

Competency Guidelines for Public Health Laboratory Professionals

CDC and the Association of Public Health Laboratories



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CDC and the Association of Public Health Laboratories

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Summary

These competency guidelines outline the knowledge, skills, and abilities necessary for public health laboratory (PHL) professionals to deliver the core services of PHLs efficiently and effectively. As part of a 2-year workforce project sponsored in 2012 by CDC and the Association of Public Health Laboratories (APHL), competencies for 15 domain areas were developed by experts representing state and local PHLs, clinical laboratories, academic institutions, laboratory professional organizations, CDC, and APHL. The competencies were developed and reviewed by approximately 170 subject matter experts with diverse backgrounds and experiences in laboratory science and public health. The guidelines comprise general, cross-cutting, and specialized domain areas and are divided into four levels of proficiency: beginner, competent, proficient, and expert. The 15 domain areas are 1) Quality Management System, 2) Ethics, 3) Management and Leadership, 4) Communication, 5) Security, 6) Emergency Management and Response, 7) Workforce Training, 8) General Laboratory Practice, 9) Safety, 10) Surveillance, 11) Informatics, 12) Microbiology, 13) Chemistry, 14) Bioinformatics, and 15) Research.

These competency guidelines are targeted to scientists working in PHLs, defined as governmental public health, environmental, and agricultural laboratories that provide analytic biological and/or chemical testing and testing-related services that protect human populations against infectious diseases, foodborne and waterborne diseases, environmental hazards, treatable hereditary disorders, and natural and human-made public health emergencies. The competencies support certain PHL workforce needs such as identifying job responsibilities, assessing individual performance, and providing a guiding framework for producing education and training programs. Although these competencies were developed specifically for the PHL community, this does not preclude their broader application to other professionals in a variety of different work settings.

Introduction

The national network of governmental public health, environmental, and agricultural laboratories, referred to collectively as public health laboratories (PHLs), is a vital part of the U.S. public health infrastructure. These laboratories perform multiple functions through provision of analytic biological and/or chemical testing and testing-related services that protect human populations from infectious diseases, foodborne and waterborne diseases, environmental hazards, treatable hereditary disorders, and other natural and human-made public health emergencies (1–3). A well-trained laboratory workforce is essential to ensuring that PHLs have the capacity to carry out the critical activities that are needed to safeguard the public's health competently and effectively (4,5).

Studies of the PHL workforce have drawn attention to several concerns about staff training and projected turnover, both of which highlight challenges to maintaining a sufficient number of highly skilled and competent workers. A 2011 national PHL workforce characterization survey found that approximately one third of PHL directors nationally expected 16%–25% of their workforce to retire, resign, or be released in the subsequent 5 years, while 12% anticipated losing 26%–50% of their workforce during that time period (6,7). Approximately 30% of the individual scientific staff respondents expected to continue working in a PHL for <5 years (6). These findings largely reflect workforce demographics, because more than half of scientific laboratory staff were aged >45 years (6). Important recruitment and retention challenges for the PHL workforce also have been identified, including the lack of

established progressive job series (commonly termed “career ladders” in the PHL community) for PHL scientists (6–8) and the lack of adequate opportunities for training and professional development (6,7). Indeed, approximately 50% of laboratories reported no, minimal, or only partial capacity to provide continuing education and training to their workers (6,7). Lack of adequate training poses challenges because PHL scientists and managers require a range of scientific, leadership, and managerial development courses, ideally based on core competencies, to function effectively in their positions (9–11).

Multiple national professional organizations, including the Institute of Medicine, the Association of Schools and Programs of Public Health, and the Public Health Foundation/Council on Linkages Between Academia and Public Health Practice (Council on Linkages), among others, have endorsed competency development as a means of strengthening the public health workforce (12–15). Competencies improve the workforce by providing a guiding framework for producing education and training programs, identifying worker roles and job responsibilities, and assessing individual performance and organizational capacity (12–18).

Competencies are action-oriented statements that delineate the essential knowledge, skills, and abilities that are critical to the effective and efficient performance of work (19); competencies should be observable and measurable. Several public health professional disciplines have developed competencies, often through federal partnerships, to address workforce education and training needs (14,15,19–24), and competency-based curriculum development has been suggested as the ideal method for training public health workers and public health students (10,11,13,18,25). In 2009, CDC and APHL collaborated to develop guidelines for biosafety laboratory competency (26), followed by development of this broader set of guidelines for PHL professional competency.

Purpose

The purpose of these guidelines is to outline the knowledge, skills, and abilities that public health laboratory professionals (principally scientists, managers, and leaders) need to deliver the core services of PHLs efficiently and effectively. These guidelines establish core competencies that can help direct workforce development efforts in PHLs in the United States. Because the competencies are universal in nature for many laboratory disciplines, the guidelines also have potential value for laboratories (including those not characterized as public health laboratories) located in both developed and developing nations.

Background

CDC and APHL have engaged collectively in multiple laboratory workforce improvement efforts over the past several years, providing the foundation for the development of these guidelines. More information about these efforts is available at <http://www.aphl.org>. The 2011 launch of the Laboratory Efficiencies Initiative (27) was intended to assist PHLs in achieving long-term sustainability and resulted in recommendations from multiple forums to focus greater efforts on PHL workforce development. As part of these efforts, APHL collaborated with CDC in 2012 to develop a comprehensive set of competencies that built on APHL’s earlier work to draft competencies for PHL professionals across several topic areas (APHL, unpublished draft, 2011). The scope of that project then was expanded to include a broader range and depth of technical and nontechnical competencies, resulting in the guidelines presented in this report. These guidelines for PHL professionals were developed through the engagement of subject matter experts from APHL, CDC, state and local PHLs, federal environmental and agricultural laboratories, clinical laboratories, and academia to ensure appropriate input and vetting.

Methodology

The PHL competencies were developed over a 2-year period through a consensus process involving 108 subject matter experts participating through a variety of committees, workgroups, and teams (Box). In August 2012, CDC and APHL established an 11-member CDC/APHL Steering Committee* to provide direction, guidance, and oversight to the overall competency development process. A 38-member Project Planning Workgroup comprising CDC, APHL, and PHL representatives encompassing a range of expertise (e.g., PHL leadership, informatics, microbiology, and environmental chemistry) was created through consultation with a nationally recognized expert in competency development and was charged with establishing the competency development process. A 2-day meeting of the Project Planning Workgroup (which included the members of the CDC/APHL Steering Committee) facilitated by AlignOrg Solutions was held in Atlanta, Georgia, in October 2012 to define the project scope and target audience, prioritize expectations of stakeholders, discuss methods and criteria for writing competencies, determine the structure of the competencies, and develop a list of draft competency domains to represent the main subject areas in which PHL professionals operate.

* A list of all of the members of the various committees, teams, and workgroups appears beginning on page 93 of this report.

Eleven Domain Teams then were established to develop competencies for 14 draft competency domains; an additional domain focused on ethics was developed later in the process. Most team leads and many members were drawn from the Project Planning Workgroup. Each team lead was responsible for making recommendations regarding team membership to the CDC/APHL Steering Committee and APHL staff, who vetted potential members. Domain Team leads were encouraged to recruit a diverse group based on employer type (government and nongovernment, and federal, state, and local), geographic locale of employment, and years and range of experience (laboratory scientists, managers, and leaders). A total of 90 subject matter experts from CDC, state and local PHLs, APHL, academic laboratories, clinical laboratories, the U.S. Department of Agriculture, and others served on the various Domain Teams.

A Development Workgroup created template documents to assist the Domain Teams in constructing their respective competency sets and to ensure uniformity to the process. This Workgroup, which comprised staff from CDC, APHL, PHL, and AlignOrg Solutions, conducted literature reviews and Internet searches to identify related materials, including laboratory association guidelines and reports as

well as competency sets for nonlaboratory audiences that had application for PHL functions or specific domain areas (e.g., management, leadership, and workforce training). Although applicable literature was located for eight domain areas (Quality Management System, Management and Leadership, Ethics, Safety, Research, Emergency Management and Response, Workforce Training, and Informatics), limited material was found related to the remaining competency domains. Formal systematic review methods were not used because of the scarcity of available literature, especially regarding laboratory-specific content. In December 2012, the Development Workgroup met to draft a template document for each competency domain, consisting of main competency statements comprising one or more subcompetencies that were further defined by draft responsibility statements at one or more proficiency levels. The Workgroup members used the available literature when applicable but relied principally on their subject matter knowledge and personal work experience as a basis for drafting the template documents.

During January 2013–April 2013, each Domain Team held regular, facilitated conference calls to develop and refine their respective domain competencies, using the template document provided by the Development Workgroup as a

BOX. Timeline for development of the competency guidelines

August 2012: The CDC/Association of Public Health Laboratories (APHL) Steering Committee for the Public Health Laboratory (PHL) Competencies Project was established.

October 2012: A Project Planning Workgroup comprising CDC, APHL, and PHL representatives met to define the scope and structure of the competencies.

December 2012: The Development Workgroup conducted a review of published literature and resources, including competency sets for non-PHL audiences. Outlines were crafted for use as a template for each domain.

January–April 2013: Eleven Domain Teams developed draft competencies for 14 domains using the expertise of 90 subject matter experts from CDC, APHL, state and local PHLs, academic laboratories, clinical laboratories, the US Department of Agriculture, and other entities. Each Domain Team held regular, facilitated conference calls to develop and refine their competencies.

April–November 2013: A Synthesis Workgroup assessed domain gaps and redundancies and harmonized language across domains.

November 2013–January 2014: The competencies were vetted by volunteer representatives from external

organizations and key stakeholders including PHL representatives, clinical laboratory representatives, APHL, and CDC.

December 2013: The Adjudication Process Workgroup, comprising APHL, CDC, and PHL representatives, established the process for the adjudication of reviewer comments by the Domain Teams.

January–March 2014: Domain Teams addressed comments received during the vetting period via conference calls. The Ethics domain was crafted as a separate domain, resulting in 15 total domains.

April 2014: The Harmonization of Domains Workgroup reviewed major changes made by the Domain Teams to the draft competencies in response to reviewer comments and resolved remaining redundancies and inconsistencies in approach and language among the competency domains.

April–July 2014: Small teams from the Harmonization of Domains Workgroup finalized the competency domains.

October 2014: The CDC/APHL Steering Committee reviewed the competency guidelines.

February 2015: CDC reviewed and approved the final guidelines.

starting point. Each team relied on member expertise to arrive at consensus on all competencies, subcompetencies, and proficiency tier statements. The 14 proposed PHL competency domains were mapped against the core functions of PHLs (2,3), the Council on Linkages Core Competencies for Public Health Professionals (14), and the CDC/Council of State and Territorial Epidemiologists Applied Epidemiology Competencies (15) to assess congruence with these materials and to identify gaps in the draft PHL competency domains.

In April 2013, a six-person Synthesis Workgroup was established to review and assess the draft domain documents for gaps and overlaps in content and to harmonize language across domains. During May–November 2013, the Workgroup's efforts focused on developing definitions for each domain, continuing to harmonize content and address gaps and overlaps, developing an online survey tool for the competency validation process, and soliciting reviewers to evaluate one or more competency domains.

Validation Process

The CDC/APHL Steering Committee identified the organizations and agencies it wanted to target for involvement in the competency validation process. Following a solicitation for reviewers, APHL staff contacted 139 potential reviewers on the basis of their knowledge and background in one or more particular domain areas. Of these, 75 were invited and agreed to participate in the review phase. Reviewers were drawn from state and local PHLs, CDC, APHL, clinical laboratory organizations, and food-testing laboratories, as well as former PHL directors and other expert consultants. Fifteen reviewers already had been involved in the competency development process in some capacity and offered to review domains that they did not take part in developing. Reviewers were given 45 days during November 2013–January 2014 to assess the validity of the content for the particular domain(s) reviewed and to provide comments and recommendations for improvement through an online survey tool. The reviewers based their responses on their knowledge and experiences in laboratory practice. In December 2013, an Adjudication Process Workgroup of APHL, CDC, and PHL representatives met to design and establish the process for adjudicating reviewer comments, including a method for each Domain Team to document its response to each comment received. At the end of the vetting period, all reviewer comments were collated and reviewed by APHL staff, and a consolidated listing of comments was forwarded for review to the Domain Teams.

The extensive nature of the comments for the General Laboratory Practice and Emergency Management and Response domains prompted the CDC/APHL Steering Committee to create dedicated teams for each of these domains. Several competencies and subcompetencies for the General Laboratory Practice domain had been extracted previously from the Chemistry and Microbiology domains, with additional content developed by a small work team. The new General Laboratory Practice Domain Team included representatives from the Chemistry, Microbiology, Quality Management System, Research, and Communication Domain Teams. Content for the Emergency Management and Response domain had also been developed initially by the Chemistry and Microbiology Domain Teams. In light of the vetting period comments, the Emergency Management and Response domain competencies were rewritten by a dedicated team that included members from APHL's Public Health Preparedness and Response department and the APHL Public Health Preparedness and Response Committee. Similarly, content for the Ethics domain had been extracted from a number of existing domains, and three Domain Team volunteers formed a new team to examine comments received. All Domain Teams held as many conference calls as needed during January–March 2014 to consider and address the vetting period comments.

In April 2014, a Harmonization of Domains Workgroup met to review major changes that the Domain Teams had made to the draft competencies in response to reviewer comments and to address any remaining overlaps in content and inconsistencies in approach and language among the competency domains. The Workgroup also resolved outstanding issues related to vetting period comments that the Domain Teams were unable to address individually in a consensus process. This workgroup comprised nine Domain Team leads, two CDC/APHL Steering Committee members, the APHL project manager, and an invited representative of CDC. Workgroup members then split into small teams and met via teleconference during April–July 2014 to finalize the competency domains.

In total, the competencies were developed and reviewed by approximately 170 professionals with diverse backgrounds and experiences in laboratory science and public health. The final draft of the competency guidelines was reviewed by the CDC/APHL Steering Committee in October 2014. The final competency guidelines were reviewed and approved by CDC in February 2015.

Guiding Principles

Scope

The competency guidelines were developed specifically for scientists working in PHLs. APHL defines PHLs as governmental public health, environmental, and agricultural laboratories that provide analytic biological and/or chemical testing and testing-related services that protect human populations against infectious diseases, foodborne and waterborne diseases, environmental hazards, treatable hereditary disorders, and natural and human-made public health emergencies (<http://www.aphl.org/aboutaphl/aboutphls/pages/default.aspx>). Although intended primarily for the continuum of scientist positions from laboratory assistant to laboratory director, these competencies can be used by other PHL staff as well. In fact, all staff (including administrative and support staff, custodial staff, and information technology specialists) can apply competencies within the Security, Safety, Emergency Management and Response, and Ethics domains. Any staff members with responsibilities for data entry, records management, client services, supply services, and other nonbench functions would benefit from application of competencies across additional domains depending on their job function and responsibilities.

Although these competencies were developed expressly for the PHL community, this does not preclude their broader application to a variety of other work settings, because many of the skill sets are similar. Scientists, trainers/educators, and leaders and managers in clinical laboratories, veterinary laboratories, academic and private research laboratories, and other laboratories may use these competencies as a basis for further development of their workforce and local/institutional staff. Laboratories using these competencies should be mindful of federal, state, local, and institutional regulations and standards addressing topics such as safety and security when adopting competencies in practice.

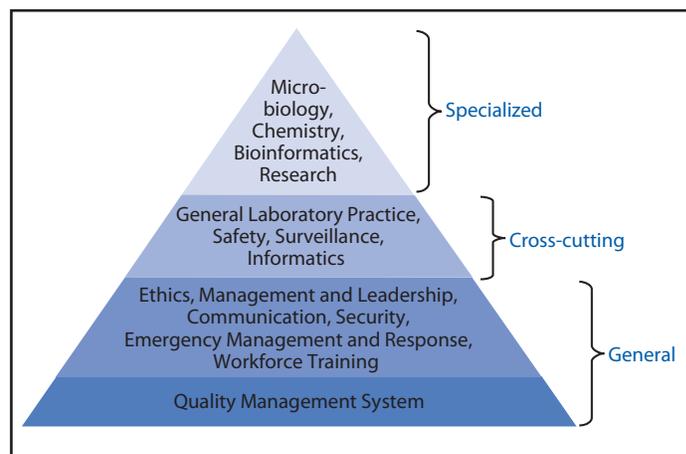
Competencies and Skill Domains

These guidelines were developed on the basis of the Dreyfus Model of Skill Acquisition, which states that five progressive stages of development are associated with skill proficiency (18,28). Learners are able to handle additional responsibility and adjust to different and more complex situations as they gain proficiency. For these competency guidelines, the Dreyfus Model was modified in that four proficiency tiers are used: beginner, competent, proficient, and expert. Descriptions of the proficiency tiers are provided (Appendix A).

Competencies were written by using Bloom's taxonomy as a framework; action verbs describing activities that are observable and measurable were used to signify or relate to a hierarchy of learning and actions (29,30). The hierarchy of responsibilities is based on the science for competency development that has been applied across numerous disciplines. Competencies typically are structured as broad statements that define what is expected of and can be demonstrated by the learner; therefore, specific tasks or methods to achieve the competency at a particular proficiency level are not delineated. Each user is responsible for deciding the needed activities, which might vary substantially because of the diversity that exists within and across public health laboratories. Consequently, competency statements do not refer to or include the frequency with which a responsibility is exercised. Nor, with rare exceptions, do they refer to specific guidelines, standards, or regulations, because these might differ by discipline and type of laboratory. The competencies focus on the knowledge, skills, and abilities required to perform a range of activities in the PHL. The competencies convey the capability for a given behavior or skill, even if the opportunity to perform that skill or behavior is not available (e.g., to serve on national committees or instruct others in policies and processes).

A total of 122 competencies and 519 subcompetencies were identified for the PHL workforce across 15 competency domains: 1) Quality Management System, 2) Ethics, 3) Management and Leadership, 4) Communication, 5) Security, 6) Emergency Management and Response, 7) Workforce Training, 8) General Laboratory Practice, 9) Safety, 10) Surveillance, 11) Informatics, 12) Microbiology, 13) Chemistry, 14) Bioinformatics, and 15) Research (Figure).

FIGURE. Schematic of competency domains for public health laboratory professionals*



* Teams of subject matter experts develop general, cross-cutting technical, and specialized competencies, with a quality management system as the foundation of every activity.

Full descriptions of these domains and listing of their competencies, subcompetencies, and responsibility statements are presented (Tables 1–15). A number and lettering schema is used to identify domains, competencies, and subcompetencies. Domains are identified by three-letter initials (e.g., QMS), competencies are identified by the domain initials and an overall number (e.g., QMS 1.00), and subcompetencies are further identified through expansion on the competency numbering system (e.g., QMS 1.01 and QMS 1.02).

Three types of domains are included in this competency set: 1) general domains that apply to the responsibilities of all PHL professionals (i.e., Quality Management System, Ethics, Management and Leadership, Communication, Security, Emergency Management and Response, and Workforce Training); 2) cross-cutting technical domains that apply to all laboratory scientists regardless of the scientific discipline in which they work (i.e., General Laboratory Practice, Safety, Surveillance, and Informatics); and 3) specialized domains that are specific to laboratory scientists working in particular scientific disciplines or specialized functional areas (i.e., Chemistry, Microbiology, Bioinformatics, and Research) (Figure). The General Laboratory Practice domain is broadly applicable because it includes general topics pertinent to the laboratory workflow across a wide array of testing areas. Many of these subcompetencies are not duplicated in the specialized domains. Consequently, the General Laboratory Practice domain serves two purposes: to be a companion to each specialized domain and to function as a quasispecialized domain for testing activities not encompassed by the Microbiology or Chemistry domains. Because many topics are relevant to more than one competency domain, the Harmonization of Domains Workgroup decided when to have intentional overlap of particular subcompetencies or topics across domains. For example, the General Laboratory Practice, Research, and Management and Leadership domains include ethics-related competencies although there is a separate Ethics domain.

For all domains, the competencies and proficiency tier statements are context-driven. A given verb is not limited to occurring at only one specific level of proficiency, as the complexity of the described action is determined by the context. In addition, some subcompetencies are similar across domains, in which case users should be mindful of the specific context. For example, sample collection, labeling, and handling are primary functions for both chemistry and microbiology. The subcompetency language for this group of activities is similar in the Chemistry and Microbiology domains, although the specific actions (tasks) needed to achieve each level of proficiency might be different between the testing disciplines.

Each subcompetency outlines a cumulative acquisition of skills, with each successive proficiency tier assuming that a person has acquired the knowledge, skills, or abilities stated in the lower proficiency tier for a given subcompetency. However, the amount of time required for a worker to achieve competency at a particular proficiency tier might be highly variable. In particular, the beginner phase could encompass a very short time frame for some subcompetencies while requiring a longer time for others, depending on the specific action described. Regardless, all beginner tier statements assume that work will be performed under supervision. Furthermore, all statements of the four proficiency tiers are written under the assumption that work will be performed according to standard operating procedures, processes, and policies approved by the administration of the laboratory and in adherence to applicable regulations and accreditation standards and guidelines.

Finally, no recommendation is made that any particular job title or academic degree is required for a particular proficiency tier, nor is the complexity of the knowledge, skills, and abilities for a given proficiency tier the same for all competencies. For example, a PHL scientist could be at the beginner tier for some subcompetencies while being at the competent or proficient tier for others. Similarly, a person might acquire some expert tier competencies early in their career despite not having supervisory or management responsibilities. Many expert competency statements, however, apply to a person occupying a position commensurate with a laboratory director, as significant experience and expertise are required.

Intended Use

These guidelines provide highly structured competencies intended to help ensure a capable, well-trained, and prepared laboratory workforce. The competence of the PHL workforce has a direct impact on the quality of the work output and products required to protect the public's health. Each competency and subcompetency within every domain might not apply to all laboratory staff. The competencies should be tailored and applied to the greatest extent possible to the individual user's situation. Personnel can use the competencies to assess their current skill level and define other areas in need of additional training, with a goal of achieving higher proficiency over time. Laboratory directors and human resources staff might find the guidelines helpful in creating standardized job descriptions, defining progressive job series, recruiting new staff, assessing organizational capacity, and developing performance objectives and appraisals that are aligned with the competencies. Laboratory managers may employ the guidelines

as a reference for performance management strategies. The competencies provide a framework for assessing performance and could be used to prepare for certification examinations and for meeting staff qualification requirements specified by governmental laboratory personnel regulations. Finally, educators and training developers may use the guidelines to develop and refine PHL workforce development plans to assess and address training needs through the design of education and training programs.

It is important for users to review the definitions associated with these guidelines (Appendix B). As terms might have different meanings in the context of different laboratory types, the terminology for this project has been standardized to provide more clarity and ease in applying the competencies to practice settings. In situations in which glossary terms contain more than one possible definition, the particular definition applicable to a domain is footnoted for that domain.

Dissemination

CDC and APHL plan to disseminate these guidelines broadly to a variety of stakeholders, including, but not limited to public health laboratories, clinical laboratories, academia, and laboratory scientist professional organizations such as the American Society for Clinical Pathology, the American Society for Clinical Laboratory Science, the Association of Food and Drug Officials, the Association of American Feed Control Officials, the Clinical Laboratory Management Association,

and the Clinical and Laboratory Standards Institute, some of which participated in the competency validation process. The competencies will be presented at meetings of public health practitioners and laboratory professionals. The guidelines also will be displayed on APHL's website (<http://www.aphl.org>).

The next stage of this PHL competency project will focus on the development of tools and resources to aid in guideline implementation. These might include sample competency-based job descriptions and examples of ways professionals can demonstrate competency in a specific area; highlight case study examples of competencies in use; and provide models for developing training and fellowship programs tied to performance metrics and competencies. For example, the Emerging Infectious Diseases Fellowship Program, which is sponsored by APHL and CDC, could use guidance in the toolkit to integrate these competencies into a training program similar to the manner in which the CDC-sponsored Epidemic Intelligence Service program (31) integrated the Applied Epidemiology Competencies (15). Tools and resources to support implementation will also be displayed on APHL's website (<http://www.aphl.org>) as they are developed.

CDC and APHL also aim to develop a sustainability plan to evaluate the adoption, use, and need for revision of these guidelines periodically. The Council on Linkages (14) and the Clinical and Laboratory Standards Institute (32) provide models for competency and guideline revision that could support this process.

Quality Management System Competency Guidelines

Purpose statement: The competencies in Quality Management System (QMS) address the knowledge, skills, and abilities required for developing a laboratory's culture of quality (Table 1). The essential elements integrate operations, services, and infrastructure into a system that meets applicable regulatory standards, professional guidelines, and customer requirements for ensuring and maintaining quality and continually improving laboratory services.

Introduction: QMS is a systematic approach for ensuring the consistent quality of the tests performed, the products created, the data generated, and the results reported. Operating within a quality system meets the needs and requirements of public health laboratories as well as the expectations of partners, stakeholders, and users (internal and external customers). A QMS is more than quality assurance and quality control — it also includes all the business processes of a laboratory that are required to ensure quality. Adhering to quality standards for laboratory operations helps laboratories generate consistent, reliable, and reproducible data and results.

As the first responsibility of the public health laboratory staff is to provide quality testing and services to support the health of the public and meet the many needs of their customers, this demand for quality is superimposed on all aspects of laboratory operations. As such, a quality management system is the foundation for every other activity within this competency set.

Notes: The structure for this domain is based upon the 12 quality system essentials (33). Multiple additional sources were identified as support documents for this domain (34–40). As the foundational domain for these guidelines, all other competencies should be viewed within its context. However, this domain is systems-oriented. Other domains contain quality-related subcompetencies that address “bench-level” quality indicators and activities and not the creation, maintenance, and evaluation of a quality management system as presented here. The verb “oversees” is used extensively in the Expert level. In this context, “oversees” is a broad term that comprises the many functions related to the management of policies, processes, and procedures to include creation, design, development, directing, monitoring, evaluation, and collaboration.

TABLE 1. Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 1.00. Organization: ensures that the laboratory's organizational structure is committed to achieving and maintaining quality*				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 1.01. Commitment to quality	Describes quality concepts and good professional practice	Demonstrates actions consistent with quality concepts and good professional practice	Sustains laboratory quality management system (QMS)* processes and procedures to ensure good professional practice	Oversees the development of policies,* processes,* and procedures* for review and maintenance of the QMS
QMS 1.02. Organizational structure	Identifies the laboratory's organizational structure that ensures quality	Explains how the laboratory's organizational structure ensures quality	Manages organizational structure to ensure quality	Coordinates organizational structure to ensure the QMS is well-integrated into all levels of laboratory operations
QMS 1.03. Quality culture	Describes the culture, programs, and communication processes regarding quality, safety, and ethical practices*	Adheres to the culture, programs, and communication processes regarding quality, safety, and ethical practices	Advocates for a culture of quality, safety, and ethics	Fosters a culture of quality, safety, and ethics
QMS 1.04. Resources	Identifies resources used to support the QMS	Requests resources to support the QMS	Makes resource allocation decisions to support the QMS	Ensures the ability to respond to unanticipated needs for resources to support the QMS
QMS 1.05. Cost of quality*	Describes how cost effective quality measures can improve laboratory performance	Analyzes quality measures to evaluate the costs of maintaining quality	Develops the procedures to estimate and compare quality costs	Creates an action plan to address the impact of quality costs on regulatory compliance, customer* service, and the operating budget

See table footnotes on page 13.

TABLE 1. (Continued) Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 2.00. Customer focus: ensures that customer needs, expectations, and requirements* are consistently met				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 2.01. Customer satisfaction	Recognizes the laboratory's internal and external customers	Responds to internal and external customer inquiries and feedback	Analyzes feedback and satisfaction data from internal and external customers	Oversees the system for measuring customer and user satisfaction
QMS 2.02. Customer services	Describes the customer services provided by the laboratory to meet customer needs, expectations, and requirements	Adheres to roles and responsibilities in meeting customer needs, expectations, and requirements	Develops procedures to address customer needs, expectations, and requirements	Oversees the policies, processes, and procedures for providing customer services that meet customer needs, expectations, and requirements
QMS 3.00. Facilities and safety: ensures that the laboratory's physical environment, maintenance, and safety programs* meet applicable requirements				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 3.01. Workplace safety	Participates in required workplace training regarding safety and maintenance of the physical environment	Manages work area to ensure staff compliance with safety requirements	Develops site-specific workplace safety policies and procedures	Oversees the policies, processes, and procedures to develop, review, and maintain a safety plan that meets requirements
QMS 3.02. Facilities	Describes the laboratory design, escape routes, and workplace accommodations	Monitors environmental controls* for good laboratory practice and testing capabilities	Ensures security and containment of staff, samples,* laboratory supplies, and laboratory equipment*	Directs the process and planning for facility design, modification, and renovation
QMS 3.03. Waste management	Describes waste management policies, processes, and procedures	Applies waste management policies, processes, and procedures to activities	Trains staff on the waste management plan,* including recycling and disposal methods	Ensures the waste management plan follows regulatory requirements
QMS 3.04. Emergency management and response	Explains own role in emergency event mitigation, preparedness, response, and recovery	Trains staff in the emergency management plan for emergency event mitigation, preparedness, response, and recovery	Provides input on emergency management and response policies, processes, and procedures	Establishes emergency management and response policies, processes, and procedures
QMS 4.00. Personnel: ensures recruitment and retention of a qualified, well-trained, and competent workforce				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 4.01. Staff qualification process	Describes education, training, and skills required for job performance	Describes process required to verify staff qualification and competency	Ensures each position has the required competencies, education, training, skills, experience, and where applicable, certification,* and licensure*	Designs a process to determine required competencies, education, training, skills, experience and where applicable, certification and licensure for each job title
QMS 4.02. Orientation and end-of-employment	Participates in orientation and end-of-employment processes	Ensures orientation and end-of-employment processes are carried out for each staff person	Facilitates orientation and end-of-employment processes	Designs an orientation and end-of-employment program
QMS 4.03. Training	Participates in required training	Ensures that training and evaluation are carried out for assigned duties	Facilitates training and evaluation processes	Oversees the policies, processes, and procedures for the training program

See table footnotes on page 13.

