contain hazardous materials	1. Determine correct equipment to use with engineering controls in order to contain hazardous materials worked with in the laboratory
2. Describe proper functioning of laboratory equipment with engineering controls a. Demonstrate correct use of laboratory equipment with engineering controls to ensure safety b. Describe methods to verify that equipment with engineering control is functioning properly to ensure safety c. Describe limitations of equipment with engineering controls to ensure laboratory safety d. Be aware of inspection and certification status of all laboratory equipment with engineering controls for safety e. Recognize when engineering controls for safety on laboratory equipment are compromised, malfunctioning, or nonfunctioning	2. Demonstrate proper functioning of laboratory equipment with engineering controls a. Same as entry level b. Demonstrate methods to verify that equipment with engineering control is functioning properly for safety c. Same as entry level d. Monitor status of inspection and certification of all laboratory equipment with engineering controls for safety e. Implement methods for ongoing assessment of whether engineering controls for safety on laboratory equipment are compromised, malfunctioning, or nonfunctioning	2. Ensure proper functioning of laboratory equipment with engineering controls a. Ensure that personnel has required knowledge regarding correct use of equipment with engineering controls for safety b. Establish methods to verify that equipment with engineering control is functioning properly to ensure safety c. Ensure that personnel who are using equipment with engineering controls are knowledgeable about limitations in ensuring laboratory safety d. Ensure that inspection and certification of all laboratory equipment with engineering controls for safety are completed as required e. Establish response protocols to address situations in which engineering controls on equipment for laboratory safety are compromised, malfunctioning, or nonfunctioning
3. Describe procedures to immediately report compromised, malfunctioning, or nonfunctioning engineering controls on laboratory equipment	3. Implement procedures required to report improperly functioning engineering controls to Senior level	3. Ensure timely remediation of improperly functioning engineering controls on laboratory equipment
4. Adhere to appropriate work practices when using laboratory equipment with engineering controls for safety a. Describe preuse, use, and postuse protocols for laboratory equipment with engineering controls for safety b. Describe cleaning and disinfection procedure for laboratory equipment with engineering controls for safety	4. Monitor adherence to appropriate work practices by staff who are using laboratory equipment with engineering controls for safety a. Monitor staff adherence to preuse, use, and postuse protocols for laboratory equipment with engineering controls for safety b. Monitor staff adherence to cleaning and disinfection protocols-procedure for laboratory equipment with engineering controls for safety	4. Establish appropriate work practices for all staff working with laboratory equipment with engineering controls for safety a. Establish preuse, use, and postuse protocols for laboratory equipment with engineering controls for safety b. Establish cleaning and disinfection protocols for laboratory equipment with engineering controls for safety
5. Not applicable	5. Monitor adherence to procedures that verify hazard awareness notification, training, and lock-out procedures for primary engineering control maintenance staff or contractors	5. Collaborate with institutional safety professionals to establish procedures to ensure hazard awareness notification, training, and lock-out procedures for primary engineering control maintenance staff or contractors

Engineering Controls — Facility (Secondary Barriers) BSL-2 & BSL-3

Entry level	Midlevel	Senior level
1. List the laboratory facility engineering controls designed to prevent exposure or release of hazardous materials a. Describe the design and operation controls of the laboratory facility pathogen containment areas b. Not applicable c. Not applicable	1. Demonstrate knowledge of the laboratory facility engineering controls designed to prevent exposure or release of hazardous materials a. Same as entry level b. Identify need for upgrades in the laboratory facility engineering controls to prevent release of hazardous organisms c. Not applicable	1. Ensure that laboratory personnel have appropriate knowledge about facility engineering controls designed to prevent exposure or release of hazardous materials from the laboratory a. Ensure that laboratory personnel have appropriate knowledge about the design and operation controls of the facility's pathogen containment areas b. Collaborate with institutional safety and facility professionals to ensure that upgrades of facility engineering controls are appropriate for overall system and meet all regulations and policies c. Ensure facility safeguards that prevent accidental release of an infectious agent from the laboratory function properly
2. Recognize when facility engineering controls are compromised or not functioning properly a. List specific procedures that must cease or begin if facility engineering controls are not functioning properly b. Adhere to all required response procedures when facility engineering controls are compromised	2. Coordinate response to any compromise in facility engineering controls a. Implement specific procedures that must cease or begin if facility engineering controls are not functioning properly b. Same as entry level	2. Develop response procedures to address any compromise in facility engineering controls a. Collaborate with institutional safety and facility professionals to identify specific procedures that must cease or begin when facility engineering controls are compromised b. Ensure that laboratory personnel adhere to response procedures when facility engineering controls are compromised
3. Adhere to correct reporting procedures when facility engineering controls are compromised	3. Implement required reporting procedures when facility engineering controls are compromised	3. Ensure correct reporting procedures are followed by all laboratory personnel when facility engineering controls are compromised
4. Describe process for routine monitoring of facility and facility engineering control systems	4. Implement process for routine monitoring of facility and facility engineering control systems	4. Ensure continuous maintenance and required recertification of facility and facility engineering control systems
5. Describe laboratory facility's controlled access system	5. Same as entry level	5. Collaborate with institutional safety and facility professionals to develop the laboratory's controlled access system
6. Adhere to facility security rules	6. Same as entry level	6. Ensure adherence to facility security rules
7. Describe facility design differences between BSL-2 and BSL-3 laboratories	7. Same as entry level	7. Advise personnel on facility design differences between BSL-2 and BSL-3 laboratories
8. Not applicable	8. Monitor adherence to procedures for cleaning of laboratory containment areas	8. Collaborate with institutional safety and maintenance professionals to determine appropriate procedures for cleaning of laboratory containment areas

