

# Competency Guidelines for Workforce Development of Health Laboratory Professionals Globally

Modified from *Competency Guidelines for Public Health Laboratory Professionals*,  
MMWR, Suppl 2015;64:1, 1-95



# Contents

<b>Summary</b> .....	<b>4</b>
<b>Introduction</b> .....	<b>5</b>
Purpose .....	6
Scope.....	6
Competencies and Skill Domains .....	6
Intended Use.....	8
Acknowledgments.....	8
<b>Quality Management System Competency Guidelines</b> .....	<b>9</b>
QMS 1.00: Organization.....	10
QMS 2.00: Customer Focus .....	10
QMS 3.00: Facilities and Safety .....	11
QMS 4.00: Personnel .....	11
QMS 5.00: Purchasing and Inventory.....	12
QMS 6.00: Laboratory Equipment .....	12
QMS 7.00: Process Management .....	13
QMS 8.00: Documents and Records.....	13
QMS 9.00: Information Management .....	14
QMS 10.00: Nonconforming Event Management.....	14
QMS 11.00: Assessments .....	15
QMS 12.00: Continual Quality Improvement .....	16
<b>Ethics Competency Guidelines</b> .....	<b>17</b>
ETH 1.00: Professional Code of Conduct.....	18
ETH 2.00: Scientific Code of Conduct .....	18
<b>Management and Leadership Competency Guidelines</b> .....	<b>19</b>
MLD 1.00: General Management .....	20
MLD 2.00: Policy Development .....	21
MLD 3.00: Financial Management.....	22
MLD 4.00: Human Resource Management .....	22
MLD 5.00: Leadership .....	24
<b>Communication Competency Guidelines</b> .....	<b>26</b>
COM 1.00: Communication Techniques.....	27
COM 2.00: Active Listening Skills .....	27
COM 3.00: Comprehension of Materials .....	27
COM 4.00: Communication Technology.....	28
COM 5.00: Communication Professionalism ..	28
COM 6.00: Professional Reports .....	28
COM 7.00: Risk Communication .....	29
COM 8.00: Health Laboratory Value .....	29
COM 9.00: Media Relations.....	30
<b>Security Competency Guidelines</b> .....	<b>31</b>
SEC 1.00: Risk Mitigation .....	32
SEC 2.00: Security Plan.....	32
SEC 3.00: Physical Security .....	33
SEC 4.00: Personnel Security Program .....	33
SEC 5.00: Information Security.....	34
SEC 6.00: Transportation Security Program ..	34
<b>Emergency Management Competency Guidelines</b> .....	<b>35</b>
EMR 1.00: Mitigation of Emergency Events ....	36
EMR 2.00: Preparation for Emergency Events	37
EMR 3.00: Responding to Emergency Events.	38
EMR 4.00: Recovering from Emergency Events .....	39
<b>Workforce Training Competency Guidelines</b> .....	<b>40</b>
WFT 1.00: Content.....	41
WFT 2.00: Training Design.....	41
WFT 3.00: Delivery Set-up .....	42
WFT 4.00: Training Delivery .....	42
WFT 5.00: Training Evaluation .....	43
WFT 6.00: Marketing .....	43
<b>General Laboratory Practice Competency Guidelines</b> .....	<b>44</b>
GEN 1.00: General Technical and Laboratory Practice Knowledge .....	45
GEN 2.00: Reagent Use and Storage .....	46
GEN 3.00: Equipment Use .....	46
GEN 4.00: Pre-examination .....	47
GEN 5.00: Examination .....	47
GEN 6.00: Post-examination .....	48
GEN 7.00: Regulatory Compliance .....	48
<b>Safety Competency Guidelines</b> ..	<b>50</b>
<b>Potential Hazards</b>	
SPH 1.00: Physical Environment.....	51
SPH 2.00: Biological Materials.....	51
SPH 3.00: Research Animals .....	52
SPH 4.00: Chemical Materials.....	53
SPH 5.00: Radiological Materials .....	53
<b>Hazard Control</b>	
SHC 1.00: Engineering Controls .....	54
SHC 2.00: Safe Work Practices.....	55
SHC 3.00: Personal Protective Equipment.....	56
SHC 4.00: Systems to Track Hazards.....	56
SHC 5.00: Preventive Maintenance .....	56
SHC 6.00: Decontamination and Laboratory Waste Management .....	57

## Administrative Controls

SAC 1.00: Safety Program Management .....	58
SAC 2.00: Guideline and Regulation Compliance .....	58
SAC 3.00: Risk Management .....	59
SAC 4.00: Occupational Health And Medical Surveillance .....	59

## Communication and Training

SCT 1.00: Hazard Communication .....	60
SCT 2.00: Safety Training .....	60

## Documents and Records

SDR 1.00: Documents and Record Keeping...	61
---	----

## Surveillance Competency Guidelines ..... 63

SRV 1.00: Function of Surveillance .....	64
SRV 2.00: Notification Rules and Protocols ...	64
SRV 3.00: Surveillance Testing .....	64
SRV 4.00: Response to Critical Surveillance Event .....	65
SRV 5.00: Information for Surveillance .....	66
SRV 6.00: Data Analysis .....	66
SRV 7.00: Data Management .....	66
SRV 8.00: Recognition of Significant Results.	67
SRV 9.00: Partnerships .....	67
SRV 10.00: Dissemination of Data .....	67

## Informatics Competency Guidelines ..... 68

INF 1.00: Laboratory Test Request and Sample Receiving .....	69
INF 2.00: Test preparation, LIMS processing, Test Results Recording and Verification .....	70
INF 3.00: Report Preparation and Distribution .....	71
INF 4.00: Laboratory Test Scheduling .....	71
INF 5.00: Prescheduled Testing .....	72

INF 6.00: Sample Tracking and Chain of Custody .....	72
INF 7.00: Media, Reagents and Controls .....	73
INF 8.00: Data Exchange and Interoperability .....	73
INF 9.00: Statistical Analysis and Surveillance .....	74
INF 10.00: Billing for Laboratory Services .....	75
INF 11.00: Contract and Grant Management ..	76
INF 12.00: Training, Education and Resource Management .....	77
INF 13.00: Laboratory Certifications, Accreditations and Licensing .....	78
INF 14.00: Customer Relationship Management .....	78
INF 15.00: Quality Control and Quality Assurance Management .....	79
INF 16.00: Laboratory Safety and Accident Investigation .....	80
INF 17.00: Laboratory Mutual Assistance and Disaster Recovery .....	81
INF 18.00: Core IT Products and Services .....	81
INF 19.00: Policies and Procedures .....	83

## Microbiology Competency Guidelines ..... 84

MCB 1.00: Concepts and Techniques .....	85
MCB 2.00: Facilities and Safety .....	85
MCB 3.00: Pre-examination .....	86
MCB 4.00: Examination .....	88
MCB 5.00: Post-examination .....	90
MCB 6.00: Regulatory Compliance .....	90

## Chemistry Competency Guidelines ..... 92

CHM 1.00: Concepts and Techniques .....	93
CHM 2.00: Facilities and Safety .....	94
CHM 3.00: Pre-examination .....	95
CHM 4.00: Examination .....	96
CHM 5.00: Post-examination .....	97
CHM 6.00: Compliance .....	98

## Bioinformatics Competency Guidelines ..... 99

BIO 1.00: Biology and Computer Science Knowledge .....	100
BIO 2.00: Statistical Methods Knowledge ...	100
BIO 3.00: Data Analysis .....	100
BIO 4.00: Data Management .....	101

## Research Competency Guidelines ..... 102

RES 1.00: Research Programs .....	103
RES 2.00: Ethical Conduct .....	104
RES 3.00: Research Foundation .....	104
RES 4.00: Testing Methodology Development ..	105
RES 5.00: Research Project Execution .....	106
RES 6.00: Research Data Management, Analysis and Application .....	106
RES 7.00: Dissemination of Research Findings .....	107
RES 8.00: Translation .....	107

## Conclusion ..... 108

## Appendix ..... 109

Laboratory Proficiency Tier Definitions .....	109
Glossary of Terms .....	110

## References ..... 121

# Summary

The Competency Guidelines outline essential knowledge, skills and abilities necessary for health laboratory professionals to effectively and efficiently deliver laboratory services. The [original version of these guidelines](#) was developed by the US Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). This version of the guide was modified to accommodate a global audience. The guidelines comprise general, cross-cutting and specialized domain areas (see callout at right) and are divided into four levels of proficiency: beginner, competent, proficient and expert.

These competency guidelines are relevant to laboratory professionals working in, directing or overseeing public health (e.g., Ministry of Health), public health clinical (medical), environmental, veterinary, food, and agricultural laboratories. Competencies identify essential laboratory workforce principles that support quality operation of laboratories. Potential uses of the guidelines include:

- **Workforce development:** as a standard reference for laboratory workforce development applicable across human, animal, environmental and other relevant health sectors.
- **Program development:** as a foundation for laboratory learning programs.
- **Job description development:** as a guide for writing standardized job descriptions.
- **Needs assessment:** as guidance for developing a tool for self-assessment, observer assessment or a combination of both to identify individual or group needs and guide staff development planning.
- **Self-assessment:** as guidance for individuals in assessing their current level of knowledge, skills and abilities, identifying areas in need of improvement and planning for achieving higher levels of proficiency.

This revised version of the *Competency Guidelines for Public Health Laboratory Professionals* (MMWR, Suppl 2015;64:1, 1-95) titled, *Competency Guidelines for Workforce Development of Health Laboratory Professionals Globally*, has been enhanced with more specific information to encompass laboratory professionals representative of countries around the world.

## Competency Domains

- |                                     |   |                           |
|-------------------------------------|---|---------------------------|
| 1. <b>Quality Management System</b> | 6. <b>Emergency Management and Response</b> | 9. <b>Safety</b>          |
| 2. <b>Ethics</b>                    | 7. <b>Workforce Training</b>                | 10. <b>Surveillance</b>   |
| 3. <b>Management and Leadership</b> | 8. <b>General Laboratory Practice</b>       | 11. <b>Informatics</b>    |
| 4. <b>Communication</b>             |   | 12. <b>Microbiology</b>   |
| 5. <b>Security</b>                  |   | 13. <b>Chemistry</b>      |
|                                     |   | 14. <b>Bioinformatics</b> |
|                                     |   | 15. <b>Research</b>       |



# Introduction

Laboratories are a vital part of the health infrastructure and serve multiple purposes through provision of testing services that may include detection and identification of infectious diseases, foodborne and waterborne diseases, environmental hazards, hereditary disorders and causes of natural events and disasters caused by human actions.<sup>1,2</sup> A competent laboratory workforce is one of the essential major components of a well-functioning health system. The guidelines can be an effective tool to use in assessments of laboratories and planning and implementation of activities that support the health system.<sup>3</sup> Laboratories have a critical role in disease detection, patient monitoring, disease prevention and health surveillance. Therefore, laboratory managers and senior managers of the Ministry of Health or other Ministries that have laboratory sections must be able to make evidence-based decisions, manage or advocate for laboratories to ensure quality services and demonstrate vision and leadership to inspire the **process** of change and continuous improvement to promote human health.

Further, laboratory leaders must be informed of and support the “One Health” initiative that aims to “optimize the health of people, animals and ecosystems.”<sup>4,5,6</sup> Collaboration across sectors and disciplines strengthens response to meet health challenges and protect against the emergence of infectious disease risks, antimicrobial resistance, food safety and environmental risks. By addressing the full spectrum of disease control, a One Health approach can contribute to global health security.

There are both differences, some considerable, and many similarities among countries regarding the purpose, capabilities, capacities, organization, roles, staffing, physical size, types and number of health laboratories as well as relevant government policies and financial support for laboratories. The gap of resource support between laboratories in high- to upper-middle income countries (HIC, UMC) and low- to lower-middle countries (LIC, LMIC) is substantial. This difference of financial support is one cause of the notable differences at the network and system levels of laboratory organization and the sustainability of **laboratory programs**. Nevertheless, there are many similar components among the laboratories, regardless of their World Bank Income Level classification.

## Elements of a National Laboratory Network or System

National Laboratory networks and systems often have these elements:

- **National Public Health Laboratory (NPHL):** A national reference laboratory that may be an organizational component of a National Public Health Institute (NPHI). The NPHL typically is the referral laboratory for the Ministry of Health (MoH) clinical laboratories, and if not part of a NPHI, often reports directly to the Minister of Health.
- **Clinical (medical) Laboratories in the MoH:** Organized in a tiered structure with 3–6 levels from the 1) apex Referral, Central or Specialized level; 2) Zonal/Referral; 3) Regional; 4) Provincial; 5) District or Rural Hospital; and 6) Health Clinic level. In all organizational schemes, there is a Referral Hospital at the top level and Health Clinics at the lowest level.
- **Ministries of Agriculture and/or Animal Health:** Exist in most countries but may have limited laboratory capabilities and capacities. The World Organization of Animal Health (182 Member states) has committed to actions to promote One Health **policy**, which provides an opportunity to develop partnerships in support of multisectoral laboratory services.

## Purpose

The Guidelines and Core Competencies are pertinent to many laboratory types and can be used to assess and direct workforce development efforts. The revised guidelines outline the knowledge, skills and abilities required for a laboratory workforce of health laboratory professionals (principally, scientists, managers, leaders and laboratory staff at all levels of a national health system) to deliver quality laboratory services, including timely data and information for patient treatment. The guidelines provide for surveillance to detect and warn of emerging disease risks and to aid health agency assessments and planning that guide and support public health interventions.

## Scope

The scope of competency guidelines is meant to bridge all laboratories within national government systems that are health-related and to promote connectedness of the health laboratories (public health, clinical, environmental, animal, agricultural and food laboratories), surveillance programs and patient diagnostic testing with the disease surveillance and health **policy** departments of national governments and their subunits. The base principle is a One Health approach.

## Competencies and Skill Domains

The original 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.<sup>7,8</sup> 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 so that four proficiency tiers are used: beginner, competent, proficient and expert. See “**Laboratory Proficiency Tier Definitions**” (**page 109**) for descriptions of the proficiency tiers.

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.<sup>9,10</sup> 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 variety that exists within and across 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 laboratory. 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 sub-competencies were identified for the public health laboratory workforce across 15 competency domains. The guidelines include general, cross-cutting technical and specialized competencies, with a **quality management system** as the foundation of every activity.

### Competency Domains

- |   |                                       |
|---|---------------------------------------|
| 1. <b>Quality Management System</b>         | 8. <b>General Laboratory Practice</b> |
| 2. <b>Ethics</b>                            | 9. <b>Safety</b>                      |
| 3. <b>Management and Leadership</b>         | 10. <b>Surveillance</b>               |
| 4. <b>Communication</b>                     | 11. <b>Informatics</b>                |
| 5. <b>Security</b>                          | 12. <b>Microbiology</b>               |
| 6. <b>Emergency Management and Response</b> | 13. <b>Chemistry</b>                  |
| 7. <b>Workforce Training</b>                | 14. <b>Bioinformatics</b>             |
|   | 15. <b>Research</b>                   |

Full descriptions of these domains and listing of their competencies, sub-competencies and responsibility statements are presented within each domain's section. A number and lettering schema is used to identify domains, competencies and sub-competencies. 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 sub-competencies 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 laboratory 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). 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 sub-competencies 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 quasi-specialized 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 sub-competencies 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 sub-competencies 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 sub-competency 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 sub-competency 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 sub-competency. 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 laboratory scientist could be at the beginner tier for some sub-competencies 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 global guidelines provide highly structured competencies intended to strengthen and energize an empowered laboratory workforce. The competence of the laboratory workforce has a direct impact on the quality of the work output and products required to protect the health of the community. Each competency and sub-competency 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 or **licensure 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 laboratory 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; terms are linked to the **“Glossary of Terms” (page 110)** where they appear in the body of the text. 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.