TABLE 1. (Continued) Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 4.00. Personnel: ensures recruitment and retention of a qualified, well-trained, and competent workforce				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 4.04. Competence assessment plan	Describes competence assessment plans	Participates in the development of an individualized competence assessment plan	Evaluates individual competence assessment plans	Oversees a competence assessment plan for the organization
QMS 4.05. Professional development plan	Participates in initial training related to assigned work position	Participates in continuing education and professional development opportunities	Manages the plan to provide professional development opportunities to all levels of staff	Designs a plan to provide professional development opportunities to all levels of staff
QMS 4.06. Performance evaluation process	Participates in the initial performance evaluation process	Participates in the ongoing performance evaluation process	Manages the performance evaluation process	Establishes a process for periodic performance evaluation
QMS 4.07. Recruitment, retention, and succession plans	Describes the recruitment and retention plan	Participates in recruitment and retention planning	Manages the recruitment, retention, and succession plans	Develops recruitment, retention, and succession plans to maintain a qualified workforce
QMS 5.00. Purchasing and inventory: ensures that requirements for supplies and services are consistently met				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 5.01. Procurement process	Describes laboratory procurement process for current work area	Participates in laboratory procurement process	Manages laboratory procurement process	Ensures that laboratory procurement incorporates organizational rules and collaboration with purchasing authorities
QMS 5.02. Inventory processes	Describes the inventory management processes used in current work area	Follows established inventory management processes, including receipt and inspection processes	Develops inventory processes for laboratory supplies, reagents, and verification* of performance	Oversees inventory management plan
QMS 5.03. Evaluation process	Describes the process to evaluate and provide feedback to suppliers	Executes the process to evaluate and provide feedback to suppliers, consultants, and contractors	Develops a process to evaluate the satisfaction with services and products from suppliers, consultants, and contractors	Oversees a quality improvement plan for purchasing and inventory
QMS 6.00. Laboratory equipment: ensures that laboratory equipment selection, installation, use, maintenance, and troubleshooting meet performance standards				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 6.01. Acquisition and decommissioning	Describes the policies, processes, and procedures for equipment acquisition and decommissioning	Provides input on the processes and procedures for equipment acquisition and decommissioning	Develops the processes and procedures for equipment acquisition and decommissioning	Oversees the policies, processes, and procedures for equipment acquisition and decommissioning
QMS 6.02. Equipment qualification plan*	Describes processes and procedures for equipment installation qualification, operational qualification, and performance qualification	Performs equipment installation, operational, and performance qualification procedures	Implements the equipment qualification plan	Oversees the policies, processes, and procedures regarding the equipment qualification plan

See table footnotes on page 13.

TABLE 1. (Continued) Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 6.00. Laboratory equipment: ensures that laboratory equipment selection, installation, use, maintenance, and troubleshooting meet performance standards				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 6.03. Maintenance process	Describes processes and procedures for the maintenance, troubleshooting, and service and repair of equipment	Performs procedures for the maintenance, troubleshooting, and service and repair of equipment	Develops the processes for equipment maintenance, troubleshooting, and service and repair	Oversees the policies, processes, and procedures for equipment maintenance, troubleshooting, service, and repair
QMS 6.04. Instrument and equipment calibration	Describes calibration of instruments and equipment	Performs calibration of instruments and equipment	Establishes calibration processes and procedures for instruments and equipment	Oversees calibration policies, processes, and procedures for instruments and equipment
QMS 7.00. Process management:* ensures that operational processes meet organizational requirements				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 7.01. Workflow [†] processes	Describes workflow processes related to job position and activities	Applies workflow processes according to laboratory policies, processes, and procedures	Develops evaluation, modification, and design of workflow processes and procedures	Oversees the policies, processes and procedures for evaluating and modifying current workflow processes and for developing new workflow processes
QMS 7.02. Process control	Describes how processes are controlled in work area	Participates in process control procedures	Develops the process control plan	Oversees the process control plan
QMS 7.03. Method validation* and performance verification processes	Describes method validation and performance verification processes	Performs procedures for method validation and performance verification	Develops method validation and performance verification processes and procedures	Oversees the policies, processes, and procedures for validation of new or modified tests or materials and for verification of existing tests or materials
QMS 8.00. Documents* and records:* ensures that there is an effective system to control and manage documents and records				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 8.01. Document management system	Describes how the laboratory controls and manages documents	Applies the policies, processes, and procedures for controlling and managing documents	Develops the policies, processes, and procedures for controlling and managing documents	Oversees the document management system to ensure staff compliance with internal policies, external regulations, and accreditation* requirements
QMS 8.02. Records management system	Describes how the laboratory controls and manages records	Applies the policies, processes, and procedures for controlling and managing records	Develops the policies, processes, and procedures for controlling and managing records	Oversees the record management system to ensure staff compliance with internal policies, external regulations, and accreditation requirements

See table footnotes on page 13.

TABLE 1. (Continued) Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 9.00. Information* management: ensures the confidentiality,* security, and integrity of generated and disseminated information				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 9.01. Confidentiality	Describes the policies, processes, and procedures for maintaining confidentiality of laboratory information	Complies with policies, processes, and procedures for maintaining confidentiality of internally and externally derived information	Develops policies, processes, and procedures for maintaining confidentiality of internally and externally derived information	Oversees the policies, processes, and procedures for ensuring confidentiality of information and staff compliance with regulations and guidelines
QMS 9.02. Security	Describes the policies, processes, and procedures related to securing information related to assigned job tasks	Complies with policies, processes, and procedures for securing information	Develops policies, processes, and procedures to ensure information is secure	Oversees the policies, processes, and procedures for securing information, including audits to meet regulations and guidelines
QMS 9.03. Information integrity	Describes the policies, processes, and procedures for ensuring integrity of information	Complies with policies, processes, and procedures to ensure the integrity of information	Develops processes and procedures to ensure the integrity of information	Oversees the policies, processes, and procedures to ensure the integrity of information
QMS 10.00. Nonconforming event* management: ensures that processes are in place for detecting and managing nonconforming events				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 10.01. Management of nonconforming events (NCEs)	Recognizes NCEs	Responds to NCEs	Investigates NCEs, including the creation of a corrective action plan	Oversees the policies, processes, and procedures related to NCEs
QMS 10.02. Documentation of NCEs	Describes the policies, processes, and procedures to record and report NCEs	Reports discovered NCEs	Performs analysis of records and reports of NCEs to identify trends	Oversees the policies, processes, and procedures to document NCEs and report NCE information to senior management and external entities
QMS 10.03. Investigation and root cause analysis*	Participates in NCE investigations and root cause analyses	Leads the process of investigating NCEs and performing root cause analyses	Assesses NCE investigations and root cause analyses to improve processes	Oversees the policies, processes, and procedures for investigating NCEs and performing root cause analyses
QMS 10.04. Notifications of recalls and technical bulletins	Describes the policies, processes, and procedures to address product recalls and technical bulletin notifications	Responds to product recalls and technical bulletin notifications	Develops processes and procedures to address product recalls and technical bulletin notifications	Oversees the policies, processes, and procedures to address product recalls and technical bulletin notifications
QMS 11.00. Assessments: ensures that processes are in place to perform internal audits* and external assessments*				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 11.01. Quality assessment* plan	Adheres to the quality assessment plan	Ensures the application of the quality assessment plan to laboratory operations	Develops the quality assessment plan	Oversees a comprehensive quality assessment plan
QMS 11.02. External assessments	Participates in external assessment activities	Performs external assessment procedures	Develops the processes and procedures to select, enroll, and participate in external assessments	Oversees the policies, processes, and procedures related to external assessment
QMS 11.03. Internal audits	Participates in internal audits	Performs internal audit procedures	Develops the processes and procedures for internal audits	Oversees the policies, processes, and procedures related to internal audits

See table footnotes on page 13.

TABLE 1. (Continued) Public health laboratory competency guidelines: Quality Management System (QMS) domain

QMS 11.00. Assessments: ensures that processes are in place to perform internal audits* and external assessments*				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 11.04. Quality indicators*	Describes the elements of pre-examination,* examination,* and postexamination* quality indicators	Employs pre-examination, examination, and postexamination quality indicators	Develops processes and procedures for determining pre-examination, examination, and postexamination quality indicators	Oversees the policies, processes, and procedures related to developing and assessing quality indicators
QMS 11.05. Quality indicator data collection and analysis	Describes the policies, processes, and procedures related to collecting and analyzing quality indicator data	Complies with policies, processes, and procedures related to collecting and analyzing quality indicator data	Develops the processes and procedures for collecting and analyzing quality indicator data	Oversees the policies, processes, and procedures related to the collection and analysis of quality indicator data
QMS 12.00. Continual improvement: ensures mechanisms for continuous quality improvement				
Subcompetency	Beginner	Competent	Proficient	Expert
QMS 12.01. Continuous Quality Improvement (CQI)* program	Describes the policies, processes, and procedures related to the CQI program	Implements changes identified through the CQI program	Develops the processes and procedures of the CQI program	Oversees the policies, processes, and procedures related to the quality improvement program
QMS 12.02. CQI activities	Participates in CQI activities	Follows CQI processes and procedures for troubleshooting and documenting required CQI activities	Documents staff compliance with CQI activities that support the CQI monitoring, evaluation, and review processes	Oversees the policies, processes, and procedures related to CQI activities
QMS 12.03. Corrective action* process	Describes the policies, processes, and procedures related to corrective action	Implements the processes and procedures related to corrective action	Develops corrective action processes and procedures to address quality improvement	Oversees the policies, processes, and procedures related to corrective action
QMS 12.04. Preventive action*	Describes the policies, processes, and procedures related to preventive action	Implements the processes and procedures related to preventive action	Develops the processes and procedures related to preventive action	Oversees the policies, processes, and procedures related to preventive action
QMS 12.05. Change management*	Describes the process to change laboratory policies, processes, and procedures	Participates in the process and procedures related to change management	Implements the change management process, including communication of changes made to established policies, processes, and procedures	Oversees activities related to policy, process, and procedural change management, including evaluation of impact on organizational processes and services

* This term is defined in Appendix B.

† Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Ethics Competency Guidelines

Purpose statement: The competencies in Ethics address the knowledge, skills, and abilities needed to fulfill basic responsibilities to perform in a collegial and ethical manner within a laboratory setting (Table 2). Ethical professional and scientific behaviors are essential when working in the public health laboratory to help ensure scientific integrity and sustain effective relationships with stakeholders and the public.

Introduction: Ethics are principles or a set of values held by a person or group, i.e., the rules or standards governing the conduct of a person or the conduct of the members of a profession. These principles and rules include characteristics such as personal accountability, maintaining confidentiality, and ensuring the accuracy of testing results. These vital but sometimes unspoken values, standards, and resulting professional and scientific codes of conduct are critical to establishing and maintaining a collegial environment in which scientific integrity is held in the highest regard.

To carry out its mission, the public health laboratory must earn and maintain the public's trust. As diligent stewards of that trust and of public funds, all public health laboratory staff should act decisively and ethically in service to the public's health. Laboratory staff should apply ethical principles in all aspects of their work, including respecting their colleagues, customers, and populations they serve. Individual laboratory staff members should apply ethical principles in decision-making to all aspects of their job performance and take responsibility for outcomes associated with their decisions. Ethics must exist at every level in the organization; and it must be championed by every staff person, not just leadership.

Notes: Multiple sources were identified as support documents for this domain (41–45). This domain is intentionally broad and includes examples of general and scientific ethics and practices in the glossary. It is the responsibility of each organization to further identify and detail the professional and scientific values and characteristics important to them. The General Laboratory Practice, Research, and Management and Leadership domains also include ethics-related competencies.

TABLE 2. Public health laboratory competency guidelines: Ethics domain

ETH 1.00. Professional code of conduct: adheres to policies* and principles governing professional ethics and rules of conduct when working in a public health laboratory				
Subcompetency	Beginner	Competent	Proficient	Expert
ETH 1.01. Personal integrity	Aligns personal integrity with organizational culture	Exemplifies integrity in interactions and activities	Coaches staff in behaviors that exemplify integrity	Creates a culture where integrity is the foundation for all interactions and activities
ETH 1.02. General ethical practices*	Applies ethical principles and professional rules of conduct to the workplace	Serves as a role model of ethical behavior by consistently conforming to the highest ethical standards and practices	Ensures staff compliance with policies and procedures related to ethical principles and professional rules of conduct	Oversees the policies, processes,* and procedures* related to ethical principles and professional rules of conduct
ETH 1.03. Stewardship of resources	Acts as a good steward of public funds and resources	Identifies methods to improve stewardship of resources	Ensures that the use of public funds and resources meet the policies for stewardship	Oversees the policies, processes, and procedures to ensure the environment supports excellence in the stewardship of resources
ETH 2.00. Scientific code of conduct: adheres to policies and principles governing scientific ethics* and rules of conduct when working in a public health laboratory				
Subcompetency	Beginner	Competent	Proficient	Expert
ETH 2.01. Scientific integrity*	Verifies scientific integrity of test results and findings	Instructs others in policies, processes, and procedures regarding scientific integrity of test results and findings	Ensures staff compliance with policies and procedures regarding scientific integrity of all results and findings	Oversees the policies, processes and procedures to ensure practices are consistent with guidelines on scientific integrity
ETH 2.02. Scientific ethics	Applies scientific ethics and rules of conduct to the workplace	Serves as a role model of scientific ethical behavior and rules of conduct by consistently conforming to the highest scientific standards and practices	Ensures staff compliance with policies and procedures related to scientific ethics and rules of conduct	Oversees the policies, processes, and procedures related to scientific ethics and rules of conduct

* This term is defined in Appendix B.

Management and Leadership Competency Guidelines

Purpose statement: The competencies in Management and Leadership address the knowledge, skills, and abilities related to managing staff (supervision), the science and practice of achieving results using available resources (management), and the process of influencing the actions of a person or group to attain desired objectives (leadership) (Table 3).

Introduction: Management and leadership are distinct and complementary roles, both of which are necessary for the success of an organization. They can be distinguished in a number of ways (46). Leadership establishes the purpose and strategic direction of the organization. Leading involves innovating, influencing, and motivating. Leadership asks “what” and “why” and mainly works with persons and their interrelationships. Management establishes the systems and processes of the organization. Managing involves administering, planning, organizing, and coordinating. Management asks “how” and “when” and mainly works with systems, processes, mechanisms, models, and structures. Leadership challenges and improves accepted policies and processes and ensures alignment with the mission and vision of the laboratory (i.e., strives to do the right things). Management works within accepted administrative policies and processes to accomplish the mission and vision of the laboratory (i.e., strives to do things right). Effective

management and leadership are both critical to accomplishing the core functions of public health laboratories (2,3).

All staff members require a certain degree of management and leadership skills. The scope of work performed by public health laboratories is complex and, therefore, requires staff members who have the crucial leadership and management knowledge and skills to be effective in such an environment. Public health laboratories have a great need to develop these skill sets, as there is a severe and continuing shortage of scientists qualified to assume management and leadership positions. This situation is made more challenging because staff members are rarely provided formal training in these areas through degree, fellowship, or other programs.

Notes: Multiple sources were identified as support documents for this domain (4,10,11,14,15,35,37,46,47), which supports all other domains in these guidelines. This domain is intended for all staff, not just those with managerial or leadership positions or job titles. It is sometimes difficult to separate a skill, behavior, or process as belonging exclusively to either management or leadership. As such, leadership subcompetencies are interwoven throughout the domain and are not limited to those within the Leadership competency (MLD 5.00). Ethics-related competencies are included in this domain that correlate with competencies found in the Ethics domain.

TABLE 3. Public health laboratory competency guidelines: Management and Leadership domain

MLD 1.00. General management: ensures sound management of laboratory operations				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 1.01. Mission, vision, and values	Contributes to activities that support the mission, vision, and values of the laboratory	Explains the relationships between activities that support the mission, vision, and values	Exemplifies the mission, vision and values for the laboratory	Develops the mission, vision and values for the laboratory
MLD 1.02. Organizational structure	Describes the organizational structure of the laboratory	Coordinates laboratory program* structure to meet organizational needs	Adapts organizational structure to meet the laboratory's mission and directives for laboratory programs	Oversees a process* to ensure organizational structure meets the laboratory's mission and directives for laboratory programs
MLD 1.03. Laws and regulations for laboratory operation	Complies with laws and regulations related to laboratory operations	Coordinates program activities according to laws and regulations related to laboratory operations	Manages laboratory programs consistent with laws and regulations related to laboratory operations	Ensures that laboratory programs are consistent with federal, state, and local laws and regulations
MLD 1.04. Technical operations management	Works collaboratively on technical and operational planning	Implements technical and operational plans	Develops processes and procedures to manage technical operations	Oversees the policies,* processes, and procedures* related to the development and evaluation of technical operations
MLD 1.05. Emergency management and response	Describes emergency management policies and procedures	Operates within assigned roles when carrying out emergency management and response duties	Manages the emergency management and response plan at the programmatic level	Oversees laboratory-wide emergency management and response

See table footnotes on page 19.

TABLE 3. (Continued) Public health laboratory competency guidelines: Management and Leadership domain

MLD 1.00. General management: ensures sound management of laboratory operations				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 1.06. Analytical and operational services	Describes the processes for introducing improved analytical and operational services	Participates in improvement of analytical and operational services	Manages the improvement of analytical and operational services	Oversees funding and stakeholder relationships needed to implement and improve analytical and operational laboratory services
MLD 1.07. Quality* testing and services	Describes quality principles	Explains the importance of providing quality laboratory testing and services	Evaluates the quality of services for continued quality improvement	Oversees the policies, processes, and procedures to ensure the quality of laboratory testing and services
MLD 1.08. Customer* service	Supports customer service needs	Evaluates customer service satisfaction and trends	Identifies strategies and activities to improve customer service	Oversees the policies, processes, and procedures to ensure the laboratory maintains a customer focus
MLD 1.09. Project management*	Uses basic project management concepts* and tools	Trains staff on project management techniques	Directs the management of projects at the programmatic level	Oversees project management across the laboratory
MLD 1.10. Program effectiveness	Contributes data for program effectiveness monitoring and evaluation	Analyzes data to assist in the monitoring and evaluation of program effectiveness	Directs activities to monitor and evaluate the effectiveness of laboratory programs	Oversees the policies, processes, and procedures regarding the measurement, analysis, and improvement of program effectiveness
MLD 2.00. Policy development: ensures the development, implementation, and review of internal policies				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 2.01. Internal policy development	Describes concepts pertinent to developing internal policies	Compiles important issues, lists of stakeholders, and various options and solutions for internal policy development	Prepares internal policies based on evaluation of short- and long-term consequences of potential policies	Oversees the internal policy development process
MLD 2.02. Internal policy implementation	Complies with documented internal policies and guidelines	Implements internal policies for a laboratory program	Ensures staff compliance with laboratory-wide policies	Oversees internal policy implementation and staff compliance
MLD 2.03. Internal policy review	Reviews internal policies for revisions and updates	Develops amendments or updates to internal policies	Evaluates internal policies	Oversees the review process for internal policies
MLD 3.00. Financial management: ensures sound financial management				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 3.01. Budgets	Complies with budgetary guidelines	Monitors staff compliance to the budget	Reconciles budget, expenditures, and income	Oversees budgets, including development and staff compliance with agency and legislative mandates
MLD 3.02. Revenue and income	Describes revenue sources associated with individual activities	Tracks revenue and income for a laboratory program	Manages revenue and income for the laboratory	Ensures that necessary revenue and income is secured
MLD 3.03. Expenditures	Adheres to guidelines and limits for expenditures	Tracks expenditures for a laboratory program	Ensures staff compliance with guidelines and limits for expenditures	Oversees the policies, process, and procedures related to the cost of operations

See table footnotes on page 19.

TABLE 3. (Continued) Public health laboratory competency guidelines: Management and Leadership domain

MLD 3.00. Financial management: ensures sound financial management				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 3.04. Financial management process	Uses designated financial management tools	Integrates financial management tools for a laboratory program	Optimizes the financial management system for the laboratory	Oversees the policies, processes, and procedures related to financial management and fiduciary responsibility
MLD 3.05. Resource management	Uses workplace resources efficiently	Optimizes use of laboratory program resources	Manages resources for the laboratory	Oversees the policies, processes, and procedures related to resource management
MLD 4.00. Human resource management: ensures effective management of human resources				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 4.01. Human resource policies	Complies with human resource rules and requirements*	Enforces human resource requirements and policies	Manages human resource requirements and policies	Oversees the policies, processes, and procedures related to the human resource system
MLD 4.02. Equal Employment Opportunity (EEO)* process	Describes the EEO process	Promotes EEO requirements and policies	Manages EEO requirements and policies	Oversees the policies, processes, and procedures related to EEO in the human resource system
MLD 4.03. Position descriptions	Provides input into job description content	Evaluates position descriptions for congruency with job functions	Manages the development and implementation processes for position descriptions	Oversees a system of position description development and implementation to maximize staff competence and meet operational requirements
MLD 4.04. Staff licensure*	Describes the basic education, skills and certifications* for laboratory staff licensure requirements	Maintains a process to ensure that staff meet licensure requirements	Performs ongoing gap analysis to address staff licensure requirements	Ensures staff compliance with licensure laws and regulations
MLD 4.05. Competency assessment	Participates in competency assessments	Manages the competency assessment program	Evaluates the competency assessment program	Ensures that staff competence levels are commensurate with job functions
MLD 4.06. Performance feedback	Participates in communications with peers and supervisors regarding performance	Integrates performance feedback into work routines	Monitors staff progress on agreed-upon performance parameters	Ensures that a system is in place that values honest and open communication about performance
MLD 4.07. Performance appraisal process	Describes how the formal performance appraisal process impacts laboratory operations	Administers performance appraisals	Evaluates effectiveness of the performance appraisal process in improving laboratory productivity and practice	Oversees the continuous improvement of the performance management system
MLD 4.08. Conflict resolution	Identifies the need for management intervention in conflict resolution	Resolves conflicts in a fair and equitable manner	Integrates mechanisms to support cooperation and manage conflict across the laboratory	Oversees the policies, processes, and procedures to ensure the fair and equitable resolution of conflicts

See table footnotes on page 19.

TABLE 3. (Continued) Public health laboratory competency guidelines: Management and Leadership domain

MLD 4.00. Human resource management: ensures effective management of human resources				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 4.09. Progressive discipline	Describes the steps of the progressive discipline process	Administers progressive discipline	Analyzes the use of progressive discipline within the laboratory	Ensures that the progressive discipline system is used to mitigate disciplinary issues
MLD 4.10. Professional development	Participates in professional development activities	Recommends professional development activities	Assesses professional development gaps to ensure and support staff competency development	Oversees the policies, processes, and procedures to encourage and address professional development
MLD 4.11. Staff advancement	Explains the policies and procedures related to staff advancement	Recommends staff for advancement	Develops criteria for staff advancement	Ensures that staff function in roles commensurate with experience, skill set, and proficiency
MLD 4.12. Succession planning	Recognizes the importance of succession planning	Implements staff development plans that align with the laboratory's succession plan	Develops succession plans that consider current and future needs	Oversees the policies, processes, and procedures related to the creation and implementation of succession plans
MLD 5.00. Leadership: models leadership behavior				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 5.01. Ethical practices* and professional code of conduct	Applies ethical principles and a professional code of conduct to the workplace	Serves as a role model of ethical and professional behavior by consistently conforming to the highest standards and practices	Ensures staff compliance with the policies and procedures related to ethical practices and a professional code of conduct	Fosters the policies, processes, and procedures related to ethical practices and a professional code of conduct
MLD 5.02. Communication	Employs active communication skills	Communicates information and feedback to colleagues and management staff	Ensures the open and frequent exchange of communication between laboratory staff	Fosters a culture of open and frequent communication
MLD 5.03. Teamwork and collaboration	Describes the value of collaboration in the workplace	Collaborates with team members within a laboratory program	Leads cross-functional teams to accomplish projects	Creates a workplace environment that encourages teamwork and collaboration
MLD 5.04. Diversity* culture	Explains the value of having a diverse workforce	Promotes a diverse workforce	Develops programs that support a culture of diversity	Fosters a culture where diversity is valued
MLD 5.05. Staff engagement*	Participates in activities to support the laboratory's goals	Implements activities that support staff engagement	Develops programs that support a culture of staff engagement	Fosters a culture of staff engagement and commitment
MLD 5.06. Staff recognition	Participates in staff recognition programs	Evaluates the effectiveness of staff recognition programs	Develops staff recognition programs	Fosters a culture that ensures staff recognition
MLD 5.07. Coaching* and mentoring*	Describes the benefits of coaching and mentoring	Develops a pool of potential coaches and mentors for staff	Establishes coaching and mentoring programs	Fosters a culture where coaching and mentoring are deeply-rooted
MLD 5.08. Critical thinking*	Develops basic critical thinking skills	Applies critical thinking to develop effective solutions to problems	Leads critical thinking activities to achieve improvements in laboratory processes	Fosters an environment that integrates critical thinking

See table footnotes on page 19.

TABLE 3. (Continued) Public health laboratory competency guidelines: Management and Leadership domain

MLD 5.00. Leadership: models leadership behavior				
Subcompetency	Beginner	Competent	Proficient	Expert
MLD 5.09. Systems thinking*	Describes systems thinking	Applies systems thinking when approaching projects and problem solving	Incorporates systems thinking into directing laboratory operations	Fosters an environment that integrates systems thinking
MLD 5.10. Strategic thinking*	Describes strategic thinking	Provides input into strategic thinking and decision-making processes	Integrates strategic thinking into decisions and long-term planning regarding laboratory operations	Fosters an environment that integrates strategic thinking
MLD 5.11. Change management*	Describes the value of change	Implements change management initiatives within a laboratory program	Leads the development of change management initiatives with the laboratory	Fosters a culture that continuously assesses change opportunities for sustaining the mission
MLD 5.12. Advocacy	Educates external stakeholders on the mission, vision, and activities of the laboratory	Collaborates with external stakeholders	Identifies gaps in engagement with external stakeholders to support the activities of the laboratory	Develops strategies to engage external stakeholders to accomplish the mission, vision, and activities of the laboratory
MLD 5.13. External policy development	Describes impacts of external policies related to the organization's mission	Communicates with stakeholders to exchange policy input	Promotes external policy development to support the organization's mission and vision	Fosters relationships with strategic partners to secure laboratory-inclusive policies consistent with the organization's mission and vision
MLD 5.14. Promotion of the health of populations	Recognizes the need for partnerships to promote the health of populations	Identifies potential partnerships to promote the health of populations	Facilitates participation of key stakeholders to promote the health of populations	Fosters partnerships with key stakeholders to promote the health of populations affected by laboratory services

* This term is defined in Appendix B.

Communication Competency Guidelines

Purpose statement: The competencies in Communication address the knowledge, skills, and abilities necessary to disseminate information in a clear and concise manner appropriate to a given audience (Table 4). Communication might occur in writing, orally, or nonverbally, and it might take place in person or through electronic means.

Introduction: Communication is the application of written, verbal, and nonverbal methods and resources, either in person or through available technologies, to convey information. Although transmission of information is critical, assurance the information is accurate, clear, tailored to the audience, and prepared with linguistic aptitude and cultural sensitivity is equally important.

Effective internal and external communication is necessary for the optimal operation of the public health laboratory. Internal communication between staff is essential to satisfy the organization's goals and quality management system. External communication is necessary to disseminate public health information and to highlight the importance of laboratory contributions in support of public health. Public health laboratories are often called upon to convey the mission, operational features, and test services (the "why," "how," and "what") of their laboratory. These tasks involve engaging traditional and nontraditional partners and are critical to ensuring continued interest and support of the public health laboratory system.

Notes: Multiple sources were identified as support documents for this domain (14,15,48,49). Communication skills are pervasive throughout other domains, including skills such as writing and instructing. Communicating or reporting test orders and results are not covered here but in the General Laboratory Practice, Chemistry, and Microbiology domains.

TABLE 4. Public health laboratory competency guidelines: Communication domain

COM 1.00 Communication techniques: deploys formal written and oral communication strategies				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 1.01. Written communication	Identifies key messages for written communication	Applies logical structure* to written communications	Incorporates tools to organize and present detailed or complex information*	Establishes content, style, tone, and form for written messages according to target audience
COM 1.02. Oral communication	Identifies key messages for oral communication	Applies language and tone in oral communications tailored to target audience	Selects communication methods* tailored to target audience	Establishes content, style, tone, and form for oral messages tailored to target audience
COM 2.00. Active listening* skills: displays active listening skills when interacting with others				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 2.01. Dialogue exchange	Provides undivided attention to the other participants in a dialogue	Summarizes the dialogue to show understanding	Provides feedback based on the dialogue summary	Facilitates dialogue exchange through paraphrasing and clarification of critical points
COM 2.02. Contextual clues	Exhibits open posture and facial expression to engage the other participants in a dialogue	Applies range of body language cues to enhance the exchange	Exhibits active listening during the dialogue exchange	Incorporates multiple behaviors of engagement during dialogue exchanges
COM 2.03. Respectful exchange	Defers judgment during dialogue exchanges	Provides counterpoints while being respectful of disagreements	Coaches others in techniques of respectful exchange	Facilitates respectful dialogue among participants in the exchange

See table footnotes on page 22.

TABLE 4. (Continued) Public health laboratory competency guidelines: Communication domain

COM 3.00. Comprehension of materials: demonstrates comprehension of written documents* and directions				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 3.01. Reading comprehension	Follows written directions	Applies knowledge acquired from written text to situations	Adapts concepts from written text for use in new situations	Extrapolates information from written text to develop new ideas that enhance work processes*
COM 4.00. Communication technology:* utilizes technology to communicate information to internal and external partners				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 4.01. Technology capability	Describes the laboratory's and partner's technological capabilities	Selects laboratory's technology options to align with partner's capabilities	Evaluates existing and potential technology to align with partner's capabilities	Establishes technology policies* that integrate with the partner's capabilities
COM 4.02. Use of technology	Describes employer's policies and procedures* for sharing information	Uses designated technology for sharing information	Manages technology policies and procedures used for sharing information	Evaluates the effectiveness of the technology used for sharing information
COM 5.00. Communication professionalism: ensures professionalism in communication with customers* and stakeholders				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 5.01. Professional attitude	Uses tone of voice and language tailored to interactions with customers and stakeholders	Displays professional demeanor in all situations with customers and stakeholders	Monitors interactions with customers and stakeholders to ensure they are conducted professionally	Establishes policies for professional customer and stakeholder interactions
COM 5.02. Information exchange	Provides information based on policies and procedures to meet the needs of customers and stakeholders	Determines information needs through collaboration with customers and stakeholders	Ensures that information exchange policies, processes, and procedures are followed to meet the needs of the customers and stakeholders	Develops overarching system for exchange of information to meet the needs of customers and stakeholders
COM 5.03. Information sharing opportunities	Shares information as directed	Selects information to share	Develops information to share	Creates opportunities for sharing information
COM 6.00. Professional reports: prepares professional written reports and oral presentations				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 6.01. Written reports	Organizes information for written reports	Creates drafts of written reports	Revises written reports	Establishes policies, processes, and procedures for written reports
COM 6.02. Oral presentations	Organizes information for oral presentations	Creates drafts of oral presentations	Revises oral presentations	Establishes policies, processes, and procedures for oral presentations
COM 7.00. Risk communication:* applies emergency and risk communication principles and techniques to explain information to targeted audiences				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 7.01. Risk communication plan	Describes the risk communication process	Adheres to the risk communication plan	Ensures staff compliance with the risk communication plan	Establishes policies, processes, and procedures related to the risk communication plan

See table footnotes on page 22.