Engineering Controls (Secondary Barriers) BSL4

Entry level	Midlevel	Senior level
1. Describe facility engineering controls to prevent release of hazardous materials a. Recall containment facility design and operation controls b. Describe BSL-4 facility design and operational controls	1. Demonstrate knowledge of engineering controls to prevent release of hazardous materials a. Describe containment facility design and operation controls b. Identify need for upgrades in engineering controls	1. Ensure personnel's knowledge of engineering controls to prevent release of hazardous materials a. Ensure personnel's knowledge of containment facility design and operation controls b. Ensure upgrades of engineering controls are appropriate
2. Describe process for routine monitoring of engineering controls a. Describe pre-entry verification procedures b. Describe verification of engineering controls c. NA	2. Implement routine monitoring of engineering controls equipment and facilities a. Demonstrate proficiency in pre-entry verification of facility functionality b. Demonstrate knowledge of unique engineering controls c. Ensure maintenance and recertification of engineering controls	2. Ensure engineering controls are adequate and functioning properly a. Same as midlevel b. Same as midlevel c. Develop protocol for ensuring maintenance and recertification of engineering controls
3. Recognize when secondary barriers are compromised or not functioning properly a. Describe reporting procedures b. Describe procedures that must cease when secondary barriers are compromised	3. Coordinate response to any compromise in engineering controls a. Implement proper reporting procedures b. Implement cessation of laboratory procedures with exposure potential when secondary barriers are compromised	3. Develop response procedures to any compromise in secondary barrier a. Ensure personnel's knowledge with proper reporting procedures b. Ensure that all personnel know which procedures should be stopped when engineering controls are compromised

