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

Supplements
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Prepared by
Renée Ned-Sykes, PhD¹
Catherine Johnson, MA²
John C. Ridderhof, DrPH¹
Eva Perlman, MPH²
Anne Pollock³
John M. DeBoy, DrPH²

¹Office of Public Health Scientific Services, Center for Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia
²Association of Public Health Laboratories, Silver Spring, Maryland

³Office of Public Health Scientific Services, Center for Surveillance, Epidemiology, and Laboratory Services, Division of Laboratory Systems, CDC, Atlanta, Georgia

Corresponding preparer: Renée Ned-Sykes, RNed@cdc.gov, 404-498-0125.

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*, *2*). 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*, *2*). Indeed, approximately 50% of laboratories reported no, minimal, or only partial capacity to provide continuing education and training

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.

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 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). 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 (<u>Appendix B</u>). 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 (<u>Table 1</u>). 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.

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 (<u>Table 2</u>). 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.

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) (<u>Table 3</u>).

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.

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 (<u>Table 4</u>). 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.

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 (<u>Table 5</u>).

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).

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.

Workforce Training Competency Guidelines

Purpose statement: The competencies in Workforce Training address the knowledge, skills, and abilities needed to train public health laboratory professionals (<u>Table 7</u>). 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.

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 (<u>Table 8</u>).

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.

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 (<u>Table 9</u>).

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 ($\underline{26}$, 51, 52, 61–74).

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 (<u>Table 10</u>). 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.

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 (<u>Table 11</u>).

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.

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 (<u>Table 12</u>).

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 (<u>26</u>,51,59,61,<u>62</u>,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).

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 (<u>Table 13</u>).

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).

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 (<u>Table 14</u>).

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.

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 (<u>Table 15</u>). 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.

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

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.

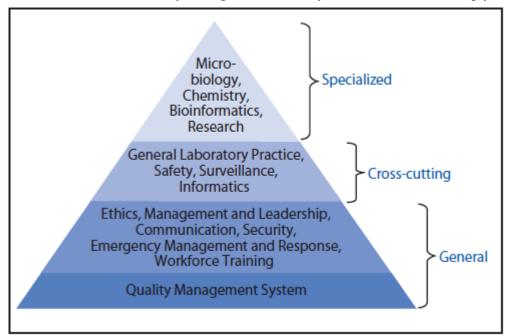
April 2014: The Harmonization of Domains Workgroup reviewed major changes made by the Domain Teams to the draft competencies in response to reviewer comments and resolved remaining redundancies and inconsistencies in approach and language among the competency domains.

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.

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.

Alternate Text: This figure is a triangle showing a schematic of competency domains for public health laboratory professionals. Teams of subject matter experts developed general, cross-cutting technical, and specialized competencies, with a quality management system as the foundation of every activity. The base of the triangle comprises general competencies: Quality Management, followed in a separate tier by Ethics, Management and Leadership, Emergency Management and Response, and Workforce Training. The middle section of the triangle comprises cross-cutting technical competences: General Laboratory Practice, Safety, Surveillance, and Informatics. The apex of the triangle comprises specialized competencies: Microbiology, Chemistry, Bioinformatics, and Research.

| TABLE 1. Public h | 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 | Analyzes quality measures to evaluate the costs of | Develops the procedures to estimate and compare quality | Creates an action plan to address the impact of quality | | |

| laboratory performance | maintaining quality | costs | costs on regulatory compliance, |
|------------------------|---------------------|-------|---------------------------------|
| | | | customer* service, and the |
| | | | operating budget |

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 | Applies waste management policies, processes, and | Trains staff on the waste management plan,* including | Ensures the waste management plan follows regulatory |

| | procedures | procedures to activities | recycling and disposal methods | 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 |

| 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 |

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 | Describes competence assessment plans | 1 | | Oversees a competence assessment plan for the |

| assessment plan | | individualized competence assessment plan | | 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 | g and inventory: ensures that red | quirements 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 |

Follows established

inventory management

and inspection processes

Executes the process to

evaluate and provide

feedback to suppliers,

consultants, and contractors

QMS 5.02. Inventory

processes

process

Describes the inventory

current work area

to suppliers

QMS 5.03. Evaluation Describes the process to

management processes used in

evaluate and provide feedback

authorities

Oversees inventory

management plan

Oversees a quality

improvement plan for

purchasing and inventory

Develops inventory processes

evaluate the satisfaction with

services and products from

suppliers, consultants, and

for laboratory supplies,

Develops a process to

performance

processes, including receipt reagents, and verification* of

| | contractors | |
|--|-------------|--|
| | | |

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 |

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* an | d records:* ensures that the | re is an effective system to | control and manage docun | nents 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 |

| - • | o . | • | | • |
|--------------------------------------|---|---|--|--|
| 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 |