TABLE 4. (Continued) Public health laboratory competency guidelines: Communication domain

COM 7.00. Risk communication:* applies emergency and risk communication principles and techniques to explain information to targeted audiences				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 7.02. Emergency information	Lists basic emergency information for target audience	Identifies specific emergency information for target audience	Develops emergency information and messages tailored to target audience	Collaborates with agency leaders and partners to deliver emergency information and messages tailored to target audience
COM 7.03. Empathetic risk communication	Describes empathetic risk communication concepts	Delivers empathetic messaging in high-risk situations or emergencies	Creates empathetic messaging in high-risk situations and emergencies	Evaluates empathetic messaging for high-risk situations and emergencies
COM 8.00. Public health laboratory value: promotes the value of the public health laboratory				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 8.01. Public relations	Describes impact of the work of the public health laboratory and system	Coordinates opportunities for promoting the public health laboratory and system	Identifies opportunities to promote the public health laboratory and system	Develops opportunities to promote the public health laboratory and system
COM 8.02. Communication to educate and inform	Supports the development and distribution of communication materials about the public health laboratory	Presents communication materials to explain the importance of the public health laboratory	Develops communication materials to explain the importance of the public health laboratory	Manages the policies, processes, and procedures regarding communication materials to explain the importance of the public health laboratory
COM 8.03. Storytelling	Shares approved public health laboratory stories	Incorporates use of stories when communicating the impact of public health laboratory work	Develops stories that convey information highlighting the impact of public health laboratory work	Evaluates the impact of storytelling in promoting the public health laboratory
COM 8.04. Marketing strategy	Participates in marketing strategies	Implements the marketing strategy for the public health laboratory	Manages the marketing strategy for the public health laboratory	Oversees the marketing strategy for the public health laboratory
COM 9.00. Media relations: works with the media to provide information about public health laboratories and public health issues				
Subcompetency	Beginner	Competent	Proficient	Expert
COM 9.01. Media relations policies and strategies	Adheres to agency media relations policies and procedures	Identifies situations where agency media relations policies and strategies apply	Monitors the application of agency media relations policies and strategies	Oversees media relations policies and strategies
COM 9.02. "Plain talk"*	Describes the value of using "plain talk"	Applies "plain talk" during public and media interactions	Develops "plain talk" language for media and public communications	Translates highly technical concepts using "plain talk" for media and public communications
COM 9.03. Key messages	Describes the value of using key messages	Applies key messages during public and media interactions	Develops key messages for media and public communications	Oversees delivery of key messages on complicated, high-risk topics

* This term is defined in Appendix B.

Security Competency Guidelines

Purpose statement: The competencies in Security address the knowledge, skills, and abilities necessary to ensure a secure, protected working environment that meets or exceeds applicable regulatory requirements and guidelines (Table 5).

Introduction: Security is a compilation of elements that include physical, operational, information, and staff protection with the intent to safeguard personnel and to protect assets and data from unauthorized access, misuse, loss and/or theft. This is accomplished through the implementation of a comprehensive security management system, founded on accepted practices,

that ensures that operations are carried out in an environment that is secure and protected at all times. Each person must consistently carry out their responsibilities to ensure the effective application of security practices.

To meet its mission, the public health laboratory must ensure the security of the environment, infrastructure, staff, and of the samples and sensitive information with which it is entrusted. Thus, the knowledge, skills, and abilities included in this domain must be integrated into all technical and nontechnical aspects of staff members' job performances.

Note: Multiple sources were identified as support documents for this domain (50–52).

TABLE 5. Public health laboratory competency guidelines: Security domain

SEC 1.00. Risk mitigation: ensures that the laboratory's risk mitigation plan* meets organizational goals, regulatory requirements,* and established standards				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 1.01. Security concepts*	Describes security concepts	Applies security concepts in support of organizational goals	Interprets security concepts to adapt policies* and procedures* to support organizational goals	Develops security policies, processes,* and procedures, including security standards
SEC 1.02. Risk assessment†	Describes the risk assessment process and procedures	Identifies assets,* vulnerabilities, and potential threats for incorporation into risk analyses	Manages the risk assessment process	Develops policies, processes, and procedures regarding risk assessment
SEC 1.03. Risk mitigation plans	Describes the policies and procedures regarding risk mitigation plans	Applies risk mitigation plans	Manages the implementation of risk mitigation plans	Develops policies, processes, and procedures regarding risk mitigation planning and implementation
SEC 1.04. Risk mitigation plan reporting	Describes policies, processes, and procedures for risk mitigation plan reporting	Implements processes and procedures for risk mitigation plan reporting	Develops procedures based on established processes for risk mitigation plan reporting	Develops policies, processes, and procedures for risk mitigation plan reporting
SEC 2.00. Security plan:* ensures that the laboratory's security plan meets organizational goals, regulatory requirements, and established standards				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 2.01. Security plans	Recognizes security risks documented in the security plan	Recommends elements to be included in the security plan to address risks	Designs laboratory's security plan in collaboration with subject matter experts	Advises organizational leadership on the security plan, including acceptability of identified risks
SEC 2.02. Security plan implementation	Describes security plan elements applicable to job	Implements the security plan	Evaluates the objectives and functions of the security system	Advises organizational leadership on selecting security strategies to protect assets and on monitoring the performance of the security plan

See table footnotes on page 25.

TABLE 5. (Continued) Public health laboratory competency guidelines: Security domain

SEC 2.00. Security plan:* ensures that the laboratory's security plan meets organizational goals, regulatory requirements, and established standards				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 2.03. Security operations	Describes the policies, processes, and procedures for maintaining security	Monitors security operations	Manages security operations to ensure defined protection measures are based on the degree of risk	Oversees security operations
SEC 2.04. Inventory records* related to security plans	Completes inventory records to comply with the laboratory's security plan	Audits inventory records	Creates tools to manage inventory records	Develops policies, processes, and procedures to manage inventory records
SEC 2.05. Security incident* response	Reports security incidents	Evaluates reported security incidents	Implements processes and procedures related to security incident response and reporting	Develops policies, processes, and procedures for security incident response and reporting
SEC 3.00. Physical security: ensures that physical security is maintained				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 3.01. Physical security infrastructure*	Describes the physical security infrastructure	Trains staff on policies, processes, procedures, and related regulations regarding physical security infrastructure	Solves difficult and complex physical security problems	Directs the resolution of major conflicts in physical security policy and program objectives
SEC 3.02. Physical security access controls*	Describes physical security access control policies, processes, procedures, and systems	Applies physical security access control procedures and systems	Manages the implementation of physical security access control policies, processes, procedures, and systems	Advises organizational authorities on methods for enhancing effectiveness and efficiency of physical security access control policies, processes, procedures, and systems
SEC 4.00. Personnel security program:* implements a personnel security program to meet organizational goals, regulatory requirements, and established standards				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 4.01. Personnel security concepts*	Describes personnel security concepts	Addresses problems or questions involving personnel security concepts	Interprets personnel security concepts to adapt processes and procedures to support organizational goals	Develops policies, processes, and procedures that incorporate personnel security concepts into personnel security program
SEC 4.02. Personnel security program	Complies with the laboratory's personnel security program	Implements the personnel security program	Solves difficult and complex personnel security problems	Directs the resolution of major conflicts in personnel security policy and program objectives
SEC 4.03. Investigations	Collects information* for personnel security investigations	Analyses actions regarding personnel security matters requiring investigation	Determines actions to be taken on personnel security investigations	Develops policies, processes, and procedures related to personnel security investigations

See table footnotes on page 25.

TABLE 5. (Continued) Public health laboratory competency guidelines: Security domain

SEC 5.00. Information security:* ensures that information security meets organizational goals, regulatory requirements, and established standards				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 5.01. Information security	Describes policies, processes, and procedures related to information security	Applies information security concepts, including principles of confidentiality, integrity, and availability (CIA)*	Interprets information security concepts to adapt policies, processes, and procedures to support organizational goals	Develops policies, processes, procedures, and organizational standards for information security to meet organizational goals
SEC 5.02. Risk identification and prioritization	Describes the risks associated with the laboratory's sensitive information* or technology related to the job being performed	Identifies risks associated with the laboratory's sensitive information and technology, including the methods of control	Implements processes and procedures for prioritizing risks associated with the laboratory's sensitive information and technology, including the methods of control	Develops policies, processes, and procedures for identifying, prioritizing, and controlling sensitive information and technology
SEC 6.00. Transportation security program: implements a transportation security plan*				
Subcompetency	Beginner	Competent	Proficient	Expert
SEC 6.01. Transport security	Complies with transport security policies, processes, and procedures	Audits transport records	Creates transport security procedures	Establishes policies and processes to specify which materials need designated levels of transport security

* This term is defined in Appendix B.

† The process of identifying risks to organizational assets (including staff) and operations (including mission, functions, image, and reputation); includes threat and vulnerability analyses and is the fundamental tool to help select the right risk mitigation measures (e.g., engineered controls, standard policies and procedures) to achieve an acceptable level of security.

Emergency Management and Response Competency Guidelines

Purpose statement: The competencies in Emergency Management and Response address the knowledge, skills, and abilities needed to mitigate, prepare for, respond to, and recover from laboratory-specific emergency events and situations (Table 6).

Introduction: Emergency Management and Response is a four-phase process involving mitigation, preparedness, response, and recovery for emergency events and situations that have a direct impact on laboratory operations and surge testing. This domain recognizes the public health laboratory's mandate to provide emergency response support to external partners. Emergency management and response encompasses events such as natural disasters or public health emergencies, facility or operation failures, in addition to the public health

responsibility to detect and respond to real or potential biological, chemical, or radiological threats.

Public health laboratory staff members are responsible for the recognition, response, and management of emergency events and situations directly impacting laboratory operations and surge testing. Staff members provide outreach, training, and communication with the sentinel clinical laboratories, first responders, and other stakeholders as a critical role in jurisdiction-wide emergency management and response.

Notes: Multiple sources were identified as support documents for this domain (21,26,51,53–57). This domain is intended to be used in conjunction with the Safety and Communication domains and is based on the Federal Emergency Management Agency's (FEMA) mission areas for national preparedness (55). Critical activities in each phase frequently overlap. This domain does not address accidents, spills, or other similar occurrences within the laboratory, which are included in the Safety domain.

TABLE 6. Public health laboratory competency guidelines: Emergency Management and Response domain

EMR 1.00. Mitigation of emergency events: mitigates emergency events

Subcompetency	Beginner	Competent	Proficient	Expert
EMR 1.01. Risk assessment*	Recognizes potential vulnerabilities and risks in their work area	Assesses potential vulnerabilities and risks in the organization	Develops the plan to reduce and ensure against risks in the organization	Manages the policies [†] , processes [†] , and procedures [†] to reduce and ensure against risks in the organization
EMR 1.02. Incident response plan [†]	Describes the incident response plan	Implements the incident response plan while maintaining safety and security of staff and facilities	Verifies staff compliance with the incident response plan while ensuring the safety and security of staff and facilities	Manages facility-wide implementation of the incident response plan
EMR 1.03. Emergency situation recognition	Recognizes emergencies and other incidents [†] in their work area that should be reported	Recognizes emergencies and other incidents in the organization that should be reported	Evaluates staff's ability to recognize emergencies and other incidents that should be reported	Creates an environment that supports the recognition and reporting of emergencies
EMR 1.04. Emergency alarms [†]	Recognizes significance of alarms	Instructs others on the significance of alarms	Evaluates staff's knowledge of alarm significance	Collaborates with persons and agencies to develop site-specific or unique alarm systems
EMR 1.05. Laboratory assets [†] important during an emergency	Describes the assets in their work area	Inventories the assets in the facility	Identifies the assets in the facility	Manages the assets in the facility
EMR 1.06. Evaluation of emergency events	Summarizes the emergency evaluation process	Assesses emergencies to determine the extent of each incident	Interprets data from evaluation of emergencies to develop specific response to each incident	Shares findings of the evaluation of, and responses to, emergency events with stakeholders to enhance mitigation

See table footnotes on page 28.

TABLE 6. (Continued) Public health laboratory competency guidelines: Emergency Management and Response domain

EMR 2.00. Preparation for emergency events: prepares for emergency events				
Subcompetency	Beginner	Competent	Proficient	Expert
EMR 2.01. Preparation for emergency events	Explains the laboratory's emergency response plan [†] and Continuity of Operations Plan (COOP) [†]	Assists with development and implementation of the laboratory's emergency response plan and COOP	Manages development and implementation of the emergency response plan and COOP for an individual area of responsibility	Oversees laboratory's emergency response plan, including implementation of the COOP with external partners
EMR 2.02. Incident command system (ICS) [†]	Demonstrates awareness of the ICS by completing a FEMA-approved introductory course	Completes higher-level FEMA-approved courses to explain the operation and management of the ICS	Implements the ICS by completing high-level FEMA-approved courses and internal training courses and exercises	Serves at a leadership level in the ICS
EMR 2.03. Emergency response training	Participates in emergency response training, exercises, and drills	Contributes to the development of emergency response training, exercises, and drills	Conducts emergency response training, exercises, and drills in collaboration with stakeholder agencies	Oversees the collaboration with stakeholder agencies to sponsor and conduct training, exercises, and drills, ensuring proper resources are available
EMR 2.04. Emergency notification	Describes requirements [†] for notification of emergencies and other incidents according to organizational plans and policies	Implements organizational plans and policies for notification of emergencies and other incidents	Develops internal policies and procedures for notification of emergencies and other incidents	Oversees the collaboration with stakeholders and agencies to develop and implement plans and policies for notification of emergencies and other incidents
EMR 2.05. Identification of key partners	Describe partners and their relationships with the institution	Interacts with partners on staff	Engages partners to sustain relationships and ensure effective response	Develops new partnerships to ensure effective emergency response
EMR 2.06. Execution of agreements	Describes emergency agreements between the institution and other partners	Updates agreements with partners to ensure emergency response capability	Trains staff on agreements in place to ensure emergency response capability	Negotiates agreements between partner organizations to ensure emergency response capability
EMR 2.07. Emergency preparedness and response networks [†]	Explains how the laboratory interacts with emergency preparedness and response networks	Describes the plans, policies and procedures the institution has in place to prepare for and respond to a public health emergency	Develops the organizational plans, policies and procedures to prepare for and respond to a public health emergency	Oversees the collaboration with emergency preparedness and response networks to develop and implement plans, policies, and procedures to prepare for and respond to a public health emergency
EMR 3.00. Responding to emergency events: responds to emergency events				
Subcompetency	Beginner	Competent	Proficient	Expert
EMR 3.01. Situational briefing	Participates in meetings and conference calls to receive information [†] on the situation	Prepares information on the situation	Facilitates the briefing of key stakeholders to create situational awareness	Manages implementation of COOP measures and ICS activation
EMR 3.02. ICS activation	Performs position responsibilities as assigned	Produces information and documentation for briefings	Confirms staff are available with proper qualifications and capabilities	Establishes organization's ICS structure, reporting procedures, and chain of command
EMR 3.03. Emergency evacuation	Locates emergency evacuation routes and assembly areas	Uses emergency evacuation routes and assembly areas	Instructs staff during evacuation	Manages emergency evacuation and assembly

See table footnotes on page 28.

TABLE 6. (Continued) Public health laboratory competency guidelines: Emergency Management and Response domain

EMR 3.00. Responding to emergency events: responds to emergency events				
Subcompetency	Beginner	Competent	Proficient	Expert
EMR 3.04. Hazardous spill [†] response	Recognizes hazardous spills or potential exposures	Complies with procedures for responding to hazardous spills or potential exposures	Instructs staff on proper response to hazardous spills or potential exposures	Manages response to hazardous spills or potential exposures
EMR 3.05. Emergency decontamination [†]	Describes emergency decontamination and exposure prevention [†] policies and procedures	Complies with emergency decontamination and exposure prevention policies and procedures	Instructs staff on policies, processes, and procedures for emergency decontamination and exposure prevention	Manages emergency decontamination and exposure prevention policies, processes, and procedures
EMR 3.06. Surge capacity	Describes circumstances for, and varying degrees of surge	Adjusts workflow [§] to ensure timeliness of diagnostic testing in collaboration with surge partners	Identifies creative strategies to manage surge or overflow testing	Implements a management system that promotes flexibility and maximizes the ability to deliver surge capacity
EMR 3.07. Emergency communication plan [†]	Describes the emergency communication plan and the policies and procedures for receiving and disseminating information with emergency response partners and/or public	Complies with the emergency communication plan and the policies and procedures for receiving and disseminating information with emergency response partners and/or public	Ensures rapid and secure communications with emergency response partners and/or public during emergencies and surge incidents	Manages the emergency communication plan and the policies, processes, and procedures for securely receiving and disseminating information with emergency response partners and the public during emergencies and surge incidents
EMR 4.00. Recovering from emergency events: recovers from emergency events				
Subcompetency	Beginner	Competent	Proficient	Expert
EMR 4.01. Short-term recovery	Follows established plans to resume normal operations after an emergency event	Implements plans to resume normal operations after an emergency event	Determines whether staff and facilities are able to return to normal operations after an emergency event	Manages re-opening and/or continuation of routine services
EMR 4.02. After Action Review (AAR) [†]	Describes the AAR process	Participates in AAR process	Assists with developing the final AAR	Oversees the AAR process
EMR 4.03. Long-term recovery	Lists improvements to laboratory plans based on the AAR	Identifies improvements to laboratory plans and operations based on the AAR	Implements improvements to laboratory plans and operations based on the AAR	Develops recommendations to improve laboratory plans and operations based on the AAR along with internal and external partners and stakeholders
EMR 4.04. Financial considerations	Lists costs relative to response and recovery activities	Explains costs relative to response and recovery activities	Determines financial and staff resources required to facilitate laboratory's response and recovery	Verifies financial and staff resources are in place to facilitate laboratory's response and recovery
EMR 4.05. Legal and regulatory issues	Describes legal and regulatory requirements for managing emergency events	Implements legal and regulatory requirements for managing emergency events	Assesses staff compliance with legal and regulatory requirements related to the managing of emergency events	Oversees staff compliance with legal and regulatory requirements related to the managing of emergency events

* The process of identifying risks to organizational assets (including staff) and operations (including mission, functions, image, and reputation); includes threat and vulnerability analyses and is the fundamental tool to help select the right risk mitigation measures (e.g., engineered controls, standard policies and procedures) to achieve an acceptable level of security.

[†] This term is defined in Appendix B.

[§] Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Workforce Training Competency Guidelines

Purpose statement: The competencies in Workforce Training address the knowledge, skills, and abilities needed to train public health laboratory professionals (Table 7). This includes the design, development, implementation, and evaluation of all types of training.

Introduction: Workforce Training is a process that uses principles of adult learning and instructional design to develop, manage, deliver, and evaluate internal and outreach education and training activities. Although training services and resources can be accessed externally, management should also support internal activities to ensure staff members possess the skills and

knowledge to carry out their responsibilities in all aspects of their job performance. This domain provides guidance to staff members on subject matter expertise and project management for the development and delivery of training.

As persons are an organization's most valuable asset, having well-trained staff members at all functional levels improves organizational performance and ensures the success of the laboratory in providing services to address public health concerns.

Notes: Sources were identified as support documents for this domain (36,58). This domain is intended for the general laboratory scientist and not solely for education or training specialists or subject matter experts. The competencies apply to all types of training modalities.

TABLE 7. Public health laboratory competency guidelines: Workforce Training domain

WFT 1.00. Content: gathers training content				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 1.01. Needs assessment*	Supports needs assessment activities	Conducts needs assessments	Develops needs assessment tools	Prioritizes training needs based on needs assessments
WFT 1.02. Adult learning methodologies	Explains adult learning methodologies	Selects principles and methodologies which underpin adult learning	Integrates principles of adult learning for use in designing training	Ensures that adult learning principles are applied in designing training
WFT 1.03. Subject matter expertise	Employs subject matter knowledge in order to train entry-level staff	Implements established science and technology content	Develops emerging science and technology content	Collaborates with national and international scientific communities to create new knowledge on subject matters
WFT 1.04. Training topics	Researches emerging training topics	Implements training for emerging training topics	Designs training for emerging training topics	Identifies emerging training topics with national and international scientific communities
WFT 1.05. Incorporation of subject matter expertise into training activities	Explains requirements* for the use of subject matter experts	Collaborates with subject matter experts to gather content	Develops new processes* to capture subject matter expertise	Identifies emerging processes to capture subject matter expertise
WFT 2.00. Training design: designs training				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 2.01. Instructional design*	Explains instructional design principles	Recognizes the instructional design principles in existing training activities	Applies instructional design principles to develop a new training activity	Evaluates instructional design and training modalities* throughout the entire menu of training for the organization
WFT 2.02. Learning objectives	Explains learning objective concepts and training activities	Develops training activities around existing learning objectives	Creates learning objectives for new training activities	Evaluates whether learning objectives were written following industry guidelines
WFT 2.03. Training modalities	Identifies different types of training modalities	Implements the modality for training	Selects the modality for the training	Provides vision and guidance for training modalities

See table footnotes on page 31.

TABLE 7. (Continued) Public health laboratory competency guidelines: Workforce Training domain

WFT 2.00. Training design: designs training				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 2.04. Cultural awareness	Explains cultural awareness and its importance as it relates to developing training activities	Applies cultural awareness principles when designing training activities	Evaluates the incorporation of cultural awareness principles into training activities	Ensures incorporation of cultural awareness principles into training activities
WFT 2.05. Instructional materials preparation	Assembles instructional materials	Prepares instructional materials for existing programs	Develops instructional materials for new programs that are aligned with the type of training activity and modality	Incorporates industry-wide instructional materials into the training program
WFT 2.06. Training materials application	Uses pre-existing training materials to design simple training	Integrates multiple types of training materials into training design	Develops training materials from industry resources	Evaluates training materials from industry resources
WFT 2.07. Training exercises	Delivers exercises within a training session	Integrates individual training lessons, including experiential exercises	Evaluates training exercises	Designs integrated training exercises with partners
WFT 2.08. Formative assessment*	Explains formative assessment	Employs formative assessments	Creates formative assessments	Evaluates effectiveness of formative assessments
WFT 2.09. Continuing education	Explains the requirements of the continuing education provider	Follows continuing education provider requirements when conducting training	Selects continuing education provider for new learning activities	Oversees the continuing education provider process
WFT 3.00. Delivery set-up: manages the logistics of set-up for training delivery				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 3.01. Equipment preparation for training delivery	Operates equipment needed to deliver training	Troubleshoots training equipment	Ensures that equipment capability aligns with the training requirements	Oversees processes for upgrading training equipment
WFT 3.02. eLearning*	Tests eLearning courses	Creates supporting materials or content for storyboards	Develops storyboards for new courses using subject matter expert materials	Ensures that eLearning delivery systems are available
WFT 3.03. Learning environment*	Provides support for learning environment processes	Manages processes of the learning environment	Develops processes to manage the learning environment	Oversees the processes for the learning environment
WFT 4.00. Training delivery: applies principles of learning to training implementation and delivery				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 4.01. Learning preferences and styles	Explains presentation materials for different learning preferences and styles	Differentiates presentation materials to address learning preferences and styles	Develops presentation materials to address learning preferences and styles	Creates strategies to address learning preferences and styles
WFT 4.02. Presentation engagement	Explains the most effective presentation tools and techniques	Uses the most effective presentation tools and techniques	Ensures implementation of the most effective presentation tools and techniques	Oversees presentation engagement strategies

See table footnotes on page 31.

TABLE 7. (Continued) Public health laboratory competency guidelines: Workforce Training domain

WFT 5.00. Training evaluation: evaluates learner knowledge and skill development				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 5.01. Training evaluation process*	Lists the steps the organization undertakes for training program evaluation	Carries out the evaluation steps for standard training evaluations for routine courses	Develops training evaluation tools* for a new activity	Oversees the evaluation of the training process for the organization
WFT 5.02. Delivery of the evaluation	Contributes to development of a training assessment rubric* to ensure training outcomes are met	Implements the training assessment rubric to ensure training outcomes are met	Creates a training assessment rubric to ensure training outcomes are met	Evaluates the training assessment rubric to ensure training outcomes are met
WFT 5.03. Training reports*	Gathers data as directed for summative training reports	Compiles tracking data into summative training reports	Develops summative training reporting tools	Interprets summative data from reports for delivery to stakeholders
WFT 5.04. Training activity effectiveness	Shares training activity observations with supervisor	Assesses participants' achievement of training objectives	Recommends improvements based on evaluation data from training assessment tools	Implements improvements to the professional development activities of the laboratory
WFT 5.05. Continuous improvement of the training program	Participates in continuous improvement activities	Identifies activities leading to the continuous improvement of a training plan	Facilitates activities leading to the continuous improvement of a training plan	Develops a training program improvement plan based on program evaluation
WFT 6.00. Marketing: markets training opportunities				
Subcompetency	Beginner	Competent	Proficient	Expert
WFT 6.01. Marketing	Participates in the marketing of training	Composes content for marketing materials	Develops organizational marketing plan for training	Manages the training marketing plan

* This term is defined in Appendix B.

General Laboratory Practice Competency Guidelines

Purpose statement: The competencies in General Laboratory Practice address the knowledge, skills, and abilities needed to fulfill basic responsibilities for performing sample analyses within a public health laboratory setting (Table 8).

Introduction: General laboratory practice is the set of foundational knowledge and capabilities needed for the testing of samples across the wide spectrum of scientific and technical activities of public health laboratories. As these practices can be applied in many areas of analysis, they have been consolidated into this domain to minimize, but not eliminate, repetition across the specialized domains and to create a domain that covers testing not specifically encompassed by the Chemistry or Microbiology domains.

These broad practices are central to the performance of laboratory testing. Laboratory scientists, regardless of their specific area of scientific or technical expertise, rely on these skills to accomplish the array of testing in public health laboratories.

Notes: Sources were identified as support documents for this domain (59,60), which is intended for both general and specialized laboratory scientists. This domain is meant to be used in conjunction with specialized domains such as Microbiology, Chemistry, and Research since it includes technical practices not addressed in those domains. The verb “oversees” is used extensively in the Expert level. In this context, “oversees” is a broad term that comprises the many functions related to the management of policies, processes and procedures to include creation, design, development, directing, monitoring, evaluation, and collaboration.

TABLE 8. Public health laboratory competency guidelines: General Laboratory Practice domain

GEN 1.00. General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing

Subcompetency	Beginner	Competent	Proficient	Expert
GEN 1.01. General scientific and laboratory concepts and theories	Applies basic scientific and laboratory concepts and theories* related to the specific testing that is conducted in work area	Instructs others in concepts and theories related to the specific testing that is conducted in work area	Ensures that accepted concepts and theories are applied to laboratory testing	Oversees that laboratory practices are in accordance with accepted scientific and laboratory concepts and theories
GEN 1.02. Mathematical and statistical concepts and practices	Applies fundamental mathematical and statistical concepts and practices in work area	Instructs others in fundamental mathematical and statistical concepts and practices	Ensures appropriate utilization of mathematical and statistical concepts and practices	Oversees the policies,* processes,* and procedures* regarding the use of mathematical and statistical concepts and practices
GEN 1.03. Scientific and technological advances	Reads scientific and technical literature relevant to own work	Discusses scientific and technical advances relevant to own work	Integrates scientific and technical advances into laboratory operations	Critiques scientific and technological advances to evaluate possible impact for the laboratory
GEN 1.04. Technical skills	Applies basic laboratory techniques to laboratory testing	Integrates basic laboratory techniques into standard operating procedures* and new laboratory practices	Ensures that staff are properly trained in the performance of technical skills	Oversees the application of technical skills to laboratory practices
GEN 1.05. Troubleshooting	Identifies routine problems related to technical duties and responsibilities	Resolves routine technical problems with methods, procedures, and laboratory equipment,* including documenting corrective action	Resolves complex technical problems with methods, procedures, and laboratory equipment, including documenting corrective action	Oversees the policies, processes, and procedures related to troubleshooting technical problems
GEN 1.06. Model laboratory practices*	Applies knowledge of model laboratory practices	Instructs others in model laboratory practices	Implements model laboratory practices	Manages policies, processes, and procedures to ensure staff comply with model laboratory practices

See table footnotes on page 35.

TABLE 8. (Continued) Public health laboratory competency guidelines: General Laboratory Practice domain

GEN 1.00. General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing

Subcompetency	Beginner	Competent	Proficient	Expert
GEN 1.07. Documentation	Documents actions and results using established paper or electronic systems	Instructs others in use of paper or electronic methods or systems for documentation	Ensures utilization of established paper and electronic documentation methods or systems	Oversees the policies, processes, and procedures for the creation and use of paper and electronic methods or systems for documentation
GEN 1.08. Stewardship of resources	Acts as a good steward of public funds and resources	Identifies methods to improve stewardship of resources	Ensures that the use of public funds and resources meet the policies for stewardship	Oversees the policies, processes, and procedures to ensure the environment supports effective stewardship of resources
GEN 1.09. Scientific ethics*	Applies scientific ethics and rules of conduct to the workplace	Serves as a role model, consistently conforming to the highest scientific standards and practices	Ensures staff compliance with the policies and procedures related to scientific ethics and rules of conduct	Oversees the policies, processes, and procedures related to scientific ethics and rules of conduct

GEN 2.00. Reagent use and storage: adheres to policies and principles regarding the use and storage of laboratory reagents and supplies

Subcompetency	Beginner	Competent	Proficient	Expert
GEN 2.01. Use and storage of reagents and supplies	Adheres to policies, processes, and procedures for use and storage of reagents and supplies	Instructs staff in use and storage of reagents and supplies	Ensures staff compliance with policies, processes, and procedures for use and storage of reagents and supplies	Oversees the use and storage of reagents and supplies
GEN 2.02. Reagent preparation	Adheres to policies, processes, and procedures for preparing reagents	Instructs staff in preparing reagents	Ensures staff compliance with policies, processes, and procedures for reagent preparation	Oversees the policies, processes, and procedures for reagent preparation

GEN 3.00. Equipment use: adheres to policies and principles regarding the use, maintenance, and calibration of laboratory equipment

Subcompetency	Beginner	Competent	Proficient	Expert
GEN 3.01. Equipment operation	Adheres to policies, processes, and procedures for operating laboratory equipment	Instructs staff in the operation of laboratory equipment	Ensures staff compliance with policies, processes, and procedures for the operation of laboratory equipment	Oversees the policies, processes, and procedures for the operation of laboratory equipment
GEN 3.02. Equipment maintenance	Performs routine system checks and maintenance	Instructs staff in procedures to ensure equipment function	Determines need for repair or replacement of laboratory equipment	Oversees the policies, processes, and procedures for the maintenance, repair, and replacement of laboratory equipment
GEN 3.03. Instrument and equipment calibration	Performs calibration of routine instruments and equipment	Performs calibration of complex instruments and equipment	Develops processes and procedures for calibration of instruments and equipment	Oversees the policies, processes, and procedures for calibration of instruments and equipment
GEN 3.04. Preventive maintenance and calibration records*	Documents maintenance and calibration activities	Inspects preventive maintenance and calibrations records for completeness	Evaluates the preventive maintenance and calibration records	Oversees the preventive maintenance and calibration program

See table footnotes on page 35.