## Acknowledgments

APHL acknowledges the work of the original [Guideline](#) developers. Some parts of the content of this global version of the Guidelines are adapted, other parts remain as written in the original guidelines.

These guidelines were made possible through the hard work and collaboration of APHL staff and Martin Evans, Kelsey Florek, Kim Lewis, David Mills, Ralph Timperi and Burton Wilcke, Jr.

# Quality Management System Competency Guidelines

**Purpose:** The competencies in **Quality Management System (QMS)** address the knowledge, skills and abilities required for developing a laboratory’s culture of quality. 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.

**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 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 health laboratory staff is to provide quality testing and services to support health 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.



## Quality Management System Domain Notes

*The structure for this domain is based upon the 12 quality system essentials.<sup>11</sup> Multiple additional sources were identified as support documents for this domain.<sup>12, 13, 14, 15, 16, 17, 18</sup> 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 sub-competencies 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.*

## QMS 1.00: Organization

Organization competencies ensure that the laboratory's organizational structure is committed to achieving and maintaining quality.

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

## QMS 2.00: Customer Focus

**Customer** focus competencies ensure that customer needs, expectations and **requirements** are consistently met.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 2.01. Customer satisfaction</b>	Recognizes the laboratory's internal and external <b>customers</b>	Responds to internal and external <b>customer</b> inquiries and feedback	Analyzes feedback and satisfaction data from internal and external <b>customers</b>	Oversees the system for measuring <b>customer</b> and user satisfaction
<b>QMS 2.02. Customer services</b>	Describes the customer services provided by the laboratory to meet <b>customer</b> needs, expectations and requirements	Adheres to roles and responsibilities in meeting <b>customer</b> needs, expectations and requirements	Develops procedures to address <b>customer</b> needs, expectations and requirements	Oversees the <b>policies, processes</b> and <b>procedures</b> for providing <b>customer</b> services that meet customer needs, expectations and requirements

## QMS 3.00: Facilities and Safety

Facilities and safety competencies ensure that the laboratory's physical environment, maintenance and safety programs meet applicable requirements.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 3.01. Workplace safety</b>	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 <u>policies, processes</u> and <u>procedures</u> to develop, review and maintain a safety plan that meets requirements
<b>QMS 3.02. Facilities</b>	Describes the laboratory design, escape routes, and workplace accommodations	Monitors <u>environmental controls</u> for good laboratory practice and testing capabilities	Ensures security and containment of staff, samples, laboratory supplies and laboratory equipment	Directs the <u>process</u> and planning for facility design, modification and renovation
<b>QMS 3.03. Waste management</b>	Describes waste management <u>policies, processes</u> and <u>procedures</u>	Applies waste management <u>policies, processes</u> and <u>procedures</u> to activities	Trains staff on the <u>waste management plan</u> , including recycling and disposal methods	Ensures the <u>waste management plan</u> follows regulatory requirements
<b>QMS 3.04. Emergency management and response</b>	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 <u>policies, processes</u> and <u>procedures</u>	Establishes emergency management and response <u>policies, processes</u> and <u>procedures</u>

## QMS 4.00: Personnel

Personnel competencies ensure recruitment and retention of a qualified, well-trained and competent workforce.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 4.01. Competence assessment plan</b>	Describes competence assessment plans	Participates in the development of an individualized competence assessment plan	Evaluates individual competence assessment plans	Oversees a competence assessment plan for the organization
<b>QMS 4.02. Professional development plan</b>	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
<b>QMS 4.03. Performance evaluation process</b>	Participates in the initial performance evaluation <u>process</u>	Participates in the ongoing performance evaluation <u>process</u>	Manages the performance evaluation <u>process</u>	Establishes a <u>process</u> for periodic performance evaluation
<b>QMS 4.04. Recruitment, retention and succession plans</b>	Describes the recruitment and retention plan	Participates in recruitment and retention plan	Manages the recruitment, retention and succession plans	Develops recruitment, retention and succession plans to maintain a qualified workforce

## QMS 5.00: Purchasing and Inventory

Purchasing and inventory competencies ensure that requirements for supplies and services are consistently met.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 5.01.</b> <b>Procurement process</b>	Describes laboratory procurement <b>process</b> for current work area	Participates in laboratory procurement <b>process</b>	Manages laboratory procurement <b>process</b>	Ensures that laboratory procurement incorporates organizational rules and collaboration with purchasing authorities
<b>QMS 5.02.</b> <b>Inventory processes</b>	Describes the inventory management <b>processes</b> used in current work area	Follows established inventory management <b>processes</b> , including receipt and inspection processes	Develops inventory <b>processes</b> for laboratory supplies, reagents and <b>verification</b> of performance	Oversees inventory management plan
<b>QMS 5.03.</b> <b>Evaluation process</b>	Describes the <b>process</b> to evaluate and provide feedback to suppliers	Executes the <b>process</b> to evaluate and provide feedback to suppliers, consultants and contractors	Develops a <b>process</b> to evaluate the satisfaction with services and products from suppliers, consultants and contractors	Oversees a quality improvement plan for purchasing and inventory

## QMS 6.00: Laboratory Equipment

Laboratory equipment competencies ensure that laboratory equipment selection, installation, use, maintenance and troubleshooting meet performance standards.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 6.01.</b> <b>Acquisition and decommissioning</b>	Describes the <b>policies, processes</b> and <b>procedures</b> for equipment acquisition and decommissioning	Provides input on the <b>processes</b> and <b>procedures</b> for equipment acquisition and decommissioning	Develops the <b>processes</b> and <b>procedures</b> for equipment acquisition and decommissioning	Oversees the <b>policies, processes</b> and <b>procedures</b> for equipment acquisition and decommissioning
<b>QMS 6.02.</b> <b>Equipment qualification plan</b>	Describes <b>processes</b> and <b>procedures</b> for equipment installation qualification, operational qualification and performance qualification	Performs equipment installation, operational and performance qualification <b>procedures</b> and adheres with the plan	Implements the <b>equipment qualification plan</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the <b>equipment qualification plan</b>
<b>QMS 6.03.</b> <b>Maintenance process</b>	Describes <b>processes</b> and <b>procedures</b> for the maintenance, troubleshooting, and service and repair of equipment	Performs <b>procedures</b> for the maintenance, troubleshooting, and service and repair of equipment	Develops the <b>processes</b> for equipment maintenance, troubleshooting, and service and repair	Oversees the <b>policies, processes</b> and <b>procedures</b> for equipment maintenance, troubleshooting, service and repair
<b>QMS 6.04.</b> <b>Instrument and equipment calibration</b>	Describes calibration of instruments and equipment	Performs calibration of instruments and equipment	Establishes calibration <b>processes</b> and procedures for instruments and equipment	Oversees calibration <b>policies, processes</b> and <b>procedures</b> for instruments and equipment

## QMS 7.00: Process Management

**Process management** competencies ensure that operational processes meet organizational requirements.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 7.01. Workflow* processes</b>	Describes <b>workflow</b> processes related to job position and activities	Applies <b>workflow</b> processes according to laboratory <b>policies, processes</b> and <b>procedures</b>	Develops evaluation, modification and design of <b>workflow</b> processes and procedures	Oversees the <b>policies, processes</b> and <b>procedures</b> for evaluating and modifying current <b>workflow</b> processes and for developing new <b>workflow</b> processes
<b>QMS 7.02. Process control</b>	Describes how processes are controlled in work area	Participates in <b>process</b> control procedures	Develops the <b>process</b> control plan	Oversees the <b>process</b> control plan
<b>QMS 7.03. Method validation and performance verification processes</b>	Describes method <b>validation</b> and performance <b>verification</b> processes	Performs procedures for method <b>validation</b> and performance <b>verification</b>	Develops method <b>validation</b> and performance <b>verification</b> processes and procedures	Oversees the <b>policies, processes</b> and <b>procedures</b> for <b>validation</b> of new or modified tests or materials and for <b>verification</b> of existing tests or materials

## QMS 8.00: Documents and Records

**Documents** and **records** competencies ensure that there is an effective system to control and manage documents and records.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 8.01. Document management system</b>	Describes how the laboratory controls and manages <b>documents</b>	Applies the <b>policies, processes</b> and <b>procedures</b> for controlling and managing <b>documents</b>	Develops the <b>policies, processes</b> and <b>procedures</b> for controlling and managing <b>documents</b>	Oversees the document management system to ensure staff compliance with internal policies, external guidelines, standards or regulations, and <b>accreditation</b> requirements
<b>QMS 8.02. Records management system</b>	Describes how the laboratory controls and manages <b>records</b>	Applies the <b>policies, processes</b> and <b>procedures</b> for controlling and managing <b>records</b>	Develops the <b>policies, processes</b> and <b>procedures</b> for controlling and managing <b>records</b>	Oversees the record management system to ensure staff compliance with internal policies, external guidelines, standards or regulations, and <b>accreditation</b> requirements

\* 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 **post-examination** procedures.

## QMS 9.00: Information Management

Information management competencies ensure the confidentiality, security and integrity of generated and disseminated information.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 9.01. Confidentiality</b>	Describes the <u>policies, processes</u> and <u>procedures</u> for maintaining <u>confidentiality</u> of laboratory information	Complies with <u>policies, processes</u> and <u>procedures</u> for maintaining <u>confidentiality</u> of internally and externally derived information	Develops <u>policies, processes</u> and <u>procedures</u> for maintaining <u>confidentiality</u> of internally and externally derived information	Oversees the <u>policies, processes</u> and <u>procedures</u> for ensuring <u>confidentiality</u> of information and staff compliance with regulations, standards and guidelines
<b>QMS 9.02. Security</b>	Describes the <u>policies, processes</u> and <u>procedures</u> related to securing information related to assigned job tasks	Complies with <u>policies, processes</u> and <u>procedures</u> for securing information	Develops <u>policies, processes</u> and <u>procedures</u> to ensure information is secure	Oversees the <u>policies, processes</u> and <u>procedures</u> for securing information, including audits to meet regulations, standards and guidelines
<b>QMS 9.03. Information integrity</b>	Describes the <u>policies, processes</u> and <u>procedures</u> for ensuring <u>integrity</u> of information	Complies with <u>policies, processes</u> and <u>procedures</u> to ensure the <u>integrity</u> of information	Develops processes and procedures to ensure the <u>integrity</u> of information	Oversees the <u>policies, processes</u> and <u>procedures</u> to ensure the <u>integrity</u> of information

## QMS 10.00: Nonconforming Event Management

Nonconforming event (NCE) management competencies ensure that processes are in place for detecting and managing NCEs.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 10.01. Management of NCEs</b>	Recognizes <u>NCEs</u>	Responds to <u>NCEs</u>	Investigates <u>NCEs</u> , including the creation of a corrective action plan	Oversees the <u>policies, processes</u> and <u>procedures</u> related to <u>NCEs</u>
<b>QMS 10.02. Documentation of NCEs</b>	Describes the <u>policies, processes</u> and <u>procedures</u> to record and report <u>NCEs</u>	Reports discovered <u>NCEs</u>	Performs analysis of <u>records</u> and reports of <u>NCEs</u> to identify trends	Oversees the <u>policies, processes</u> and <u>procedures</u> to document <u>NCEs</u> and report NCE information to senior management and external entities
<b>QMS 10.03. Investigation and root cause analysis</b>	Participates in <u>NCE</u> investigations and <u>root cause analyses</u>	Leads the <u>process</u> of investigating <u>NCEs</u> and performing <u>root cause analyses</u>	Assesses <u>NCE</u> investigations and <u>root cause analyses</u> to improve processes	Oversees the <u>policies, processes</u> and <u>procedures</u> for investigating <u>NCEs</u> and performing <u>root cause analyses</u>
<b>QMS 10.04. Notifications of re-calls and technical bulletins</b>	Describes the <u>policies, processes</u> and <u>procedures</u> 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 <u>policies, processes</u> and <u>procedures</u> to address product recalls and technical bulletin notifications

## QMS 11.00: Assessments

Assessment competencies ensure that processes are in place to perform internal audits and external assessments.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 11.01.</b> <b><u>Quality assessment plan</u></b>	Adheres to the <b><u>quality assessment plan</u></b>	Ensures the application of the <b><u>quality assessment plan</u></b> to laboratory operations	Develops the <b><u>quality assessment plan</u></b>	Oversees a comprehensive <b><u>quality assessment plan</u></b>
<b>QMS 11.02.</b> <b><u>External assessments</u></b>	Participates in <b><u>external assessments</u></b> activities	Performs <b><u>external assessment procedures</u></b>	Develops the processes and procedures to select, enroll and participate in <b><u>external assessments</u></b>	Oversees the <b><u>policies, processes and procedures</u></b> related to <b><u>external assessment</u></b>
<b>QMS 11.03.</b> <b><u>Internal audits</u></b>	Participates in <b><u>internal audits</u></b>	Performs <b><u>internal audit procedures</u></b>	Develops the processes and procedures for <b><u>internal audits</u></b>	Oversees the <b><u>policies, processes and procedures</u></b> related to <b><u>internal audits</u></b>
<b>QMS 11.04.</b> <b><u>Quality indicators</u></b>	Describes the elements of <b><u>pre-examination, examination and post-examination quality indicators</u></b>	Employs <b><u>pre-examination, examination and post-examination quality indicators</u></b>	Develops processes and procedures for determining <b><u>pre-examination, examination and post-examination quality indicators</u></b>	Oversees the <b><u>policies, processes and procedures</u></b> related to developing and assessing <b><u>quality indicators</u></b>
<b>QMS 11.05.</b> <b><u>Quality indicator data collection and analysis</u></b>	Describes the <b><u>policies, processes and procedures</u></b> related to collecting and analyzing quality indicator data	Complies with <b><u>policies, processes and procedures</u></b> related to collecting and analyzing quality indicator data	Develops the processes and procedures for collecting and analyzing quality indicator data	Oversees the <b><u>policies, processes and procedures</u></b> related to the collection and analysis of quality indicator data

## QMS 12.00: Continual Quality Improvement

Continual quality improvement (CQI) competencies ensure mechanisms for CQI.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>QMS 12.01.</b> <b>CQI program</b>	Describes the <b>policies, processes</b> and <b>procedures</b> related to the <b>CQI</b> program	Implements changes identified through the <b>CQI</b> program	Develops the processes and procedures of the <b>CQI</b> program	Oversees the <b>policies, processes</b> and <b>procedures</b> related to the quality improvement program
<b>QMS 12.02.</b> <b>CQI activities</b>	Participates in <b>CQI</b> activities	Follows <b>CQI</b> processes and procedures for troubleshooting and documenting required <b>CQI</b> activities	Documents staff compliance with <b>CQI</b> activities that support the <b>CQI</b> monitoring, evaluation and review processes	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>CQI</b> activities
<b>QMS 12.03.</b> <b>Corrective action process</b>	Describes the <b>policies, processes</b> and <b>procedures</b> 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 <b>policies, processes</b> and <b>procedures</b> related to corrective action
<b>QMS 12.04.</b> <b>Preventive action</b>	Describes the <b>policies, processes</b> and <b>procedures</b> related to <b>preventive action</b>	Implements the processes and procedures related to <b>preventive action</b>	Develops the processes and procedures related to <b>preventive action</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>preventive action</b>
<b>QMS 12.05.</b> <b>Change management</b>	Describes the <b>process</b> to change laboratory <b>policies, processes</b> and <b>procedures</b>	Participates in the <b>process</b> and procedures related to <b>change management</b>	Implements the <b>change management process</b> , including communication of changes made to established <b>policies, processes</b> and <b>procedures</b>	Oversees activities related to <b>policy, process</b> and procedural <b>change management</b> , including evaluation of impact on organizational processes and services

# Ethics Competency Guidelines

**Purpose:** 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. Ethical professional and scientific behaviors are essential when working in the health laboratory to help ensure scientific integrity and sustain effective relationships with stakeholders and the public.