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. Nonconfo | rming event* management: | ensures that processes are in J | place for detecting and manag | ing 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. | Describes the policies, | Reports discovered NCEs | Performs analysis of records | Oversees the policies, processes, |

Leads the process of

processes, and procedures

to record and report NCEs

Participates in NCE

Documentation of

NCEs

QMS 10.03.

Ducksiant

and reports of NCEs to

Assesses NCE investigations

identify trends

and procedures to document

NCEs and report NCE

management and external

Oversees the policies, processes,

information to senior

entities

| Investigation and root cause analysis* | investigations and root cause analyses | investigating NCEs and performing root cause analyses | and root cause analyses to improve 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. Assessmen | nts: ensures that processes a | are in place to perform interna | l audits* and external assessn | nents* |
| 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 |

| 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 | Employs pre-examination, examination, and postexamination quality indicators | Develops processes and procedures for determining pre-examination, examination, and postexamination quality | Oversees the policies, processes, and procedures related to developing and assessing quality indicators |

| | indicators | | 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 | | services |
|----------|--|----------|
|----------|--|----------|

^{*} This term is defined in Appendix B.

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 | <u> </u> | with policies and procedures | Oversees the policies, processes and procedures to ensure practices are consistent with |

[†] 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.

| ETH 2.02. Scientific ethics and rules of conduct to the workplace Applies scientific ethics and rules of conduct to the workplace Applies scientific ethics and rules of conduct to the workplace Serves as a role model of scientific ethic and rules of conduct by consistently conforming to the highest scientific standards and practices Serves as a role model of scientific ethics and procedures related to scientific ethics and rules of conduct rules of conduct rules of conduct | | | results and findings | of all results and findings | guidelines on scientific integrity |
|---|-------------------|-------------------------|--|---|--|
| | Scientific ethics | and rules of conduct to | ethical behavior and rules of conduct by consistently conforming to the highest scientific | with policies and procedures related to scientific ethics and | processes, and procedures related to scientific ethics and |

^{*} This term is defined in Appendix B.

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 | management and response | Oversees laboratory-wide emergency management and response |

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 dev | elopment: ensures the dev | velopment, implementation, an | d 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 sou | nd 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 |

| MLD 3.00. Financial m | 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 res | ource management: ensures e | ffective management of | f 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 |

| 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 | Recommends staff for advancement | Develops criteria for staff advancement | Ensures that staff function in roles commensurate with | |

| | | T | 1 | T . |
|---|--|---|--|---|
| | staff advancement | | | 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 behav | ior | | |
| 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 | Participates in staff | Evaluates the effectiveness of | Develops staff recognition | Fosters a culture that ensures |

| recognition | recognition programs | staff recognition programs | programs | staff recognition |
|------------------------------------|---|--|--|--|
| MLD 5.07. 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 |

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.

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 |
|---------------|--|-----------------------|---------------------------|---|
| | Provides undivided attention to the other participants in a dialogue | <u> </u> | | Facilitates dialogue exchange through paraphrasing and clarification of critical points |
| COM 2.02. | Exhibits open posture and facial | Applies range of body | Exhibits active listening | Incorporates multiple |

| Contextual clues | expression to engage the other participants in a dialogue | language cues to enhance the exchange | | behaviors of engagement during dialogue exchanges |
|----------------------------------|---|--|------------------------|--|
| COM 2.03. Respectful exchange | | Provides counterpoints while being respectful of disagreements | of respectful exchange | Facilitates respectful dialogue among participants in the exchange |

| | | anagreements | | enemange | |
|---|---|--|--|--|--|
| TABLE 4. (Continued | d) Public health laboratory co | mpetency guidelines: Com | munication 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. Commun | ication technology:* utilizes to | echnology to communicate | information to internal and extern | al 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. Commun | ication professionalism: ensur | es professionalism in com | nunication with customers* and st | akeholders | |
| Subcompetency | Beginner | Competent | Proficient | Expert | |
| COM 5.01. Professional attitude | Uses tone of voice and language tailored to interactions with customers | Displays professional demeanor in all situations with customers and | Monitors interactions with customers and stakeholders to ensure they are conducted | Establishes policies for professional customer and stakeholder interactions | |

| | and stakeholders | stakeholders | professionally | |
|--|---|--|--|---|
| 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 | |
| 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 |
|---------------|--|-----------|-------------------------|---|
| | Describes the risk communication process | | risk communication plan | Establishes policies, processes, and procedures related to the risk communication plan |