TABLE 8. (Continued) Public health laboratory competency guidelines: General Laboratory Practice domain

GEN 4.00. Pre-examination:* performs steps in the pre-examination phase of testing				
Subcompetency	Beginner	Competent	Proficient	Expert
GEN 4.01. Sample management*	Follows policies, processes, and procedures for the management of samples*	Instructs others in policies, processes, and procedures for sample management	Monitors staff compliance with established sample management policies, processes, and procedures	Oversees sample management policies, processes, and procedures
GEN 5.00. Examination:* performs steps in the examination phase of testing				
Subcompetency	Beginner	Competent	Proficient	Expert
GEN 5.01. Sample analyses	Performs sample analyses	Instructs staff in sample analyses	Ensures staff compliance with policies, processes, and procedures for sample analyses	Oversees the policies, processes, and procedures related to sample analyses
GEN 5.02. Testing workflow [†]	Adheres to policies, processes, and procedures for testing workflow	Instructs staff in policies, processes, and procedures regarding testing workflow	Ensures staff compliance in following established testing workflow	Oversees the policies, processes and procedures that optimize and improve testing workflow
GEN 5.03. Quality control (QC)* analysis	Performs QC activities	Interprets QC data prior to reporting results	Examines QC data over time to establish QC ranges and limits	Oversees the policies, processes, and procedures related to QC activities, including staff compliance
GEN 6.00. Postexamination:* performs steps in the postexamination phase of testing				
Subcompetency	Beginner	Competent	Proficient	Expert
GEN 6.01. QC evaluation	Assembles QC data for evaluation	Evaluates QC data for a given data reporting period	Ensures staff compliance with established policies, processes, and procedures for QC evaluation activities	Oversees the policies, processes, and procedures related to QC evaluation activities
GEN 6.02. Test analysis and results interpretation	Assembles test data for review and action	Analyzes test data	Interprets complex or ambiguous results	Oversees the policies, processes, procedures, and algorithms related to data analysis and results interpretation
GEN 6.03. Results reporting and data release	Adheres to policies, processes, and procedures related to reporting and release of examination results and notifiable results*	Instructs staff in the policies, processes, and procedures related to reporting and release of examination results and notifiable results	Ensures staff compliance with policies, processes, and procedures related to reporting and release of examination results and notifiable results	Oversees the policies, processes, and procedures related to reporting and release of examination results and notifiable results to partners
GEN 6.04. Turnaround time (TAT)	Performs laboratory testing and reporting within specified or expected TAT	Monitors TAT performance	Identifies process efficiencies to improve TAT	Oversees the policies, processes, and procedures related to TAT
GEN 6.05. Quality assurance (QA)*	Explains the differences between QA and QC	Collects data for reporting on QA indicators and processes	Evaluates QA indicator data	Oversees the policies, processes, and procedures related to QA

See table footnotes on page 35.

TABLE 8. (Continued) Public health laboratory competency guidelines: General Laboratory Practice domain

GEN 7.00. Regulatory compliance: complies with regulations and guidelines governing laboratory testing

Subcompetency	Beginner	Competent	Proficient	Expert
GEN 7.01. Regulatory compliance	Complies with regulatory requirements* and guidelines related to laboratory testing	Instructs staff on regulatory requirements and guidelines related to laboratory testing	Ensures staff compliance with regulatory requirements and guidelines related to laboratory testing	Oversees the policies, processes, and procedures regarding regulatory requirements and guidelines related to laboratory testing
GEN 7.02. Proficiency testing* (PT) and alternative assessment*	Performs PT and alternative assessment	Reviews PT and alternative assessment results	Monitors to ensure the PT and alternative assessment program meets regulatory requirements	Oversees the policies, processes, and procedures related to PT and alternative assessments
GEN 7.03. Proficiency testing (PT) and alternative assessment reporting	Reports PT and alternative assessment	Reviews submissions of PT and alternative assessment results	Ensures staff compliance with reporting of PT and alternative assessment results	Oversees the policies, processes, and procedures related to PT and alternative assessment reporting
GEN 7.04. Method validation* and performance verification*	Participates in performance of method validation and performance verification	Compiles results of method validation and performance verification	Evaluates method validation and performance verification results	Oversees the policies, processes, and procedures related to method validation and performance verification
GEN 7.05. Protected information*	Complies with policies, processes, and procedures regarding protected information	Instructs staff in policies, processes, and procedures regarding protected information	Ensures staff compliance with policies, processes, and procedures regarding protected information	Oversees that organizational policies, processes, and procedures related to protected information align with laws and regulatory requirements and guidelines

* This term is defined in Appendix B.

† Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Safety Competency Guidelines

Purpose statement: The competencies in Safety address the knowledge, skills, and abilities necessary to ensure a safe working environment that meets or exceeds applicable regulatory requirements and guidelines (Table 9).

This domain comprises five subdomains:

- Potential Hazards, which addresses the knowledge, skills, and abilities needed to recognize potential hazards within a given laboratory setting;
- Hazard Control, which addresses the knowledge, skills, and abilities needed to support and maintain a health and safety management system to control or prevent workplace hazards;
- Administrative Controls, which addresses the knowledge, skills, and abilities needed to develop a laboratory safety program that is compliant with regulatory, accreditation, and licensing requirements;
- Communication and Training, which addresses the knowledge, skills, and abilities needed to ensure staff members are informed of all safety hazards through effective communication and the provision of related education and training; and
- Documents and Records, which addresses the knowledge, skills, and abilities needed to document activities related to safety policies, processes, and procedures.

Introduction: Safety focuses on the occupational and personal safety of staff members and the environments in which they work. A culture of safety encourages reporting of

actual and potential situations which might place staff members and others at risk, openly assesses those risks, and implements redundant systems to keep risk to the absolute minimum. It is essential that leadership and management staff members ensure a comprehensive safety culture for those working in the public health laboratory.

A safety culture is fundamental to ensuring the protection of the laboratory facility, its staff, and the surrounding environment from hazards and risks related to laboratory operations and services. Safety is the background against which all staff members must perform all aspects of their job. A culture of safety recognizes that to err is human, and establishes procedures and processes to minimize errors and avoid harm. To be effective, all staff members are expected to be part of the culture of safety.

This domain is based on the 2011 "Guidelines for Biosafety Laboratory Competency" (26), with the content revised and restructured to fit within this comprehensive set of public health laboratory competencies. This domain supplements and expands upon the 2011 Guidelines. Some reformulation of concepts from the former "Midlevel" and "Senior level" tiers were introduced here to ensure a wider breadth of bench-level and managerial responsibilities. However, the 2011 Biosafety Laboratory Competencies include critical task-level details that could not be captured here due to the directives for competency development that were adopted. The 2011 Guidelines are, therefore, an important companion to this domain.

Note: Multiple sources were identified as support documents for this domain (26,51,52,61–74).

TABLE 9. Public health laboratory competency guidelines: Safety domain

Safety subdomain: potential hazards				
SPH 1.00. Physical environment: works safely in the physical environment of the laboratory facility*				
Subcompetency	Beginner	Competent	Proficient	Expert
SPH 1.01. Physical hazards* in the laboratory facility	Describes the physical hazards in the laboratory facility	Recognizes new physical hazards in the laboratory facility	Assesses staff knowledge of the physical hazards in the laboratory facility	Evaluates the laboratory facility for physical hazards
SPH 1.02. Control measures* to be used when physical hazards are present	Describes control measures to be used when physical hazards are present in the laboratory facility	Implements control measures to be used when physical hazards are present in the laboratory facility	Ensures staff knowledge of control measures to be used when physical hazards are present in the laboratory facility	Establishes the control measures to be used when physical hazards are present in the laboratory facility
SPH 1.03. Work practices* to be used when physical hazards are present	Describes work practices to be used when physical hazards are present in the laboratory facility	Implements work practices to be used when physical hazards are present in the laboratory facility	Ensures that staff implement the established work practices when physical hazards are present in the laboratory facility	Establishes the work practices to be used when physical hazards are present in the laboratory facility

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: potential hazards				
SPH 2.00. Biological materials:* works safely with biological materials in the laboratory				
Subcompetency	Beginner	Competent	Proficient	Expert
SPH 2.01. Biological materials used in the laboratory	Lists the biological materials in the laboratory	Distinguishes biohazardous materials* from nonbiohazardous materials in the laboratory	Manages the inventory of biological materials to ensure it is complete and updated	Establishes the policies* processes* and procedures* for implementing a biological materials inventory system
SPH 2.02. Hazards associated with the biological materials handled in the laboratory	Describes hazards associated with the biological materials handled in the laboratory	Recognizes hazards associated with new biological materials used in laboratory procedures	Assesses staff knowledge of the hazards associated with biological materials used in laboratory procedures	Ensures that staff are skilled in describing and recognizing hazards associated with the biological materials used in the laboratory
SPH 2.03. Control measures to be used when working with biological materials	Describes the control measures to be used when working with biological materials	Implements the control measures to be used when working with biological materials	Ensures that staff implement the established control measures when working with biological materials	Establishes the control measures to be used when working with biological materials
SPH 2.04. Work practices to be used when working with biological materials	Describes the work practices to be used when working with biological materials	Implements the work practices to be used when working with biological materials	Ensures that staff implement the established work practices when working with biological materials	Establishes the work practices to be used when working with biological materials
SPH 2.05. Hazards associated with laboratory procedures	Describes hazards associated with the laboratory procedures employed	Trains staff in the hazards associated with the laboratory procedures employed	Manages the hazards associated with laboratory procedures	Ensures that staff are capable of recognizing, training, and managing the hazards associated with laboratory procedures
SPH 3.00. Research animals:* works safely with research animals				
Subcompetency	Beginner	Competent	Proficient	Expert
SPH 3.01. Hazards associated with research animals	Describes hazards associated with working with research animals	Identifies hazards associated with the particular species of animals used in the laboratory's research	Assesses staff knowledge of the hazards associated with the particular species of animals used in the laboratory's research	Ensures that staff are skilled in describing and recognizing hazards associated with the research animals used in the laboratory's research
SPH 3.02. Route of exposure* to infectious agents in the animal care setting	Describes possible route(s) of exposure to infectious agents in relation to animal procedures	Identifies the possible route(s) of exposure to infectious agents in relation to the animal procedures used in the laboratory or animal facility	Assesses staff knowledge of the hazards associated with the animal procedures used in the laboratory or animal facility	Evaluates possible route(s) of exposure to infectious agents in relation to the animal procedures used in the laboratory and animal facilities
SPH 3.03. Control measures to be used when working with research animals	Describes control measures to be used when working with research animals	Implements control measures to be used when working with research animals	Ensures that staff implement the established control measures when working with research animals	Establishes the control measures to be used when working with research animals
SPH 3.04. Work practices to be used when working with research animals	Describes work practices to be used when working with research animals	Implements work practices to be used when working with research animals	Ensures that staff implement the established work practices when working with research animals	Establishes the work practices to be used when working with research animals

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: potential hazards

SPH 4.00. Chemical materials:* works safely with chemical materials in the laboratory

Subcompetency	Beginner	Competent	Proficient	Expert
SPH 4.01. Chemicals used in the laboratory	Identifies chemicals used in the laboratory	Distinguishes hazardous chemicals* from nonhazardous chemicals in the laboratory	Manages the chemical inventory to ensure it is complete and updated	Establishes the policies, processes, and procedures for implementing a chemical inventory system
SPH 4.02. Hazards associated with chemicals used in the laboratory	Describes hazards associated with chemicals used in the laboratory	Recognizes hazards associated with new chemicals used in the laboratory	Assesses staff knowledge of the hazards associated with chemicals used in the laboratory	Ensures that staff are skilled in describing and recognizing hazards associated with chemicals used in the laboratory
SPH 4.03. Control measures to be used when working with chemicals in the laboratory	Describes control measures to be used when working with chemicals as documented in the laboratory's Chemical Hygiene Plan*	Implements established control measures when working with chemicals according to the laboratory's Chemical Hygiene Plan	Ensures that staff implement the established control measures when working with chemicals in compliance with the laboratory's Chemical Hygiene Plan	Establishes the laboratory's Chemical Hygiene Plan, including specific control measures to be used when working with chemicals
SPH 4.04. Work practices to be used when working with chemicals in the laboratory	Describes the work practices to be used when working with chemicals as documented in the laboratory's Chemical Hygiene Plan	Implements established work practices when working with chemicals according to the laboratory's Chemical Hygiene Plan	Ensures that staff implement established work practices when working with chemicals in compliance with the laboratory's Chemical Hygiene Plan	Establishes the laboratory's Chemical Hygiene Plan, including specific work practices to be used when working with chemicals

SPH 5.00. Radiological materials:* works safely with radiological materials in the laboratory

Subcompetency	Beginner	Competent	Proficient	Expert
SPH 5.01. Radiological materials used in the laboratory	Lists the radiological materials used in the laboratory	Describes the characteristics of the radiological materials used in the laboratory	Manages the inventory of radiological materials to ensure it is complete and updated	Establishes the policies, processes, and procedures for implementing a radiological materials inventory system
SPH 5.02. Hazards associated with the use of radiological materials	Describes the hazards associated with radiological materials used in the laboratory	Recognizes hazards associated with new radiological materials used in the laboratory	Assesses staff knowledge of the hazards associated with radiological materials used in the laboratory	Ensures that staff are skilled in describing and recognizing the hazards associated with radiological materials used in the laboratory
SPH 5.03. Control measures to be used when working with radiological materials	Recognizes control measures to be used when working with radiological materials in the laboratory	Implements control measures to be used when working with radiological materials in the laboratory	Ensures that staff implement established control measures when working with radiological materials in the laboratory	Establishes, in collaboration with radiation safety staff, the control measures to be used when working with radiological materials in the laboratory
SPH 5.04. Work practices to be used when working with radiological materials	Describes work practices to be used when working with radiological materials in the laboratory	Implements work practices to be used when working with radiological materials in the laboratory	Ensures that staff implement established work practices when working with radiological materials in the laboratory	Establishes, in collaboration with radiation safety staff, the work practices to be used when working with radiological materials in the laboratory
SPH 5.05. Radiation monitoring devices*	Describes monitoring devices for the radiological materials used in the laboratory	Demonstrates operation and use of monitoring devices for the radiological materials used in the laboratory	Ensures the operation and use by staff of radiation monitoring devices	Evaluates use and suitability of monitoring devices for the radiological materials used in the laboratory

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: hazard control*

SHC 1.00. Engineering controls:* implements intervention strategies to control hazards by systematically minimizing, isolating, or removing hazards from the workplace

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 1.01. Engineering controls	Describes engineering controls	Employs engineering controls to eliminate or reduce targeted laboratory hazards	Develops standard operating procedures (SOPs)* and work instructions that incorporate engineering controls	Ensures the implementation of policies, processes, and procedures related to engineering control design, creation, and use
SHC 1.02. Training on engineering controls	Completes required training before using engineering controls	Trains staff on engineering controls	Develops required training for engineering controls	Ensures that training is adequate and appropriate for the engineering controls used in the laboratory
SHC 1.03. Function verification* and maintenance of engineering controls	Describes function verification, maintenance, and troubleshooting procedures for engineering controls	Performs function verification, maintenance, and troubleshooting processes and procedures for engineering controls	Manages the procedures for function verification, maintenance, and troubleshooting for engineering controls	Develops policies, processes, and procedures to ensure function verification, maintenance, and troubleshooting for engineering controls
SHC 1.04. Malfunction of engineering controls	Recognizes when engineering controls are compromised, malfunctioning, or nonfunctioning, and the resulting reporting requirements*	Implements procedures to address and report when engineering controls are compromised, malfunctioning, or nonfunctioning	Manages processes and procedures for addressing and reporting situations in which engineering controls are compromised, malfunctioning, or nonfunctioning	Develops policies, processes, and procedures for remediation and reporting of engineering control malfunctions to ensure minimal exposure and release of targeted hazards

SHC 2.00. Safe work practices: designs work practices and procedures to minimize exposure to hazards and to adhere to regulatory requirements

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 2.01. Good housekeeping procedures*	Describes good housekeeping procedures	Practices good housekeeping procedures	Develops processes and procedures related to the establishment and maintenance of good housekeeping	Oversees the implementation of policies, processes, and procedures related to good housekeeping
SHC 2.02. Personal hygiene procedures*	Describes personal hygiene procedures	Complies with personal hygiene procedures	Develops personal hygiene procedures	Ensures staff adherence to personal hygiene policies, processes, and procedures
SHC 2.03. Safety practices and procedures	Describes proper work practices and procedures	Uses proper work practices and procedures	Develops proper work practices and procedures	Ensures staff knowledge and use of proper work practices and procedures
SHC 2.04. Work schedules	Describes how adherence to own scheduled work activities and tasks minimizes exposure	Monitors staff adherence to established work schedules and assigned tasks	Implements procedures to ensure scheduling of work activities and/or workers' tasks minimize staff exposure levels	Designs processes and procedures to ensure scheduling of work activities and/or workers' tasks minimize staff exposure levels

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain**Safety subdomain: hazard control*****SHC 3.00. Personal Protective Equipment (PPE):* employs the selection, use, and care of personal protective equipment while being continually mindful of its limitations**

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 3.01. PPE selection	Describes appropriate PPE and its limitations for jobs assigned	Selects appropriate PPE for jobs assigned	Develops procedures for the appropriate selection of PPE	Ensures staff knowledge of procedures for the appropriate selection of PPE
SHC 3.02. PPE use	Describes specific PPE and its limitations for use with each laboratory procedure	Uses specific PPE for each laboratory procedure	Determines procedures for use of specific PPE	Ensures staff compliance with procedures for use of specific PPE
SHC 3.03. PPE inspection	Describes pre-and postinspection procedures for PPE	Implements pre-and postinspection procedures for PPE	Develops pre-and postinspection procedures for PPE	Ensures staff knowledge of pre-and postinspection procedures for PPE

SHC 4.00. Systems to track hazards: establishes a system to detect and to control or eliminate the underlying causes of hazards or exposures

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 4.01. Hazard reporting, tracking, and investigation	Describes the procedures for reporting hazardous conditions	Implements procedures for reporting and tracking all hazards	Develops procedures to report, track and investigate hazards in their workspace	Ensures staff compliance with reporting, tracking, and investigating hazards in the workplace

SHC 5.00. Preventive maintenance: conducts regular maintenance to ensure effective functioning of laboratory equipment* and to extend the life of equipment

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 5.01. Planned maintenance	Performs required preventive maintenance functions	Complies with processes and procedures to ensure equipment continues to function effectively	Implements the processes and procedures to ensure equipment continues to function effectively	Develops the policies, processes, and procedures to ensure equipment continues to function effectively
SHC 5.02. Corrective maintenance	Describes troubleshooting methods to determine whether equipment is malfunctioning and the cause	Complies with processes and procedures to ensure equipment repairs	Implements the processes and procedures to ensure equipment repairs	Develops the policies, processes, and procedures to ensure repairs are conducted in accordance with organizational safety and health procedures

SHC 6.00. Decontamination* and laboratory waste management: establishes a laboratory waste management plan* that adheres to federal, state, and local regulations

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 6.01. Decontamination of laboratory waste	Describes procedures for spill cleanup and decontamination of laboratory waste	Implements procedures for spill cleanup and decontamination of laboratory waste	Manages procedures for spill cleanup and decontamination of laboratory waste	Develops policies, processes, and procedures for spill cleanup and decontamination of laboratory waste
SHC 6.02. Segregated waste categorization* and handling	Describes procedures for laboratory waste categorization and handling	Implements procedures for laboratory waste categorization and handling	Manages procedures for laboratory waste categorization and handling	Ensures staff compliance with laboratory waste categorization and handling policies, processes, and procedures
SHC 6.03. Treatment and disposal	Describes procedures for disposal and treatment of laboratory waste	Implements procedures for disposal and treatment of laboratory waste	Manages procedures for disposal and treatment of laboratory waste	Ensures staff compliance with policies, processes, and procedures for disposal and treatment of laboratory waste

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: hazard control*

SHC 6.00. Decontamination* and laboratory waste management: establishes a laboratory waste management plan* that adheres to federal, state, and local regulations

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 6.04. Waste reduction	Describes procedures for laboratory waste reduction	Implements procedures for laboratory waste reduction	Manages procedures for laboratory waste reduction	Ensures staff compliance with policies, processes, and procedures for laboratory waste reduction
SHC 6.05. Regulated waste* access	Describes procedures for preventing public access to regulated waste	Implements procedures for preventing public access to regulated waste	Manages procedures for preventing public access to regulated waste	Ensures staff compliance with policies, processes, and procedures for preventing public access to regulated waste
SHC 6.06. Waste management issues and problems	Describes procedures for reporting and responding to issues or problems regarding laboratory waste management	Implements procedures for reporting and responding to issues or problems regarding laboratory waste management	Develops procedures to ensure that issues or problems regarding laboratory waste management are reported and addressed	Ensures staff compliance with policies, processes, and procedures to address laboratory waste management issues or problems
SHC 6.07. Monitoring and evaluation	Describes procedures for monitoring the laboratory waste management plan	Implements procedures for monitoring the laboratory waste management plan	Develops procedures for monitoring the laboratory waste management plan	Ensures staff compliance with policies, processes, and procedures for monitoring the laboratory waste management plan

Safety subdomain: administrative controls*

SAC 1.00. Safety program* management: manages the laboratory safety program

Subcompetency	Beginner	Competent	Proficient	Expert
SAC 1.01. Safety program	Complies with the safety program requirements for the jobs performed	Ensures staff compliance with safety program requirements	Implements the safety program and related training programs	Ensures that comprehensive safety policies, processes, and procedures are developed as part of the safety program
SAC 1.02. Program audits	Participates in audits of the safety program	Conducts audits of the safety program	Designs safety program audits	Evaluates the safety program audit results to identify problem areas
SAC 1.03. Safety inspections	Explains the importance of safety inspections	Participates in safety inspections	Conducts safety inspections	Ensures staff compliance with safety inspections
SAC 1.04. Program evaluation	Provides feedback on the safety program	Collects data relating to the effectiveness of the safety program	Prepares evaluation reports for the safety program	Designs evaluation reports for the safety program

SAC 2.00. Guideline and regulation compliance: ensures staff compliance with guidelines and regulations

Subcompetency	Beginner	Competent	Proficient	Expert
SAC 2.01. Regulatory requirements and guidelines	Describes current regulatory requirements and guidelines governing the safe performance of laboratory procedures	Complies with current regulatory requirements and guidelines governing the safe performance of laboratory procedures	Instructs staff on current regulatory requirements and guidelines governing the safe performance of laboratory procedures	Ensures staff compliance with current regulatory requirements and guidelines governing the safe performance of laboratory procedures
SAC 2.02. Institutional safety committees*	Describes institutional safety committees	Complies with institutional safety committee requirements	Participates in a leadership role on institutional safety committees	Ensures staff compliance with institutional safety committee requirements

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: administrative controls*

SAC 3.00. Risk management: manages risks through systematic practices to evaluate, minimize, or eliminate them

Subcompetency	Beginner	Competent	Proficient	Expert
SAC 3.01. Risk assessment [†]	Describes the risk assessment process	Implements control measures identified in risk assessments	Manages the risk assessment process	Oversees the policies, processes, and procedures related to risk assessment to ensure controls are appropriate for activities, agents and materials used in laboratory
SAC 3.02. Incident* reporting	Reports any incidents, including near-misses	Reviews reports of incidents to identify root causes and problems	Conducts routine monitoring of staff compliance regarding incident reporting	Designs policies, processes, and procedures for reporting and performing root-cause analyses of incidents

SAC 4.00. Occupational health and medical surveillance: complies with occupational health and medical surveillance policies

Subcompetency	Beginner	Competent	Proficient	Expert
SAC 4.01. Vaccination program	Describes the organization's vaccination program	Identifies staff eligible to participate in the vaccination program	Monitors staff compliance with the vaccination program	Designs the vaccination program based on exposure risks and regulatory requirements
SAC 4.02. Medical surveillance program*	Describes the organization's medical surveillance program	Identifies staff eligible to participate in the medical surveillance program	Monitors staff compliance with the medical surveillance program	Designs the medical surveillance program based on risks encountered and regulatory requirements
SAC 4.03. Exposure monitoring*	Describes exposure monitoring procedures	Complies with exposure monitoring procedures	Ensures staff compliance with exposure monitoring policies and processes	Develops the exposure monitoring policies and processes based on risks encountered and regulatory requirements
SAC 4.04. Occupational incidents	Identifies the process to obtain medical services after an occupational incident	Complies with organizational requirements and healthcare provider treatment plans pertaining to an occupational incident	Prepares summary of occupational incidents	Develops occupational incident response plan* including regular review and revisions following an occupational incident

Safety subdomain: communication and training

SCT 1.00. Hazard communication:* promotes safety through effective hazard communication

Subcompetency	Beginner	Competent	Proficient	Expert
SCT 1.01. Safety signage*	Describes safety signage and documentation as well as how signage is used to convey information	Adheres to information and directives in safety signage and documents*	Evaluates safety signage and document placement and usage	Ensures staff compliance with safety signage and documents
SCT 1.02. Safety communication tools	Describes a variety of communication tools and techniques promoting the work practices employed in own area of responsibility	Employs a variety of communication tools and techniques promoting the work practices employed in own area of responsibility	Implements a variety of communication tools and techniques for the promotion of safe work practices	Ensures a variety of communication tools and techniques promoting work practices are employed in their area of responsibility

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: communication and training				
SCT 1.00. Hazard communication:* promotes safety through effective hazard communication				
Subcompetency	Beginner	Competent	Proficient	Expert
SCT 1.03. Labeling	Describes labeling of samples* and containers	Adheres to procedures for labeling of samples and containers	Implements procedures to ensure staff compliance with regulatory requirements for labeling of samples and containers	Ensures staff compliance with regulatory requirements for labeling of samples and containers
SCT 1.04. Signals and alarms	Recognizes signals and alarms in areas assigned	Explains signals and alarms in the laboratory facility	Assesses staff knowledge of signals and alarms	Ensures the implementation of all signals and alarms
SCT 2.00. Safety training: ensures that safety training needs are identified and training solutions are implemented to meet performance and productivity goals				
Subcompetency	Beginner	Competent	Proficient	Expert
SCT 2.01. Safety training	Complies with requirements to obtain safety training	Provides training on the work practices and techniques required for staff to safely perform their job duties	Assesses safety training needs and the impact of safety training	Ensures development and implementation of safety training for all staff
SCT 2.02. Training documentation	Describes requirements for documenting safety training	Adheres to procedures for recording safety training of staff	Implements procedures for documenting staff safety training	Develops policies, processes, and procedures for documentation and verification of staff training records*
Safety subdomain: documents and records				
SDR 1.00. Documents and record keeping: ensures staff compliance with agency quality management system (QMS)* and statutory, regulatory, accreditation* and licensing* requirements for documentation and recordkeeping in relation to the health and safety management systems				
Subcompetency	Beginner	Competent	Proficient	Expert
SDR 1.01. Safety document management	Describes procedures for safety document management	Adheres to procedures for safety document management	Manages safety document management process	Designs the safety document management system
SDR 1.02. Safety document access	Identifies any restricted or confidential safety documents	Ensures restricted or confidential safety documents are not disclosed	Implements processes and procedures for maintaining confidentiality* of internally and externally derived safety information	Designs policies, processes, and procedures for document control and access that adhere to regulatory and accreditation requirements
SDR 1.03. Occupational injuries and illnesses documentation	Describes responsibilities for documenting Occupational Safety and Health Administration (OSHA)* recordable occupational injuries and illnesses	Complies with documentation procedures for OSHA-recordable occupational injuries and illnesses	Ensures staff compliance with reporting of OSHA-recordable occupational injuries and illnesses	Designs policies, processes, and procedures to ensure reporting for OSHA-recordable occupational injuries and illnesses
SDR 1.04. Medical surveillance documentation	Describes responsibilities in complying with established medical surveillance recordkeeping procedures	Complies with established medical surveillance documentation and recordkeeping procedures	Implements processes and procedures for medical surveillance documentation	Designs policies, processes, and procedures for medical surveillance documentation

See table footnotes on page 44.

TABLE 9. (Continued) Public health laboratory competency guidelines: Safety domain

Safety subdomain: documents and records				
SDR 1.00. Documents and record keeping: ensures staff compliance with agency quality management system (QMS)* and statutory, regulatory, accreditation* and licensing* requirements for documentation and recordkeeping in relation to the health and safety management systems				
Subcompetency	Beginner	Competent	Proficient	Expert
SDR 1.05. Exposure monitoring documentation	Describes the procedures for documenting exposure monitoring	Adheres to procedures for documenting exposure monitoring	Implements procedures for documentation and retention of exposure monitoring information as required by regulations	Designs policies, processes, and procedures for documentation and retention of exposure monitoring information as required by regulations
SDR 1.06. Safety inspection documentation	Describes safety inspection documentation	Complies with procedures for safety inspection documentation	Develops procedures for safety inspection documentation	Designs policies, processes, and procedures for safety inspection documentation
SDR 1.07. Hazardous waste documentation	Describes procedures for documenting the handling and transport of hazardous waste	Complies with procedures for documenting the handling and transport of hazardous waste	Develops procedures for documenting the handling and transport of hazardous waste	Ensures staff compliance with policies, processes, and procedures for documenting the handling and transport of hazardous waste
SDR 1.08. Safety reports to staff members	Reads safety reports	Complies with recommendations and mandates of safety reports	Ensures staff compliance to recommendations and mandates made in safety reports	Designs policies, processes, and procedures ensuring staff compliance to recommendations and mandates made in safety reports

* This term is defined in Appendix B.