Ethics are principles, or a set of core 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 health laboratory must earn and maintain the public's trust. As diligent stewards of that trust and of funds, all 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.



## Ethics Domain Notes

Multiple sources were identified as support documents for this domain.<sup>19, 20, 21, 22, 23</sup> 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.

## ETH 1.00: Professional Code of Conduct

Professional code of conduct competencies ensure adherence to policies and principles governing professional ethics and rules of conduct when working in a health laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>ETH 1.01. Personal integrity</b>	Aligns personal integrity with organizational culture	Exemplifies integrity in interactions and activities	Coaches staff in behaviors that exhibit integrity	Creates a culture where integrity is the basis for all interactions and activities
<b>ETH 1.02. General ethical practices</b>	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 <b>procedures</b> related to ethical principles and professional rules of conduct	Oversees the <b>policies, processes</b> and <b>procedures</b> related to ethical principles and professional rules of conduct
<b>ETH 1.03. Stewardship of resources</b>	Acts as a good steward of institutional funds and resources	Identifies methods to improve stewardship of resources	Ensures that the use of institutional funds and resources meet the policies for stewardship	Oversees the <b>policies, processes</b> and <b>procedures</b> to ensure the environment supports excellence in the stewardship of resources
<b>ETH 1.04. Ethics and patient care</b>	Applies ethical principles and professional rules of conduct to protect patient's rights and privacy	Identifies methods to improve the ethical treatment of patients	Ensures staff compliance with policies and <b>procedures</b> related to patients and their ethical care	Oversees the policies, processes and <b>procedures</b> related to patients and their ethical care

## ETH 2.00: Scientific Code of Conduct

Scientific code of conduct competencies ensure adherence to policies and principles governing **scientific ethics** and rules of conduct when working in a health laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>ETH 2.01. Scientific integrity</b>	Verifies <b>scientific integrity</b> of test results and findings	Explain <b>policies, processes</b> and <b>procedures</b> regarding <b>scientific integrity</b> of test results and findings	Ensures staff compliance with policies and <b>procedures</b> regarding <b>scientific integrity</b> of all results and findings	Oversees the policies, processes and <b>procedures</b> to ensure practices are consistent with guidelines on <b>scientific integrity</b>
<b>ETH 2.02. Scientific ethics</b>	Applies <b>scientific ethics</b> and rules of conduct to the workplace	Serves as a role model of scientific ethical behavior and rules of conduct by consistently conforming to the highest scientific standards and practices	Ensures staff compliance with policies and <b>procedures</b> related to <b>scientific ethics</b> and rules of conduct	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>scientific ethics</b> and rules of conduct

# Management and Leadership Competency Guidelines

**Purpose:** 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).

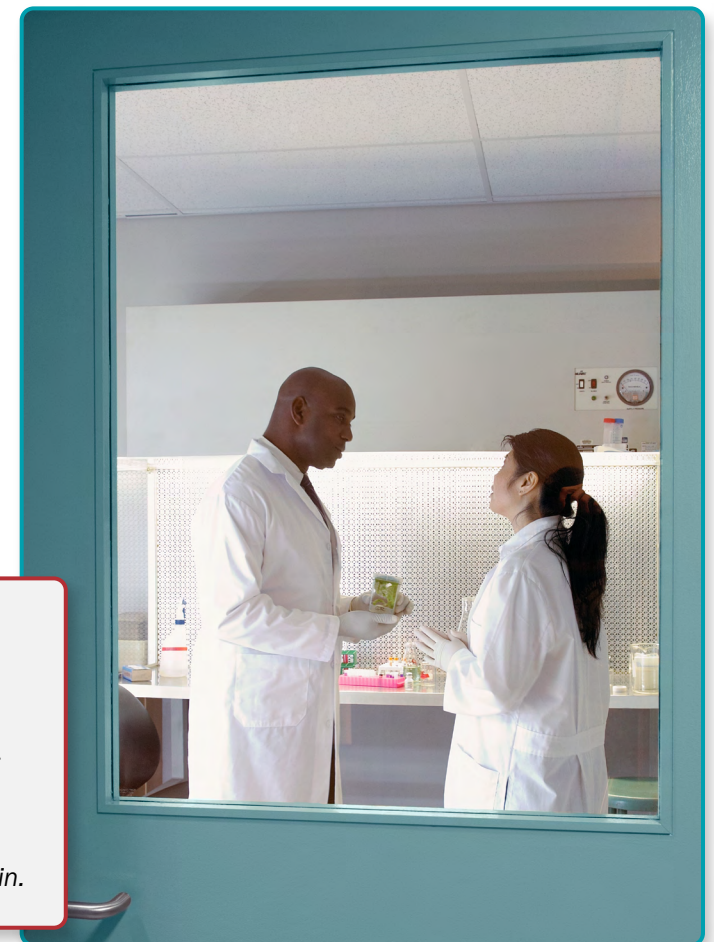
Management and leadership are distinct and complementary roles, both of which are necessary for the success of an organization. They can be distinguished in a number of ways.<sup>24</sup> Leadership establishes the purpose and strategic direction of the organization. Leading involves innovating, influencing 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 planning, organizing, controlling, coordinating and directing.

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). Depending on the situation, effective management and leadership are both critical to accomplishing the core functions of health laboratories.<sup>25, 26</sup>

All staff members require a certain degree of management and leadership skills. The scope of work performed by 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. 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.

## Management and Leadership Domain Notes

*Multiple sources were identified as support documents for this domain<sup>13, 15, 24, 27, 28, 29, 30, 31, 32</sup> 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 sub-competencies 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.*



## MLD 1.00: General Management

General management competencies ensure sound management of laboratory operations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 1.01.</b> <b>Mission, vision and values</b>	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
<b>MLD 1.02.</b> <b>Organizational structure</b>	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 <b>laboratory programs</b>	Oversees a <b>process</b> to ensure organizational structure meets the laboratory's mission and directives for <b>laboratory programs</b>
<b>MLD 1.03.</b> <b>Laws and regulations for laboratory operation</b>	Complies with laws and regulations related to laboratory operations	Implements program activities according to laws and regulations related to laboratory operations	Manages <b>laboratory programs</b> consistent with laws and regulations related to laboratory operations	Ensures that <b>laboratory programs</b> are consistent with international, national and local laws and regulations
<b>MLD 1.04.</b> <b>Technical operations management</b>	Works collaboratively on technical and operational planning	Implements technical and operational plans	Develops processes and procedures to manage technical operations	Oversees the <b>policies, processes</b> and <b>procedures</b> related to the development and evaluation of technical operations
<b>MLD 1.05.</b> <b>Emergency management and response</b>	Describes emergency management policies and procedures	Operates within assigned roles when carrying out emergency management and response duties	Manages the emergency management and response plan at the programmatic level	Oversees laboratory-wide emergency management and response
<b>MLD 1.06.</b> <b>Analytical and operational services</b>	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
<b>MLD 1.07.</b> <b>Quality testing and services</b>	Describes quality principles	Explains the importance of providing quality laboratory testing and services	Evaluates the quality of services for continued quality improvement	Oversees the <b>policies, processes</b> and <b>procedures</b> to ensure the quality of laboratory testing and services
<b>MLD 1.08.</b> <b>Customer service</b>	Supports <b>customer</b> service needs	Evaluates <b>customer</b> service satisfaction and trends	Identifies strategies and activities to improve <b>customer</b> service	Oversees the <b>policies, processes</b> and <b>procedures</b> to ensure the laboratory maintains a <b>customer</b> focus

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 1.09. Project management</b>	Uses basic <b>project management concepts</b> and tools	Directs the management of projects at the programmatic level	Trains staff on <b>project management</b> techniques	Oversees <b>project management</b> across the laboratory
<b>MLD 1.10. Program effectiveness</b>	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 <b>laboratory programs</b>	Oversees the <b>policies, processes and procedures</b> regarding the measurement, analysis and improvement of program effectiveness

## MLD 2.00: Policy Development

**Policy** development competencies ensure the development, implementation and review of internal policies.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 2.01. Internal policy development</b>	Describes concepts pertinent to developing internal policies	Compiles important issues, lists of stakeholders, and various options and solutions for internal <b>policy</b> development	Prepares internal policies based on evaluation of short- and long-term consequences of potential policies	Oversees the internal <b>policy</b> development <b>process</b>
<b>MLD 2.02. Internal policy implementation</b>	Complies with documented internal policies and guidelines	Implements internal policies for a laboratory program	Ensures staff compliance with laboratory-wide policies	Oversees internal <b>policy</b> implementation and staff compliance
<b>MLD 2.03. Internal policy review</b>	Compiles internal policies to prepare for review and revision	Reviews internal policies for revisions and updates	Evaluates internal policies and develops amendments or updates to internal policies	Oversees the review <b>process</b> for internal policies

## MLD 3.00: Financial Management

Financial management competencies ensure sound financial management.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 3.01. Budgets</b>	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
<b>MLD 3.02. Revenue and income</b>	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
<b>MLD 3.03. Expenditures</b>	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, <b>process</b> and procedures related to the cost of operations
<b>MLD 3.04. Financial management process</b>	Uses designated financial management tools	Integrates financial management tools for a laboratory program	Optimizes the financial management system for the laboratory	Oversees the <b>policies, processes</b> and <b>procedures</b> related to financial management and fiduciary responsibility
<b>MLD 3.05. Resource management</b>	Uses workplace resources efficiently	Optimizes use of laboratory program resources	Manages resources for the laboratory	Oversees the <b>policies, processes</b> and <b>procedures</b> related to resource management

## MLD 4.00: Human Resource Management

Human resource management competencies ensure management of human resources.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 4.01. Human resource policies</b>	Complies with human resource rules and <b>requirements</b>	Enforces human resource <b>requirements</b> and policies	Manages human resource <b>requirements</b> and policies	Oversees the <b>policies, processes</b> and <b>procedures</b> related to the human resource system
<b>MLD 4.02. Equal Employment Opportunity (EEO)</b> (or other national or international labor standards on equality of opportunity and treatment)	Describes the <b>EEO process</b>	Promotes <b>EEO requirements</b> and policies	Manages <b>EEO requirements</b> and policies	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>EEO</b> in the human resource system

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 4.03.</b> <b>Position descriptions</b>	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 <b>requirements</b>
<b>MLD 4.04.</b> <b>Staff licensure</b>	Describes the basic education, skills and <b>certifications</b> for laboratory staff <b>licensure requirements</b>	Maintains a <b>process</b> to ensure that staff meet <b>licensure requirements</b>	Performs ongoing gap analysis to address staff <b>licensure requirements</b>	Ensures staff compliance with <b>licensure</b> laws and regulations
<b>MLD 4.05.</b> <b>Competency assessment</b>	Participates in competency assessments	Conducts the competency assessment program	Evaluates the competency assessment program	Ensures that staff competence levels are commensurate with job functions
<b>MLD 4.06.</b> <b>Performance feedback</b>	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
<b>MLD 4.07.</b> <b>Performance appraisal process</b>	Describes how the formal performance appraisal <b>process</b> impacts laboratory operations	Participates in performance appraisals	Evaluates effectiveness of the performance appraisal <b>process</b> in improving laboratory productivity and practice	Oversees the continuous improvement of the performance management system
<b>MLD 4.08.</b> <b>Conflict resolution</b>	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 <b>policies, processes</b> and <b>procedures</b> to ensure the fair and equitable resolution of conflicts
<b>MLD 4.09.</b> <b>Progressive discipline</b>	Describes the steps of the progressive discipline <b>process</b>	Participates in progressive discipline <b>process</b>	Analyzes the use of progressive discipline within the laboratory	Ensures that the progressive discipline system is used to mitigate disciplinary issues
<b>MLD 4.10.</b> <b>Professional development</b>	Participates in professional development activities	Contributes to professional development activities	Assesses professional development gaps to ensure and support staff competency development	Oversees the <b>policies, processes</b> and <b>procedures</b> to encourage and address professional development
<b>MLD 4.11.</b> <b>Staff advancement</b>	Explains the policies and procedures related to staff advancement	Recommends staff for advancement	Develops criteria for staff advancement	Ensures that staff function in roles commensurate with experience, skill set and proficiency

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 4.12. Succession planning</b>	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 <b>policies, processes</b> and <b>procedures</b> related to the creation and implementation of succession plans

## MLD 5.00: Leadership

Leadership competencies model leadership behavior.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 5.01. Ethical practices and professional code of conduct</b>	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 <b>ethical practices</b> and a professional code of conduct	Fosters the <b>policies, processes</b> and <b>procedures</b> related to <b>ethical practices</b> and a professional code of conduct
<b>MLD 5.02. Communication</b>	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
<b>MLD 5.03. Teamwork and collaboration</b>	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
<b>MLD 5.04. Staff engagement</b>	Participates in activities to support the laboratory's goals	Implements activities that support <b>staff engagement</b>	Develops programs that support a culture of <b>staff engagement</b>	Fosters a culture of <b>staff engagement</b> and commitment
<b>MLD 5.05. Staff recognition</b>	Participates in staff recognition programs	Contributes to the effectiveness of staff recognition programs	Develops staff recognition programs	Fosters a culture that ensures staff recognition
<b>MLD 5.06. Coaching and mentoring</b>	Describes the benefits of <b>coaching</b> and <b>mentoring</b>	Participates in <b>coaching</b> and <b>mentoring</b> of staff	Establishes <b>coaching</b> and <b>mentoring</b> programs	Fosters a culture where <b>coaching</b> and <b>mentoring</b> are deeply rooted
<b>MLD 5.07. Critical thinking</b>	Develops basic <b>critical thinking</b> skills	Applies <b>critical thinking</b> to develop effective solutions to problems	Leads <b>critical thinking</b> activities to achieve improvements in laboratory processes	Fosters an environment that integrates <b>critical thinking</b>
<b>MLD 5.08. Systems thinking</b>	Describes <b>systems thinking</b>	Applies <b>systems thinking</b> when approaching projects and problem solving	Incorporates <b>systems thinking</b> into directing laboratory operations	Fosters an environment that integrates <b>systems thinking</b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MLD 5.9. Strategic thinking</b>	Describes <b>strategic thinking</b>	Provides input into <b>strategic thinking</b> and decision-making processes	Integrates <b>strategic thinking</b> into decisions and long-term planning regarding laboratory operations	Fosters an environment that integrates <b>strategic thinking</b>
<b>MLD 5.10. Change management</b>	Describes the value of change	Implements <b>change management</b> initiatives within a laboratory program	Leads the development of <b>change management</b> initiatives with the laboratory	Fosters a culture that continuously assesses change opportunities for sustaining the mission
<b>MLD 5.11. Advocacy</b>	Describes the mission, vision and activities of the laboratory to external stakeholders	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
<b>MLD 5.12. External policy development</b>	Describes impacts of external policies related to the organization's mission	Communicates with stakeholders to exchange <b>policy</b> input	Promotes external <b>policy</b> 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
<b>MLD 5.13. Promotion of the health of populations</b>	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

# Communication Competency Guidelines

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

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 health laboratory. Internal communication between staff is essential to satisfy the organization's goals and **quality management system**. External communication is necessary to disseminate health information and to highlight the importance of laboratory contributions in support of human, animal and environmental health. 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 health laboratory system.