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 he | 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. | | | | |

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 | * | Develops policies, processes, and procedures regarding risk assessment |
| SEC 1.03. Risk | Describes the policies | Applies risk mitigation | Manages the implementation | Develops policies, processes, and |

| mitigation plans | and procedures regarding risk mitigation plans | plans | of risk mitigation plans | procedures regarding risk mitigation planning and implementation |
|--|--|--------------|---|---|
| SEC 1.04. Risk mitigation plan reporting | Describes policies, 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 | system | Advises organizational leadership on selecting security strategies to protect assets and on monitoring the performance of the security plan |

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 | Completes inventory | Audits inventory records | Creates tools to manage | Develops policies, processes, and |

| security plans | records to comply with the laboratory's security plan | | inventory records | procedures to manage inventory records |
|----------------|---|---------------------------------------|-------------------|---|
| 1 | • | Evaluates reported security incidents | * | 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 | Implements the personnel security program | Solves difficult and complex personnel security problems | Directs the resolution of major conflicts in personnel security policy |

| | security program | | | and program objectives |
|--------------------------|---|---|---|---|
| SEC 4.03. Investigations | Collects information* for personnel security investigations | 1 | Determines actions to be taken on personnel security investigations | Develops policies, processes, and procedures related to personnel security investigations |

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 polices, 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.

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 ¹ , processes ¹ , and procedures ¹ 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 ¹ 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 |
|--|--|------------|
| | | |

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

EMR 2.00. Preparation for emergency events: prepares for emergency events

| Zivik 2.00. i repurut | T | pares for emergency events | T | T |
|--|--|---|---|--|
| 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 |
|-----------------------------------|---|---|--|---|
| • • | 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 |

| TABLE 6. (Continued) Public health laboratory | y competency guidelines: | Emergency Management a | nd Response domain |
|---|--------------------------|-------------------------------|--------------------|
| | | | |

EMR 3.00. Responding to emergency events: responds to emergency events

| Subcompetency | Beginner | Competent | Proficient | Expert |
|------------------------|--|--|------------|---|
| EMR 3.04. Hazardous | Recognizes hazardous spills or potential exposures | Complies with procedures for responding to hazardous | 1 | Manages response to hazardous spills or potential exposures |

| spill*response | | spills or potential exposures | spills or potential | |
|--|---|---|---|--|
| 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 workflows 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. Recove | ering from emergency events: rec | covers 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 | Describes the AAR process | Participates in AAR process | Assists with developing the final AAR | Oversees the AAR process |

| (AAR) [†] | | | | |
|--|---|---|--|---|
| 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.

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 | | Ensures that adult learning principles are applied in designing |

[†]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.

| | | underpin adult learning | designing training | 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 |

| 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 Explains cultural awareness Applies cultural awareness Evaluates the incorporation of Ensures incorporation of | | | | | |

| awareness | and its importance as it relates to developing training activities | principles when designing training activities | cultural awareness principles into training activities | 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 s | et-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 deli | 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 | | |

| 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 | | |

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

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 | |

| Subcompetency | Beginner | Competent | Proficient | Expert |
|---------------------|----------|-----------|------------|-------------------------------------|
| WFT 6.01. Marketing | | * | 1 0 | Manages the training marketing plan |

^{*} This term is defined in <u>Appendix B</u>.