† The evaluation of 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.

Surveillance Competency Guidelines

Purpose statement: The competencies in Surveillance address the knowledge, skills, and abilities required for the collection and analysis of data to support public health decision making to ensure the health of the community (Table 10). This includes continuous laboratory testing, data compilation, and data dissemination on infectious organisms, chemical analytes, radiological materials, and evidence of hereditary anomalies.

Introduction: Surveillance is the continuous, systematic collection, analysis, and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice (75). With surveillance, the spread of disease (i.e., any condition that causes injuries, disabilities, disorders, syndromes, infections, or symptoms) is monitored to establish patterns of progression to predict, observe, and minimize the harm caused by the disease. Well-developed surveillance capacity is the foundation on which health departments detect, evaluate, and design effective responses to public health threats. Laboratory information and services are essential to public health surveillance, as the collection, validation, analysis, interpretation, dissemination, and use of

laboratory-generated results are crucial to target public health prevention and ensure the health of communities. Public health laboratory scientists and epidemiologists need to work closely to ensure effective population-based disease control and prevention. Effective laboratory reporting to epidemiologists, providers, or other submitters also requires an electronic laboratory reporting (ELR) system that is interoperable with electronic health records and notifiable condition reporting for both care and surveillance.

The public health laboratory plays a unique role in public health surveillance by providing crucial information on the appropriate samples and testing methods, by identifying harmful substances and agents, and by providing the ability to investigate and communicate unusual findings. It is essential for laboratory staff members to understand both their individual role and the laboratory's role in surveillance, testing, reporting, and disease and exposure monitoring.

Notes: Multiple sources were identified as support documents for this domain (15,75–77). Because all public health laboratory testing has a direct or indirect impact on surveillance, this domain is intended for all staff members and not just for persons involved in dedicated surveillance activities.

TABLE 10. Public health laboratory competency guidelines: Surveillance domain

SRV 1.00. Function of surveillance: recognizes the function of laboratory testing in surveillance

Subcompetency	Beginner	Competent	Proficient	Expert
SRV 1.01. Function of laboratory surveillance	Describes the importance of public health laboratory surveillance testing	Explains the integration of public health laboratory testing into broader surveillance programs	Ensures selected laboratory testing and reporting procedures* are aligned with surveillance activities and program requirements*	Oversees the policies,* processes,* and procedures that ensure laboratory data will support public health surveillance activity and program requirements

SRV 2.00. Notification rules and regulations: complies with national and jurisdictional rules and regulations regarding notifiable results*

Subcompetency	Beginner	Competent	Proficient	Expert
SRV 2.01. Notification	Describes notification rules and regulations	Reports data to laboratory management	Manages the approval and communication of public health surveillance test results	Contributes to determination of national, state, and local notification conditions

SRV 3.00. Surveillance testing: performs surveillance testing

Subcompetency	Beginner	Competent	Proficient	Expert
SRV 3.01. Surveillance testing systems	Describes test sample* collection, storage, and analytical requirements	Identifies the functional requirements of surveillance testing protocols [†]	Creates surveillance testing protocols that include functional requirements	Directs development and modifications to surveillance testing systems based on jurisdictional guidance and analytical capabilities

See table footnotes on page 48.

TABLE 10. (Continued) Public health laboratory competency guidelines: Surveillance domain

SRV 3.00. Surveillance testing: performs surveillance testing				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 3.02. Surveillance testing workflow ⁵	Describes test sample collection, storage, and analytical method workflows	Employs established testing workflow and test methods for the surveillance target requirements	Customizes testing workflow policies and procedures to the surveillance target requirements	Directs development and modifications to surveillance testing system workflows
SRV 3.03. Surveillance testing	Tests samples for surveillance	Participates in performance evaluation of surveillance test methods and testing capabilities	Applies technical knowledge to develop test methods and testing capabilities used in surveillance	Oversees the selection and creation of public health surveillance tests
SRV 3.04. Outbreak* or exposure event* detection	Describes at least one definition of an outbreak or exposure event	Informs supervisor of potential outbreak or exposure event	Reports potential outbreak or exposure events to key stakeholders	Contributes to the modification of outbreak or exposure event recognition processes or definitions
SRV 3.05. Sample collection for outbreak or exposure events	Receives outbreak or exposure event samples for testing	Ensures that outbreak or exposure event samples meet sample collection criteria	Collaborates with key stakeholders to determine the best samples to collect	Contributes to sample collection guidelines for outbreak or exposure event scenarios
SRV 3.06. Testing for outbreak or exposure events	Follows sample prioritization schema for testing during an outbreak or exposure event	Ensures that outbreak or exposure event samples are prioritized according to schema	Reports outbreak or exposure event testing results to key stakeholders	Represents the laboratory in After Action Reviews* for outbreak or exposure events
SRV 4.00. Response to critical surveillance event:* responds to critical surveillance events				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 4.01. Critical event planning	Describes critical event response processes and procedures related to surveillance	Applies critical event processes and procedures related to surveillance	Evaluates plans and After Action Review findings following critical events	Modifies the policies, processes, and procedures for critical surveillance events based on results of exercises or actual events
SRV 4.02. Critical event response	Describes own critical event response duties related to surveillance	Manages resources required to respond to critical events	Implements the critical event response plan	Oversees the activation and termination of the critical event response plan
SRV 4.03. Coordination of response	Describes the need to coordinate testing priorities	Communicates testing priorities to staff and laboratory management	Coordinates testing activities during critical events to align with identified testing priorities	Ensures implementation of response plans during critical events
SRV 4.04. New testing capabilities	Identifies when current testing capabilities do not exist to test an analyte or organism	Applies technical knowledge to implement new testing capabilities	Develops plans to address testing capabilities for a specific new organism or analyte during critical surveillance events	Determines the overall strategy for development of new testing capabilities during critical surveillance events

See table footnotes on page 48.

TABLE 10. (Continued) Public health laboratory competency guidelines: Surveillance domain

SRV 5.00. Information for surveillance: recognizes vital information needed for surveillance				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 5.01. Demographic information	Enters demographic information that is necessary to carry out surveillance testing activities	Communicates the required demographic information to submitters	Ensures submission of crucial demographic information by submitters	Determines demographic information fields required in informatics systems, requisition forms, and reports
SRV 5.02. Sample information	Enters sample information that is necessary to carry out surveillance testing activities	Monitors the capture of sample information	Ensures collection of sample information	Determines policies, processes, and procedures for sample information collection based on jurisdictional requirements and guidelines
SRV 6.00. Data analysis: analyzes data from surveillance testing systems				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 6.01. Data analysis	Describes surveillance data analysis methods	Analyses laboratory surveillance data	Interprets laboratory surveillance data	Develops standards for data analysis and for interpretation of laboratory surveillance data
SRV 7.00. Data management: manages public health surveillance data using secure data management systems				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 7.01. Data collection	Conducts data entry	Determines validity and reliability of data collection instruments and methods	Ensures data collection system adheres to laboratory, local, and national standards	Coordinates modifications to data collection systems using state and national guidance and methods
SRV 7.02. Data storage and retrieval	Uses secure and stable data storage and retrieval systems	Ensures that the design of storage and retrieval databases include the necessary variables and data dictionary	Develops secure and stable data storage and retrieval systems, including creating new variables as necessary to support analysis of data	Develops standards for secure and stable data storage and retrieval
SRV 8.00. Recognition of significant results: recognizes significant results in surveillance data				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 8.01. Significant values and results	Adheres to policies and procedures to verify significant results	Reports significant results with interpretation to laboratory management and customers*	Monitors significant results to ensure staff compliance with policies for reporting	Develops plans with customers to identify significant results in the population or environment
SRV 8.02. Trends in data	Provides trend results to laboratory management	Identifies trends in surveillance data	Explains trends in surveillance data to laboratory management and customers	Evaluates testing capabilities based on trend data to address customer needs and public health issues

See table footnotes on page 48.

TABLE 10. (Continued) Public health laboratory competency guidelines: Surveillance domain

SRV 9.00. Partnerships: maintains partnerships to conduct surveillance				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 9.01. Multidisciplinary teamwork	Communicates approved laboratory information to other institutions	Implements the multi-disciplinary surveillance communication plan	Manages the multi-disciplinary surveillance communication plan	Develops a multi-disciplinary surveillance communication plan
SRV 9.02. Education and feedback for partners	Explains sample requirements and testing procedures	Guides partners in selection of laboratory methods, data collection, and evaluation	Evaluates effectiveness and efficiency of surveillance processes and procedures between laboratory and partners	Develops surveillance policies, processes, and procedures with partners
SRV 10.00. Dissemination of data: disseminates data relevant to audience				
Subcompetency	Beginner	Competent	Proficient	Expert
SRV 10.01. Presentation of surveillance and monitoring data	Describes importance and use of oral and written communication in presenting surveillance and monitoring data	Reports surveillance and monitoring data orally or in writing to laboratory management and epidemiologists	Explains surveillance and monitoring data orally or in writing to external stakeholders	Synthesizes surveillance and monitoring data orally and in writing for national and international audiences for policy decision-making purposes

* This term is defined in Appendix B.

† A detailed plan for conducting a scientific procedure.

§ Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Informatics Competency Guidelines

Purpose statement: The competencies in Informatics address the knowledge, skills, and abilities needed to systematically apply information science, computer science, and information technology to support public health practice, research, and learning (Table 11).

Introduction: Informatics is a broad field encompassing information science, information technology, algorithms, and social science. In addition to electronic recordkeeping and automated data management, informatics includes such activities as test analyses, clinical decision support, messaging, and knowledge management. Once thought of as a support function, the delivery of laboratory informatics services has now evolved to be a mission-critical and central component of laboratory operations.

Informatics is critically important to the public health laboratory's role in protecting the public from infectious diseases, environmental dangers, and other health threats. Public health laboratory informatics must be cross-cutting and interoperable to support a nationally integrated electronic

laboratory reporting (ELR) system and electronic health record (EHR) system. Since all laboratories must rely on informatics capabilities and often have limited access to informaticians or informatics specialists, it is essential that all staff members maintain varying levels of informatics competencies.

Notes: Multiple sources were identified as support documents for this domain (20,78–81). In particular, the competencies defined in this domain are based on the content and framework of a 2013 comprehensive public health laboratory informatics self-assessment tool (78). In turn, this tool was framed on an earlier document (79) outlining consensus on the business requirements of laboratory information management systems. Some of the competencies provided in these guidelines, particularly the Expert level, might appear beyond the reach of the typical bench scientist. While laboratory scientists might initially have competencies limited to the Beginner or Competent level, a long-term goal is to ensure that public health laboratories have within their ranks scientists with competencies at the Proficient and Expert levels. This domain includes paper systems as part of the laboratory information system.

TABLE 11. Public health laboratory competency guidelines: Informatics domain

INF 1.00. Laboratory test request and sample* receiving: manages sample receiving and the processing of laboratory test requests

Subcompetency	Beginner	Competent	Proficient	Expert
INF 1.01. Sample receiving and accessioning	Describes electronic modules* used to log in samples with corresponding electronic requests	Verifies electronic accessioning activities to ensure completeness and accuracy	Evaluates the electronic modules needed for sample receiving and accessioning	Designs log-in screens to automate sample receiving and accessioning and to automate processing of electronic test request messages
INF 1.02. Electronic data exchange regarding test requests	Describes electronic modules used to receive data on samples using one or more standard message types*	Performs oversight of entered data to ensure accurate mapping of client data to comparable fields in electronic systems	Manages daily electronic data exchange activities regarding test requests to ensure efficient operations and resolution of root causes of errors	Designs systems to automate electronic test orders and work processes*
INF 1.03. Vocabulary standards*	Lists local codes and standardized codes	Manages use of vocabulary standards across parties	Evaluates use of vocabulary standards for identification of missing or misidentified codes	Develops codes for generation of messages using multiple standardized vocabulary formats and integration of local and new codes and vocabulary standards
INF 1.04. Test orders	Describes processes and procedures* for test orders	Verifies the electronic assignment of tests to specific laboratory programs*	Evaluates the need for new test orders and associated meta data	Designs workflows [†] and modules to automate assignment of test orders to specific laboratory programs
INF 1.05. Hardware to promote sample handling efficiency	Uses basic hardware, scanners, and robotics	Troubleshoots installation and operation of basic automation hardware	Configures a variety of complex hardware to ensure proper operation	Integrates use of new technologies for sample accessioning

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 1.00. Laboratory test request and sample* receiving: manages sample receiving and the processing of laboratory test requests				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 1.06. Capture of auxiliary data	Describes required identifiers and core data elements	Verifies the routine entry of metadata and pass-through auxiliary data	Manages problem resolution concerning entry of metadata and auxiliary data	Designs modules to automate the entry of auxiliary data, the identification of core data elements, and the inclusion of new data elements
INF 2.00. Test preparation, Laboratory Information Management System (LIMS)* processing, test results recording and verification: manages systems for electronic test preparation, LIMS processing, and test results recording and verification				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 2.01. Test preparation and receipt of samples	Describes use of predefined electronic modules to assign samples or batches* of samples to processes in the laboratory	Verifies the assignment of samples to individual test processes or test processing combinations	Manages prioritization for preparation and handling of samples	Designs systems to automate the electronic management of pre-examination* operations on samples received individually or in batch
INF 2.02. Electronic test requests from submitters	Describes how to use electronic modules to manage individual or batches of samples from submitters	Verifies the receipt of samples and associated electronic test requests from submitters	Ensures that valid values and test codes are properly harmonized between submitters and receiving laboratory	Designs systems to automate the electronic management of test requests from submitters
INF 2.03. LIMS tracking of testing processes and associated sample sources	Describes how to use electronic modules to track testing processes and associated sample sources	Verifies effectiveness of ongoing sample source tracking and submitter's monitoring efforts	Evaluates the LIMS tracking of testing processes and associated sample sources	Designs systems to automate and manage the tracking of testing processes and associated sample sources
INF 2.04. Test results recording	Describes electronic modules, vocabulary, and usage for specific test results	Populates test results data using pre-existing modules	Troubleshoots automated test results data capture utilities	Designs analytical sequences for instrument integration and data capture utilities to automate data transfer from instruments
INF 2.05. Data review	Describes preparation of data summaries that are used for review processes	Verifies data and results using predefined progress reports	Evaluates the need for new tracking reports to facilitate data review	Develops workflows and utilities to ensure that needed data are supplied
INF 2.06. Data verification	Explains test result choices that exist for specific test requests	Verifies that the electronic transfer of quality assurance (QA)* and quality control (QC)* data* occurs to ensure that test results meet procedural requirements* and auto-assignment	Institutes rules to ensure that laboratory programs have tools to manage data verification processes	Designs the processes for automating data verification and associating QA and QC data with individual sample tests and batches before reporting
INF 2.07. Auto-assignment of reflex* or repeat testing	Describes the electronic processes that define auto-assignment of reflex or repeat testing	Verifies that auto-assignment of reflex or repeat testing is performed	Evaluates the processes for auto-assignment of reflex or repeat testing	Develops code for design and configuration of processes for automating the assignment of reflex or repeat testing

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 3.00. Report preparation and distribution: manages test result report creation and distribution				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 3.01. Processing of data for reports	Describes electronic modules used to print data and information* in automated reports	Verifies analytical data, information, and reports	Appraises solutions for data selection for nonroutine reports and for research purposes	Constructs queries for <i>ad hoc</i> data searches
INF 3.02. Report production	Describes use of electronic modules to generate automated and manual reports or test results	Selects results for reporting using standardized predefined report formats	Evaluates report production processes	Develops code to query and report laboratory data
INF 3.03. Electronic reporting	Sends predefined reports via electronic reporting formats	Reports test results using predefined electronic messages that meet agreed-upon standards	Manages the tracking and needs assessment* of electronic reporting of data	Develops reports that contain electronic messages for test results using agreed-upon standards and vocabulary for message creation and transport
INF 3.04. Management of reports	Prints predefined reports according to policies*	Verifies that reports adhere to submitters' data exchange format requirements for electronic results submittal and reporting	Modifies noncomplex electronic formats to meet customer* requirements	Develops automated processes to manage reporting of results
INF 4.00. Laboratory test scheduling: manages laboratory test scheduling				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 4.01. Scheduling documents*	Prints existing worksheets, work lists, and test scheduling documents	Prioritizes test scheduling to resolve conflicts and turnaround time	Develops work lists, worksheets, and test scheduling documents	Develops processes for integration of documents to link test orders with test results
INF 4.02. Management of test schedules	Enters data to remove or restore completed test requests	Uses specific data elements associated with process improvement to manage test schedules	Evaluates the workflow for process improvement opportunities	Develops codes to automate the creation of test status reports and workflows
INF 4.03. Prioritization of tests	Logs in samples according to predefined generic priorities	Manages test requests using laboratory-specified criteria	Organizes specific data elements associated with process improvement indicators* to prioritize test scheduling	Develops systems to electronically generate a real-time test schedule
INF 5.00. Prescheduled testing: manages prescheduled testing				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 5.01. Prescheduling	Describes electronic modules for receipt and processing of pre-scheduled samples and kit distribution	Manages scheduling of single or recurring test requests	Troubleshoots electronic systems to preschedule tests and to predict and adjust workload	Develop automated processes to manage the receipt and processing of pre-scheduled samples, recurring test requests, and kit distribution

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 6.00. Sample tracking and chain of custody:* manages the tracking of physical samples and chain of custody				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 6.01. Tracking samples at accessioning	Uses predefined electronic modules to enter data relevant to track all steps in the sample lifecycle*	Assigns identifiers to samples	Evaluates automated modules that verify system operations regarding tracking	Develops systems to determine sample tracking and location
INF 6.02. Chain of custody	Uses predefined modules to track and document custody of the sample from receipt to disposal or return to submitter	Ensures staff compliance with chain of custody policies and procedures	Manages electronic tracking data by validating that chain of custody is complete and documented	Develops systems to electronically automate the communication of chain of custody data tracking to users and submitters
INF 6.03. Chain of custody data elements	Uses predefined modules to link demographic data with data on chain of custody, sample appropriateness,* sample handling, and elements of sample analyst location, time, and defined storage parameters	Verifies that predefined modules allow creation, tracking, and maintenance of sample and aliquot hierarchy through the LIMS throughout the laboratory	Evaluates existing and future modules for tracking data elements	Develops systems to integrate data elements into automated chain of custody management
INF 6.04. Tracking samples in analytical processes	Uses predefined modules to track samples assigned to laboratory programs during analytical processes	Verifies the routine tracking of aliquots, instrument sequence numbers, and work lists	Creates work lists, worksheets, and workgroups to improve the tracking of samples	Develops modules to incorporate factors that affect automated assignment of samples to work lists and integration of sample tracking into routine laboratory functions
INF 7.00. Media, reagents, and controls: manages the manufacturing and inventory of media, reagents, and controls electronically				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 7.01. Supplies tracking	Applies predeveloped electronic modules to order supplies and control inventory	Verifies the tracking, management, and maintenance of inventory	Determines the availability and cost-effectiveness of in-house manufacturing and use of supplies	Designs code or scripts to automate activities to track, order, and manage inventory
INF 7.02. Inventory production	Performs data entry into existing electronic modules to document production of inventory	Validates the production of inventory	Evaluates data to improve the current and future states of inventory production	Writes code or scripts to automate inventory control
INF 7.03. Manufacturing formulations	Accesses manufacturing formulations electronically	Maintains the database of manufacturing formulations	Validates manufacturing formulations and SOPs	Develops workflows for manufacturing formulations
INF 7.04. Supply orders and vendors	Enters inventory order data into electronic order systems	Verifies the use of codes and parameters necessary to automate electronic orders of supplies	Manages order frequency and timetables	Develops workflows to automate the ordering of supplies from vendors

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 8.00. Data exchange and interoperability: manages the electronic exchange of laboratory data with data partners				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 8.01. Laboratory data collection	Explains data elements and formats necessary for data collection and exchange	Identifies analytical data and results and the exchange of this information using predefined modules	Develops automated interfaces to export data from instruments to electronic storage	Configures modules to automate the export of analytical data to electronic storage
INF 8.02. Electronic messaging	Describes use of predefined modules to deliver predefined messages to partners	Performs predefined queries of analytical data for electronic messaging	Develops <i>ad hoc</i> queries for electronic messaging	Maps electronic data to form messages consistent with client message structure, format, and vocabulary for export
INF 8.03. Electronic messaging transport	Describes predefined electronic messaging transport protocols ⁹	Sends automated electronic results to partners according to established electronic messaging transport protocols	Determines secure electronic messaging transport protocols	Ensures the use of secure electronic messaging transport protocols
INF 8.04. Message vocabulary	Describes vocabulary necessary for data exchange	Verifies local codes are pre-mapped to nationally accepted standard codes for test requests and test results	Evaluates processes that automate the linking of local and national codes	Automates the mapping of test codes and results to all standardized notifiable diseases and conditions
INF 8.05. Test order creation	Describes standard test order vocabulary	Communicates test orders with partners using predefined modules	Manages the automation of test orders in collaboration with partners	Develops protocols for automated electronic test order creation
INF 8.06. Test order receipt and notification	Describes standard test order receipt and notification vocabulary	Processes test orders received from partners using predefined modules	Manages the automation of test order receipts and notification in collaboration with partners	Develops protocols for electronic test order receipts and notification
INF 8.07. Test results reporting	Describes standard test results vocabulary	Communicates test results with partners using predefined modules	Manages the automation of test results reporting in collaboration with partners	Develops protocols for electronic test order results reporting
INF 8.08. Test results acknowledgment	Describes test results receipt acknowledgment	Verifies test results receipt with partners using predefined modules	Manages the automation of test results receipts in collaboration with partners	Develops protocols for electronic test results receipts
INF 8.09. Exchange networks	Describes exchange networks	Performs routine data exchange using predefined modules	Troubleshoots exchange network interfacing	Manages the workflow and operation of exchange networks according to information exchange standards

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 9.00. Statistical analysis and surveillance: generates statistical analyses of analytical results for public health surveillance				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 9.01. Meta data and demographic data	Enters meta data and demographic data associated with laboratory testing	Verifies the collection and editing of meta data and demographic data using predefined modules	Ensures the ability to capture, retrieve, and link meta data and demographic data associated with laboratory testing	Develops modules and workflows to electronically capture, retrieve, and link meta data and demographic data associated with laboratory testing
INF 9.02. Statistical analysis	Explains how automated statistical evaluation tools link meta data and demographic data within reports	Performs predefined queries on collected data for predefined statistical analyses to link meta data and demographic data within reports	Develops <i>ad hoc</i> queries to collect extracts of data for unique statistical analyses to link meta data and demographic data within reports	Writes code or procedure code for third-party software to automate the querying and reporting of statistical data to link meta data and demographic data within reports
INF 9.03. Laboratory performance analyses	Describes the production of laboratory performance reports	Provides reporting and evaluation of laboratory program performance data using predefined reports	Develops <i>ad hoc</i> statistical analyses to evaluate key performance indicators	Develops workflows and automation tools to ensure the implementation of laboratory performance-based analyses
INF 9.04. Spatial data	Describes modules for entering geographic information system (GIS) data	Uses predefined tools to integrate GIS data with laboratory testing results and with meta and demographic data	Evaluates the availability of validated tools to integrate GIS data with laboratory testing results and with meta and demographic data	Develops modules for LIMS-associated or third-party software to integrate GIS data with laboratory testing results and with meta and demographic data
INF 10.00. Billing for laboratory services: manages billing for laboratory services				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 10.01. Billing data	Links existing billing code(s) with associated laboratory services at time of accessioning	Troubleshoots billing data associated with laboratory services	Evaluates the automated capability to link billing data with laboratory services	Develops workflows and modules to manage the collection of financial data
INF 10.02. Accounts receivable*	Enters billing data in an accounts receivable program	Performs advanced functions of automated electronic billing and linking of laboratory services to accounts receivable systems	Manages accounts receivable systems regarding billing of services rendered	Develops workflows and modules to automate the integration of billing information with accounts receivable software and financial services
INF 10.03. Cost of testing and other laboratory services	Identifies accounting codes assigned for laboratory services rendered	Verifies that correct accounting codes are consistent with the cost of services and are linked to laboratory services rendered	Manages accounts for cost of laboratory services to individual customers	Develops workflows and modules to track the cost of laboratory services with customers and to manage the accounts receivable system

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 10.00. Billing for laboratory services: manages billing for laboratory services				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 10.04. Integration of laboratory billing with enterprisewide billing	Describes billing functions for multiple systems that handle billing of laboratory services	Verifies that accounting of laboratory services is being collected from disparate systems	Evaluates centralized functionality regarding an enterprise-wide capability to account for costs	Develops workflows and systems to consolidate cross-enterprise billing and accounting for laboratory services
INF 10.05. Budgeting*	Describes billing modules	Performs routine reporting of billing and revenue data for fiscal analyses	Generates detailed budgetary summaries of billing data	Develops systems to link billing data for budgeting and trend analysis
INF 11.00. Contract* and grant* management: manages grants and contractual instruments*				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 11.01. Document management systems	Describes centralized electronic document management systems that track and store grants, contractual instruments, and project management* materials	Verifies the entry and timeliness of laboratory program deliverables into document management systems	Evaluates document management systems to recommend improvements and efficiency and to meet contractual and grant obligations	Develops enterprise-wide workflows and communications to ensure an automated and secure document management system for grants and contractual instruments
INF 11.02. Contractual instruments	Describes informatics support available to laboratory through contractual instruments	Verifies the use of existing contractual instruments	Manages contractual instruments	Creates contractual instruments with partners to ensure informatics and information technology (IT) needs are captured
INF 11.03. Activity tracking	Describes informatics contractual and grant deliverables	Tracks activities and deliverables of grants and contractual instruments using predefined electronic modules	Evaluates the laboratory's ability to track delivery of individual informatics components related to budgetary, personnel, legal, and laboratory procedures and processes	Develops systems to define, organize, monitor, and track the activities of grants and contractual instruments with outside parties using electronic processes
INF 11.04. Enterprise-wide systems	Describes contractual informatics instruments relevant to the enterprise	Explains contractual instruments developed for individual laboratory programs for enterprise management	Evaluates informatics contractual instruments with outside parties using electronic documentation processes	Develops an enterprise-wide approach to information systems implementation
INF 12.00. Training, education, and resource management: manages training, education, and information resources				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 12.01. Electronic master record*	Accesses electronic information on staff training, education, and capabilities	Verifies that electronic documentation of training, education, and management of educational resources is up-to-date	Evaluates that electronic documentation of training, education, and related information meets operational requirements	Develops modules to ensure electronic content, access, and security exist to meet the educational needs of the laboratory
INF 12.02. Resource summaries	Lists available electronic reports that summarize laboratory resources, including staff	Verifies that electronic reports regarding laboratory resources are accurate and complete	Evaluates the need for additional and revised reports on laboratory resources	Develops modules to ensure electronic summary reports of laboratory resources are available

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 12.00. Training, education, and resource management: manages training, education, and information resources				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 12.03. Workforce development	Describes informatics systems for tracking documented staff needs and knowledge gained from training opportunities	Verifies that informatics processes remain up-to-date and demonstrate the acquired informatics capabilities of staff	Evaluates laboratory informatics needs to ensure the existence of resources and avenues to support staff education and training	Develops informatics programs to ensure that staff education and training is aligned with the business needs and directions for laboratory services and the professional growth of staff
INF 12.04. Training activities for external partners	Describes existing electronic documentation on trainings offered to external partners	Verifies electronic documentation on training activities for external partners are accurate and complete	Evaluates electronic training activities for external partners to ensure they meet current and future requirements	Develops electronic training materials and associated documentation for external partners
INF 12.05. Knowledge management (KM)*	Describes own role(s) in supporting the collective knowledge within a laboratory program	Verifies the participation and integration of program staff to ensure electronic KM within the organization	Evaluates the effectiveness of electronic KM practices organizationally	Develops a strategy for the creation, collection, and management of KM performance measures electronically
INF 12.06. Lifecycle management strategy* for IT investments	Describes laboratory IT project management resources	Ensures the use of IT project management resources	Evaluates staff compliance with a comprehensive lifecycle management strategy for IT investments	Develops a comprehensive laboratory IT lifecycle management strategy
INF 12.07. Informatics communication strategy	Describes the strategy for communicating with internal and external partners regarding informatics capabilities and resourcing priorities	Ensures the implementation of the communication strategy	Evaluates staff compliance with the communication strategy	Develops a strategy for communication of informatics capabilities and resourcing priorities to internal and external partners
INF 13.00. Laboratory certifications,* accreditations,* and licensing:* ensures adherence to local, state, and federal certification, accreditation, and licensing requirements				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 13.01. Certification, accreditation, and licensing (CAL) compliance	Explains applicable CAL electronic data requirements related to work area	Verifies the implementation of predefined data processing standards and form management associated with CAL for a laboratory program	Evaluates electronic data processing standards in order to ensure laboratory adherence to current and new CAL requirements	Develops workflows and modules to automate laboratory adherence to data processing standards associated with CAL
INF 13.02. External certification	Enters data into predefined modules	Verifies performance of predefined electronic systems regarding external certifications	Evaluates current capabilities to manage external certifications and future needs	Develops electronic modules to automate the management of external certifications
INF 13.03. Privacy and security	Describes electronic standards for own job classification related to the privacy and security of protected information*	Ensures that individual laboratory programs adhere to electronic security and privacy standards	Evaluates individual electronic security and privacy standards that the laboratory must meet	Develops workflows and modules to ensure electronic systems meet security and privacy standards and adhere to regulatory requirements