## Communication Domain Notes

*Multiple sources were identified as support documents for this domain<sup>30, 31, 33, 34</sup> 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.*



## COM 1.00: Communication Techniques

Communication technique competencies deploy formal written and oral communication strategies.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 1.01.</b> <b>Written communication</b>	Identifies key messages for written communication	Applies <b>logical structure</b> 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
<b>COM 1.02.</b> <b>Oral communication</b>	Identifies key messages for oral communication	Applies language and tone in oral communications tailored to target audience	Selects <b>communication methods</b> tailored to target audience	Establishes content, style, tone and form for oral messages tailored to target audience

## COM 2.00: Active Listening Skills

Active listening skill competencies display active listening skills when interacting with others.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 2.01.</b> <b>Dialogue exchange</b>	Provides undivided attention to the other participants in a dialogue	Summarizes the dialogue to show understanding	Provides feedback based on the dialogue summary	Facilitates dialogue exchange through appropriate exchange and clarification of critical points
<b>COM 2.02.</b> <b>Contextual clues</b>	Exhibits open posture and facial expression to engage the other participants in a dialogue	Applies range of body language cues to enhance the exchange	Exhibits <b>active listening</b> during the dialogue exchange	Incorporates multiple behaviors of engagement during dialogue exchanges
<b>COM 2.03.</b> <b>Respectful exchange</b>	Defers judgment during dialogue exchanges	Provides counterpoints while being respectful of disagreements	Coaches others in techniques of respectful exchange	Facilitates respectful dialogue among participants in the exchange

## COM 3.00: Comprehension of Materials

Comprehension of materials competencies demonstrate comprehension of written documents and directions.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 3.01.</b> <b>Reading comprehension</b>	Follows written directions	Applies knowledge acquired from written text to situations	Adapts concepts from written text for use in new situations	Extrapolates information from written text to develop new ideas that enhance work processes

## COM 4.00: Communication Technology

Communication technology competencies utilize technology to communicate information to internal and external partners and stakeholders.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 4.01.</b> <b>Technology capability</b>	Describes the laboratories 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
<b>COM 4.02.</b> <b>Use of technology</b>	Describes employer's policies and <b>procedures</b> for sharing information	Uses designated technology for sharing information	Manages technology policies and <b>procedures</b> used for sharing information	Evaluates the effectiveness of the technology used for sharing information

## COM 5.00: Communication Professionalism

Communication professionalism competencies ensure professionalism in communication with customers and stakeholders.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 5.01.</b> <b>Professional attitude</b>	Uses tone of voice and language tailored to interactions with customers and stakeholders	Displays professional demeanor in all situations with customers and stakeholders	Monitors interactions with customers and stakeholders to ensure they are conducted professionally	Establishes policies for professional customer and stakeholder interactions
<b>COM 5.02.</b> <b>Information exchange</b>	Provides information based on policies and <b>procedures</b> to meet the needs of customers and stakeholders	Determines information needs through collaboration with customers and stakeholders	Ensures that information exchange <b>policies, processes</b> and <b>procedures</b> are followed to meet the needs of the customers and stakeholders	Develops overarching system for exchange of information to meet the needs of customers and stakeholders
<b>COM 5.03.</b> <b>Information sharing opportunities</b>	Shares information as directed	Selects information to share	Develops information to share	Creates opportunities for sharing information

## COM 6.00: Professional Reports

Professional report competencies ensure preparation of professional written reports and oral presentations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 6.01.</b> <b>Written reports</b>	Organizes information for written reports	Creates drafts of written reports	Revises written reports	Establishes <b>policies, processes</b> and <b>procedures</b> for written reports
<b>COM 6.02.</b> <b>Oral presentations</b>	Organizes information for oral presentations	Creates drafts of oral presentations	Revises oral presentations	Establishes <b>policies, processes</b> and <b>procedures</b> for oral presentations

## COM 7.00: Risk Communication

**Risk communication** competencies apply emergency and risk communication principles and techniques to explain information to targeted audiences.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 7.01. Risk communication plan</b>	Describes the <b>risk communication</b> process	Adheres to the <b>risk communication</b> plan	Ensures staff compliance with the <b>risk communication</b> plan	Establishes policies, processes and <b>procedures</b> related to the <b>risk communication</b> plan
<b>COM 7.02. Emergency information</b>	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
<b>COM 7.03. Empathetic risk communication</b>	Describes empathetic <b>risk communication</b> 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: Health Laboratory Value

**Health laboratory value** competencies promote the value of the diagnostic laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 8.01. Public relations</b>	Describes impact of the work of the health laboratory and system	Coordinates opportunities for promoting the health laboratory and system	Identifies opportunities to promote the health laboratory and system	Develops opportunities to promote the health laboratory and system
<b>COM 8.02. Communication to educate and inform</b>	Supports the development and distribution of communication materials about the health laboratory	Presents communication materials to explain the importance of the health laboratory	Develops communication materials to explain the importance of the health laboratory	Manages the policies, processes and <b>procedures</b> regarding communication materials to explain the importance of the health laboratory
<b>COM 8.03. Storytelling</b>	Shares approved health laboratory stories	Incorporates use of stories when communicating the impact of health laboratory work	Develops stories that convey information highlighting the impact of health laboratory work	Evaluates the impact of storytelling in promoting the health laboratory
<b>COM 8.04. Marketing strategy</b>	Participates in marketing strategies	Implements the marketing strategy for the health laboratory	Manages the marketing strategy for the health laboratory	Oversees the marketing strategy for the public health laboratory

## COM 9.00: Media Relations

Media relations competencies enable effective work with the media to provide information about health laboratories and health issues.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>COM 9.01.</b> <b>Media relations policies and strategies</b>	Adheres to agency media relations policies and <b>procedures</b>	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
<b>COM 9.03.</b> <b>Key messages</b>	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

# Security Competency Guidelines

**Purpose:** 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.

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 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.

## Security Domain Notes

*Multiple sources were identified as support documents for this domain.<sup>35, 36, 37</sup>*



## SEC 1.00: Risk Mitigation

Risk mitigation competencies ensure that the laboratory's **risk mitigation plan** meets organizational goals, national **requirements** and established standards.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 1.01. Security concepts</b>	Describes <b>security concepts</b>	Applies <b>security concepts</b> in support of organizational goals	Interprets <b>security concepts</b> to adapt <b>policies</b> and <b>procedures</b> to support organizational goals	Develops security <b>policies, processes</b> and <b>procedures</b> , including security standards
<b>SEC 1.02. Risk assessment*</b>	Describes the <b>risk assessment</b> process and <b>procedures</b>	Identifies <b>assets</b> , vulnerabilities and potential threats for incorporation into risk analyses	Manages the <b>risk assessment</b> process	Develops <b>policies, processes</b> and <b>procedures</b> regarding <b>risk assessment</b>
<b>SEC 1.03. Risk mitigation plans</b>	Describes the policies and <b>procedures</b> regarding risk mitigation plans	Applies risk mitigation plans	Manages the implementation of risk mitigation plans	Develops policies, processes and <b>procedures</b> regarding risk mitigation planning and implementation
<b>SEC 1.04. Risk mitigation plan reporting</b>	Describes policies, processes and <b>procedures</b> for <b>risk mitigation plan</b> reporting	Implements processes and <b>procedures</b> for <b>risk mitigation plan</b> reporting	Develops <b>procedures</b> based on established processes for <b>risk mitigation plan</b> reporting	Develops policies, processes and <b>procedures</b> for <b>risk mitigation plan</b> reporting

## SEC 2.00: Security Plan

**Security plan** competencies ensure that the laboratory's security plan meets organizational goals, national **requirements** and established standards.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 2.01. Security plans</b>	Recognizes security risks documented in the <b>security plan</b>	Recommends elements to be included in the <b>security plan</b> to address risks	Designs laboratory's <b>security plan</b> in collaboration with subject matter experts	Advises organizational leadership on the <b>security plan</b> , including acceptability of identified risks
<b>SEC 2.02. Security plan implementation</b>	Describes <b>security plan</b> elements applicable to job	Implements the <b>security plan</b>	Evaluates the objectives and functions of the security system	Advises organizational leadership on selecting security strategies to protect assets and on monitoring the performance of the <b>security plan</b>
<b>SEC 2.03. Security operations</b>	Describes the policies, processes and <b>procedures</b> for maintaining security	Monitors security operations	Manages security operations to ensure defined protection measures are based on the degree of risk	Oversees security operations

\* 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.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 2.04. <u>Inventory records related to security plans</u></b>	Completes <b><u>inventory records</u></b> to comply with the laboratory's <b><u>security plan</u></b>	Audits <b><u>inventory records</u></b>	Creates tools to manage <b><u>inventory records</u></b>	Develops policies, processes and <b><u>procedures</u></b> to manage <b><u>inventory records</u></b>
<b>SEC 2.05. <u>Security incident response</u></b>	Reports security incidents	Evaluates reported security incidents	Implements processes and <b><u>procedures</u></b> related to security <b><u>incident response</u></b> and reporting	Develops policies, processes and <b><u>procedures</u></b> for security <b><u>incident response</u></b> and reporting

## SEC 3.00: Physical Security

Physical security competencies ensure that physical security is maintained.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 3.01. <u>Physical security infrastructure</u></b>	Describes the <b><u>physical security infrastructure</u></b>	Trains staff on policies, processes, <b><u>procedures</u></b> and related regulations or guidelines regarding <b><u>physical security infrastructure</u></b>	Solves difficult and complex physical security problems	Directs the resolution of major conflicts in physical security <b><u>policy</u></b> and program objectives
<b>SEC 3.02. <u>Physical security access controls</u></b>	Describes physical security access control policies, processes, <b><u>procedures</u></b> and systems	Applies physical security access control <b><u>procedures</u></b> and systems	Manages the implementation of physical security access control policies, processes, <b><u>procedures</u></b> and systems	Advises organizational authorities on methods for enhancing effectiveness and efficiency of physical security access control policies, processes, <b><u>procedures</u></b> and systems

## SEC 4.00: Personnel Security Program

**Personnel security program** competencies ensure implementation of a personnel security program to meet organizational goals, national **requirements** and established standards.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 4.01. <u>Personnel security concepts</u></b>	Describes <b><u>personnel security concepts</u></b>	Addresses problems or questions involving <b><u>personnel security concepts</u></b>	Recognizes <b><u>personnel security concepts</u></b> to adapt processes and <b><u>procedures</u></b> to support organizational goals	Develops policies, processes and <b><u>procedures</u></b> that incorporate <b><u>personnel security concepts</u></b> into <b><u>personnel security program</u></b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 4.02. Personnel security program</b>	Complies with the laboratory's <b>personnel security program</b>	Implements the <b>personnel security program</b>	Solves difficult and complex personnel security problems	Evaluates the security program for challenges and success in meeting program objectives
<b>SEC 4.03. Inquiry</b>	Collects information for personnel security investigations	Analyses actions regarding personnel security matters requiring investigation	Develops policies, processes and <b>procedures</b> related to personnel security investigations	Validates inquiry <b>procedures</b> related to personnel security investigations

## SEC 5.00: Information Security

Information security competencies ensure that information security meets organizational goals, national **requirements** and established standards.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 5.01. Information security</b>	Describes policies, processes and <b>procedures</b> related to <b>information security</b>	Applies <b>information security</b> concepts, including principles of <b>confidentiality, integrity and availability (CIA)</b>	Recognizes <b>information security</b> concepts to adapt policies, processes and <b>procedures</b> to support organizational goals	Evaluates policies, processes, <b>procedures</b> and organizational standards for <b>information security</b> to meet organizational goals
<b>SEC 5.02. Risk identification and prioritization</b>	Describes the risks associated with the laboratory's <b>sensitive information</b> or technology related to the job being performed	Identifies risks associated with the laboratory's <b>sensitive information</b> and technology, including the methods of control	Implements processes and <b>procedures</b> for prioritizing risks associated with the laboratory's <b>sensitive information</b> and technology, including the methods of control	Recommends policies, processes and <b>procedures</b> for identifying, prioritizing and controlling <b>sensitive information</b> and technology

## SEC 6.00: Transportation Security Program

Transportation security program competencies ensure implementation of a **transportation security plan**.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SEC 6.01. Transport security</b>	Complies with transport security policies, processes and <b>procedures</b>	Audits transport <b>records</b>	Creates transport security <b>procedures</b>	Establishes policies and processes to specify which materials need designated levels of transport security

# Emergency Management Competency Guidelines

**Purpose:** The competencies in Emergency Management (encompassing emergency preparedness, response and recovery) address the knowledge, skills and abilities needed to mitigate, prepare for, respond to and recover from laboratory-specific emergency events and situations.

Emergency Management 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 health laboratory's mandate to provide emergency response support to external partners. Emergency management and response encompasses events such as natural disasters or health emergencies, facility, or operation failures, in addition to the responsibility to detect and respond to real or potential biological, chemical or radiological threats.

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.

## Emergency Management Domain Notes

*Multiple sources were identified as support documents for this domain.<sup>36, 38, 39, 40, 41, 42, 43, 44</sup> This domain is intended to be used in conjunction with the Safety and Communication domains and is based on the US Federal Emergency Management Agency's (FEMA) mission areas for national preparedness.<sup>42</sup> 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.*



# EMR 1.00: Mitigation of Emergency Events

Mitigation of emergency event competencies ensure mitigation of emergency events.

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

\* 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.