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 |

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 | paper or electronic methods or systems for | 1 1 | Oversees the policies, processes, and procedures for the creation and use of paper and electronic methods or systems for documentation |

| | 1 | 1 | | |
|--|---|--|--|--|
| 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 p | olicies and principles regard | ling the use and storage of labo | oratory 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 an | d principles regarding the u | se, maintenance, and calibratio | on 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 |

| calibration records* | | calibrations records for completeness | records | program | | |
|---|--|---|--|---|--|--|
| TABLE 8. (Continued) Public health laboratory competency guidelines: General Laboratory Practice domain | | | | | | |
| GEN 4.00. Pre-exam | ination:* performs steps in th | ne pre-examination phase of t | 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 | h Oversees sample management policies, processes, and procedures | | |
| GEN 5.00. Examinat | ion:* performs steps in the ex | xamination 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 analyse | processes, and procedures | | |
| 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 | Performs QC activities | Interprets QC data prior to | Examines QC data over time t | Oversees the policies, | | |

| control (QC)* analysis | | reporting results | establish QC ranges and limits | processes, and procedures related to QC activities, including staff compliance |
|--|--|---|--|---|
| GEN 6.00. Postexam | ination:* performs steps in tl | ne postexamination phase of te | sting | |
| 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 |

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 <u>Appendix B</u>.

TABLE 9. Public health laboratory competency guidelines: Safety domain

[†]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 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 |

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 | Describes hazards associated with the biological materials | Recognizes hazards associated with new biological materials used in laboratory procedures | Assesses staff knowledge of the hazards associated with biological materials | Ensures that staff are skilled in describing and recognizing hazards associated with the |

| handled in the laboratory | handled in the laboratory | | used in laboratory procedures | 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 anima | als:* 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 | Identifies the possible route(s) of exposure to infectious agents in relation to the animal procedures used in the laboratory or animal | Assesses staff knowledge of the hazards associated with the animal procedures used in the laboratory or | Evaluates possible route(s) of exposure to infectious agents in relation to the animal procedures used in the |

| | procedures | facility | animal facility | 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 |

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 | Describes control measures to be used when working with chemicals as | Implements established control measures when working with chemicals | Ensures that staff implement the established control measures when working with | Establishes the laboratory's Chemical Hygiene Plan, including specific control |

| chemicals in the laboratory | documented in the laboratory's Chemical Hygiene Plan* | according to the laboratory's Chemical Hygiene Plan | chemicals in compliance with the laboratory's Chemical Hygiene Plan | 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 m | aterials:* works safely with | radiological materials in the | e 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 | Describes work practices to be used when working | Implements work practices to be used when working | Ensures that staff implement established work practices | Establishes, in collaboration with radiation safety staff, the |

| working with radiological materials | with radiological materials in the laboratory | with radiological materials in the laboratory | when working with radiological materials in the laboratory | 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 |

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 |

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

| Safety subdomain: hazard control | Safety | subdon | nain: ha | zard 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 preand 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 | | 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 | Describes troubleshooting | Complies with processes | Implements the processes | Develops the policies, processes, |
|----------------------|---------------------------|--------------------------|--------------------------|-----------------------------------|
| maintenance | methods to determine | and procedures to ensure | and procedures to ensure | and procedures to ensure repairs |
| | whether equipment is | equipment repairs | equipment repairs | are conducted in accordance with |
| | malfunctioning and the | | | organizational safety and health |
| | cause | | | 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 |

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 | <u> </u> | | C 1 | 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 | Explains the importance of | Participates in safety | Conducts safety inspections | Ensures staff compliance with |

| inspections | safety inspections | inspections | | 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 | SAC 2.00. Guideline and regulation compliance: ensures staff compliance with guidelines and regulations | | | | |
| Subcompetency | Beginner | Competent | Proficient | Expert | |
| SAC 2.01. | Describes current regulatory | Complies with current | Instructs staff on current | Ensures staff compliance with | |

| Subcompetency | Beginner | Competent | Proficient | Expert |
|--|---|--|---|--|
| SAC 2.01. Regulatory requirements and guidelines | | 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 |

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 | Designs policies, processes, and procedures for reporting and performing root-cause analyses of |

| | | | incident reporting | incidents |
|---|---|--|--|---|
| SAC 4.00. Occupati | onal health and medical survei | llance: complies with occupati | ional health and medical su | rveillance 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 c | ommunication:* promotes safe | ety through effective hazard co | mmunication | |
| 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 | Describes a variety of | Employs a variety of | Implements a variety of | Ensures a variety of |

| communication | communication tools and | communication tools and | communication tools and | communication tools and | |
|---------------|----------------------------|----------------------------|-------------------------|---------------------------------|--|
| tools | techniques promoting the | techniques promoting the | techniques for the | techniques promoting work | |
| | work practices employed in | work practices employed in | promotion of safe work | practices are employed in their | |
| | own area of responsibility | own area of responsibility | practices | area of responsibility | |

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 |

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.