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 14.00. Customer relationship management: manages customer relationships				
Subcompetency	Beginner	Competent	Proficient	Expert
14.01. Tracking customer and staff feedback	Describes predefined modules to record customer and staff feedback	Verifies the implementation of predefined modules to record customer and staff feedback	Evaluates current and future needs to handle customer relationships and perform <i>ad hoc</i> queries to improve regulatory compliance and business management	Develops workflow and modules that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of customer and staff feedback
INF 14.02. Tracking laboratory errors and information requests	Describes predefined modules to record laboratory errors and information requests	Verifies the implementation of predefined modules to record laboratory errors and information requests	Evaluates current and future needs to track and perform <i>ad hoc</i> queries on laboratory errors and information requests	Develops workflow and modules that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of laboratory errors and information requests
INF 14.03. Tracking corrective actions and reports	Describes predefined modules that summarize reporting and corrective actions	Verifies the implementation of predefined modules to summarize corrective actions and generate reports	Evaluates current and future needs to track, perform <i>ad hoc</i> queries, and provide reports regarding corrective actions	Develops workflow and modules that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of correction actions
INF 15.00. QC and QA management: manages quality control and quality assurance processes				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 15.01. QC data associated with sample results	Describes predefined modules that collect QC data associated with sample results	Verifies the electronic set-up, extraction, and transmission of QC data using predefined modules and data capture utilities for automated instruments	Evaluates automated systems for QC data set up, extraction, and transmission	Develops automated processes for QC data set up, extraction, and transmission
INF 15.02. Data review and validation	Lists QC data that are collected electronically to support validation of test results	Performs review and validation of data	Validates final data prior to release to customers using configurable rules-based functionality	Develops workflows and modules to assist in automating the validation of test results
INF 15.03. Data trending	Enters QC data to support tracking, trending, and analysis of method accuracy and precision	Verifies the use of automated software to support analysis of QC data related to tracking, trending, and analysis of method accuracy and precision	Evaluates automated tracking, trending, and analysis of method accuracy and precision	Develops the workflows and automation processes to support automated tracking, trending, and analysis of method accuracy and precision
INF 15.04. QC reporting	Uses predefined modules to produce electronic and paper results that include QC data associated with test runs	Verifies the reporting and evaluation of QC data associated with analytical testing using predefined modules	Evaluates automated reporting of QC data associated with analytical batches	Develops reports that meet method requirements and customer needs to capture and deliver QC data in multiple formats and messages

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 15.00. QC and QA management: manages quality control and quality assurance processes				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 15.05. QA and quality management systems (QMS)*	Describes organizational structure, policies, processes, procedures, and resources that address QA related to informatics activities	Performs day-to-day oversight of organizational structure, policies, processes, procedures, and resources that address QA- and QMS-related to informatics activities	Evaluates organizational structure, policies, processes, procedures, and resources that address QA- and QMS-related to informatics activities	Develops informatics workflows and the organizational structure, policies, processes, procedures, and resources to address QMS and QA related to informatics activities
INF 15.06. Responses to QC data	Describes data elements needed to support automated auto-alerts, qualifiers, or triggering of responses to QC data	Verifies that data to support auto-alerts, qualifiers, or triggering of responses to QC data are associated with test results	Validates data elements using configurable rules-based functionality to provide auto- alerts, qualifiers, or triggering of responses to QC data	Develops automated workflows to provide auto-alerts, qualifiers, and triggering of responses to QC data
INF 16.00. Laboratory safety and accident investigation: manages laboratory safety and accident investigations				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 16.01. Hazardous materials* management	Describes electronic data entry and access to hazardous material locations, safety data sheets (SDS),* procedures, disposal records,* current practice standards, and master records	Verifies the central management of hazardous materials using predefined electronic modules for reporting and tracking	Evaluates the electronic, centralized management of hazardous materials	Develops an electronic, centralized system to manage hazardous materials
INF 16.02. Incident* tracking	Describes predefined modules to track incidents	Ensures staff compliance with electronic reporting of laboratory safety activities and accident investigations	Manages laboratory electronic safety and accident investigation processes and procedures	Develops electronic workflows, processes, and procedures to track and manage safety and accident investigations
INF 16.03. Select agent* management	Describes predefined modules related to the federal Select Agent Program* and registry	Ensures staff compliance with regulations associated with the federal Select Agent Program and registry	Evaluates automated processes to adhere to the federal Select Agent Program and registry	Develops electronic modules that adhere to the federal Select Agent Program and registry
INF 16.04. Hazardous material alerts*	Describes system alerts associated with hazardous materials	Verifies the generation of package and sample labels once an alert is received electronically	Evaluates current and future electronic hazardous material alert requirements	Develops electronic modules to manage and track activities associated with hazardous material alerts
INF 16.05. Hazardous risk management	Lists electronic central documents that define laboratory processes related to hazardous risk management	Verifies that documentation systems track laboratory processes related to hazardous risk management	Evaluates the documentation systems for laboratory processes related to hazardous risk management	Develops task workflow analyses to ensure the electronic management of hazardous risks

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 17.00. Laboratory mutual assistance and disaster recovery: manages laboratory mutual assistance and disaster recovery				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 17.01. Continuity of Operations Plan (COOP)*	Outlines coverage of informatics and IT services within the laboratory's COOP	Verifies that laboratory program responsibilities are carried out during the implementation of a COOP	Evaluates the informatics and IT aspects of the laboratory COOP to ensure they are complete and up-to-date	Develops informatics COOP workflows and procedures to restore informatics and IT support
INF 17.02. COOP contractual instruments	Describes COOP formal contractual instruments involving informatics	Verifies the performance of laboratory program informatics responsibilities pertaining to COOP contractual instruments	Manages the documentation supporting existing informatics contractual instruments pertaining to disaster recovery and mutual assistance through drills	Develops work plans and project management processes to ensure that comprehensive informatics contractual instruments are in place
INF 17.03. Electronic catalogue of capacities and services	Explains the importance of a catalogue of electronic capabilities and services, and of schedules for testing their effectiveness during disaster recovery and emergency situations	Verifies the accuracy and access to a catalogue of electronic capabilities, services, and schedules for testing their effectiveness during disaster recovery and emergency situations	Evaluates electronic catalogue capabilities, services, and schedules for testing their effectiveness during disaster recovery and emergency situations	Develops workflows and project management processes to validate the electronic catalogue of capabilities, services, schedules, and testing of effectiveness during disaster recovery and emergency situations
INF 18.00. Core IT products and services: manages core IT hardware, software, and services				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 18.01. Client-side systems and software	Employs client-side computer systems including LIMS access protocols and routine office software	Verifies the correct use of LIMS and advanced use of office software	Evaluates modifications, upgrades, and new releases to laboratory instrument software and systems	Evaluates client-side options regarding LIMS installation, management, and use
INF 18.02. Electronic communication	Describes communication tools for electronic information	Determines content for electronic information communication tools	Evaluates the use and requirements of electronic information communication tools	Develops the technology to support electronic information communication tools
INF 18.03. Enterprise-wide LIMS availability	Describes LIMS management processes	Verifies LIMS processes for data collection, data processing and reporting for laboratory business needs	Evaluates LIMS functionality to meet laboratory and customer needs	Manages the continuous availability and development of an enterprise-wide LIMS to ensure a fully functional and mature system
INF 18.04. Networking	Describes network access protocols and use of the laboratory network	Verifies laboratory use of predefined network protocols	Evaluates the use of networks to support laboratory activities	Manages the administration of network servers
INF 18.05. IT help desk	Describes access to available IT support	Documents the delivery of support to laboratory programs	Evaluates IT support needed for laboratory operations	Develops formal contractual instruments, workflows, and project management processes for the delivery of IT support throughout the laboratory

See table footnotes on page 61.

TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 18.00. Core IT products and services: manages core IT hardware, software, and services				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 18.06. Software development life cycle (SDLC)*	Describes the processes to use and improve electronic laboratory workflows and algorithms	Verifies needs for software process improvements	Evaluates the resources that impact the SDLC	Manages the SDLC at the enterprise-level, including change management*
INF 18.07. Enterprise integration engine*	Lists predefined functions that use an integration engine	Verifies the use of predefined integration engine modules	Evaluates integration functions with partners and customers	Develops automated workflows and processes regarding data capture and use of an integration engine to message data
INF 18.08. Legacy data systems*	Defines legacy data systems	Verifies access to, and use of, legacy data systems	Evaluates the accessibility and searchability of legacy data	Develops workflows and processes to ensure that legacy data are accessible and searchable
INF 18.09. LIMS communication with third-party data systems	Describes predefined modules to support LIMS communication with third-party data systems	Verifies the proper use of predefined modules to support LIMS communication with third-party data systems	Evaluates the ability of the LIMS to communicate with third-party data systems	Develops workflows and processes to support LIMS communications with third-party systems
INF 18.10. Access and audit trails	Describes modules that provide a view of audit trails	Verifies staff access to electronic audit trails	Evaluates the ability of the LIMS to manage access and audit trails	Develops protocols to manage access and audit trails
INF 18.11. Instrument analysis software	Describes instrument analysis software systems	Uses instrument analysis software	Evaluates analytical instrument software	Develops analytical instrument software systems
INF 18.12. Computer maintenance and troubleshooting	Identifies basic computer problems	Performs routine computer maintenance and troubleshooting	Performs complex computer maintenance and troubleshooting	Manages the computer maintenance and troubleshooting processes
INF 19.00. Policies and procedures: manages operational, budgeting and funding policies and procedures				
Subcompetency	Beginner	Competent	Proficient	Expert
INF 19.01. Informatics policy	Describes existing informatics policies	Ensures laboratory program adherence to existing informatics policies	Evaluates informatics policies	Develops processes for informatics policy making
INF 19.02. Change control [¶]	Describes change control processes related to informatics	Ensures laboratory program adherence to the change control processes related to informatics	Evaluates the effectiveness of change control processes related to informatics	Develops informatics policies, processes, and procedures to manage change control and ensure staff compliance
INF 19.03. Documentation for standardized laboratory IT processes	Provides documentation for standardized laboratory IT processes	Verifies that paper and electronic documentation of laboratory IT processes are centrally located and accessible	Evaluates completeness of documentation for standardized laboratory IT processes	Develops workflows and processes to ensure paper and electronic documentation is centrally located and accessible
INF 19.04. Operational budgeting strategy	Describes the importance of electronic budgetary processes	Identifies informatics business needs of the laboratory program for operational budgeting strategizing	Evaluates the operational budgeting strategy	Develops a budgeting strategy for the laboratory's informatics systems and services

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TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain

INF 19.00. Policies and procedures: manages operational, budgeting and funding policies and procedures

Subcompetency	Beginner	Competent	Proficient	Expert
INF 19.05. Capital budgeting*	Describes the capital budgeting processes for informatics-related assets*	Provides the listing of capital budget needs regarding laboratory informatics	Evaluates capital budgeting needs regarding laboratory informatics	Develops capital budgets for electronic information systems and services
INF 19.06. Partnership channels	Lists established stakeholders and partnership channels	Presents short- and long-term informatics business needs to management staff	Ensures that laboratory informatics business needs are presented to stakeholders and partnership channels	Develops partnerships to facilitate funding for informatics

* This term is defined in Appendix B.

† All of the tasks, in the proper order, required to carry out a process.

§ A set of technical rules for the transmission and receipt of information between computers.

¶ A process for implementing changes to software or other information technology solutions using a coordinated approach.

Microbiology Competency Guidelines

Purpose statement: The competencies in Microbiology address the knowledge, skills, and abilities needed to safely and securely detect, identify, and report infectious agents of concern to the public while following the laboratory path of workflow (Table 12).

Introduction: Microbiology is the scientific study of microorganisms and infectious agents as applied to the diagnosis, treatment, and prevention of disease, disability, and death. Microbiology includes the subspecialties of virology, mycology, parasitology, mycobacteriology and bacteriology that are encompassed in the disciplines of clinical, food, and environmental microbiology.

Microbiology is critical to the public health role of detecting and identifying outbreaks, emerging diseases, and biological threats. Public health laboratories serve many public health programs and provide reference and specialized testing that relate to disease control and prevention in the population.

The testing services address multiple modes of transmission and include molecular methods for epidemiology and disease surveillance. In addition, public health laboratories provide many specialized tests that are not commercially available.

Notes: Multiple sources were identified as support documents for this domain (26,51,59,61,62,82). This domain is not expected to be all-inclusive of functions performed in every microbiology subspecialty in the laboratory. The General Laboratory Practice and Safety domains are companions to this domain; all are intended to be used together, though some overlap in content exists. The verb “oversees” is used extensively in the Expert level. In this context, “oversees” is a broad term that comprises the many functions related to the management of policies, processes and procedures to include creation, design, development, directing, monitoring, evaluation, and collaboration. There is an assumption for the Beginner level, especially with use of the verbs “performs” and “adheres to,” that there is a degree of training and supervision still occurring that is providing needed guidance and information (e.g., on why it is critical to perform steps and processes as directed).

TABLE 12. Public health laboratory competency guidelines: Microbiology domain

MCB 1.00. Concepts and techniques: adheres to policies* and principles governing actions and behaviors that are essential when working in a microbiology laboratory

Subcompetency	Beginner	Competent	Proficient	Expert
MCB 1.01. Microbiological concepts and theories*	Describes basic microbiological concepts and theories	Relates microbiological concepts and theories to the specific tests that are conducted	Ensures microbiological concepts and theories are applied in laboratory testing	Evaluates laboratory practices for adherence to accepted microbiological concepts and theories
MCB 1.02. Basic microbiological techniques	Applies basic microbiological techniques to laboratory testing	Integrates basic microbiological techniques into new laboratory practices and procedures*	Trains staff on basic microbiological techniques	Ensures implementation of basic microbiological techniques into laboratory practices

MCB 2.00. Facilities and safety: works safely with microbiological agents within a laboratory facility*

Subcompetency	Beginner	Competent	Proficient	Expert
MCB 2.01. Laboratory hazards related to microbiological agents	Recognizes laboratory hazards and hazard communication* related to microbiological agents	Instructs others on laboratory hazards and hazard communication related to microbiological agents	Ensures staff compliance with policies, processes* and procedures addressing laboratory hazards related to microbiological agents	Develops policies, processes, and procedures regarding hazards related to microbial agents based on risk assessments [†]
MCB 2.02. Safe work practices*	Adheres to policies, processes, and procedures regarding safe work practices related to microbiological agents	Instructs others in policies, processes, and procedures regarding safe work practices related to microbiological agents	Ensures staff compliance with policies, processes, and procedures regarding safe work practices related to microbiological agents	Creates a culture of biosafety by ensuring that policies, processes, and procedures regarding safe work practices related to microbiological agents are aligned with current standards and regulatory requirements

See table footnotes on page 67.

TABLE 12. (Continued) Public health laboratory competency guidelines: Microbiology domain

MCB 2.00. Facilities and safety: works safely with microbiological agents within a laboratory facility*

Subcompetency	Beginner	Competent	Proficient	Expert
MCB 2.03. Personal protective equipment (PPE)*	Adheres to policies, processes, and procedures regarding PPE use for work related to microbiological agents	Instructs staff in policies, processes, and procedures regarding PPE use for work related to microbiological agents	Ensures staff compliance with policies, processes, and procedures regarding PPE use for work related to microbiological agents	Establishes policies, processes, and procedures regarding PPE use for work related to microbiological agents
MCB 2.04. Biosafety cabinets and other engineering controls*	Adheres to policies, processes, and procedures regarding the use of biosafety cabinets and other engineering controls	Instructs staff in use of biosafety cabinets and other engineering controls	Ensures laboratory adherence to biosafety cabinet certification* and staff compliance with policies, processes, and procedures regarding the use of biosafety cabinets and other engineering controls	Establishes policies, processes, and procedures, including training, to ensure implementation and use of biosafety cabinets and other engineering controls
MCB 2.05. Waste management related to microbiological agents	Adheres to policies, processes, and procedures regarding waste management related to microbiological agents	Instructs staff in waste management policies, processes, and procedures related to microbiological agents	Establishes waste management processes and procedures related to microbiological agents	Oversees the waste management plan* related to microbiological agents
MCB 2.06. Decontamination*	Adheres to policies, processes, and procedures regarding decontamination	Instructs staff in the policies, processes, and procedures regarding decontamination for different microorganisms	Ensures staff compliance with policies, processes, and procedures regarding decontamination	Develops policies, processes, and procedures related to decontamination
MCB 2.07. Storage of microbiological materials	Adheres to policies, processes, and procedures regarding storage of microbiological materials	Instructs staff in policies, processes, and procedures regarding the storage of microbiological materials for different microorganisms	Ensures staff compliance with policies, processes, and procedures that address the storage of microbiological materials	Develops policies, processes, and procedures related to the storage of microbiological materials

MCB 3.00. Pre-examination:* assesses microbiological samples* during the pre-examination phase

Subcompetency	Beginner	Competent	Proficient	Expert
MCB 3.01. Sample collection, labeling, and handling	Describes routine sample collection, labeling, and handling policies, processes, and procedures for microbiological examination	Consults on nonroutine sample collection, labeling, and handling procedures for microbiological examination	Monitors staff compliance with established policies, processes, and procedures regarding microbiological sample collection, labeling, and handling	Oversees the policies, processes, and procedures for sample collection, labeling, and handling for microbiological examination
MCB 3.02. Packaging and shipping	Performs packing and shipping of Category A* and Category B* infectious substances	Instructs others on packing and shipping of Category A and Category B infectious substances	Ensures staff compliance with policies, processes, and procedures regarding the packing and shipping of Category A and Category B infectious substances	Develops policies, processes, and procedures to ensure staff compliance with packing and shipping regulations concerning Category A and Category B infectious substances
MCB 3.03. Material transport	Describes the importance of adhering to established policies, processes, and procedures regarding microbiological material transport	Instructs others on microbiological material transport policies, processes, and procedures	Develops microbiological material transport processes and procedures	Oversees the policies, processes, and procedures regarding microbiological material transport

See table footnotes on page 67.

TABLE 12. (Continued) Public health laboratory competency guidelines: Microbiology domain

MCB 3.00. Pre-examination:* assesses microbiological samples* during the pre-examination phase

Subcompetency	Beginner	Competent	Proficient	Expert
MCB 3.04. Biological threats	Describes policies, processes, and procedures for the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Adheres to policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Ensures staff compliance with policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Oversees the policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern
MCB 3.05. Accessioning and receipt	Performs procedures for accessioning and receipt of microbiological samples	Instructs staff in policies, processes, and procedures regarding accessioning and receipt of microbiological samples	Develops processes and procedures for microbiological sample accessioning and receipt	Oversees the policies, processes, and procedures regarding microbiological sample accessioning and receipt
MCB 3.06. Sample tracking	Performs systematic tracking of microbiological samples from receipt to final disposition	Instructs staff on policies, processes, and procedures for the systematic tracking of microbiological samples from receipt to final disposition	Develops processes and procedures for the systematic tracking of microbiological samples from receipt to final disposition	Oversees the policies, processes, and procedures for the systematic tracking of microbiological samples from receipt to final disposition
MCB 3.07. Sample evaluation and appropriateness* for testing	Assesses sample appropriateness for a particular microbiological examination	Instructs others in the appropriateness of routine and nonroutine samples for microbiological examination	Develops processes and procedures for assessment of routine and nonroutine sample appropriateness for microbiological examination	Oversees the policies, processes, and procedures regarding assessment of routine and nonroutine sample appropriateness for microbiological examination
MCB 3.08. Testing workflow [§]	Adheres to policies, processes, and procedures regarding testing workflow	Instructs staff in policies, processes, and procedures regarding testing workflow	Ensures staff compliance with policies, processes, and procedures related to testing workflow	Establishes policies, processes, and procedures related to testing workflow
MCB 3.09. Nucleic Acid Amplification Tests (NAAT) workflow (facility specific)	Adheres to policies, processes, and procedures regarding NAAT workflow	Instructs staff in policies, processes, and procedures regarding NAAT workflow, including pre- and postamplification areas	Ensures staff compliance with policies, processes, and procedures regarding NAAT workflow	Establishes policies, processes, and procedures for NAAT workflow
MCB 3.10. Sample set-up	Performs sample set-up procedures for microbiological examinations	Instructs staff in sample set-up for microbiological examinations	Develops processes and procedures regarding sample set-up for microbiological examinations	Oversees the policies, processes, and procedures regarding sample set-up for microbiological examinations
MCB 3.11. Sample storage and handling	Performs procedures for microbiological sample storage and handling prior to examination	Instructs staff in procedures for microbiological sample storage and handling prior to examination	Develops processes and procedures for microbiological sample storage and handling prior to examination	Oversees the policies, processes, and procedures regarding microbiological sample storage and handling prior to examination
MCB 3.12. Epidemiologic collaboration	Describes which microbiological examination requests require epidemiologic notification and consultation	Reports to epidemiologists when microbiological examination requests warrant notification	Ensures staff compliance with policies, processes, and procedures for notification and consultation with epidemiologists regarding microbiological examination requests	Oversees the policies, processes, and procedures for notification and consultation with epidemiologists regarding microbiological examination requests

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TABLE 12. (Continued) Public health laboratory competency guidelines: Microbiology domain

MCB 4.00. Examination:* assesses microbiological samples during the examination phase				
Subcompetency	Beginner	Competent	Proficient	Expert
MCB 4.01. Preparation of culture media	Prepares culture media according to policies, processes, and procedures	Instructs staff on the preparation of culture media	Ensures staff compliance with policies, processes, and procedures regarding quality practices for media preparation	Oversees the policies, processes, and procedures for media preparation
MCB 4.02. Selection of media	Selects media according to procedures	Instructs staff in the media selection process	Ensures staff compliance with policies, processes and procedures regarding quality practices for media selection	Oversees the policies, processes, and procedures regarding media selection
MCB 4.03. Culture inoculation	Performs culture inoculation using aseptic techniques	Instructs staff in how to inoculate cultures using aseptic technique	Ensures staff compliance with policies, processes and procedures regarding quality practices for culture inoculation	Oversees the policies, processes, and procedures regarding culture inoculation
MCB 4.04. Microscopic examination with morphological characteristics	Recognizes the morphological characteristics of different organisms	Instructs staff in morphological identification and differentiating organisms from artifacts	Ensures staff compliance with policies, processes and procedures regarding quality practices for morphological identification	Oversees the policies, processes, and procedures regarding morphological identification
MCB 4.05. Culture growth characteristics	Recognizes growth characteristics of microorganisms	Instructs staff in identifying growth characteristics of microorganisms	Ensures staff compliance with policies, processes and procedures regarding quality practices for identifying microorganism growth characteristics	Oversees the policies, processes, and procedures for interpretation of microorganism growth characteristics
MCB 4.06. Manual identification* and susceptibility testing* methods	Performs identification and susceptibility testing using manual methods	Instructs staff in the performance of identification and susceptibility testing using manual methods	Ensures staff compliance with policies, processes, and procedures regarding quality practices for performing identification and susceptibility testing using manual methods	Oversees the policies, processes, and procedures regarding the performance of identification and susceptibility testing using manual methods
MCB 4.07. Automated identification* and susceptibility testing* systems	Performs identification and susceptibility testing using automated systems	Instructs staff in the performance of identification and susceptibility testing using automated systems, including how to utilize algorithms to determine additional testing	Ensures staff compliance with policies, processes, and procedures regarding quality practices for performing identification and susceptibility testing using automated systems	Oversees the policies, processes, and procedures regarding the performance of identification and susceptibility testing using automated systems
MCB 4.08. Agent-specific antigen detection*	Performs antigen detection methods	Instructs staff in how to perform antigen detection methods	Ensures staff compliance with policies, processes, and procedures regarding quality practices for antigen detection methods	Oversees the policies, processes, and procedures for antigen detection
MCB 4.09. Nucleic acid (NA) sequencing of infectious agents	Performs NA sequencing of infectious agents	Instructs staff in the performance of NA sequencing for the identification of infectious agents	Ensures staff compliance with policies, processes, and procedures regarding quality practices for NA sequencing of infectious agents, including the selection and utilization of databases	Oversees the policies, processes, and procedures regarding NA sequencing and sequence-based identification

See table footnotes on page 67.

TABLE 12. (Continued) Public health laboratory competency guidelines: Microbiology domain

MCB 4.00. Examination:* assesses microbiological samples during the examination phase				
Subcompetency	Beginner	Competent	Proficient	Expert
MCB 4.10. Strain typing methods*	Performs strain typing	Instructs staff in how to perform strain typing	Ensures staff compliance with policies, processes, and procedures regarding quality practices for strain typing	Oversees the policies, processes, and procedures regarding strain typing
MCB 4.11. Rule-out testing for agents of concern	Explains the policies, processes, and procedures regarding rule-out testing and referral	Performs rule-out testing and referral for identification, confirmation, and characterization of agents of concern	Ensures the laboratory responds quickly to needs for rapid testing with timely notification and secure messaging of results	Oversees the policies, processes, and procedures regarding rule-out testing and referral
MCB 4.12. Quality control (QC)* analysis	Performs QC activities	Interprets QC data prior to reporting results	Examines QC data over time to establish QC ranges and limits	Ensures the QC program adheres to regulatory requirements*
MCB 5.00. Postexamination:* performs postexamination procedures of microbiological testing				
Subcompetency	Beginner	Competent	Proficient	Expert
MCB 5.01. QC evaluation	Assembles QC data for evaluation	Evaluates QC data for a given data reporting period	Ensures staff compliance with established policies, processes, and procedures for QC evaluation activities	Oversees the policies, processes, and procedures related to QC evaluation activities
MCB 5.02. Test analysis and results interpretation	Assembles test data for review and action	Analyzes test data	Interprets complex or ambiguous results	Oversees the policies, processes, procedures, and algorithms related to data analysis and results interpretation
MCB 5.03. Results reporting and data release	Adheres to policies, processes and procedures related to reporting and release of examination results and notifiable results*	Instruct staff in the policies, processes, and procedures related to reporting and release of examination results and notifiable results	Ensures staff compliance with policies, processes and procedures related to reporting and release of examination results and notifiable results	Oversees the policies, processes, and procedures, related to reporting and release of examination results and notifiable results to partners
MCB 5.04. Quality assurance (QA)*	Explains the differences between QA and QC	Collects data for reporting on QA indicators	Evaluates QA indicator data	Oversees the policies, processes, and procedures related to QA

See table footnotes on page 67.

TABLE 12. (Continued) Public health laboratory competency guidelines: Microbiology domain

MCB 6.00. Regulatory compliance: ensures regulatory compliance				
Subcompetency	Beginner	Competent	Proficient	Expert
MCB 6.01. Nonconforming event (NCE)* tracking	Recognizes NCEs in laboratory processes	Documents NCEs on discovery for implementation of corrective actions	Analyzes NCEs for corrective actions and documentation	Designs a management system for NCEs
MCB 6.02. Proficiency testing (PT)* and alternative assessment*	Performs PT and alternative assessment	Reviews PT and alternative assessment results	Monitors to ensure the PT and alternative assessment program meets regulatory requirements	Oversees the policies, processes, and procedures related to PT and alternative assessments
MCB 6.03. Method validation* and performance verification*	Participates in performance of method validation and performance verification	Compiles results of method validation and performance verification	Evaluates method validation and performance verification results	Oversees the policies, processes, and procedures related to method validation and performance verification
MCB 6.04. Development and validation of laboratory-developed tests (LDTs)*	Participates in the development of LDTs	Evaluates LDT validation data	Creates processes and procedures for the development and validation of LDTs	Oversees the policies, processes, and procedures regarding the development and validation of LDTs
MCB 6.05. Select agents*	Describes the policies, processes, and procedures related to the federal Select Agent Program* including the securing, safe handling, and testing of select agents and the documentation of activities	Complies with policies, processes, and procedures related to the federal Select Agent Program, including the securing, safe handling, and testing of select agents and the documentation of activities	Implements policies, processes, and procedures regarding select agent security, biosafety, testing, and incident response plans*	Oversees select agent security, biosafety, testing, and incident response plans to ensure alignment with select agent regulations

* This term is defined in Appendix B.

† The evaluation of 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.

§ Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Chemistry Competency Guidelines

Purpose statement: The competencies in Chemistry address the knowledge, skills, and abilities needed for the qualitative and quantitative analysis of chemicals of concern to the public in biological and environmental matrices (Table 13).

Introduction: Chemistry is the science of detection, measurement, and characterization of chemicals of public health importance in samples (e.g., human and animal, food and feed, water and soil). Chemistry encompasses numerous subdisciplines in areas of both organic and inorganic testing.

Chemistry programs within public health laboratories provide a first line of defense in the rapid recognition of toxic chemical exposures and also support environmental health and epidemiological programs that investigate human exposures to chemicals in the environment. Chemistry programs also provide a wide array of specialized services related to clinical diagnostics for evaluating individual health, identification of environmental health issues, and investigation of population

exposures through epidemiological programs' studies. They also aid in the response to chemical emergencies or chemical terrorism events by providing rapid and definitive testing to identify and quantify chemical agents.

Notes: Sources were identified as support documents for this domain (60,83). This domain is not expected to be all-inclusive of all chemistry-related laboratory activities. The General Laboratory Practice and Safety domains are companions to this domain; all are intended to be used together, though some overlap in content exists. The verb "oversees" is used often in the Expert level. In this context, "oversees" is a broad term that comprises the many functions related to the management of policies, processes and procedures to include creation, design, development, directing, monitoring, evaluation, and collaboration. There is an assumption for the Beginner level, especially with use of the verbs "performs" and "adheres to," that there is a degree of training and supervision still occurring that is providing needed guidance and information (e.g., on why it is critical to perform steps and processes as directed).

TABLE 13. Public health laboratory competency guidelines: Chemistry domain

CHM 1.00. Concepts and techniques: applies knowledge of chemical concepts* and techniques to studies of biological and environmental matrices				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 1.01. Chemical properties	Applies knowledge of the properties of matter to assist in chemical analyses	Integrates knowledge of the properties of matter into new chemical analyses	Differentiates chemical properties to improve chemical analyses	Integrates new understandings of chemical properties to address occupational exposures or environmental or other public health issues
CHM 1.02. Chemical concepts	Describes chemical concepts	Applies chemical concepts to analyses	Differentiates chemical concepts in analyses	Formulates new chemical concepts to improve determinations
CHM 1.03. Laboratory statistics	Explains statistical concepts and practices	Collects data for statistical analyses	Evaluates summarized data for statistical analyses	Oversees the development and use of statistical programs
CHM 1.04. Equations and calculations	Performs chemical calculations	Instructs staff in the performance of chemical calculations	Determines when and which chemical equations and calculations are needed	Oversees the use and interpretation of chemical equations and calculations
CHM 1.05. Measurements	Performs measurements and unit conversion calculations	Instructs staff in measurements and unit conversion calculations	Determines the needed accuracy and precision of measurements	Develops processes* and procedures* to maximize the accuracy and precision of measurements and techniques

See table footnotes on page 71.