## EMR 2.00: Preparation for Emergency Events

Preparation for emergency events competencies ensures preparation for emergency events.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>EMR 2.01. Preparation for emergency events</b>	Explains the laboratory's <b><u>emergency response plan</u></b>	Assists with development and implementation of the laboratory's <b><u>emergency response plan</u></b>	Manages development and implementation of the <b><u>emergency response plan</u></b>	Oversees implementation of the laboratory's <b><u>emergency response plan</u></b>
<b>EMR 2.02. Incident management system (IMS)</b>	Demonstrates awareness of the <b><u>IMS</u></b>	Supports the operation and management of the <b><u>IMS</u></b>	Implements the <b><u>IMS</u></b>	Serves at a leadership level in the <b><u>IMS</u></b>
<b>EMR 2.03. Emergency response training</b>	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
<b>EMR 2.04. Emergency notification</b>	Describes <b><u>requirements</u></b> 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 <b><u>procedures</u></b> 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
<b>EMR 2.05. Identification of key partners</b>	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
<b>EMR 2.06. Execution of agreements</b>	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
<b>EMR 2.07. Emergency preparedness and response networks</b>	Explains how the laboratory interacts with <b><u>emergency preparedness and response networks</u></b>	Describes the plans, policies and <b><u>procedures</u></b> the institution has in place to prepare for and respond to a health emergency	Develops the organizational plans, policies, and <b><u>procedures</u></b> to prepare for and respond to a health emergency	Oversees the collaboration with <b><u>emergency preparedness and response networks</u></b> to develop and implement plans, policies, and <b><u>procedures</u></b> to prepare for and respond to a health emergency

## EMR 3.00: Responding to Emergency Events

Responding to emergency events competencies ensure proper response to emergency events.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>EMR 3.01. Situational briefing</b>	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 <b>COOP</b> measures and ICS activation
<b>EMR 3.02. EOS activation</b>	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 <b>procedures</b> , and chain of command
<b>EMR 3.03. Emergency evacuation</b>	Locates emergency evacuation routes and assembly areas	Uses emergency evacuation routes and assembly areas	Instructs staff during evacuation	Manages emergency evacuation and assembly
<b>EMR 3.04. Hazardous spill response</b>	Recognizes <b>hazardous spill</b> or potential exposures	Complies with <b>procedures</b> for responding to <b>hazardous spills</b> or potential exposures	Instructs staff on proper response to <b>hazardous spills</b> or potential exposures	Manages response to <b>hazardous spills</b> or potential exposures
<b>EMR 3.05. Emergency decontamination</b>	Describes emergency <b>decontamination</b> and <b>exposure prevention</b> policies and <b>procedures</b>	Complies with emergency <b>decontamination</b> and <b>exposure prevention</b> policies and <b>procedures</b>	Instructs staff on <b>policies, processes</b> and <b>procedures</b> for emergency <b>decontamination</b> and <b>exposure prevention</b>	Manages emergency <b>decontamination</b> and <b>exposure prevention policies, processes</b> and <b>procedures</b>
<b>EMR 3.06. Surge capacity</b>	Describes circumstances for, and varying degrees of surge	Adjusts <b>workflow</b> * 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
<b>EMR 3.07. Emergency communication plan</b>	Describes the <b>emergency communication plan</b> and the policies and <b>procedures</b> for receiving and disseminating information with emergency response partners and/or public	Complies with the <b>emergency communication plan</b> and the policies and <b>procedures</b> 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 <b>emergency communication plan</b> and the <b>policies, processes</b> and <b>procedures</b> for securely receiving and disseminating information with emergency response partners and the public during emergencies and surge incidents

\* 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 **post-examination procedures**.

## EMR 4.00: Recovering from Emergency Events

Recovering from emergency events competencies ensure recovery from emergency events.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>EMR 4.01. Short-term recovery</b>	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
<b>EMR 4.02. After Action Review (AAR)</b>	Describes the AAR process	Participates in AAR process	Assists with developing the final AAR	Oversees the AAR process
<b>EMR 4.03. Long-term recovery</b>	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
<b>EMR 4.04. Financial considerations</b>	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
<b>EMR 4.05. Legal and national issues</b>	Describes legal and national <u>requirements</u> for managing emergency events	Implements legal and national <u>requirements</u> for managing emergency events	Assesses staff compliance with legal and regulatory national related to the managing of emergency events	Oversees staff compliance with legal and regulatory national related to the managing of emergency events

# Workforce Training Competency Guidelines

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

Workforce Training is a process that uses principles of adult learning and **instructional design** to assess training needs, 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 personnel 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 health concerns.

## Workforce Training Domain Notes

Sources were identified as support documents for this domain.<sup>14, 45</sup> 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.



## WFT 1.00: Content

Content competencies gathers training content.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 1.01. Needs assessment</b>	Supports needs assessment activities	Conducts needs assessments	Develops needs assessment tools	Prioritizes training needs based on needs assessments
<b>WFT 1.02. Adult learning methodologies</b>	Explains adult learning methodologies	Selects principles and methodologies which underpin adult learning	Integrates principles of adult learning for use in designing training	Ensures that adult learning principles are applied in designing training
<b>WFT 1.03. Subject matter expertise</b>	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
<b>WFT 1.04. Training topics</b>	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
<b>WFT 1.05. Incorporation of subject matter expertise into training activities</b>	Explains <b>requirements</b> 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

Training design competencies ensures trainings are developed with intention.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 2.04. Cultural awareness</b>	Explains cultural awareness and its importance as it relates to developing training activities	Applies cultural awareness principles when designing training activities	Evaluates the incorporation of cultural awareness principles into training activities	Ensures incorporation of cultural awareness principles into training activities
<b>WFT 2.05. Instructional materials preparation</b>	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 <b>modality</b>	Incorporates industry-wide instructional materials into the training program
<b>WFT 2.06. Training materials application</b>	Uses pre-existing training materials to design simple training	Integrates multiple types of training materials into training design	Develops training materials from institutional resources	Evaluates training materials from institutional resources

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 2.07. Training exercises</b>	Delivers exercises within a training session	Integrates individual training lessons, including experiential exercises	Evaluates training exercises	Designs integrated training exercises with partners
<b>WFT 2.08. Formative assessment</b>	Explains <b>formative assessment</b>	Employs <b>formative assessments</b>	Creates <b>formative assessments</b>	Evaluates effectiveness of <b>formative assessments</b>
<b>WFT 2.09. Continuing education</b>	Explains the <b>requirements</b> of the continuing education provider	Follows continuing education provider <b>requirements</b> when conducting training	Selects continuing education provider for new learning activities	Oversees the continuing education provider process

## WFT 3.00: Delivery Set-up

Delivery set-up competencies ensure management of the logistics of set-up for training delivery.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 3.01. Equipment preparation for training delivery</b>	Operates equipment needed to deliver training	Troubleshoots training equipment	Ensures that equipment capability aligns with the training <b>requirements</b>	Oversees processes for upgrading training equipment
<b>WFT 3.02. eLearning</b>	Tests <b>eLearning</b> courses	Creates supporting materials or content for storyboards	Develops storyboards for new courses using subject matter expert materials	Ensures that <b>eLearning</b> delivery systems are available
<b>WFT 3.03. Learning environment</b>	Provides support for <b>learning environment</b> processes	Manages processes of the <b>learning environment</b>	Develops processes to manage the <b>learning environment</b>	Oversees the processes for the <b>learning environment</b>

## WFT 4.00: Training Delivery

Training delivery competencies apply principles of learning to training implementation and delivery.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 4.01. Learning preferences and styles</b>	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
<b>WFT 4.02. Presentation engagement</b>	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

Training evaluation competencies evaluate learner knowledge and skill development.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 5.01. Training evaluation process</b>	Lists the steps the organization undertakes for training program evaluation	Carries out the evaluation steps for standard training evaluations for routine courses	Develops <b>training evaluation tools</b> for a new activity	Oversees the evaluation of the training process for the organization
<b>WFT 5.02. Delivery of the evaluation</b>	Contributes to development of a training <b>assessment rubric</b> to ensure training outcomes are met	Implements the training <b>assessment rubric</b> to ensure training outcomes are met	Creates a training <b>assessment rubric</b> to ensure training outcomes are met	Evaluates the training <b>assessment rubric</b> to ensure training outcomes are met
<b>WFT 5.03. Training reports</b>	Gathers data as directed for summative <b>training reports</b>	Compiles tracking data into summative <b>training reports</b>	Develops summative training reporting tools	Interprets summative data from reports for delivery to stakeholders
<b>WFT 5.04. Training activity effectiveness</b>	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
<b>WFT 5.05. Continuous improvement of the training program</b>	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

Marketing competencies ensure training opportunities are adequately marketed.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>WFT 6.01. Marketing</b>	Participates in the marketing of training	Composes content for marketing materials	Develops organizational marketing plan for training	Manages the training marketing plan

# General Laboratory Practice Competency Guidelines

**Purpose:** The competencies in General Laboratory Practice address the knowledge, skills and abilities needed to fulfill basic responsibilities for performing sample analyses and ensuring quality test results are reported within a health laboratory setting.

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 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 health laboratories.



## General Laboratory Practice Domain Notes

Sources were identified as support documents for this domain,<sup>46, 47</sup> 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.

# GEN 1.00: General Technical and Laboratory Practice Knowledge

General technical and laboratory practice knowledge competencies demonstrate general knowledge and skills related to the scientific and technical components of laboratory testing.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 1.01. General scientific and laboratory concepts and theories</b>	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
<b>GEN 1.02. Mathematical and statistical concepts and practices</b>	Applies fundamental mathematical and statistical concepts and practices in work area	Explains to others the fundamental mathematical and statistical concepts and practices	Ensures appropriate utilization of mathematical and statistical concepts and practices	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the use of mathematical and statistical concepts and practices
<b>GEN 1.03. Scientific and technological advances</b>	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
<b>GEN 1.04. Technical skills</b>	Applies basic laboratory techniques to laboratory testing	Integrates basic laboratory techniques into standard operating <b>procedures</b> 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
<b>GEN 1.05. Troubleshooting</b>	Identifies routine problems related to technical duties and responsibilities	Resolves routine technical problems with methods, <b>procedures</b> and <b>laboratory equipment</b> , including documenting corrective action	Resolves complex technical problems with methods, <b>procedures</b> and <b>laboratory equipment</b> , including documenting corrective action	Oversees the <b>policies, processes</b> and <b>procedures</b> related to troubleshooting technical problems
<b>GEN 1.06. Model laboratory practices</b>	Applies knowledge of <b>model laboratory practices</b>	Explains to others <b>model laboratory practices</b>	Implements <b>model laboratory practices</b>	Manages <b>policies, processes</b> and <b>procedures</b> to ensure staff comply with <b>model laboratory practices</b>
<b>GEN 1.07. Documentation</b>	Documents actions and results using established paper or electronic systems	Explains the use of paper or electronic methods or systems for documentation	Ensures utilization of established paper and electronic documentation methods or systems	Oversees the <b>policies, processes</b> and <b>procedures</b> for the creation and use of paper and electronic methods or systems for documentation
<b>GEN 1.08. Management of resources</b>	Acts as a good steward of all funds and resources	Identifies methods to improve management of resources	Ensures that the use of public funds and resources meet the policies for management	Oversees the <b>policies, processes</b> and <b>procedures</b> to ensure the environment supports effective management of resources

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 1.09. Scientific ethics</b>	Applies <b>scientific ethics</b> 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 <b>procedures</b> related to <b>scientific ethics</b> and rules of conduct	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>scientific ethics</b> and rules of conduct

## GEN 2.00: Reagent Use and Storage

Reagent use and storage competencies ensure adherence to policies and principles regarding the use and storage of laboratory reagents and supplies.

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

## GEN 3.00: Equipment Use

Equipment use competencies ensure adherence to policies and principles regarding the use, maintenance, and calibration of **laboratory equipment**.

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

## GEN 4.00: Pre-examination

**Pre-examination** competencies ensure steps in the pre-examination phase of testing are performed.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 4.01. <u>Sample management</u></b>	Follows <b>policies, processes</b> and <b>procedures</b> for the management of samples	Explains <b>policies, processes</b> and <b>procedures</b> for <b>sample management</b>	Monitors staff compliance with established <b>sample management policies, processes</b> and <b>procedures</b>	Oversees <b>sample management policies, processes</b> and <b>procedures</b>

## GEN 5.00: Examination

**Examination** competencies ensure steps in the examination phase of testing are performed.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 5.01. <u>Sample analyses</u></b>	Performs <b>sample</b> analyses	Explains <b>sample</b> analyses	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> for <b>sample</b> analyses	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>sample</b> analyses
<b>GEN 5.02. <u>Testing workflow</u></b>	Adheres to <b>policies, processes</b> and <b>procedures</b> for testing <b>workflow</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding testing <b>workflow</b>	Ensures staff compliance in following established testing <b>workflow</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> that optimize and improve testing <b>workflow</b>
<b>GEN 5.03. <u>Quality control (QC) analysis</u></b>	Performs <b>QC</b> activities	Interprets <b>QC</b> data prior to reporting results	Examines <b>QC</b> data over time to establish <b>QC</b> ranges and limits	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>QC</b> activities, including staff compliance

## GEN 6.00: Post-examination

Post-examination competencies ensure steps in the post-examination phase of testing are performed.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 6.01. QC evaluation</b>	Assembles <b>QC</b> data for evaluation	Evaluates <b>QC</b> data for a given data reporting period	Ensures staff compliance with established <b>policies, processes</b> and <b>procedures</b> for <b>QC</b> evaluation activities	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>QC</b> evaluation activities
<b>GEN 6.02. Test analysis and results interpretation</b>	Assembles test data for review and action	Analyzes test data	Interprets complex or ambiguous results	Oversees the policies, processes, <b>procedures</b> , and algorithms related to data analysis and results interpretation
<b>GEN 6.03. Results reporting and data release</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> related to reporting and release of examination results and <b>notifiable results</b>	Explains the <b>policies, processes</b> and <b>procedures</b> related to reporting and release of examination results and <b>notifiable results</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> related to reporting and release of examination results and <b>notifiable results</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> related to reporting and release of examination results and <b>notifiable results</b> to partners
<b>GEN 6.04. Turnaround time (TAT)</b>	Performs laboratory testing and reporting within specified or expected TAT	Monitors TAT performance	Identifies process efficiencies to improve TAT	Oversees the <b>policies, processes</b> and <b>procedures</b> related to TAT
<b>GEN 6.05. Quality assurance (QA)</b>	Explains the differences between <b>QA</b> and <b>QC</b>	Collects data for reporting on <b>QA</b> indicators and processes	Evaluates <b>QA</b> indicator data	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>QA</b>

## GEN 7.00: Regulatory Compliance

Regulatory compliance competencies ensure compliance with regulations and guidelines governing laboratory testing.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 7.01. Regulatory compliance</b>	Complies with regulatory <b>requirements</b> and guidelines related to laboratory testing	Explains regulatory <b>requirements</b> and guidelines related to laboratory testing	Ensures staff compliance with regulatory <b>requirements</b> and guidelines related to laboratory testing	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding regulatory <b>requirements</b> and guidelines related to laboratory testing
<b>GEN 7.02. Proficiency testing (PT) and alternative assessment</b>	Performs <b>PT</b> and alternative assessment	Reviews <b>PT</b> and alternative assessment results	Monitors to ensure the <b>PT</b> and alternative assessment program meets regulatory <b>requirements</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>PT</b> and alternative assessments

Subcompetency	Beginner	Competent	Proficient	Expert
<b>GEN 7.03. <u>PT and alternative assessment reporting</u></b>	Reports <b>PT</b> and alternative assessment	Reviews submissions of <b>PT</b> and alternative assessment results	Ensures staff compliance with reporting of <b>PT</b> and alternative assessment results	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>PT</b> and alternative assessment reporting
<b>GEN 7.04. <u>Method validation and performance verification</u></b>	Participates in performance of method <b>validation</b> and performance <b>verification</b>	Compiles results of method <b>validation</b> and performance <b>verification</b>	Evaluates method <b>validation</b> and performance <b>verification</b> results	Oversees the <b>policies, processes</b> and <b>procedures</b> related to method <b>validation</b> and performance <b>verification</b>
<b>GEN 7.05. <u>Protected information</u></b>	Complies with <b>policies, processes</b> and <b>procedures</b> regarding <b>protected information</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding <b>protected information</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding <b>protected information</b>	Oversees that organizational <b>policies, processes</b> and <b>procedures</b> related to <b>protected information</b> align with laws and regulatory <b>requirements</b> and guidelines

# Safety Competency Guidelines

**Purpose:** The competencies in Safety address the knowledge, skills and abilities necessary to ensure a safe working environment that meets or exceeds applicable regional, national or international regulatory requirements and guidelines.

Safety focuses on the occupational and personal safety of staff members and the environments in which they work. A culture of safety (defined as an organization's shared perceptions, beliefs, values and attitudes that combine to create a commitment to safety and an effort to minimize harm) encourages reporting of actual and potential situations which might place staff members and others or the community 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 a 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,"<sup>39</sup> with the content revised and restructured to fit within this comprehensive set of 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.