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 |
|---------------|------------------------------------|--|---|--|
| | Describes the importance of public | Explains the integration of public health laboratory | Ensures selected laboratory testing and reporting procedures* | Oversees the policies,* processes,* and procedures that ensure |

[†] 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 | health laboratory surveillance testing | testing into broader surveillance programs | are aligned with surveillance activities and program requirements* | laboratory data will support public health surveillance activity and program requirements |
|--|---|---|---|---|
| SRV 2.00. Notification | on rules and regulations | complies with national and | d jurisdictional rules and regulation | ons 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. Surveillan | ce testing: performs sur | veillance 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 |

| TABLE 10. (| Continued) | Public health | laboratory | competency | guidelines: | Surveillance do | omain |
|--------------------|------------|----------------------|------------|------------|-------------|-----------------|-------|
| \ \ \ | , | | • | | 0 | | |

SRV 3.00. Surveillance testing: performs surveillance testing

| Subcompetency | Beginner | Competent | Proficient | Expert |
|--|--|---|--|--|
| SRV 3.02. Surveillance testing workflow ⁸ | 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 | Describes at least one | Informs supervisor of | Reports potential outbreak or | Contributes to the modification of |

| exposure event* detection | definition of an outbreak or exposure event | potential outbreak or exposure event | exposure events to key stakeholders | 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 o | critical surveillance event: | * responds to critical survei | llance 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 | Identifies when current | Applies technical | Develops plans to address | Determines the overall strategy |

| | not exist to test an analyte or organism | new testing capabilities | specific new organism or analyte during critical surveillance events | capabilities during critical surveillance events | | | | |
|-----------------------------------|---|--|---|--|--|--|--|--|
| TABLE 10. (Contin | TABLE 10. (Continued) Public health laboratory competency guidelines: Surveillance domain | | | | | | | |
| SRV 5.00. Informat | ion for surveillance: recog | gnizes 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 ana | lysis: 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 mai | nagement: manages public | c health surveillance data using | g secure data management system | ns | | | | |
| 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 | Provides trend results to | Identifies trends in | Explains trends in surveillance | Evaluates testing capabilities | | |

| TABLE 10. (Continued | TABLE 10. (Continued) Public health laboratory competency guidelines: Surveillance domain | | | | | | |
|---|---|---|---|---|--|--|--|
| SRV 9.00. Partnership | 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 | | | |

issues

| 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 <u>Appendix B</u>.

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 | Develops codes for generation of messages using multiple |

[†]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.

| | | | missing or misidentified codes | 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 ¹ 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 |

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 | 1 | 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 | | 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 autoassignment | 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 |

| TABLE 11. (Continu | TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain | | | | | |
|--|---|--|---|--|--|--|
| INF 3.00. Report pro | 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. Laborator | y test scheduling: manages | laboratory test scheduling | T | Т | | |
| 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. | Enters data to remove or | Uses specific data elements | Evaluates the workflow for | Develops codes to automate the | | |

| Management of test schedules | restore completed test requests | associated with process improvement to manage test schedules | process improvement opportunities | creation of test status reports and workflows |
|------------------------------|--|--|--|---|
| | 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 | | Manages scheduling of single or recurring test requests | · · | Develop automated processes to manage the receipt and processing of pre-scheduled samples, recurring test requests, and kit distribution |

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, rea | agents, and controls: manages the ma | nufacturing and inventory of | media, reagents, and co | ntrols 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 inhouse 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 | Enters inventory order data into | Verifies the use of codes and | Manages order | Develops workflows to |

| orders and vendors | electronic order systems | parameters necessary to | frequency and | automate the ordering of |
|--------------------|--------------------------|-------------------------------|---------------|--------------------------|
| | | automate electronic orders of | timetables | supplies from vendors |
| | | supplies | | |

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 ^s | 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 | Describes standard test order receipt and | Processes test orders received from partners using predefined | Manages the automation of test order receipts and | Develops protocols for electronic test order receipts |

| notification | notification vocabulary | modules | notification in collaboration with partners | 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 |

| TABLE 11. (Continue | TABLE 11. (Continued) Public health laboratory competency guidelines: Informatics domain | | | | | |
|--|--|--|--|---|--|--|
| INF 9.00. Statistical a | 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: man | ages billing for laboratory ser | vices | |
| 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 |

| data | code(s) with associated laboratory services at time of accessioning | associated with laboratory services | capability to link billing data with laboratory services | 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 |