TABLE 13. (Continued) Public health laboratory competency guidelines: Chemistry domain

CHM 2.00. Facilities and safety: works safely with hazardous materials* within a laboratory facility*

Subcompetency	Beginner	Competent	Proficient	Expert
CHM 2.01. Chemical hazards	Recognizes chemical hazards and chemical hazard communication*	Instructs others on chemical hazards and hazard communication	Implements hazard communication procedures and training	Develops strategies to reduce chemical hazards based on risk assessments [†]
CHM 2.02. Safe work practices*	Adheres to safe work practices related to chemical hazards	Instructs others in safe work practices, policies, and procedures related to chemical hazards	Ensures staff compliance with policies,* processes, and procedures related to safe work practices related to chemical hazards	Creates a culture of safety by ensuring that policies, processes, and procedures regarding safe work practices related to chemical hazards are aligned with current standards and regulatory requirements
CHM 2.03. Personal protective equipment (PPE)*	Adheres to policies, processes, and procedures regarding PPE use	Instructs staff in the use of PPE	Ensures that staff are trained and comply with policies, processes, and procedures regarding the use of PPE	Establishes policies, processes, and procedures regarding the use of PPE
CHM 2.04. Engineering controls*	Adheres to policies, processes, and procedures regarding the use of engineering controls	Instructs staff in the use of engineering controls	Ensures that staff are trained and comply with policies, processes, and procedures regarding the use of engineering controls	Establishes policies, processes, and procedures regarding the use of engineering controls
CHM 2.05. Waste management related to samples*	Adheres to policies, processes, and procedures related to sample waste management	Instructs staff in sample waste management policies, processes, and procedures	Establishes sample waste management policies, processes, and procedures	Oversees the sample waste management plan*

CHM 3.00. Pre-examination:* performs chemistry pre-examination procedures

Subcompetency	Beginner	Competent	Proficient	Expert
CHM 3.01. Sample collection, labeling, and handling	Describes routine sample collection, labeling, and handling policies, processes, and procedures for chemical examination	Consults on nonroutine sample collection, labeling, and handling procedures for chemical examination	Monitors staff compliance with established policies, processes, and procedures regarding chemical sample collection, labeling, and handling	Oversees the policies, processes, and procedures for the collection and handling of samples for chemical examination
CHM 3.02. Packaging and shipping	Performs the packing and shipping of hazardous samples	Instructs others on packing and shipping of hazardous samples	Ensures staff compliance with policies, processes, and procedures regarding the packing and shipping of hazardous samples	Develops policies, processes, and procedures to ensure staff compliance with packing and shipping regulations concerning hazardous samples
CHM 3.03. Material transport	Describes the importance of adhering to established policies, processes, and procedures regarding transport of materials for chemical examination	Instructs others on material transport policies, processes, and procedures	Develops material transport processes and procedures	Oversees the policies, processes, and procedures for the transport of materials for chemical examination
CHM 3.04. Chemical threats	Describes the policies, processes, and procedures for the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Adheres to policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Ensures staff compliance with policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Oversees the policies, processes, and procedures regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern

See table footnotes on page 71.

TABLE 13. (Continued) Public health laboratory competency guidelines: Chemistry domain

CHM 3.00. Pre-examination:* performs chemistry pre-examination procedures				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 3.05. Accessioning and receipt	Performs procedures for sample accessioning and receipt	Instructs staff on policies, processes, and procedures regarding sample accessioning and receipt	Manages the policies, processes, and procedures for sample accessioning and receipt	Designs policies, processes, and procedures regarding sample accessioning and receipt
CHM 3.06. Sample tracking	Performs systematic tracking of samples from receipt to final disposition	Instructs staff on policies, processes, and procedures for the systematic tracking of samples from receipt to final disposition	Manages the policies, processes, and procedures for the systematic tracking of samples from receipt to final disposition	Designs policies, processes, and procedures for the systematic tracking of samples from receipt to final disposition
CHM 3.07. Sample evaluation and appropriateness* for testing	Assesses appropriateness of routine samples for chemical examination	Instructs others in appropriateness of routine and nonroutine samples for chemical examination	Manages the policies, processes, and procedures for assessment of routine and nonroutine sample appropriateness for chemical examination	Establishes policies, processes, and procedures regarding the assessment of routine and nonroutine sample appropriateness for chemical examination
CHM 3.08. Testing workflow [§]	Adheres to policies, processes, and procedures regarding testing workflow	Instructs staff in policies, processes, and procedures regarding testing workflow	Ensures laboratory processes and procedures include use of testing workflow	Develops policies, processes, and procedures related to testing workflow
CHM 3.09. Sample processing	Performs sample processing procedures for routine chemical examinations	Performs sample processing for complex chemical examinations	Instructs staff on sample processing for routine and complex chemical examinations	Develops policies, processes, and procedures regarding sample processing for routine and complex chemical examinations
CHM 3.10. Pre-examination sample storage and handling	Performs procedures for sample storage and handling prior to examination	Instructs staff in procedures for sample storage and handling prior to examination	Manages processes and procedures for sample storage and handling prior to examination	Designs policies, processes, and procedures regarding sample storage and handling prior to examination
CHM 3.11. Epidemiologic collaboration	Describes which chemical examination requests require epidemiologic notification and consultation	Reports to epidemiologists when chemical examination requests warrant notification	Manages the policies, processes, and procedures for notification and consultation with epidemiologists regarding chemical examination requests	Designs policies, processes, and procedures regarding notification and consultation with epidemiologists regarding chemical examination requests
CHM 4.00. Examination:* performs chemistry examination procedures				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 4.01. Examination	Performs chemistry examination procedures	Instructs staff in chemistry examination procedures	Monitors staff compliance with chemistry examination policies, processes, and procedures	Oversees chemistry examination policies, processes, and procedures
CHM 4.02. Chemical extractions	Performs routine chemical extraction methods	Performs nonroutine chemical extractions	Selects chemical extractions for an identified purpose	Develops new and improved types of chemical extractions
CHM 4.03. Quality control (QC)* analysis	Performs QC activities	Interprets QC data prior to reporting results	Examines QC data over time to establish QC ranges and limits	Ensures the QC program adheres to regulatory requirements*
CHM 4.04. Equipment troubleshooting	Identifies basic laboratory equipment* problems	Corrects equipment problems or failures	Monitors equipment functioning during its lifecycle	Develops equipment troubleshooting processes and procedures

See table footnotes on page 71.

TABLE 13. (Continued) Public health laboratory competency guidelines: Chemistry domain

CHM 4.00. Examination:* performs chemistry examination procedures				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 4.05. Sample storage and handling after examination	Performs procedures for sample storage and handling after examination	Instructs staff in procedures for sample storage and handling after examination	Manages processes and procedures for sample storage and handling after examination	Designs policies, processes, and procedures for sample storage and handling after examination
CHM 5.00. Postexamination:* performs chemistry postexamination procedures				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 5.01. QC evaluation	Assembles QC data for evaluation	Evaluates QC data for a given data reporting period	Ensures staff compliance with established policies, processes, and procedures for QC evaluation activities	Oversees the policies, processes, and procedures related to QC evaluation activities
CHM 5.02. Test analysis and results interpretation	Assembles test data for review and action	Analyzes test data	Interprets complex or ambiguous results	Oversees the policies, processes, procedures, and algorithms related to data analysis and results interpretation
CHM 5.03. Results reporting and data release	Adheres to policies, processes and procedures related to reporting and release of examination results and notifiable results*	Instruct staff in the policies, processes, and procedures related to reporting and release of examination results and notifiable results	Ensures staff compliance with policies, processes and procedures related to reporting and release of examination results and notifiable results	Oversees the policies, processes, and procedures, related to reporting and release of examination results and notifiable results to partners
CHM 5.04. Quality assurance (QA)*	Explains the differences between QA and QC	Collects data for reporting on QA indicators	Evaluates QA indicator data	Oversees the policies, processes, and procedures related to QA
CHM 6.00. Regulatory compliance: ensures regulatory compliance				
Subcompetency	Beginner	Competent	Proficient	Expert
CHM 6.01. Nonconforming event (NCE)* tracking	Recognizes NCEs in laboratory processes	Documents NCEs on discovery for implementation of corrective actions	Analyzes NCEs for corrective actions and documentation	Designs a management system for NCEs
CHM 6.02. Proficiency testing (PT)* and alternative assessment*	Performs PT and alternative assessment	Reviews PT and alternative assessment results	Monitors to ensure the PT and alternative assessment program meets regulatory requirements	Oversees the policies, processes, and procedures related to PT and alternative assessments
CHM 6.03. Method validation* and performance verification*	Participates in performance of method validation and performance verification	Compiles results of method validation and performance verification	Evaluates method validation and performance verification results	Oversees the policies, processes, and procedures related to method validation and performance verification
CHM 6.04. Development and validation of laboratory-developed tests (LDTs)*	Participates in the development of LDTs	Evaluates LDT validation data	Creates processes and procedures for the development and validation of LDTs	Oversees the policies, processes, and procedures regarding the development and validation of LDTs

* This term is defined in Appendix B.

† The evaluation of 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.

§ Sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures.

Bioinformatics Competency Guidelines

Purpose statement: The competencies in Bioinformatics address the knowledge, skills, and abilities needed to collect, classify, and analyze biological and biochemical information through the development and use of computer databases, algorithms, and statistical techniques (Table 14).

Introduction: Bioinformatics is the field of science that bridges the gap between biology, computer science, and information technology by merging them into a single discipline. There are three important subdisciplines within bioinformatics: the development of new algorithms and statistics with which to assess relationships among members of large data sets; the analysis and interpretation of various types of data including nucleotide and amino acid sequences,

protein domains, and protein structures; and the development and implementation of tools that enable efficient access and management of different types of information.

Bioinformatics capability and capacity have become progressively more important within public health laboratories because of rapid advances in molecular technologies and laboratory techniques. As a result, the amount of data that a typical laboratory can generate has increased dramatically over the past decade. This increase in data requires new competencies for laboratory scientists to analyze and interpret large datasets, and communicate complex and complete results to audiences of varied backgrounds.

Notes: Sources were identified as support documents for this domain (84,85). This domain is intended for all laboratory scientists in addition to bioinformatics specialists.

TABLE 14. Public health laboratory competency guidelines: Bioinformatics domain

BIO 1.00. Biology and computer science knowledge: integrates knowledge of biology and computer science				
Subcompetency	Beginner	Competent	Proficient	Expert
BIO 1.01. Domain-specific biology principles	Identifies potential biological problems to be addressed by computer science techniques	Determines biological problems to be addressed by computer science techniques	Evaluates the effectiveness of the selected computer science technique(s) in addressing biological problems	Selects biological problems to be addressed by computer science techniques
BIO 1.02. Domain-specific computer science principles	Identifies computer science domains* to apply to biological problems	Applies computer science domains to biological problems	Evaluates computer science domains to apply to biological problems	Develops new understandings of computer science domains to apply to biological problems
BIO 2.00. Statistical methods knowledge: applies knowledge of statistical methods for analysis of biological data				
Subcompetency	Beginner	Competent	Proficient	Expert
BIO 2.01. Statistical analysis	Prepares data for processing	Uses simple statistical analysis to analyze trends and patterns and to draw conclusions related to the biological data	Compares findings to any related data sets	Oversees selection of advanced statistical methods applicable to specific bioinformatics analyses

See table footnotes on page 73.

TABLE 14. (Continued) Public health laboratory competency guidelines: Bioinformatics domain

BIO 3.00. Data analysis: analyzes biological data				
Subcompetency	Beginner	Competent	Proficient	Expert
BIO 3.01. Data analysis	Selects which existing tools and algorithms to use for any given analysis	Determines options and parameters of tools to meet specified needs of a given data analysis	Implements new software tools to address unmet needs or improve current processes*	Creates stand-alone analysis tools
BIO 3.02. Data interpretation	Identifies data pertinent to the analysis problem	Formulates results of analyses, including information in the form of graphs, charts, and tables	Interprets results within the context of the analysis problem	Generates hypotheses to predict future implications based on the evaluation of data analyses
BIO 3.03. Data visualization and representation	Uses data visualization and representation tools to present results of data analyses	Selects visualization and representation tools for specified bioinformatics problems	Evaluates representation and visualization tools for summarizing data analyses	Modifies existing visualization and representation tools to provide insight into bioinformatics analyses
BIO 3.04. Communication	Discusses bioinformatics with other scientists within their institution	Initiates bioinformatics collaborations with colleagues	Facilitates knowledge-sharing with stakeholders	Contributes to new findings and meaningful advancements in bioinformatics through the evaluation and sharing of knowledge
BIO 4.00. Data management: conducts data management, storage, and retrieval				
Subcompetency	Beginner	Competent	Proficient	Expert
BIO 4.01. Data structures*	Demonstrates basic knowledge of data structures	Applies knowledge of data structures to relevant problems	Manipulates data structures to address biological problems	Develops new data structures
BIO 4.02. Data management	Describes data management techniques	Applies knowledge of data management techniques to relevant problems	Evaluates data management techniques	Develops new data management techniques
BIO 4.03. Data storage and retrieval	Describes data storage and retrieval techniques	Applies knowledge of data storage and retrieval techniques	Evaluates data storage and retrieval techniques	Develops new data storage and retrieval techniques
BIO 4.04. Allocation of computing resources	Describe available computing resources and capacity	Allocates computing resources	Manages allocation of multiple computing resources	Develops new methods for allocation of computing resources

* This term is defined in Appendix B.

Research Competency Guidelines

Purpose statement: The competencies in Research address the knowledge, skills, and abilities needed to conduct a systematic, hypothesis-driven investigation that includes research development, testing, and evaluation designed to advance public health knowledge, methods, and/or practice (Table 15).

Introduction: Research is a systematic investigation designed to develop or contribute to generalizable knowledge. It also includes product or method development, assessment, and evaluation. Scientific research provides information to solve new or existing problems, to reaffirm results of previous work, and to support or develop new hypotheses.

Research is critical to the public health enterprise, as communities are continually challenged with new diseases and unknown environmental public health threats. The public

health laboratory community is also challenged by changes in virulence or drug susceptibility of pathogens, which impact exposure investigation and response, and the need for advanced diagnostics and analyses to support surveillance.

Notes: Multiple sources were identified as support documents for this domain (41,44,86,87). This domain is intended for use in conjunction with the General Laboratory Practice and Safety domains. The verb “oversees” is used extensively in the Expert level. In this context, “oversees” is a broad term that comprises the many functions related to the management of policies, processes and procedures to include creation, design, development, directing, monitoring, evaluation, and collaboration. This domain does not address areas of assessment and evaluation of laboratory practices, which is included in the Quality Management System and Management and Leadership domains.

TABLE 15. Public health laboratory competency guidelines: Research domain

RES 1.00. Research programs: develops research programs				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 1.01. Research objectives and agenda	Describes the laboratory's research objectives	Illustrates how research projects fit within the laboratory's research objectives and agenda	Formulates research projects that align with the laboratory's research objectives and agenda	Develops hypothesis-driven research objectives and a research agenda for the laboratory
RES 1.02. Research funding	Describes general funding mechanisms that support public health research	Participates in writing funding proposals for research projects	Leads drafting of research funding proposals	Manages the overall processes* for obtaining and sustaining research funds
RES 1.03. Funding proposal reviews	Describes basics of the proposal review process	Reviews internal proposals to verify adherence to guidelines and recommended principles	Serves as an <i>ad hoc</i> reviewer for research proposal reviews	Serves on research proposal review committees
RES 1.04. Research staffing needs	Describes own role as part of the research staff	Recognizes research staffing needs	Participates in hiring research staff	Develops the strategic plan to recruit and retain researchers
RES 1.05. Research resource management	Uses financial and material resources judiciously	Considers available financial, human, and material resources when planning experiments	Assesses financial, human, and material resources when planning research projects	Aligns financial, human, and material resources to support the research program
RES 1.06. Regulatory requirements*	Complies with regulatory requirements in the performance of research	Identifies noncompliance with regulatory requirements pertaining to the performance of research	Manages processes regarding staff compliance with regulatory requirements concerning the performance of research	Ensures that laboratory programs operate consistent with regulatory requirements concerning the performance of research

See table footnotes on page 77.

TABLE 15. (Continued) Public health laboratory competency guidelines: Research domain

RES 2.00. Ethical conduct: ensures the ethical and responsible conduct of research				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 2.01. Ethical conduct in research*	Complies with policies* processes, and procedures* related to ethical conduct in research	Instructs others in policies, processes, and procedures regarding ethical conduct in research	Ensures staff compliance to policies and procedures related to ethical research practices	Oversees the policies, processes, and procedures for implementing and maintaining ethical research practices
RES 2.02. Human and nonhuman subjects	Complies with policies, processes, and procedures related to doing research in human and nonhuman subjects	Instructs others in policies, processes, and procedures related to doing research in human and nonhuman subjects	Ensures staff compliance to policies and procedures related to doing research in human and nonhuman subjects	Oversees the policies, processes, and procedures for implementing and maintaining ethical practices* related to doing research in human and nonhuman subjects
RES 2.03. Collaboration	Complies with established agreements with collaborators	Describes complexities regarding issues of collaboration, including authorship	Ensures staff compliance with established agreements for research collaboration	Builds research collaborations
RES 2.04. Sharing research data	Complies with established agreements pertaining to research data sharing and the use of intellectual property	Describes issues that might arise pertaining to data ownership and the sharing of data	Ensures staff compliance with established agreements regarding data sharing	Establishes guidelines for sharing research data
RES 3.00. Research foundation: integrates scientific and technical knowledge for use as a foundation for research				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 3.01. Literature searches	Performs basic literature searches using a limited number of sources	Performs complex searches, aggregating results from multiple sources	Validates appropriateness of how searches are performed	Rectifies gaps in data generated from searches
RES 3.02. Critique of scientific literature	Reads scientific and technical literature relevant to own work	Assesses quality of literature and pertinence to own work	Synthesizes scientific evidence derived from literature	Evaluates scientific literature and data to determine impact on laboratory research programs
RES 3.03. Statistical concepts and tests	Recognizes meaning of common statistical concepts and tests	Applies appropriate statistical concepts and tests in performance of research	Interprets statistical tests and concepts used in literature	Critiques statistical tests and concepts used in literature
RES 3.04. Study designs	Explains characteristics of common study designs	Recognizes strengths and limitations of study designs	Considers study design characteristics when planning research activities	Evaluates evidence-based research guidelines to select or develop study designs
RES 3.05. Scientific and technical concepts and procedures	States scientific and technical concepts and procedures	Discusses scientific and technical concepts and procedures	Critiques scientific and technical concepts and procedures	Generates novel scientific and technical concepts and procedures
RES 3.06. Emerging trends	States latest scientific and technical advances relevant to current research	Discusses latest scientific and technical advances relevant to current research	Identifies emerging trends in scientific and technical advances and possible impact to laboratory	Analyzes emerging trends in scientific and technical advances to make decisions regarding impact on laboratory

See table footnotes on page 77.

TABLE 15. (Continued) Public health laboratory competency guidelines: Research domain

RES 4.00. Testing methodology development: develops new testing methodology				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 4.01. New testing methodologies	States the purpose of each step in existing testing methodologies employed	Describes limitations of existing methodologies	Proposes concepts for improved methodologies	Oversees plans for the development of new methodologies
RES 4.02. Pilot testing, method validation* and performance verification*	Contributes to pilot testing, method validation, or performance verification	Performs pilot testing, method validation, or performance verification	Designs strategies for pilot testing, method validation, or performance verification	Oversees pilot testing, method validation, and performance verification studies
RES 4.03. New methodology application	Participates in implementation of new methodologies	Implements new methodologies into laboratory practice	Manages implementation of new methodologies	Oversees the implementation of new methodologies within the laboratory
RES 5.00. Research project execution: conducts research to address a public health issue or answer a public health question				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 5.01. Research project design	Explains how own tasks and activities support specific research projects	Summarizes the public health issues and research questions addressed by specific research projects	Designs research projects	Oversees research projects to address the identified public health issues or questions
RES 5.02. Experimental strategy and design	States the purpose of each step performed in individual experiments	Explains the overall experimental strategy	Designs individual experiments	Generates the overall experimental strategy and hypotheses for specific research projects
RES 5.03. Conduct of experiments	Uses established research protocols [†]	Provides input regarding research protocols and the conduct of experiments	Develops research protocols to guide the conduct of experiments	Oversees the conduct of experiments
RES 6.00. Research data management, analysis, and application: conducts research according to professional standards of data management, analysis, and application				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 6.01. Data collection and quality*	Records experimental procedures and data	Monitors quality and integrity of recorded information and data	Designs data collection and entry methods that meet data quality standards	Develops policies, processes, and procedures to ensure data quality and integrity
RES 6.02. Data management	Complies with policies and procedures for data management	Assists with the management of data for individual experiments	Manages project data	Oversees the management of research data for the laboratory
RES 6.03. Data analysis and results interpretation	Assists with data analysis of individual experiments	Analyzes project data	Interprets data for individual research projects	Oversees data analysis plans and results interpretation for the laboratory's research projects
RES 6.04. Data summaries	Describes data tables and graphs	Summarizes experimental data using multiple formats	Develops outlines and formats for data summaries	Critiques data summaries
RES 6.05. Application of research findings to current research	States laboratory's research findings	Examines the laboratory's research data to determine its significance in the context of the scientific literature	Implements integration of internal and external research findings into laboratory's research practices	Oversees integration of internal and external research findings into revised research agenda, objectives, and/or experimental strategies

See table footnotes on page 77.

TABLE 15. (Continued) Public health laboratory competency guidelines: Research domain

RES 7.00. Dissemination of research findings: disseminates research findings				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 7.01. Meeting and conference presentations	Attends institutional scientific presentations	Presents research to colleagues within the organization or via poster at external events	Presents research via oral presentation for discipline-wide audiences	Serves as an invited speaker at external meetings and conferences
RES 7.02. Manuscript preparation	Assists in manuscript drafting and editing	Drafts sections of research manuscripts	Publishes as first author or senior author in journals of the discipline	Publishes as senior author for multi-laboratory or multi-institutional research projects or in high-impact interdisciplinary journals
RES 7.03. Manuscript peer review process	Reads drafts of manuscripts submitted for peer review	Informally critiques manuscripts submitted for peer review	Participates in the peer review process as a formal reviewer	Participates in the manuscript peer review process as member of the editorial board
RES 8.00. Translation: translates research findings to public health practice				
Subcompetency	Beginner	Competent	Proficient	Expert
RES 8.01. Translation of research findings into public health practice	States research findings as they relate to current public health practices	Describes implications of research findings on public health practices	Directs translation of research findings to public health practices	Oversees translation of research discoveries into meaningful changes in public health practices

* This term is defined in Appendix B.

† A detailed plan for conducting a scientific procedure.

Conclusion

These competency guidelines outline the knowledge, skills, and abilities needed by the PHL workforce to fulfill the responsibilities of, and demands on, the PHL system. They were developed with consideration of the diversity and complexity of PHLs. The competencies should serve as a foundation for workforce development efforts to identify and support training standards and performance expectations; develop standardized job descriptions; periodically assess individual staff and organizational capacity; and develop and implement training plans with the competencies as a guide. The competency guidelines might also be used as a framework for developing progressive job series (career ladders) for PHL workers, which has been identified as a significant barrier to worker recruitment and retention (6–8).

CDC and APHL recognize the existence of possible obstacles and challenges that might affect the implementation of these competencies. Although the uses and benefits of implementing the competencies are numerous, their adoption by PHLs might be affected by organizational and resource constraints. Acceptance and adoption of competencies in a workplace require ongoing leadership support for successful assimilation of competencies into human resources processes such as job descriptions or for integration into the curriculum of the laboratory's training and continuing education programs. Because most laboratories' human resource functions are managed by an ancillary department outside the laboratory, a collaborative effort will be needed to weave competencies into the performance management systems and hiring processes. There is also a need to educate laboratory professionals about the value of applying competencies to their daily work and a need for understanding how competencies can be used as a career ladder and management tool. On the basis of experience with the biosafety laboratory competencies published in 2011 (26), it might take several years before competencies are integrated into daily work practices (16). Successful assimilation of these competency guidelines will depend on the resources available to fully adopt and implement them and on the receptivity of laboratory professionals across the spectrum of job positions and titles. Sustained effort in these areas will be critical to strengthening the workforce and its ability to support and manage the national laboratory system.

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Appendix A

Public Health Laboratory Proficiency Tier Definitions

Proficiency tier	Definition*
Beginner	A beginner worker is one who can demonstrate an elementary level of performance. Beginners might have gained enough classroom or on-the-job training to note (or to have pointed out to them by a mentor) recurring principles and themes but might not yet be able to apply them consistently. The beginner worker might have sufficient subject matter knowledge, but has limited experiential knowledge needed to perform a task, behavior, or function without frequent guidance or oversight.
Competent	A competent professional is one who has been in the same or similar job and who begins to see their actions within the context of the laboratory's long-range goals and plans. The competent laboratory scientist is developing knowledge and experience to recognize a situation in terms of an overall picture or in terms of which aspects are most salient or most important. The competent worker has the necessary ability to cope with and address many contingencies of laboratory operations, as this person has a feeling of adequacy and is able to perform a task, behavior, or function with a high degree of independence.
Proficient	A proficient laboratory professional understands situations as a whole and perceives their meaning in terms of the laboratory's mission and long-term goals. The proficient person learns from experience what typical events to expect in a given situation and how plans need to be modified in response to these events. The proficient laboratory scientist uses established principles to manage the many contingencies of laboratory operations and has developed sufficient mastery to integrate or design a new task, behavior, or function.
Expert	The expert laboratory scientist, with substantial experience and knowledge, has an intuitive grasp of situations and focuses on the root of the problem. The expert operates from a deep understanding of the total situation and integrates systems thinking, collaborative relationships, and the resources at their disposal to achieve the laboratory's mission. The expert laboratory scientist has acquired mastery to design new strategies, policies, tasks, behaviors, and functions that support quality operations.

Sources: Benner, P. *From novice to expert: promoting excellence and power in clinical nursing practice*. Menlo Park, CA: Addison-Wesley; 1984. Dreyfus SE, Dreyfus HL. *A five-stage model of the mental activities involved in directed skill acquisition*. Berkeley, CA: University of California–Berkeley; 1980.

* Definitions were developed by two CDC/APHL Steering Committee members by adopting Dreyfus's Model of Skill Acquisition and modifying Benner's Stages of Clinical Competence. Tiers do not correspond directly to grade levels or job titles.

Appendix B

Terms Used in These Guidelines

Accounts receivable: the tracking of payments owed to the laboratory from the provision of goods and services, and the management of invoices generated for clients and other customers.

Accreditation: the process by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.

Active listening: a communication technique in which a listener is attentive and empathetic, accepts the speaker's message without judgment, asks questions, and restates or paraphrases the speaker's message to get all the information needed to make a decision and to ensure full comprehension by both parties.

Administrative controls: measures concerning 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.

After Action Review (AAR): a structured activity or de-brief process for analyzing what happened, why it happened, and how it can be done better.

Agent-specific antigen detection: methods designed to test for specific antigens of microbial agents (e.g., bacteria, fungi, parasites, viruses) or for microbial antigen-specific antibodies. Testing might be performed using enzyme immunoassays (EIA) or immunofluorescent assays for direct detection of the antigen in a clinical sample or for identification of a given agent after it has been cultivated.

Alternative assessment: a system for determining the reliability of tests for which proficiency testing is either not available or not required. Appropriate alternative assessment procedures might include split-sample analysis with reference or other laboratories; split-sample analysis with an established in-house method; analysis using assayed materials or regional pools; clinical validation by chart review; or other suitable and documented means. Alternative assessment may also be considered performance testing.

Assessment: a systematic process of collecting and analyzing data to determine the current, historical, or projected condition of an organization, process, or activity; also referred to as inspection or survey.

Assessment rubric: a scoring tool that explicitly represents the performance expectations for an assignment or piece of work.

Assets: the resources of an organization or facility (e.g., staff, equipment, instruments, computers, materials including

select agents and toxins, and controlled chemicals and other chemical materials).

Automated identification system: an automated, computerized system developed for the identification of bacteria and yeasts in clinical and nonclinical samples. Such systems can be semi-automated or fully automated. Examples include biochemical methods, nucleic acid amplification tests (NAAT), antimicrobial susceptibility testing panels, high-performance liquid chromatography (HPLC), and mass spectrometry.

Automated susceptibility testing system: an automated, computerized system developed for the detection of the sensitivity of organisms to one or more antimicrobial agents.

Basic scientific and laboratory concepts and theories: concepts and theories applied by staff during the performance of sample analyses. Examples include the effects of temperature on samples and organisms; the principles of acids, bases, and pH; molarity; accuracy and precision; sensitivity and specificity; the different wavelengths of light (and uses in the laboratory); the concepts behind different kinds of microscopy; the science behind distillation, filtration, extraction, and chromatography; and the principles of polymerase chain reaction (PCR), sequencing, enzyme-linked immunosorbent assay (ELISA) and other techniques.

Batch: a sequenced grouping of both test samples and all associated quality control samples required by a testing method.

Biohazardous materials: infectious agents or hazardous biological 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 living organisms or cause significant impact to the environment or community.

Biological materials: any biologically derived materials or materials that contain biological species (e.g., microorganisms, genetically modified organisms or microorganisms, viruses, or prions). These materials are not necessarily pathogenic or hazardous. Examples include, but are not limited to, cellular lines, DNA materials, tissues, organs, body fluids, cultured cells, allergens, and select agents and toxins.

Biosecurity: the discipline addressing the security of biological agents and toxins and the threats posed to human and animal health, the environment, and the economy by misuse or release. It includes the protection of microbial agents, biological materials, and research-related information from unauthorized possession, loss, theft, misuse, diversion, or intentional release.

Budgeting: the process of developing plans for the laboratory's anticipated income and expenditures.

Capital budgeting: the process of planning funding for long-lived assets such as equipment and buildings.

Category A infectious substance: an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to the substance occurs. Examples include *Bacillus anthracis* (cultures only), *Clostridium botulinum* (cultures only), Hepatitis B virus (cultures only), West Nile virus (cultures only), and hemorrhagic fever-causing viruses such as the Ebola and Lassa viruses (in any form).

Category B infectious substance: an infectious substance not transported in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to the substance occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. Examples include *Vibrio cholera*, Hepatitis A virus, Epsilon toxin of *Clostridium perfringens*, and food safety threats such as *Salmonella* species and *Campylobacter jejuni*.

Certification: a process by which a third party gives written assurance that a service or person conforms to specified requirements.