## Safety Domain Notes

Multiple sources were identified as support documents for this domain.<sup>36, 37, 39, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61</sup>

This domain comprises five subdomains:

- **Potential Hazards:** Addresses the knowledge, skills and abilities needed to recognize potential hazards within a given laboratory setting
- **Hazard Control:** 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:** 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:** 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
- **Documents and Records:** Addresses the knowledge, skills and abilities needed to document activities related to safety **policies, processes** and **procedures**



# Potential Hazards

## SPH 1.00: Physical Environment

Physical environment competencies ensure safety in the physical environment of the laboratory facility.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 1.01. Physical hazards in the laboratory facility</b>	Describes the <b>physical hazards</b> in the <u>laboratory facility</u>	Recognizes new <b>physical hazards</b> in the <u>laboratory facility</u>	Assesses staff knowledge of the <b>physical hazards</b> in the <u>laboratory facility</u>	Evaluates the <b>laboratory facility</b> for <b>physical hazards</b>
<b>SPH 1.02. Control measures to be used when physical hazards are present</b>	Describes <b>control measures</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Implements <b>control measures</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Ensures staff knowledge of <b>control measures</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Establishes the <b>control measures</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>
<b>SPH 1.03. Work practices to be used when physical hazards are present</b>	Describes <b>work practices</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Implements <b>work practices</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Ensures that staff implement the established <b>work practices</b> when <b>physical hazards</b> are present in the <u>laboratory facility</u>	Establishes the <b>work practices</b> to be used when <b>physical hazards</b> are present in the <u>laboratory facility</u>

## SPH 2.00: Biological Materials

Biological materials competencies ensure safety when working with biological materials in the laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 2.01. Biological materials used in the laboratory</b>	Lists the biological materials in the laboratory	Distinguishes <b>biohazardous materials</b> from non-biohazardous materials in the laboratory	Manages the inventory of biological materials to ensure it is complete and updated	Establishes the <b>policies, processes</b> and <b>procedures</b> for implementing a biological materials inventory system
<b>SPH 2.02. Hazards associated with the biological materials handled in the laboratory</b>	Describes hazards associated with the biological materials handled in the laboratory	Recognizes hazards associated with new biological materials used in laboratory procedures	Assesses staff knowledge of the hazards associated with biological materials used in laboratory procedures	Ensures that staff are skilled in describing and recognizing hazards associated with the biological materials used in the laboratory
<b>SPH 2.03. Control measures to be used when working with biological materials</b>	Describes the <b>control measures</b> to be used when working with biological materials	Implements the <b>control measures</b> to be used when working with biological materials	Ensures that staff implement the established <b>control measures</b> when working with biological materials	Establishes the <b>control measures</b> to be used when working with biological materials

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 2.04. Work practices to be used when working with biological materials</b>	Describes the <b>work practices</b> to be used when working with biological materials	Implements the <b>work practices</b> to be used when working with biological materials	Ensures that staff implement the established <b>work practices</b> when working with biological materials	Establishes the <b>work practices</b> to be used when working with biological materials
<b>SPH 2.05. Hazards associated with laboratory procedures</b>	Describes hazards associated with the laboratory procedures employed	Explains the hazards associated with the laboratory procedures employed	Manages the hazards associated with laboratory procedures	Ensures that staff are capable of recognizing, training, and managing the hazards associated with laboratory procedures

## SPH 3.00: Research Animals

Research animals competencies ensure safety when working with research animals.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 3.01. Hazards associated with research animals</b>	Describes hazards associated with working with <b>research animals</b>	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 <b>research animals</b> used in the laboratory's research
<b>SPH 3.02. Route of exposure to infectious agents in the animal care setting</b>	Describes possible <b>route(s) of exposure</b> to infectious agents in relation to animal procedures	Identifies the possible <b>route(s) of exposure</b> to infectious agents in relation to the animal procedures used in the laboratory or animal facility	Assesses staff knowledge of the hazards associated with the animal procedures used in the laboratory or animal facility	Evaluates possible <b>route(s) of exposure</b> to infectious agents in relation to the animal procedures used in the laboratory and animal facilities
<b>SPH 3.03. Control measures to be used when working with research animals</b>	Describes <b>control measures</b> to be used when working with <b>research animals</b>	Implements <b>control measures</b> to be used when working with <b>research animals</b>	Ensures that staff implement the established <b>control measures</b> when working with <b>research animals</b>	Establishes the <b>control measures</b> to be used when working with <b>research animals</b>
<b>SPH 3.04. Work practices to be used when working with research animals</b>	Describes <b>work practices</b> to be used when working with <b>research animals</b>	Implements <b>work practices</b> to be used when working with <b>research animals</b>	Ensures that staff implement the established <b>work practices</b> when working with <b>research animals</b>	Establishes the <b>work practices</b> to be used when working with <b>research animals</b>

## SPH 4.00: Chemical Materials

**Chemical materials** competencies ensure safety when working with chemical materials in the laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 4.01. Chemicals used in the laboratory</b>	Identifies chemicals used in the laboratory	Distinguishes <b>hazardous chemicals</b> from nonhazardous chemicals in the laboratory	Manages the chemical inventory to ensure it is complete and updated	Establishes the <b>policies, processes and procedures</b> for implementing a chemical inventory system
<b>SPH 4.02. Hazards associated with chemicals used in the laboratory</b>	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
<b>SPH 4.03. Control measures to be used when working with chemicals in the laboratory</b>	Describes <b>control measures</b> to be used when working with chemicals as documented in the laboratory's Chemical Safety Manual	Implements established <b>control measures</b> when working with chemicals according to the laboratory's Chemical Safety Manual	Ensures that staff implement the established <b>control measures</b> when working with chemicals in compliance with the laboratory's Chemical Safety Manual	Establishes the laboratory's Chemical Safety Manual, including specific <b>control measures</b> to be used when working with chemicals
<b>SPH 4.04. Work practices to be used when working with chemicals in the laboratory</b>	Describes the <b>work practices</b> to be used when working with chemicals as documented in the laboratory's Chemical Safety Manual	Implements established <b>work practices</b> when working with chemicals according to the laboratory's Chemical Safety Manual	Ensures that staff implement established <b>work practices</b> when working with chemicals in compliance with the laboratory's Chemical Safety Manual	Establishes the laboratory's Chemical Safety Manual, including specific <b>work practices</b> to be used when working with chemicals

## SPH 5.00: Radiological Materials

**Radiological materials** competencies ensure safety when working with radiological materials in the laboratory.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 5.01. Radiological materials used in the laboratory</b>	Lists the <b>radiological materials</b> used in the laboratory	Describes the characteristics of the <b>radiological materials</b> used in the laboratory	Manages the inventory of <b>radiological materials</b> to ensure it is complete and updated	Establishes the <b>policies, processes and procedures</b> for implementing a <b>radiological materials</b> inventory system
<b>SPH 5.02. Hazards associated with the use of radiological materials</b>	Describes the hazards associated with <b>radiological materials</b> used in the laboratory	Recognizes hazards associated with new <b>radiological materials</b> used in the laboratory	Assesses staff knowledge of the hazards associated with <b>radiological materials</b> used in the laboratory	Ensures that staff are skilled in describing and recognizing the hazards associated with <b>radiological materials</b> used in the laboratory

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SPH 5.03. Control measures to be used when working with radiological materials</b>	Recognizes <b>control measures</b> to be used when working with <b>radiological materials</b> in the laboratory	Implements <b>control measures</b> to be used when working with <b>radiological materials</b> in the laboratory	Ensures that staff implement established <b>control measures</b> when working with <b>radiological materials</b> in the laboratory	Establishes, in collaboration with radiation safety staff, the <b>control measures</b> to be used when working with <b>radiological materials</b> in the laboratory
<b>SPH 5.04. Work practices to be used when working with radiological materials</b>	Describes <b>work practices</b> to be used when working with <b>radiological materials</b> in the laboratory	Implements <b>work practices</b> to be used when working with <b>radiological materials</b> in the laboratory	Ensures that staff implement established <b>work practices</b> when working with <b>radiological materials</b> in the laboratory	Establishes, in collaboration with radiation safety staff, the <b>work practices</b> to be used when working with <b>radiological materials</b> in the laboratory
<b>SPH 5.05. Radiation monitoring devices</b>	Describes monitoring devices for the <b>radiological materials</b> used in the laboratory	Demonstrates operation and use of monitoring devices for the <b>radiological materials</b> used in the laboratory	Ensures the operation and use by staff of <b>radiation monitoring devices</b>	Evaluates use and suitability of monitoring devices for the <b>radiological materials</b> used in the laboratory

## Hazard Control

### SHC 1.00: Engineering Controls

Engineering control competencies ensure implementation of intervention strategies to control hazards by systematically minimizing, isolating or removing hazards from the workplace.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SHC 1.01. Engineering controls</b>	Describes <b>engineering controls</b>	Employs <b>engineering controls</b> to eliminate or reduce targeted laboratory hazards	Develops <b>standard operating procedures (SOPs)</b> and work instructions that incorporate <b>engineering controls</b>	Ensures the implementation of <b>policies, processes</b> and <b>procedures</b> related to engineering control design, creation and use
<b>SHC 1.02. Training on engineering controls</b>	Completes required training before using <b>engineering controls</b>	Explains <b>engineering controls</b>	Develops required training for <b>engineering controls</b>	Ensures that training is adequate and appropriate for the <b>engineering controls</b> used in the laboratory
<b>SHC 1.03. Function verification and maintenance of engineering controls</b>	Describes function <b>verification</b> , maintenance and troubleshooting procedures for <b>engineering controls</b>	Performs function <b>verification</b> , maintenance and troubleshooting processes and procedures for <b>engineering controls</b>	Manages the procedures for function <b>verification</b> , maintenance and troubleshooting for <b>engineering controls</b>	Develops <b>policies, processes</b> and <b>procedures</b> to ensure function <b>verification</b> , maintenance and troubleshooting for <b>engineering controls</b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SHC 1.04. Malfunction of engineering controls</b>	Recognizes when <b>engineering controls</b> are compromised, malfunctioning or non-functioning, and the resulting reporting <b>requirements</b>	Implements procedures to address and report when <b>engineering controls</b> are compromised, malfunctioning or non-functioning	Manages processes and procedures for addressing and reporting situations in which <b>engineering controls</b> are compromised, malfunctioning or non-functioning	Develops <b>policies, processes</b> and <b>procedures</b> for remediation and reporting of engineering control malfunctions to ensure minimal exposure and release of targeted hazards

## SHC 2.00: Safe Work Practices

Safe work practice competencies ensure **work practices** and procedures are designed to minimize exposure to hazards and to adhere to national or international **requirements**, standards or regulations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SHC 2.01. Good facilities maintenance and repair procedures</b>	Describes <b>good facilities maintenance and repair procedures</b>	Practices <b>good facilities maintenance and repair procedures</b>	Develops processes and procedures related to the establishment and maintenance of <b>good facilities maintenance and repair</b>	Oversees the implementation of <b>policies, processes</b> and <b>procedures</b> related to <b>good facilities maintenance and repair</b> keeping
<b>SHC 2.02. Personal hygiene procedures</b>	Describes <b>personal hygiene procedures</b>	Complies with <b>personal hygiene procedures</b>	Develops <b>personal hygiene procedures</b>	Ensures staff adherence to personal hygiene <b>policies, processes</b> and <b>procedures</b>
<b>SHC 2.03. Safety practices and procedures</b>	Describes proper <b>work practices</b> and procedures	Uses proper <b>work practices</b> and procedures	Develops proper <b>work practices</b> and procedures	Ensures staff knowledge and use of proper <b>work practices</b> and procedures
<b>SHC 2.04. Work schedules</b>	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

## SHC 3.00: Personal Protective Equipment

Personal protective equipment (PPE) competencies ensure the selection, use and care of PPE while being continually mindful of its limitations.

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

## SHC 4.00: Systems to Track Hazards

Systems to track hazards competencies establish a system to detect and to control or eliminate the underlying causes of hazards or exposures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SHC 4.01. Hazard reporting, tracking, and investigation</b>	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

Preventive maintenance competencies ensure conduct of regular maintenance to ensure effective functioning of laboratory equipment and to extend the life of equipment.

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

## SHC 6.00: Decontamination and Laboratory Waste Management

**Decontamination** and laboratory waste management competencies establish a laboratory **waste management plan** that adheres to national, regional and local policies and regulations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SHC 6.01. Decontamination of laboratory waste</b>	Describes procedures for spill cleanup and <b>decontamination</b> of laboratory waste	Implements procedures for spill cleanup and <b>decontamination</b> of laboratory waste	Manages procedures for spill cleanup and <b>decontamination</b> of laboratory waste	Develops <b>policies, processes</b> and <b>procedures</b> for spill cleanup and <b>decontamination</b> of laboratory waste
<b>SHC 6.02. Categorization and handling of segregated waste</b>	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 <b>policies, processes</b> and <b>procedures</b>
<b>SHC 6.03. Treatment and disposal</b>	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 <b>policies, processes</b> and <b>procedures</b> for disposal and treatment of laboratory waste
<b>SHC 6.04. Waste reduction</b>	Describes procedures for laboratory waste reduction	Implements procedures for laboratory waste reduction	Manages procedures for laboratory waste reduction	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> for laboratory waste reduction
<b>SHC 6.05. Control access to regulated waste</b>	Describes procedures for preventing public access to <b>regulated waste</b>	Implements procedures for preventing public access to <b>regulated waste</b>	Manages procedures for preventing public access to <b>regulated waste</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> for preventing public access to <b>regulated waste</b>
<b>SHC 6.06. Waste management issues and problems</b>	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 <b>policies, processes</b> and <b>procedures</b> to address laboratory waste management issues or problems
<b>SHC 6.07. Monitoring and evaluation</b>	Describes procedures for monitoring the laboratory <b>waste management plan</b>	Implements procedures for monitoring the laboratory <b>waste management plan</b>	Develops procedures for monitoring the laboratory <b>waste management plan</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> for monitoring the laboratory <b>waste management plan</b>

# Administrative Controls

## SAC 1.00: Safety Program Management

**Safety program** management competencies ensure management of the laboratory safety program.

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

## SAC 2.00: Guideline and Regulation Compliance

Guideline and regulation compliance competencies ensure staff compliance with guidelines and regulations.

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

## SAC 3.00: Risk Management

Risk management competencies ensure risks are managed through systematic practices to evaluate, minimize or eliminate them.

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

## SAC 4.00: Occupational Health And Medical Surveillance

Occupational health and medical surveillance competencies ensure compliance with occupational health and medical surveillance policies.