Decontamination and Laboratory Waste Management

Entry level	Midlevel	Senior level
1. Describe laboratory waste segregation procedures for biologic, chemical, and radiologic materials	1. Implement laboratory waste segregation procedures for biologic, chemical, and radiologic materials	1. Establish facility waste segregation procedures for biologic, chemical, and radiologic materials in compliance with all required regulations and policies
2. Describe laboratory waste procedures for biologic materials a. Describe proper disposal of different types of biologic waste b. Describe packaging procedure for transport to remote treatment location	2. Monitor adherence to laboratory waste management procedures for biologic materials a. Demonstrate proper disposal of different types of biologic waste b. Implement packaging procedures for transporting waste to remote treatment location	2. Establish facility waste management procedures for biologic materials a. Develop protocols for biologic waste disposal b. Establish packaging procedures for transporting waste to remote treatment location
3. Describe disinfection, decontamination, and sterilization methods a. Describe how to prepare items for decontamination b. Describe proper disposal of laboratory sharps c. Describe proper use of any specific equipment (e.g., autoclave, vapor phase decontamination equipment) d. Describe process validation procedures e. Describe routine surface decontamination procedures i. List name and correct use of surface disinfectants and chemical sterilants	3. Implement disinfection, decontamination, and sterilization methods a. Demonstrate preparation of items for decontamination b. Demonstrate proper disposal of laboratory sharps c. Implement procedures for proper use of specific equipment (e.g., autoclave and vapor phase decontamination equipment) d. Implement process validation procedures e. Implement routine surface decontamination procedures i. Demonstrate correct use of surface disinfectants and chemical sterilants	3. Establish methods of disinfection, decontamination, and sterilization a. Ensure correct preparation of items for decontamination b. Ensure proper disposal of laboratory sharps c. Establish procedures for use of specific equipment (e.g., autoclave and vapor phase decontamination equipment) d. Ensure compliance with process validation procedures e. Develop routine surface decontamination procedures i. Determine surface disinfectants and chemical sterilants to be used
4. Describe procedures for hazardous chemical waste collection and disposal a. Describe satellite accumulation area requirements b. Describe waste container labeling requirements c. Describe routine surface decontamination protocols	4. Monitor compliance with procedures for hazardous chemical waste collection and disposal a. Ensure satellite accumulation area protocol is followed b. Ensure waste containers are properly labeled c. Implement routine surface decontamination protocols	4. Establish regulatory compliant procedures for hazardous chemical waste collection and disposal a. Establish satellite accumulation area protocols b. Establish waste container labeling requirements c. Establish routine surface decontamination protocols
5. Describe procedures for radioactive waste collection and disposal a. Describe security requirements for radioactive waste b. Describe waste container labeling requirements c. Describe routine surface decontamination protocols	5. Monitor compliance with procedures for radioactive waste collection and disposal a. Ensure that radioactive waste is secured b. Ensure that waste containers are properly labeled c. Same as entry level	5. Collaborate with radiation safety professionals to acquire required licensing and establish procedures for radioactive waste collection and disposal a. Establish security protocol for radioactive waste b. Establish waste container labeling requirements c. Develop protocols for routine decontamination of laboratory surfaces
6. Adhere to procedures for safely removing equipment and instruments from the laboratory a. Adhere to procedures for discarding, servicing, or transferring equipment and instruments	6. Monitor compliance with procedures for safely removing equipment and instruments from the laboratory a. Implement procedures for discarding, servicing, or transferring equipment and instruments	6. Establish procedures for safely removing equipment and instruments from the laboratory a. Establish procedures for discarding, servicing, or transferring equipment and instruments in compliance with regulations and policies

III. SKILL DOMAIN: ADMINISTRATIVE CONTROLS

Purpose statement: This skill domain describes competencies associated with a variety of administrative controls that can be used to reduce the duration, frequency, and severity of exposure to hazardous materials or situations. These controls include: hazard communication, signage, institutional guidelines, regulatory requirements, the overall safety program, occupational health and medical surveillance, and the management of risk. Each facility should tailor its safety program to its mission and facilitate meeting the requirements and adherence to guidelines. These minimum competencies only serve as a basis for individual facilities to build upon.

Hazard Communication and Signage

Entry level	Midlevel	Senior level
1. Explain safety signs, labels, and posted information a. Adhere to safety signs, labels, and posted information as described by operating procedures b. Not applicable	1. Implement safety signs, labels, and posted information a. Monitor adherence to safety signs, labels, and posted information, as described by operating procedures b. Evaluate effectiveness of safety signs, labels, and posted information	1. Determine required safety signs, labels, and posted information a. Ensure adherence to safety signs, labels, and posted information b. Implement changes to safety signs, labels, and posted information, as needed
2. Describe labeling of samples, containers, and cultures according to appropriate regulatory requirements	2. Implement labeling of samples, containers, and cultures according to appropriate regulatory requirements	2. Ensure the implementation of labeling of samples, containers, and cultures is compliant with appropriate regulatory requirements
3. Describe process to communicate sample-specific hazard information according to standard operating procedures (SOPs) a. Not applicable b. Describe procedures to identify hazardous materials in the laboratory	3. Implement process to communicate sample-specific hazard information according to SOPs a. Convey information regarding potential hazardous materials in nonroutine specimens brought into the laboratory b. Apply procedures to identify hazardous materials in the laboratory	3. Develop procedures to communicate sample-specific hazard information according to SOPs a. Advise laboratory staff regarding potential hazardous materials in nonroutine specimens brought into the laboratory b. Ensure personnel's knowledge of procedures to identify hazardous materials in the laboratory
4. Describe communication processes for applicable regulatory requirements	4. Implement communication processes for applicable regulatory requirements	4. Ensure personnel's knowledge of communication processes for applicable regulatory requirements
5. Describe methods of internal communication (BSL-3 and BSL-4 only)	5. Demonstrate methods of internal communication (BSL-3 and BSL-4 only)	5. Ensure personnel's knowledge of internal communication methods (BSL-3 and BSL-4 only)
6. Recognize signals and alarms	6. Explain signals and alarms	6. Ensure personnel's knowledge of signals and alarms