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* a | 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 | Develops systems to define, organize, monitor, and track the activities of grants and contractual instruments with outside parties using electronic | |

| | | | laboratory procedures and processes | 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, e | ducation, and resource mana | gement: manages training, | education, and information res | sources |
| 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 |

| FABLE 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 | | Verifies that informatics | Evaluates laboratory | Develops informatics programs |
| development | • | processes remain up-to-date and demonstrate the | informatics needs to ensure the existence of resources | to ensure that staff education and training is aligned with the |
| | knowledge gained from training opportunities | acquired informatics capabilities of staff | and avenues to support staff education and training | 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. | Explains applicable CAL | Verifies the implementation | Evaluates electronic data | Develops workflows and |
| Certification, | electronic data requirements | of predefined data | processing standards in | modules to automate laboratory |
| accreditation, and | related to work area | processing standards and | order to ensure laboratory | adherence to data processing |
| licensing (CAL) | | form management associated | adherence to current and | standards associated with CAL |
| compliance | | with CAL for a laboratory | new CAL requirements | |

| | | program | | |
|-----------------------------------|---|---|--|---|
| 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 |

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 | Describes predefined modules that summarize | Verifies the implementation of predefined modules to | Evaluates current and future needs to track, perform ad | Develops workflow and modules that automate the |

| reports | reporting and corrective actions | summarize corrective actions and generate reports | hoc queries, and provide reports regarding corrective actions | collection of data to track and to perform <i>ad hoc</i> queries and reporting of correction actions |
|---|--|---|---|--|
| INF 15.00. QC and QA | A management: manages | quality control and quality assur | rance 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 |

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. Laborator | ry safety and accident investigat | ion: manages laboratory safety | y 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 |

| TABLE 11. (Contin | ABLE 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 upto-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: manage | es 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 | Evaluates IT support needed for laboratory | Develops formal contractual instruments, workflows, and |

| programs | operations | project management processes |
|----------|------------|--------------------------------|
| | | for the delivery of IT support |
| | | throughout the laboratory |

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 p | NF 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 ¹ | 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 | | |

| 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 | 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. | Lists established | Presents short- and long-term | Ensures that laboratory informatics | Develops partnerships to |
|----------------------|----------------------|-------------------------------|-------------------------------------|--------------------------|
| Partnership channels | stakeholders and | informatics business needs to | business needs are presented to | facilitate funding for |
| | partnership channels | management staff | stakeholders and partnership | informatics |
| | | | channels | |

^{*} This term is defined in Appendix B.

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. | Recognizes laboratory | Instructs others on | Ensures staff compliance | Develops policies, processes, and |
| Laboratory hazards | hazards and hazard | laboratory hazards and | with policies, processes.* | procedures regarding hazards related |
| related to | communication* related to | hazard communication | and procedures addressing | to microbial agents based on risk |
| microbiological | microbiological agents | related to microbiological | laboratory hazards related to | assessments [†] |
| agents | | agents | microbiological agents | |

[†] 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.

¹A process for implementing changes to software or other information technology solutions using a coordinated approach.

| MCB 2.02. Safe work | Adheres to policies, | Instructs others in policies, | Ensures staff compliance | Creates a culture of biosafety by |
|---------------------|---------------------------|-------------------------------|-------------------------------|--|
| practices* | processes, and procedures | processes, and procedures | with policies, processes, and | ensuring that policies, processes, and |
| | regarding safe work | regarding safe work | procedures regarding safe | procedures regarding safe work |
| | practices related to | practices related to | work practices related to | practices related to microbiological |
| | microbiological agents | microbiological agents | microbiological agents | agents are aligned with current |
| | | | | standards and regulatory |
| | | | | requirements |

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. | Adheres to policies, | Instructs staff in the | Ensures staff compliance with | Develops policies, processes, |

| 7 | | | | 1 |
|---|---|--|---|--|
| Decontamination* | processes, and procedures regarding decontamination | policies, processes, and procedures regarding decontamination for different microorganisms | policies, processes, and procedures regarding decontamination | 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-examin | nation:* assesses microbiolo | gical samples* during the p | re-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 | 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 |

| microbiological material | | |
|--------------------------|--|--|
| transport | | |

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 ^s | 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 |