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

# Communication and Training

## SCT 1.00: Hazard Communication

**Hazard communication** competencies promote safety through effective hazard communication.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SCT 1.01. Safety signage</b>	Describes <b>safety signage</b> and documentation as well as how signage is used to convey information	Adheres to information and directives in <b>safety signage</b> and <b>documents</b>	Evaluates <b>safety signage</b> and document placement and usage	Ensures staff compliance with <b>safety signage</b> and <b>documents</b>
<b>SCT 1.02. Safety communication tools</b>	Describes a variety of communication tools and techniques promoting the <b>work practices</b> employed in own area of responsibility	Employs a variety of communication tools and techniques promoting the <b>work practices</b> employed in own area of responsibility	Implements a variety of communication tools and techniques for the promotion of safe <b>work practices</b>	Ensures a variety of communication tools and techniques promoting <b>work practices</b> are employed in their area of responsibility
<b>SCT 1.03. Labeling</b>	Describes labeling of samples and containers	Adheres to procedures for labeling of samples and containers	Implements procedures to ensure staff compliance with regulatory <b>requirements</b> for labeling of samples and containers	Ensures staff compliance with regulatory <b>requirements</b> for labeling of samples and containers
<b>SCT 1.04. Signals and alarms</b>	Recognizes signals and alarms in areas assigned	Explains signals and alarms in the <b>laboratory facility</b>	Assesses staff knowledge of signals and alarms	Ensures the implementation of all signals and alarms

## SCT 2.00: Safety Training

**Safety training** competencies ensure that safety training needs are identified and training solutions are implemented to meet performance and productivity goals.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SCT 2.01. Safety training</b>	Complies with <b>requirements</b> to obtain safety training	Explains the <b>work practices</b> 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
<b>SCT 2.02. Training documentation</b>	Describes <b>requirements</b> for documenting safety training	Adheres to procedures for recording safety training of staff	Implements procedures for documenting staff safety training	Develops <b>policies, processes</b> and <b>procedures</b> for documentation and <b>verification</b> of staff training <b>records</b>

# Documents and Records

## SDR 1.00: Documents and Record Keeping

**Documents** and record keeping competencies ensure staff compliance with agency **QMS** and statutory, regulatory, **accreditation** and **licensing requirements** for documentation and record keeping in relation to the health and safety management systems.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SDR 1.01. Safety document management</b>	Describes procedures for safety document management	Adheres to procedures for safety document management	Manages safety document management process	Designs the safety document management system
<b>SDR 1.02. Safety document access</b>	Identifies any restricted or confidential safety <b>documents</b>	Ensures restricted or confidential safety <b>documents</b> are not disclosed	Implements processes and procedures for maintaining <b>confidentiality</b> of internally and externally derived safety information	Designs <b>policies, processes</b> and <b>procedures</b> for document control and access that adhere to regulatory and <b>accreditation requirements</b>
<b>SDR 1.03. Occupational injuries and illnesses documentation</b>	Describes responsibilities for documenting <b>Occupational Safety and Health Administration (OSHA)</b> -recordable occupational injuries and illnesses	Complies with documentation procedures for <b>OSHA</b> -recordable occupational injuries and illnesses	Ensures staff compliance with reporting of <b>OSHA</b> -recordable occupational injuries and illnesses	Designs <b>policies, processes</b> and <b>procedures</b> to ensure reporting for <b>OSHA</b> -recordable occupational injuries and illnesses
<b>SDR 1.04. Medical surveillance documentation</b>	Describes responsibilities in complying with established medical surveillance record keeping procedures	Complies with established medical surveillance documentation and record keeping procedures	Implements processes and procedures for medical surveillance documentation	Designs <b>policies, processes</b> and <b>procedures</b> for medical surveillance documentation
<b>SDR 1.05. Exposure monitoring documentation</b>	Describes the procedures for documenting <b>exposure monitoring</b>	Adheres to procedures for documenting <b>exposure monitoring</b>	Implements procedures for documentation and retention of <b>exposure monitoring</b> information as required by regulations, standards or guidelines	Designs <b>policies, processes</b> and <b>procedures</b> for documentation and retention of <b>exposure monitoring</b> information as required by regulations, standards or guidelines
<b>SDR 1.06. Safety inspection documentation</b>	Describes safety inspection documentation	Complies with procedures for safety inspection documentation	Develops procedures for safety inspection documentation	Designs <b>policies, processes</b> and <b>procedures</b> for safety inspection documentation

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SDR 1.07. Hazardous waste documentation</b>	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 <b>policies, processes</b> and <b>procedures</b> for documenting the handling and transport of hazardous waste
<b>SDR 1.08. Safety reports to staff members</b>	Reads safety reports	Complies with recommendations and mandates of safety reports	Ensures staff compliance to recommendations and mandates made in safety reports	Designs <b>policies, processes</b> and <b>procedures</b> ensuring staff compliance to recommendations and mandates made in safety reports

# Surveillance Competency Guidelines

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

Surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation and evaluation of public health practice.<sup>62</sup> 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 health threats. Laboratory information and services are essential to public health surveillance, as the collection, **validation**, analysis, interpretation, dissemination and use of laboratory-generated test results are crucial to target health prevention and ensure the health of communities. 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 ideally involves an **electronic laboratory reporting (ELR)** system that is interoperable with electronic health **records** and notifiable condition reporting for both care and surveillance. However, in some settings, an ELR is not available, and the use of a manual system can be effective.

The 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**.



## Surveillance Domain Notes

Multiple sources were identified as support documents for this domain.<sup>31, 62, 63, 64</sup> Because all 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.

## SRV 1.00: Function of Surveillance

Function of surveillance competencies ensure recognition of the function of laboratory testing in surveillance.

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

## SRV 2.00: Notification Rules and Protocols

Notification rules and protocols competencies ensure compliance with national and jurisdictional protocols or regulations regarding **notifiable results**.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 2.01. Notification</b>	Describes notification protocols or regulations	Reports data to laboratory management	Manages the approval and communication of health surveillance test results	Contributes to determination of national, regional, and local notification conditions

## SRV 3.00: Surveillance Testing

Surveillance testing competencies ensure performance of surveillance testing.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 3.01. Surveillance testing systems</b>	Describes test <b>sample</b> collection, storage and analytical <b>requirements</b>	Identifies the functional <b>requirements</b> of surveillance testing protocols*	Creates surveillance testing protocols that include functional <b>requirements</b>	Directs development and modifications to surveillance testing systems based on jurisdictional guidance and analytical capabilities
<b>SRV 3.02. Surveillance testing workflow†</b>	Describes test <b>sample</b> collection, storage, and analytical method workflows	Employs established testing <b>workflow</b> and test methods for the surveillance target <b>requirements</b>	Customizes testing <b>workflow</b> policies and procedures to the surveillance target <b>requirements</b>	Directs development and modifications to surveillance testing system workflows
<b>SRV 3.03. Surveillance testing</b>	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 health surveillance tests

\* 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 **post-examination** procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 3.04. Outbreak or exposure event detection</b>	Describes at least one definition of an <b>outbreak</b> or <b>exposure event</b>	Informs supervisor of potential <b>outbreak</b> or <b>exposure event</b>	Reports potential <b>outbreak</b> or <b>exposure events</b> to key stakeholders	Contributes to the modification of <b>outbreak</b> or <b>exposure event</b> recognition processes or definitions
<b>SRV 3.05. Sample collection for outbreak or exposure events</b>	Receives <b>outbreak</b> or <b>exposure event</b> samples for testing	Ensures that <b>outbreak</b> or <b>exposure event</b> samples meet <b>sample</b> collection criteria	Collaborates with key stakeholders to determine the best samples to collect	Contributes to <b>sample</b> collection guidelines for <b>outbreak</b> or <b>exposure event</b> scenarios
<b>SRV 3.06. Testing for outbreak or exposure events</b>	Follows <b>sample</b> prioritization schema for testing during an <b>outbreak</b> or <b>exposure event</b>	Ensures that <b>outbreak</b> or <b>exposure event</b> samples are prioritized according to schema	Reports <b>outbreak</b> or <b>exposure event</b> testing results to key stakeholders	Represents the laboratory in <b>After Action Reviews</b> for <b>outbreak</b> or <b>exposure events</b>

## SRV 4.00: Response to Critical Surveillance Event

Response to **critical surveillance event** competencies ensure appropriate responses to critical surveillance events.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 4.01. Critical event planning</b>	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 <b>policies, processes</b> and <b>procedures</b> for <b>critical surveillance events</b> based on results of exercises or actual events
<b>SRV 4.02. Critical event response</b>	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
<b>SRV 4.03. Coordination of response</b>	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
<b>SRV 4.04. New testing capabilities</b>	Identifies when current testing capabilities do not exist to test an analyte or organism	Applies technical knowledge to implement new testing capabilities	Develops plans to address testing capabilities for a specific new organism or analyte during <b>critical surveillance events</b>	Determines the overall strategy for development of new testing capabilities during <b>critical surveillance events</b>

## SRV 5.00: Information for Surveillance

Information for surveillance competencies recognize vital information needed for surveillance.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 5.01. Demographic information</b>	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
<b>SRV 5.02. Sample information</b>	Enters <u>sample</u> information that is necessary to carry out surveillance testing activities	Monitors the capture of <u>sample</u> information	Ensures collection of <u>sample</u> information	Determines <u>policies, processes</u> and <u>procedures</u> for <u>sample</u> information collection based on jurisdictional <u>requirements</u> and guidelines

## SRV 6.00: Data Analysis

Data analysis competencies ensure analysis of data from surveillance testing systems.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 6.01. Data analysis</b>	Describes surveillance data analysis methods	Analyses laboratory surveillance data	Interprets laboratory surveillance data	Develops standards for data analysis and for interpretation of laboratory surveillance data

## SRV 7.00: Data Management

Data management competencies ensure management of surveillance data using secure data management systems.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 7.01. Data collection</b>	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
<b>SRV 7.02. Data storage and retrieval</b>	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

Recognition of significant results competencies ensure recognition of significant results in surveillance data.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 8.01. Significant values and results</b>	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
<b>SRV 8.02. Trends in data</b>	Provides trend results to laboratory management	Identifies trends in surveillance data	Explains trends in surveillance data to laboratory management and customers	Evaluates testing capabilities based on trend data to address customer needs and health issues

## SRV 9.00: Partnerships

Partnerships competencies help maintain partnerships to conduct surveillance.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 9.01. Multidisciplinary teamwork</b>	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
<b>SRV 9.02. Education and feedback for partners and stakeholders</b>	Explains <b>sample requirements</b> 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 <b>policies, processes</b> and <b>procedures</b> with partners

## SRV 10.00: Dissemination of Data

Dissemination of data competencies ensure dissemination of data relevant to the necessary authorities.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>SRV 10.01. Presentation of surveillance and monitoring data</b>	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 <b>policy</b> decision-making purposes

# Informatics Competency Guidelines

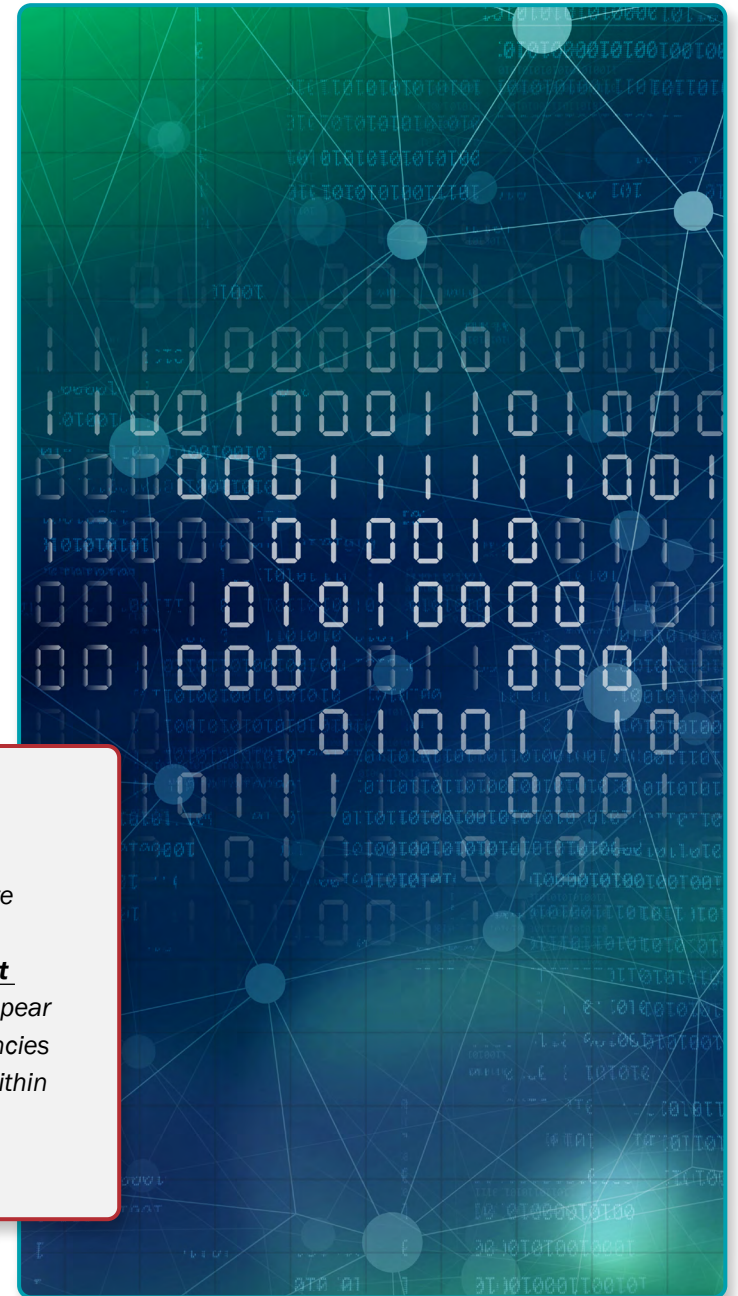
**Purpose:** The competencies in Informatics address the knowledge, skills and abilities needed to systematically apply information science, computer science and information technology to support public health practice, research and learning.

Informatics is a broad field encompassing information science, information technology, algorithms, and social science. In addition to electronic record keeping 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 health laboratory's role in protecting the public from infectious diseases, environmental dangers and other health threats. Health laboratory informatics must be cross-cutting, multisectoral and interoperable to support a nationally integrated **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.