Guideline and Regulation Compliance

Entry level	Midlevel	Senior level
1. Describe current regulatory requirements and applicable guidelines that govern appropriate laboratory procedures a. Adhere to procedures of the records management system b. Adhere to applicable guidelines and regulations for laboratory procedures	1. Implement current regulatory requirements and applicable guidelines a. Implement the records management system b. Implement applicable guidelines and regulations for laboratory procedures	1. Ensure personnel have knowledge of current regulatory requirements and applicable guidelines a. Develop the records management system b. Ensure compliance with applicable guidelines and regulations for laboratory procedures
2. Follow laboratory manuals and plans a. Identify location of required laboratory manuals and plans b. Not applicable	2. Implement laboratory manuals and plans a. Same as entry level b. Not applicable	2. Develop and maintain laboratory manuals and plans to comply with current regulatory requirements and applicable guidelines a. Same as entry level b. Ensure manuals and plans are current
3. Describe applicable institutional committees a. Not applicable	3. Same as entry level a. Not applicable	3. Ensure compliance with applicable institutional committee requirements a. Communicate with applicable institutional committees
4. Adhere to security requirements	4. Adhere to communication processes in compliance with regulatory requirements	4. Advise regarding regulatory communications requirements

Safety Program Management

Entry level	Midlevel	Senior level
1. Comply with institution's safety and occupational health programs a. Adhere to work practice requirements b. Adhere to safety practices and SOPs c. Describe safety information resources d. Describe occupational health plan	1. Implement institution's safety and occupational health programs a. Implement work practice requirements b. Monitor compliance with safety practices and SOPs c. Same as entry level d. Monitor compliance with occupational health plan	1. Collaborate in the development of the institution's safety and occupational health programs a. Determine work practice requirements b. Ensure compliance with safety practices and SOPs c. Ensure access to safety information resources d. Ensure compliance with occupational health plan
2. Complete required safety training a. Not applicable b. Not applicable c. Not applicable	2. Monitor site-specific safety training program a. Ensure that required safety training is completed b. Mentor introductory staff on established safety procedures c. Not applicable	2. Develop site-specific safety training program a. Ensure compliance with safety training requirements b. Develop mentoring program on established safety procedures c. Assess effectiveness of training program
3. Describe routine monitoring process of equipment and facilities	3. Implement routine monitoring process of equipment and facilities	3. Develop procedures for routine monitoring of equipment and facilities
4. Recognize deviations from normal operations and procedures a. Recognize deviations that lead to unsafe work practices and conditions b. Recognize deviations that lead to safer work practices and conditions	4. Investigate deviations from normal operations and procedures a. Implement reporting of deviations that lead to unsafe work practices and conditions b. Implement deviations that lead to safer work practices and conditions	4. Resolve investigation of deviations from normal operations and procedures a. Assess response to deviations that lead to unsafe work practices and conditions b. Assess response to deviations that lead to safer work practices and conditions
5. Describe the quality assurance program	5. Implement quality assurance program	5. Develop quality assurance program
6. Describe records management system	6. Implement records management system	6. Develop records management system

Occupational Health — Medical Surveillance

Entry level	Midlevel	Senior level
1. Describe the medical surveillance plan a. Not applicable	1. Implement the medical surveillance plan a. Not applicable	1. Collaborate in the development of the medical surveillance plan a. Assess medical surveillance plan periodically
2. Describe the benefits for monitoring personal health status changes a. Describe how to report personal health status changes	2. Same as entry level a. Same as entry level	2. Ensure personnel's knowledge of the benefits for monitoring personal health status changes a. Ensure personnel's knowledge on procedures to report personal health status changes
3. Describe incident exposure reporting procedures a. Describe signs and symptoms following incident exposure b. Not applicable	3. Implement procedures for incident exposure reporting a. Same as entry level b. Not applicable	3. Collaborate in the development of incident exposure reporting procedures a. Develop intervention procedures for incident exposures b. Develop list of infectious disease, radiation, and chemical experts to be contacted in event of an unintentional exposure
4. Describe signs and symptoms in humans following exposure to hazardous materials a. Not applicable	4. Same as entry level a. Initiate the intervention for a person demonstrating symptoms apparently resulting from exposure	4. Ensure personnel's knowledge of signs and symptoms after exposure to hazardous materials a. Ensure the intervention for a person demonstrating symptoms apparently resulting from exposure