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 | Oversees the policies, processes, and procedures regarding the performance of identification and |

| | | | identification and susceptibility testing using manual methods | 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 |

| 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 | * * * * * * * * * * * * * * * * * * * | 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. Postexam | ination:* performs postexai | mination procedures of microbio | ological 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 |

| | ļ | TABLE 12. (| Continued | Public health laborator | y 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 |

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 |

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

^{*} 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.

| 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-exam | mination:* performs chemistr | y pre-examination procedure | s | | |
| Subcompetency | Beginner | Competent | Proficient | Expert | |
| CHM 3.01. Sample | Describes routine sample | Consults on nonroutine | Monitors staff compliance | Oversees the policies, | |

| collection, labeling, and handling | collection, labeling, and handling policies, processes, and procedures for chemical examination | sample collection, labeling, and handling procedures for chemical examination | with established policies, processes, and procedures regarding chemical sample collection, labeling, and handling | 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 |

| 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 | Performs procedures for sample accessioning and | • | | Designs policies, processes, and procedures regarding sample | |

| receipt | receipt | regarding sample accessioning and receipt | sample accessioning and receipt | 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 polices, 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 ^s | 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 | Reports to epidemiologists when chemical examination requests warrant notification | Manages the policies, processes, and procedures for notification and consultation | Designs policies, processes, and procedures regarding notification and consultation |

| Subcompetency | Beginner | Competent | Proficient | Expert |
|--|---|--|--|--|
| CHM 5.00. Postexamin | nation:* performs chemist | ry postexamination procedur | res | |
| CHM 4.05. Sample storage and handling after examination Performs procedures for sample storage and handling after examination | | Instructs staff in procedure for sample storage and handling after examination | procedures for sample storage | · • |
| Subcompetency | Beginner | Competent | Proficient | Expert |
| CHM 4.00. Examination | on:* performs chemistry e | xamination procedures | | |
| TABLE 13. (Continued | d) Public health laboratory | competency guidelines: Che | emistry domain | |
| Equipment troubleshooting | Equipment equipment* problems p | | functioning during its lifecycle | troubleshooting processes and procedures |
| CHM 4.03. Quality control (QC)* analysis | Performs QC activities Identifies basic laboratory | Interprets QC data prior to reporting results Corrects equipment | Examines QC data over time to establish QC ranges and limits Monitors equipment | Ensures the QC program adheres to regulatory requirements* Develops equipment |
| 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 4.01. 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 |
| Subcompetency | Beginner | Competent | Proficient | Expert |
| CHM 4.00. Examination | on:* performs chemistry e | xamination procedures | | |
| | consultation | | chemical examination requests | chemical examination requests |
| | notification and | | with epidemiologists regarding | with epidemiologists regarding |

| 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 | | 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 of | compliance: ensures regulat | tory 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 | Participates in | Compiles results of method | Evaluates method validation | Oversees the policies, |
| · · · · · · · · · · · · · · · · · · · | | | | |

| validation* and performance verification* | performance of method validation and performance verification | validation and performance verification | and performance verification results | 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 | _ | Oversees the policies, processes, and procedures regarding the development and validation of LDTs |

^{*} This term is defined in Appendix B.

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 | related data sets | Oversees selection of advanced statistical methods applicable to specific |

[†]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.

| | | to the biological data | | bioinformatics analyses |
|---|--|--|--|---|
| TABLE 14. (Contin | ued) Public health laboratory | competency guidelines: Bioint | formatics domain | |
| <u>`</u> | ysis: analyzes biological data | competency guidenness 210m | | |
| 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 man | agement: conducts data mana | agement, storage, and retrieva | 1 | |
| 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.

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 |

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 | Describes issues that might arise pertaining to data ownership and the sharing | Ensures staff compliance with established agreements regarding data sharing | Establishes guidelines for sharing research data |

| | the use of intellectual property | of data | | |
|--|--|---|---|--|
| RES 3.00. Research for | undation: integrates scientif | ic and technical knowledge | for use as a foundation for res | search |
| 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 |

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 |

| TABLE 15. (Continued) Pr | 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 | Publishes as senior author for multi- laboratory or multi-institutional | | |

| | | | in journals of the discipline | 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 |
|------------------------|---------------------------|-----------------------------|----------------------|---|
| research findings into | as they relate to current | research findings on public | research findings to | Oversees translation of research discoveries into meaningful changes in public health practices |

^{*} This term is defined in Appendix B.

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[†] A detailed plan for conducting a scientific procedure.