Chain of custody: procedures and the unbroken chain of documentation that account for the integrity of an item of evidence by tracking its movement, location, and possession from its point of collection to its final disposition.

Change control: 1) a structured method of revising any policy, process, or procedure; 2) a process for implementing changes to software or other information technology (IT) solutions using a coordinated approach.

Change management: a process to support moving from a current state through a transition state to a future state. From a process perspective, it is a structured method of revising any policy, process, or procedure (also referred to as Change Control). This includes activities such as transition planning and the design of hardware and software. It also includes revisions to all associated documents and records. From a personnel perspective, it is an approach to transitioning persons, teams, and organizations to a desired future state.

Chemical concepts: basic concepts and theories related to chemicals and their characteristics that staff should be able to apply in performing their job responsibilities. Examples include the principles of acids, bases, and pH; the theories underlying distillation, filtration, extraction, and chromatography; optical techniques; enzymes and rate analysis; principles of immunochemical techniques; principles of molecular biology; and the types of environmental media (e.g., water, soil, food, and animal feed) and the chemicals commonly found in each.

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

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.

Coaching: a specific behavior modification technique to improve another person's performance quantitatively and qualitatively.

Communication methods: methods that include in-person and virtual meetings, phone calls, and electronic methods (e.g., e-mail, social media, podcasts, and webinars).

Communication technology: the means by which information is exchanged between persons through the application of technical processes, methods, or knowledge (e.g., the use of e-mail, web-based presentations, or social media).

Computer science domains: subfields of computer science that can be directly applied to biological problems such as artificial intelligence, image processing, pattern recognition, data mining, knowledge representation, and natural language processing.

Confidentiality: a principle regarding the preservation of authorized restrictions on the access and disclosure of information, including means for protecting personal privacy and proprietary information. However, "confidentiality" is not synonymous with "privacy" (the right of a person to keep his or her information private).

Confidentiality, Integrity, and Availability (CIA): a compound term that refers to the following three elements:

- Confidentiality: preserving authorized restrictions on the access and disclosure of information, including means for protecting personal privacy and proprietary information;
- Integrity: guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;
- Availability: ensuring timely and reliable access to, and use of, information.

Continuity of Operations Plan (COOP): a strategic plan that details how essential functions of an agency will be handled during a wide range of emergencies or situations that might disrupt normal operations, including localized acts of nature, accidents, and technological or attack-related emergencies.

Continuous Quality Improvement (CQI): a recurring activity to increase the ability to fulfill quality requirements. CQI includes the actions taken throughout an organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to the customer and organization.

Contract: a legally binding agreement between two parties for the purpose of obtaining goods or services. Contracts often contain specific obligations for both payor and recipient; and, there is usually significant programmatic involvement by the payor during the performance of the activities. Typically, dollars are drawn down as services defined in the agreement are performed.

Contractual instruments: documents that include Service Level Agreements (SLA), memoranda of understanding (MOU), memoranda of agreement (MOA), contracts with IT and other vendors, and data exchange agreements with data exchange partners.

Control measures: methods used to eliminate or reduce the potential for exposure to a hazard.

Corrective action: action that eliminates the cause(s) of a detected nonconforming event or other undesirable situation. Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence.

Cost of quality: the total of the tangible and intangible costs incurred by investing in the prevention of nonconforming events according to requirements, appraising a product or service for conformance to requirements, and reworking products or services to conform to requirements.

Critical surveillance event: a situation in which there is an active surveillance system for a specified reason and period usually initiating an urgent and highly-controlled systematic process. There is a significant need for use of staff and resources to support the determination of the agent at the center of the event.

Critical thinking: the thought processes used to conceptualize and evaluate information, and to the practice of using conclusions to guide individual and organizational behavior. Critical thinking involves clarifying goals, examining assumptions, discerning hidden values, evaluating evidence, and assessing conclusions.

Customer: an organization or person that receives a product or service. Examples include consumers, clients, end users, retailers, beneficiary purchasers, patients, and health-care providers. A customer can be internal or external to the organization. Laboratory staff may be regarded as internal customers.

Data structure: an organized form, such as an array list or string, in which connected data items are held in a computer.

Decontamination: the process of reducing or eliminating biologic, radioactive, or chemical agents from a surface or space. Decontamination includes disinfection and sterilization.

Diversity: the inclusion of different types of persons in a group or organization. Differing elements or qualities might include race, ethnicity, sex, sexual orientation, socioeconomic status, age, physical abilities, religious beliefs, political beliefs, or other ideologies.

Documents: paper-based or electronic media that communicate information. Generally, documents need to be updated periodically and require revision control.

eLearning: learning that utilizes electronic technologies to access training and educational curriculum outside of a traditional classroom. In many cases, it refers to a course, program or degree delivered completely online, though delivery can also include videotape, DVD, and interactive television.

Electronic laboratory reporting (ELR): the automated transmission of laboratory-related data from commercial, public health, hospital, and other laboratories to state and local public health departments through an electronic health records (EHR) system or a Laboratory Information Management System (LIMS).

Emergency alarm: a piece of equipment and/or device designed to inform staff that an emergency exists or to signal the presence of a hazard requiring urgent attention.

Emergency communication plan: a plan that is used during the response and recovery phases of an emergency or surge event to effectively and efficiently communicate with all staff internally and with emergency response personnel and the public externally.

Emergency preparedness and response networks: federal, state, and local networks that collaborate to provide emergency preparedness and response capabilities. Such networks include, but are not limited to, the National Incident Management System (NIMS) and the Integrated Consortium of Laboratory Networks (ICLN), which comprises the Laboratory Response Network for biological threats (LRN-B), the Laboratory Response Network for chemical threats (LRN-C), the Food Emergency Response Network (FERN), the National Animal Health Laboratory Network (NAHLN), the National Plant Diagnostic Network (NPDN), the Environmental Response Laboratory Network (ERLN), and the U.S. Department of Defense Laboratory Network (DLN).

Emergency response plan: a written plan that details step-by-step procedures to follow in emergencies such as fire, external chemical spills, or a major accident. An emergency response plan also includes information such as whom to notify, who should do what, and the location of emergency stocks.

Engineering controls: methods to remove a hazard or to place a protective barrier between the worker and the workplace hazard, which usually involves specialized equipment and elements of building design. Examples include safety equipment (e.g., biosafety cabinets), facility egress, and directional airflow.

Environmental controls: the conditions within a laboratory facility that accommodate the correct performance of laboratory testing. Examples of environmental controls are lighting, humidity, temperature, and floor space clearance.

Equal Employment Opportunity (EEO): policies and practices in employment and other areas that prohibit discrimination against an applicant or employee on the basis of race, color, sex (including pregnancy), age, religion, national origin, mental or physical disability, or genetic information.

Equipment qualification plan: a plan that addresses the three steps of laboratory equipment qualification (i.e., installation qualification, operational qualification, and performance qualification). Laboratory staff must perform the equipment performance qualification, and the equipment manufacturer may perform the installation qualification and operational qualification.

Ethical conduct in research: the application of rules and professional codes of conduct that promote the aims of research, encourage essential collaborations, ensure researchers are accountable and promote moral and social values. These principles include honesty in conducting and reporting research, objectivity, integrity, carefulness, openness, respect for intellectual property, confidentiality, responsible authorship and peer review, social responsibility, nondiscrimination, competence, legality, animal welfare, and protection of human subjects.

Ethical practices: values and standards such as personal accountability and credibility, honesty, fairness, forthrightness, striving for excellence, transparency, impartiality, respect for colleagues and partners, relationship building, diversity and inclusiveness, social responsibility, environmental responsibility, upholding privacy and confidentiality, and adhering to policies regarding conflict of interest.

Examination (analytical phase): a set of operations (analyses) having the objective of determining the value or characteristics of a property or sample, ending when the postexamination phase begins.

Exposure event: a specified set of conditions in which a person or group is subject to a harmful substance that is a potential cause of disease or an altered health state (e.g., a laboratory accident occurs causing workers to be exposed to radiation).

Exposure monitoring: a record of any measurements taken to monitor staff exposures and any medical consultation and examinations (including tests or written opinions).

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

External assessment: a system to ensure compliance, competency, accuracy and precision of test system components, environment, and operator performance through evaluation by external groups or comparison using external samples. Examples include external audits and proficiency testing.

Federal Select Agent Program: a program that oversees the possession, use, and transfer of biological select agents and toxins. It comprises staff from CDC's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service/Agricultural Select Agent Services.

Formative assessment: the gathering of information or data about a training course or program that is used to guide improvements in teaching and learning. Formative assessment takes place before the training implementation and includes such activities as pilot-testing.

Good housekeeping procedures; procedures related to the maintenance and management of the facilities, property, and equipment of an institution. Good housekeeping procedures prevent accidents and reduce the risk of harmful exposures to all laboratory and service staff.

Grant: a legally binding agreement between two parties usually for the purpose of transferring money, property, or services to a recipient, though it can also be used to procure products or services. Grants usually involve minimal programmatic involvement by the grantor. Typically, monies are given in a lump sum at the start of the agreement or according to a set disbursement schedule.

Hazardous chemical: any chemical which is classified as a health hazard or simple asphyxiant in accordance with the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard.

Hazard communication: a written program that conveys information concerning hazards. Hazard communication includes, but is not limited to, use of safety signage, Safety Data Sheets (SDS), 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.

Hazardous material alert: an alert triggered by use of a hazardous material or safety equipment that requires either a notification (e.g., a label or signage) and/or a response (e.g., clean up or safety precaution).

Hazardous materials: solids, liquids, gases, or radioactive substances that can harm persons, other living organisms, property, or the environment.

Hazardous spill: a breach of a substance from its container (e.g., can, jar, drum, vessel, or pipe) in some fashion in the

environment or community that results in exposure to high concentrations of toxic substances; situations that are life or injury threatening; imminent danger to life and health (IDLH) environments; situations that present an oxygen deficient atmosphere; conditions that pose fire or explosion hazards; situations that require evacuation of the area; and/or situations that require immediate attention because of the danger posed to persons in the area. The properties of the hazardous substance, the circumstances of the release, and the mitigating factors in the work area combine to define the distinction between a release requiring an emergency response and one that does not.

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

Incident Command System (ICS): a standardized, on-scene, all-hazards incident management approach that allows for the integration of facilities, equipment, staff, procedures and communications that operate within a common organizational structure; enables a coordinated response among various jurisdictions and functional agencies, both public and private; and establishes common processes for planning and managing resources.

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

Information: knowledge derived from study, experience, instruction, communication, intelligence, or news. It includes resources and materials that are created and distributed, including graphs or charts. Information also includes knowledge of specific events or situations that has been gathered or received.

Information security: the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide confidentiality, integrity, and availability (CIA). Information security measures include backup systems, passwords, and shredding of sensitive information before disposal.

Institutional safety committee: a group comprising a cross-section of staff members and other stakeholders 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 local committees such as the safety committee, radiation safety committee, institutional animal care and use committee, institutional review board, and environmental programs advisory panel.

Instructional design: the systematic development of instructional specifications using learning and instructional theory to maximize the quality of instruction, making the acquisition of knowledge and skill more efficient, effective, and appealing. Instructional design is the entire process of analysis

of learning needs and goals and the development of a delivery system to meet those needs.

Integration engine is software that works as a go-between for different systems.

Internal audit: an activity carried out by laboratory staff that verifies laboratory operations adhere to the requirements of the management system, the customer, and/or regulatory agencies.

Inventory record: a record that tracks the quantity, form, location, and disposition of any biologic, chemical, or radiological material in use, stored, or disposed of in a laboratory.

Knowledge management (KM): the process of organizing, accessing, and leveraging a laboratory's intellectual resources and information systems to generate value-added benefits internal and external to the laboratory.

Laboratory-developed test (LDT): an *in vitro* device (IVD) that is intended for clinical use and designed, manufactured, and used within a single laboratory. LDTs are not approved or cleared by the U.S. Food and Drug Administration (FDA).

Laboratory equipment: the wide array of manual and automated machines (including instrumentation) used to perform sample preparation and analyses. This includes simple equipment (e.g., incubators, centrifuges, balances, water baths) and complex equipment (e.g., PCR machines, sequencers, mass spectrometers, multi-channel analyzers, ELISA readers).

Laboratory facility: the physical spaces within a public health laboratory building, including office spaces; meeting and conference rooms; areas where food is stored, prepared, or eaten; and areas where pre-examination, examination, and postexamination testing activities are performed. This also includes areas where laboratory supplies and reagents are stored, prepared, cleaned, and sterilized.

Laboratory Information Management System (LIMS): a collection of software/computerized methods that offers a set of critical features that support a laboratory's operations, including the acquisition, analysis, storage, and reporting of laboratory data. A LIMS is a highly configurable application that is customized to facilitate a wide variety of models for laboratory testing workflow. Sometimes referred to as LIS (Laboratory Information System).

Laboratory program: an organizational activity (e.g., quality assurance, safety, system improvement, training) or component that covers a major laboratory discipline (e.g., environmental chemistry, public health microbiology, newborn screening, environmental microbiology, molecular biology), which might include more than one laboratory section.

Learning environment: the physical and emotional states that the learner brings to the learning endeavor, as well as the social setting that the student finds in the learning space.

Legacy data system: an old or outmoded system being maintained because it contains historical data or other useful business intelligence.

Licensing: a documented approval process usually granted by governments (federal or state) to entities such as hospitals, laboratories, and persons to conduct a specific scope of activities within relevant jurisdictions.

Licensure: the official “permission to practice” for staff of defined occupations and professions. Licensure is often granted through a professional body or regulatory agency comprising advanced practitioners who oversee the applications for licenses. This often involves accredited training and examinations, but varies a great deal for different activities.

Lifecycle management strategy: the continuous process of managing the laboratory’s IT investments and its procedures for testing, modifying, and implementing changes to existing computing systems, including hardware, software, documentation, and installing new systems throughout the lifecycle.

Logical structure: an introduction, supporting information, and conclusion.

Manual identification methods: various biochemical tests that are manually performed and used to identify bacteria, yeast and fungi. These tests may be performed either singly, such as spot tests or tube biochemicals (e.g., catalase, oxidase, indole, Triple Sugar Iron [TSI], or motility), or combined into multiple panels distributed commercially as strips or cards.

Manual susceptibility testing methods: various materials containing specific concentrations of antibiotics that are manually applied to media that has been plated with a specific concentration of an organism. The presence or absence of growth around the antibiotic disc or strip after incubation is measured and interpreted to determine the susceptibility of the organism to the antibiotic. Examples include the Kirby-Bauer method and Epsilometer test (E-test).

Master record: a record containing a comprehensive profile and other details about a person, material, or organization associated with the laboratory.

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, chemical, and radiological materials and toxicants in persons working with those materials. This includes a program for pre-employment screening, ongoing monitoring, and postexposure management.

Memoranda of agreement (MOA): documents describing in detail the specific responsibilities of, and actions to be taken by, specific parties so that goals might be accomplished.

Memoranda of understanding (MOU): documents that describe broad concepts of mutual understanding, goals, and plans shared by parties.

Mentoring: a developmental partnership between a staff member and a subject matter expert for the purposes of sharing technical information, institutional knowledge, and insight with respect to a particular occupation, profession, organization, or endeavor. Typically, a mentor is a more experienced and knowledgeable person providing guidance to a mentee who is a less experienced and knowledgeable person.

Message type: the kind of a message communicated between systems that specifies its name, structure, and content data type.

Microbiological concepts and theories: concepts and theories that relate to characteristics of microorganisms and infectious agents that staff should be able to apply in performing their job responsibilities. Examples include taxonomy, pathogenic versus nonpathogenic microorganisms, incubation period, containment, principles of microbial culture, detection limits, antimicrobial susceptibility, and medium and mode of disease transmission.

Model laboratory practices: activities and processes integral to the provision of laboratory testing services that optimize the quality of the result. These practices are guided by certain industry standards and are adopted by a laboratory to maximize safety, effectiveness, efficiency, timeliness, and public health/community outcomes. These practices are usually independent of the test or measurement techniques employed and are not to be confused with U.S. Food and Drug Administration regulations on Good Laboratory Practice (FDA regulation 21 CFR 58). In the recent past, these practices were referred to as “best practices,” but it is now acknowledged that there is not one collection of best practices for each laboratory or situation.

Module: a software component that is part of a larger enterprise software system and performs a specific, independent, and interchangeable function of the larger system.

Nonconforming event (NCE): an event that does not fulfill a requirement. Other terms frequently used include accident, adverse event, discrepancy, error, incident, nonconformity, and occurrence.

Notifiable result: a result generated by a laboratory from a sample related to an infectious disease or organism, hazardous agent, or condition that when identified by a laboratory, must be reported by the laboratory to specified public health entities as set forth under local, state, and/or federal law.

Occupational Safety and Health Administration (OSHA): the chief federal agency charged with the enforcement of safety and health legislation.

Outbreak: the occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period. Usually, the cases are presumed to have a common cause or to be related to one another in some way. Sometimes the cases are distinguished from an epidemic as being more localized.

Personal hygiene procedures: practices performed by persons that serve to promote or preserve health when working in the laboratory. Examples include washing hands after working with potentially hazardous materials and before leaving the laboratory; not eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing food for human consumption in the laboratory; and not mouth pipetting.

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

Personnel security concepts: activities pursued in an attempt to evaluate a person's suitability for a given position. Typical personnel security concepts include verifying identity and personal information, professional information (e.g., previous employment and education), a person's character (e.g., through checking references), and a person's suitability for particular job responsibilities (e.g., through checking criminal records, court records, and credit reports).

Personnel security program: a system for addressing insider threats to ensure that only trusted persons are given authorized access to restricted areas. The program includes policies and procedures to ensure that persons that work within an organization are trustworthy and competent to carry out an organization's mission. This includes conducting interviews of applicants, evaluating positions, and verifying applicant suitability (e.g., through a National Agency Check with Inquiries [NACI] and special background investigations).

Physical hazards: unsafe conditions in the workplace that can cause injury or illness. Examples include ergonomic hazards; electrical shock hazards; loud noises; slip, trip, and fall hazards; exposure to hot and cold temperatures; compressed gas cylinders; and sharps (i.e., items capable of cutting or piercing human skin such as 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 the presence of infectious agents]; and other types of broken or unbroken glassware [e.g., microscope slides and cover slips]).

Physical security access controls: restrictions that provide reasonable assurance that only authorized staff are allowed to enter a restricted area. The type of access controls depends on the level of security required (e.g., something one has [such as a physical or electronic key], something one knows [such as a PIN number], or some natural/innate characteristic or trait [i.e., one that can be detected by biometric devices]).

Physical security infrastructure: the aggregate collection of physical elements, such as locks, access controls, alarms, closed-circuit television monitoring systems, fences and other

barriers, sign-in logs, and security guards, designed to protect and safeguard the physical components of a facility, including staff and other assets.

Plain talk: nontechnical communication that does not use technical jargon or field-specific language. The speaker or writer conveys the meaning of the communication clearly and simply so that the information is easily understood. Also referred to as "plain language."

Policy: a set of basic principles or guidelines to direct plans, actions, and decisions of staff and the organization.

Postexamination (postanalytical phase): processes following examination (sample analysis) that include systematic review, formatting, and interpretation; authorization for release; and reporting and transmission of the results. This phase also includes storage of samples that have undergone laboratory analysis.

Pre-examination (pre-analytical phase): processes starting with, in chronological order, the submitter's test order and including: the examination (analysis) requisition; preparation of the patient (if applicable); collection of the primary sample; and transportation to and within the laboratory, ending when the examination (analytical) phase begins.

Preventive action: action that eliminates the cause(s) of a potential nonconforming event or any other potential undesirable situation. Preventive action is taken to prevent occurrence, whereas corrective action is taken to prevent recurrence.

Procedure: a specified way to carry out an activity of a process.

Process: a set of interrelated or interacting activities to achieve a particular end.

Process improvement indicators: measures that track results and efficiencies gained in a laboratory following the modification of laboratory testing business processes.

Process management: activities that directly or indirectly relate to the laboratory's path of workflow to optimize effectiveness and efficiency.

Proficiency testing: an evaluation of the laboratory's performance on analysis of samples of external origin for the purposes of determining adequacy of the laboratory's pre-examination, examination, and postexamination activities.

Project management: the practice of planning and managing laboratory projects to ensure that they stay within scope, time, quality, and cost limits.

Project management concepts: principles regarding the management of projects that include controlling the process, meeting management, time management, scheduling, managing resources, and team building.

Protected information: any information about a person that is maintained by an organization that relates to issues of privacy (the right of a person to keep his or her information private)

and confidentiality (ensuring that information is accessible only to those authorized to have access). Protected information includes any information that can be used to distinguish or trace a person's identity and any other personal, health, or medical information that is linked or linkable to a person. Notable regulations include the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, which governs the protection, use, and disclosure of individually identifiable health information, and the HIPAA Security Rule, which governs the security of certain health information that is held or transferred in electronic form.

Protocol: 1) a detailed plan for conducting a scientific procedure; 2) a set of technical rules for the transmission and receipt of information between computers.

Quality: the degree to which a set of inherent characteristics fulfills requirements.

Quality assessment: a means to determine the quality of the results generated by the laboratory. It is usually an external evaluation of the laboratory's performance. Quality assessment is a challenge to the effectiveness of the quality assurance and quality control programs and can be described as a system of procedures, checks, and audits to judge and control the quality of measurements and reduce the uncertainty of data.

Quality assurance (QA): planned and systematic activities implemented in a quality system so that quality requirements and goals for a product, service, or activity will be fulfilled. From a quality-improvement viewpoint, it is a system for ensuring a desired level of quality in the development, production, or delivery of products and services. From a bench-level viewpoint, it is the practice of assessing performance in all steps of the laboratory testing cycle including pre-analytical, analytical, and postanalytical phases to promote excellent outcomes in public health.

Quality control (QC): an integral component of quality assurance and is the aggregate of processes and techniques to detect, reduce, and correct deficiencies in an analytical process. It also refers to the measures that must be included during each assay to verify that a test is working properly.

Quality control (QC) data: QC measures intended to reflect the quality of laboratory testing processes and the accuracy, precision, and reliability of the test results.

Quality indicators: observations, statistics, or data defined by the organization or service that typify the performance of a given work process and provide evidence that the organization or service is meeting its quality intentions. Quality indicators are also referred to as "key performance indicators" or "quality metrics," and might be reported in various formats such as a "dashboard" or "scorecard."

Quality management system (QMS): coordinated activities to direct and control an organization with regard to quality. In a QMS, all aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to ensure quality.

Radiation monitoring device: a scientific determination of amount, rate, and distribution of radiation emitted from a source of ionizing radiation. An example is a Geiger counter.

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

Records: evidence of results achieved or activities performed. Records can be used, for example, to demonstrate traceability and to provide evidence of verification, preventive action, or corrective action. Generally, records need not be under revision control.

Reflex testing: follow-up testing when initial test results are positive or outside normal parameters and indicate that additional, related testing is clinically appropriate.

Regulated waste: liquid or semi-liquid blood or other potentially infectious materials, contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed, items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling, contaminated sharps, and pathological and microbiological wastes containing blood or other potentially infectious materials.

Requirement: a condition or capability needed to achieve an objective that must be met or possessed by a system or system component to satisfy a standard or specification.

Research animal: any live animal used or intended for use in research, research training, experimentation, biological testing or for related purposes. Examples include mice and rats. When evaluating hazards of research animals, staff should consider the risks inherent to the species itself, those associated with handling the animals (e.g., bites, scratches, and allergens), and the risks associated with handling the bedding and other associated waste products.

Risk assessment (risk analysis): 1) the process of identifying risks to organizational assets (including staff) and operations (including mission, functions, image, and reputation); includes threat and vulnerability analyses and is the fundamental tool to help select the right risk mitigation measures (e.g., engineered controls, standard policies and procedures) to achieve an acceptable level of security; 2) the evaluation of 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.

Risk communication: a style of communication used to exchange information and establish effective dialogue during emergency or highly sensitive situations by those responsible for assessing, minimizing, and regulating risk to those who might be affected by the outcomes of those risks.

Risk mitigation plan: an evaluation of threats, vulnerabilities, and consequences based on a site-specific risk assessment.

Root cause analysis: a process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a nonconforming event.

Route of exposure: the path by which humans or other living organisms come into contact with a hazardous substance. Examples include breathing (inhalation), eating or drinking (ingestion), and contact with skin (dermal absorption).

Safety Data Sheet (SDS): a fact sheet that summarizes: information regarding material identification for a chemical product or mixture, including hazardous ingredients; health, physical, and fire hazards and the necessary or suggested first aid procedures to employ; chemical reactivities and incompatibilities; spill, leak, and disposal procedures; and protective measures required for safe handling and storage.

Safety program: the general safety, biosafety, biosecurity, chemical, radiological, and emergency plans of an institution that all staff are required to follow in order to manage possible workplace hazards. The safety program also includes policies related to staffing, organizing safety committees, and conducting safety assessments.

Safety signage: a mechanism to communicate information related to hazards of a material or space. Examples include pictograms, container labels, and other posted signs.

Sample: a small part of, or a selection from, something intended to show the quality, style, or nature of the whole. In all domains of this competency set, “sample” is meant to include clinical and nonclinical samples and specimens.

Sample appropriateness: the physical, chemical, and biological characteristics of a sample that are necessary to yield accurate and representative test results.

Sample lifecycle: a comprehensive description of all sample processes, sample management, transfers, and data collection, with their corresponding LIMS actions throughout the period the laboratory interacts with the sample.

Sample management: the collection, handling, labeling, packaging, shipping, transport, accessioning, receipt, tracking, evaluation (including testing for sample appropriateness), and storage of clinical and nonclinical samples or specimens.

Scientific ethics: principles, rules, and standards guiding the performance of persons and the conduct of laboratory testing that include values and standards such as scientific credibility, scientific accountability, objectivity, assurance of scientific integrity, responsible collaboration, responsible authorship

and peer review, adhering to intellectual property laws, and adhering to chain of custody rules and policies.

Scientific integrity: principles and standards such as validity, verification, and appropriateness. It also includes data integrity, by which information produced and results reported are whole, complete, and accurate; are obtained using proper methods; and are not altered by any unauthorized additions, deletions, or modifications.

Security concepts: aspects critical to the management of the security of an organization (including staff and other assets) and its activities. These concepts include assurance (that a security system will behave as expected), risks, threats, countermeasures, vulnerability, exploits, and defense in depth (relying on multiple security measures).

Security plan: a formal document that provides the systematic design for implementing an organization’s security goals. It is a blueprint for how an organization secures its assets. It establishes the performance goals for the system and metrics for performance. Security plans are designed according to a site-specific risk assessment.

Segregated waste categorization: the procedures for categorizing, segregating, color-coding, storing, transporting, and tracking laboratory waste.

Select agents: a subset of biological agents and toxins that the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The Select Agent Regulations are contained in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

Sensitive information: privileged or proprietary information which, if compromised through alteration, corruption, loss, misuse, or unauthorized disclosure, could cause serious harm to the organization owning it. Sensitive information, which includes protected information, can only be released to the subject of the information and to those who have a legitimate need to know, to outside entities with the subject’s written permission, and to others as allowed by law. In many cases, the use of this information is protected by either state or federal law.

Service level agreement (SLA): a contractual agreement between an internal or external service provider and the customer that specifies performance guarantees with associated penalties should the service not be performed as contracted.

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 (e.g., microscope slides and cover slips).

Software development life cycle (SDLC): a guideline for developing systems or software that involves progressive phases spanning the life cycle of the system from initiation to disposition.

Staff engagement: the heightened connection between staff and their work, their organization, or the persons for or with whom they work. Engaged staff find personal meaning in their work, take pride in what they do and where they do it, and believe that their organization values them.

Standard operating procedures (SOPs): 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.

Strain typing methods: methods to distinguish different strains of infectious agents. Examples include pulse-field gel electrophoresis (PFGE), multiple-locus variable number tandem repeat analysis (MLVA), and whole-genome sequencing (WGS).

Strategic thinking: a process by which a person develops a vision or goal and then works backward to develop a plan to accomplish that vision or goal.

Systems thinking: the set of habits or processes that permits a person to approach problems by visualizing and understanding interrelationships rather than linear-cause-effect chains, and by perceiving change as a series of on-going processes or events rather than as a single endpoint.

Training evaluation process: the gathering of information or data that takes place at the end of the training implementation or a specified period of time following training. It measures the effectiveness of the training (e.g., participant learning outcomes).

Training evaluation tools: methods that include assessment of skills and knowledge gaps, impact evaluation, return on investment, and participant reaction evaluation. It is usually an assessment tool administered to participants after the training activity to determine whether or not course design efforts were successful from the participants' perspectives.

Training modality: the delivery method used to provide training and education (e.g., in-person seminars, eLearning, web-based interaction, conferences, workshops, or teleconferences).

Training report: a document produced during the development of, and following, the delivery of a training activity. Reports might include training program evaluation summaries, attendance and continuing education credits

awarded summaries, or statement of deliverables and outcomes realized through a training activity included in a funding reconciliation report.

Transportation security plan: a written security plan based on an assessment of possible transportation-related security risks for shipments of hazardous materials that includes appropriate measures to address these risks. The security plan should address staff security, unauthorized access, and en-route security.

Validation: the action (or process) of proving that a new procedure, process, test system, or method used works as expected and achieves the intended results. It includes determination of performance characteristics (i.e., accuracy, precision, sensitivity, specificity). Examples include validation of a new diagnostic assay or information system.

Verification: the ongoing process that confirms specified requirements (predetermined by validation) are fulfilled. Verification is needed when the laboratory replaces a test system or instrument; adds a new test; or changes the manufacturer of a test kit. The laboratory must verify the manufacturer's performance specifications are substantiated. An example includes the confirmation of results obtained on an automated testing analyzer of an assay approved by the U.S. Food and Drug Administration.

Vocabulary standard: vocabularies and systems of encoding data that have been defined by various standards development organizations. Reliance on these standards for terminology and coding of data greatly improves semantic understanding and, therefore, the value of the data in analyses and decision-making.

Waste management plan: a written set of procedures that describe decontamination practices and how the different waste streams (e.g., biologic, chemical, or radiological) generated in the laboratory will be handled to comply with regulatory and organizational requirements.

Work practices: actions performed by workers, such as decontaminating a work surface, with the goal of preventing or reducing the risk of exposure to hazardous materials or situations.

Workflow: 1) sequential steps in a laboratory's activities that transform a submitter's test order into the laboratory information captured in the report of results, including pre-examination, examination, and postexamination procedures; 2) all of the tasks, in the proper order, required to carry out a process.

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