Risk Management

Entry level	Midlevel	Senior level
1. Describe the differences in work practices between biosafety levels	1. Explain the differences in work practices between biosafety levels in regards to potential hazard	1. Ensure personnel have knowledge of the differences in work practices between biosafety levels
2. Recognize potential hazards associated with laboratory materials and procedures	2. Assess the ability to identify potential hazards associated with laboratory materials and procedures	2. Ensure that potential hazards associated with laboratory materials and procedures are identified
3. Describe the risk assessment process on identified hazards	3. Demonstrate the ability to conduct a risk assessment on identified hazards	3. Ensure risk assessment is performed in accordance with institutional policy
4. Describe control measures identified in the risk assessment, including communication	4. Implement control measures identified in the risk assessment, including communication	4. Ensure that control measures identified in the risk assessment are implemented, including communication
5. Recognize effectiveness and noneffectiveness of new control measures	5. Assess effectiveness of control measures	5. Determine if controls have reduced the risk to an acceptable level

IV. SKILL DOMAIN: EMERGENCY PREPAREDNESS AND RESPONSE

Purpose statement: This domain consists of competencies to manage emergency preparedness and response. Institutions are responsible for referencing applicable standards of practice for their operations and for the development of response plans for incidents that affect them. This domain does not include emergency response to security, biosecurity, and biosurety events.

Emergencies and Incident Response

Entry level	Midlevel	Senior level
1. Recognize emergencies and other incidents that should be reported a. Recognize significance of alarms	1. Same as entry level a. Same as entry level	1. Ensure personnel's ability to recognize emergencies and other incidents that should be reported a. Ensure personnel's knowledge of alarm significance
2. Describe reporting requirements for emergencies and other incidents according to institutional plans and policies a. Not applicable	2. Implement institutional plans and policies for reporting emergencies and other incidents a. Not applicable	2. Collaborate with appropriate persons and agencies to develop plans and policies for reporting emergencies and other incidents a. Be aware of the incident command structure
3. Describe assigned role in responding to emergencies and other incidents a. Recall emergency response plan b. Describe emergency disinfection and exposure prevention procedures c. Describe procedures for responding to spills or potential exposures d. Describe emergency evacuation routes and assembly areas e. Not applicable f. Not applicable	3. Implement required response actions for emergencies and other incidents a. Same as entry level b. Demonstrate emergency disinfection and exposure prevention procedures c. Demonstrate procedures for responding to spills or potential exposures d. Demonstrate emergency evacuation routes and assembly areas e. Not applicable f. Not applicable	3. Develop procedures to respond to emergencies and other incidents according to institutional plans and policies a. Collaborate in developing emergency response plans b. Ensure that emergency disinfection and exposure prevention procedures are performed c. Ensure proper response to spills or potential exposures d. Ensure personnel's knowledge of emergency evacuation routes and assembly areas e. Implement developed plans f. Maintain developed plans

Exposure Prevention and Hazard Mitigation

Entry level	Midlevel	Senior level
1. Describe laboratory's incident follow-up process	1. Implement laboratory's incident follow-up process	1. Develop laboratory's incident follow-up process to include the following: review of incident report, initiation of investigation process, conducting of root-cause analysis, development of an action plan to mitigate root causes, and reporting after taking action
2. Not applicable a. Not applicable	2. Report effectiveness of response to senior level a. Implement corrective actions	2. Assess effectiveness of response to incident a. Ensure implementation of corrective actions

Emergency Response Exercises and Drills

Entry level	Midlevel	Senior level
1. Comply with personnel emergency response training requirements a. Participate in entry-level personnel training b. Not applicable c. Not applicable	1. Conduct required emergency response training of laboratory personnel a. Demonstrate ability to train entry-level staff b. Not applicable c. Not applicable	1. Develop required emergency response training a. Evaluate ability of mid-level staff to train all laboratory personnel b. Ensure adherence to laboratory's emergency response training requirements c. Evaluate effectiveness of the laboratory's emergency response training
2. Participate in drills and exercises for laboratory personnel a. Not applicable b. Not applicable	2. Implement drills and exercises for laboratory personnel a. Not applicable b. Not applicable	2. Collaborate in the development of drills and exercises for laboratory personnel a. Assess effectiveness of drills and exercises b. Incorporate lessons learned into training program

Biosafety Laboratory Competencies Working Group

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