## Informatics Domain Notes

*Multiple sources were identified as support documents for this domain.<sup>65, 66, 67, 68, 69</sup> 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.<sup>66</sup> In turn, this tool was framed on an earlier document<sup>67</sup> 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 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.*



## INF 1.00: Laboratory Test Request and Sample Receiving

Laboratory test request and sample receiving competencies ensure management of sample receiving and the processing of laboratory test requests.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 1.01. Sample receiving and accessioning</b>	Describes electronic <b>modules</b> used to log in <b>samples</b> with corresponding electronic requests	Verifies electronic accessioning activities to ensure completeness and accuracy	Evaluates the electronic <b>modules</b> needed for <b>sample</b> receiving and accessioning	Designs log-in screens to automate <b>sample</b> receiving and accessioning and to automate processing of electronic test request messages
<b>INF 1.02. Electronic data exchange regarding test requests</b>	Describes electronic <b>modules</b> used to receive data on <b>samples</b> using one or more standard <b>message types</b>	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
<b>INF 1.03. Vocabulary standards</b>	Lists local codes and standardized codes	Manages use of <b>vocabulary standards</b> across parties	Evaluates use of <b>vocabulary standards</b> for identification of missing or misidentified codes	Develops codes for generation of messages using multiple standardized vocabulary formats and integration of local and new codes and <b>vocabulary standards</b>
<b>INF 1.04. Test orders</b>	Describes <b>processes</b> and <b>procedures</b> for test orders	Verifies the electronic assignment of tests to specific <b>laboratory programs</b>	Evaluates the need for new test orders and associated meta data	Designs <b>workflows</b> and <b>modules</b> to automate assignment of test orders to specific <b>laboratory programs</b>
<b>INF 1.05. Hardware to promote sample handling efficiency</b>	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 <b>sample</b> accessioning
<b>INF 1.06. Capture of auxiliary data</b>	Describes required identifiers and core data elements	Verifies the routine entry of meta-data and pass-through <b>auxiliary data</b>	Manages problem resolution concerning entry of metadata and <b>auxiliary data</b>	Designs <b>modules</b> to automate the entry of <b>auxiliary data</b> , the identification of core data elements, and the inclusion of new data elements

## INF 2.00: Test preparation, LIMS processing, Test Results Recording and Verification

Test preparation, Laboratory Information Management System (LIMS) processing, test results recording and verification competencies ensure management of systems for electronic test preparation, LIMS processing, and test results recording and verification.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 2.01. Test preparation and receipt of <u>samples</u></b>	Describes use of predefined electronic <u>modules</u> to assign <u>samples</u> or <u>batches</u> of samples to processes in the laboratory	Verifies the assignment of <u>samples</u> to individual test processes or test processing combinations	Manages prioritization for preparation and handling of <u>samples</u>	Designs systems to automate the electronic management of <u>pre-examination</u> operations on <u>samples</u> received individually or in <u>batch</u>
<b>INF 2.02. Electronic test requests from submitters</b>	Describes how to use electronic <u>modules</u> to manage individual or <u>batches</u> of <u>samples</u> from submitters	Verifies the receipt of <u>samples</u> 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
<b>INF 2.03. LIMS tracking of testing processes and associated <u>sample</u> sources</b>	Describes how to use electronic <u>modules</u> to track testing processes and associated <u>sample</u> sources	Verifies effectiveness of ongoing <u>sample</u> source tracking and submitter's monitoring efforts	Evaluates the <u>LIMS</u> tracking of testing processes and associated <u>sample</u> sources	Designs systems to automate and manage the tracking of testing processes and associated <u>sample</u> sources
<b>INF 2.04. Test results recording</b>	Describes electronic <u>modules</u> , vocabulary, and usage for specific test results	Populates test results data using pre-existing <u>modules</u>	Troubleshoots automated test results data capture utilities	Designs analytical sequences for instrument integration and data capture utilities to automate data transfer from instruments
<b>INF 2.05. Data review</b>	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 <u>workflows</u> and utilities to ensure that needed data are supplied
<b>INF 2.06. Data verification</b>	Explains test result choices that exist for specific test requests and describes results approval Process and the <u>verification</u> process	Verifies that the electronic transfer of <u>quality assurance (QA)</u> and <u>quality control (QC) data</u> occurs to ensure that test results meet procedural <u>requirements</u> and auto-assignment	Institutes rules to ensure that <u>laboratory programs</u> have tools to manage <u>data verification</u> processes	Designs the processes for automating <u>data verification</u> and associating <u>QA</u> and <u>QC</u> data with individual <u>sample</u> tests and <u>batches</u> before reporting
<b>INF 2.07. Auto-assignment of reflex or repeat testing</b>	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

## INF 3.00: Report Preparation and Distribution

Report preparation and distribution competencies ensure management of test result report creation and distribution.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 3.01. Processing of data for reports</b>	Describes electronic <b>modules</b> used to print data and <b>information</b> in automated reports	Verifies analytical data, <b>information</b> and reports	Appraises solutions for data selection for non-routine reports and for research purposes	Constructs queries for ad hoc data searches
<b>INF 3.02. Report production</b>	Describes use of electronic <b>modules</b> 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
<b>INF 3.03. Electronic reporting</b>	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
<b>INF 3.04. Management of reports</b>	Prints predefined reports according to <b>policies</b>	Verifies that reports adhere to submitters' data exchange format <b>requirements</b> for electronic results submittal and reporting	Modifies non-complex electronic formats to meet <b>customer requirements</b>	Develops automated processes to manage reporting of results

## INF 4.00: Laboratory Test Scheduling

Laboratory test scheduling competencies ensure management of laboratory test scheduling.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 4.01. Scheduling documents</b>	Prints existing worksheets, work lists, and test scheduling <b>documents</b>	Prioritizes test scheduling to resolve conflicts and turnaround time	Develops work lists, worksheets, and test scheduling <b>documents</b>	Develops processes for integration of <b>documents</b> to link test orders with test results
<b>INF 4.02. Management of test schedules</b>	Enters data to remove or restore completed test requests	Uses specific data elements associated with process improvement to manage test schedules	Evaluates the <b>workflow</b> for process improvement opportunities	Develops codes to automate the creation of test status reports and <b>workflows</b>
<b>INF 4.03. Prioritization of tests</b>	Logs in <b>samples</b> according to predefined generic priorities	Manages test requests using laboratory-specified criteria	Organizes specific data elements associated with <b>process improvement indicators</b> to prioritize test scheduling	Develops systems to electronically generate a real-time test schedule

## INF 5.00: Prescheduled Testing

Prescheduled testing competencies ensure management of prescheduled testing.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 5.01. Prescheduling</b>	Describes electronic <b>modules</b> for receipt and processing of pre-scheduled <b>samples</b> and kit distribution	Manages scheduling of single or recurring test requests	Troubleshoots electronic systems to preschedule tests and to predict and adjust workload	Develop automated processes to manage the receipt and processing of pre-scheduled <b>samples</b> , recurring test requests and kit distribution

## INF 6.00: Sample Tracking and Chain of Custody

**Sample tracking** and **chain of custody** competencies ensure the tracking of physical samples and chain of custody.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 6.01. Tracking samples at accessioning</b>	Uses predefined electronic <b>modules</b> to enter data relevant to track all steps in the <b>sample</b> lifecycle	Assigns unique identifiers to <b>samples</b>	Evaluates automated <b>modules</b> that verify system operations regarding tracking	Develops systems to determine <b>sample</b> tracking and location
<b>INF 6.02. Traceability</b>	Uses predefined <b>modules</b> to track and document custody of the <b>sample</b> from receipt to disposal or return to submitter	Ensures staff compliance with traceability policies and procedures	Manages electronic tracking data by validating that traceability is complete and documented	Develops systems to electronically automate the traceability of custody data tracking to users and submitters
<b>INF 6.03. Traceability data elements</b>	Uses predefined <b>modules</b> to link demographic data with data on <b>chain of custody, sample appropriateness</b> , sample handling, and elements of sample analyst location, time, and defined storage parameters	Verifies that predefined <b>modules</b> allow creation, tracking, and maintenance of <b>sample</b> and aliquot hierarchy through the <b>LIMS</b> throughout the laboratory	Evaluates existing and future <b>modules</b> for tracking data elements	Develops systems to integrate data elements into automated traceability management
<b>INF 6.04. Tracking samples in analytical processes</b>	Uses predefined <b>modules</b> to track <b>samples</b> assigned to <b>laboratory programs</b> 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 <b>samples</b>	Develops <b>modules</b> to incorporate factors that affect automated assignment of <b>samples</b> to work lists and integration of <b>sample</b> tracking into routine laboratory functions

## INF 7.00: Media, Reagents and Controls

Media, reagents and controls competencies ensure the manufacturing and inventory of media, reagents and controls electronically.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 7.01. Supplies tracking</b>	Applies predeveloped electronic <b>modules</b> to order supplies and control inventory	Verifies the tracking, management and maintenance of inventory	Determines the <b>availability</b> and cost-effectiveness of in-house manufacturing and use of supplies	Designs code or scripts to automate activities to track, order and manage inventory
<b>INF 7.02. Inventory production</b>	Performs data entry into existing electronic <b>modules</b> 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
<b>INF 7.03. Manufacturing formulations</b>	Accesses manufacturing formulations electronically	Maintains the database of manufacturing formulations	Validates manufacturing formulations and <b>SOPs</b>	Develops <b>workflows</b> for manufacturing formulations
<b>INF 7.04. Supply orders and vendors</b>	Enters inventory order data into electronic order systems	Verifies the use of codes and parameters necessary to automate electronic orders of supplies	Manages order frequency and timetables	Develops <b>workflows</b> to automate the ordering of supplies from vendors

## INF 8.00: Data Exchange and Interoperability

Data exchange and interoperability competencies ensure the electronic exchange of laboratory data with data partners.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 8.01. Laboratory data collection</b>	Explains data elements and formats necessary for data collection and exchange	Identifies analytical data and results and the exchange of this <b>information</b> using predefined <b>modules</b>	Develops automated interfaces to export data from instruments to electronic storage	Configures <b>modules</b> to automate the export of analytical data to electronic storage
<b>INF 8.02. Electronic messaging</b>	Describes use of predefined <b>modules</b> to deliver predefined messages to partners	Performs predefined queries of analytical data for electronic messaging	Develops ad hoc queries for electronic messaging	Maps electronic data to form messages consistent with client message structure, format and vocabulary for export
<b>INF 8.03. Electronic messaging transport</b>	Describes predefined electronic messaging transport protocols*	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

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

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 8.04. Message vocabulary</b>	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
<b>INF 8.05. Test order creation</b>	Describes standard test order vocabulary	Communicates test orders with partners using predefined <b>modules</b>	Manages the automation of test orders in collaboration with partners	Develops protocols for automated electronic test order creation
<b>INF 8.06. Test order receipt and notification</b>	Describes standard test order receipt and notification vocabulary	Processes test orders received from partners using predefined <b>modules</b>	Manages the automation of test order receipts and notification in collaboration with partners	Develops protocols for electronic test order receipts and notification
<b>INF 8.07. Test results reporting</b>	Describes standard test results vocabulary	Communicates test results with partners using predefined <b>modules</b>	Manages the automation of test results reporting in collaboration with partners	Develops protocols for electronic test order results reporting
<b>INF 8.08. Test results acknowledgment</b>	Describes test results receipt acknowledgment	Verifies test results receipt with partners using predefined <b>modules</b>	Manages the automation of test results receipts in collaboration with partners	Develops protocols for electronic test results receipts
<b>INF 8.09. Exchange networks</b>	Describes <b>exchange networks</b>	Performs routine data exchange using predefined <b>modules</b>	Troubleshoots exchange network interfacing	Manages the <b>workflow</b> and operation of <b>exchange networks</b> according to <b>information exchange standards</b>

## INF 9.00: Statistical Analysis and Surveillance

Statistical analysis and surveillance competencies ensure generation of statistical analyses of analytical results for health surveillance.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 9.01. Meta data and demographic data</b>	Enters meta data and demographic data associated with laboratory testing	Verifies the collection and editing of meta data and demographic data using predefined <b>modules</b>	Ensures the ability to capture, retrieve, and link meta data and demographic data associated with laboratory testing	Develops <b>modules</b> and <b>workflows</b> to electronically capture, retrieve, and link meta data and demographic data associated with laboratory testing

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 9.02. Statistical analysis</b>	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 ad hoc queries to collect extracts of data for unique statistical analyses to link meta data and demographic data within reports	Writes code or <b>procedure</b> code for third-party software to automate the querying and reporting of statistical data to link meta data and demographic data within reports
<b>INF 9.03. Laboratory performance analyses</b>	Describes the production of laboratory performance reports	Provides reporting and evaluation of <b>laboratory program</b> performance data using predefined reports	Develops ad hoc statistical analyses to evaluate key performance indicators	Develops <b>workflows</b> and automation tools to ensure the implementation of laboratory performance-based analyses
<b>INF 9.04. Spatial data</b>	Describes <b>modules</b> for entering geographic <b>information</b> system (GIS) data	Uses predefined tools to integrate GIS data with laboratory testing results and with meta and demographic data	Evaluates the <b>availability</b> of validated tools to integrate GIS data with laboratory testing results and with meta and demographic data	Develops <b>modules</b> for <b>LIMS</b> -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

Billing for laboratory services competencies ensure management of billing for laboratory services.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 10.01. Billing data</b>	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 <b>workflows</b> and <b>modules</b> to manage the collection of financial data
<b>INF 10.02. Accounts receivable</b>	Enters billing data in an <b>accounts receivable</b> program	Performs advanced functions of automated electronic billing and linking of laboratory services to <b>accounts receivable</b> systems	Manages <b>accounts receivable</b> systems regarding billing of services rendered	Develops <b>workflows</b> and <b>modules</b> to automate the integration of billing <b>information</b> with <b>accounts receivable</b> software and financial services
<b>INF 10.03. Cost of testing and other laboratory services</b>	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 <b>workflows</b> and <b>modules</b> to track the cost of laboratory services with customers and to manage the <b>accounts receivable</b> system

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 10.04. Integration of laboratory billing with enterprise-wide billing</b>	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 <b>workflows</b> and systems to consolidate cross-enterprise billing and accounting for laboratory services
<b>INF 10.05. Budgeting</b>	Describes billing <b>modules</b>	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 <b>budgeting</b> and trend analysis

## INF 11.00: Contract and Grant Management

**Contract** and **grant** management competencies ensure management of grants and contractual instruments.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 11.01. Document management systems</b>	Describes centralized electronic document management systems that track and store grants, contractual instruments and <b>project management</b> materials	Verifies the entry and timeliness of <b>laboratory program</b> deliverables into document management systems	Evaluates document management systems to recommend improvements and efficiency and to meet contractual and <b>grant</b> obligations	Develops enterprise-wide <b>workflows</b> and communications to ensure an automated and secure document management system for grants and contractual instruments
<b>INF 11.02. Contractual instruments</b>	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
<b>INF 11.03. Activity tracking</b>	Describes informatics contractual and <b>grant</b> deliverables	Tracks activities and deliverables of grants and contractual instruments using predefined electronic <b>modules</b>	Evaluates the laboratory's ability to track delivery of individual informatics components related to budgetary, personnel, legal and laboratory procedures and processes	Develops systems to define, organize, monitor and track the activities of grants and contractual instruments with outside parties using electronic processes
<b>INF 11.04. Enterprise-wide systems</b>	Describes contractual informatics instruments relevant to the enterprise	Explains contractual instruments developed for individual <b>laboratory programs</b> for enterprise management	Evaluates informatics contractual instruments with outside parties using electronic documentation processes	Develops an enterprise-wide approach to <b>information</b> systems implementation

## INF 12.00: Training, Education and Resource Management

Training, education and resource management competencies ensure management of training, education and information resources.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 12.01. Electronic master record</b>	Accesses electronic <b>information</b> 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 <b>information</b> meets operational <b>requirements</b>	Develops <b>modules</b> to ensure electronic content, access and security exist to meet the educational needs of the laboratory
<b>INF 12.02. Resource summaries</b>	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 <b>modules</b> to ensure electronic summary reports of laboratory resources are available
<b>INF 12.03. Workforce development</b>	Describes informatics systems for tracking documented staff needs and knowledge gained from training opportunities	Verifies that informatics processes remain up-to-date and demonstrate the acquired informatics capabilities of staff	Evaluates laboratory informatics needs to ensure the existence of resources and avenues to support staff education and training	Develops informatics programs to ensure that staff education and training is aligned with the business needs and directions for laboratory services and the professional growth of staff
<b>INF 12.04. Training activities for external partners</b>	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 <b>requirements</b>	Develops electronic training materials and associated documentation for external partners
<b>INF 12.05. Knowledge management (KM)</b>	Describes own role(s) in supporting the collective knowledge within a <b>laboratory program</b>	Verifies the participation and integration of program staff to ensure electronic <b>KM</b> within the organization	Evaluates the effectiveness of electronic <b>KM</b> practices organizationally	Develops a strategy for the creation, collection and management of <b>KM</b> performance measures electronically
<b>INF 12.06. Lifecycle management strategy for IT investments</b>	Describes laboratory IT <b>project management</b> resources	Ensures the use of IT <b>project management</b> resources	Evaluates staff compliance with a comprehensive <b>lifecycle management strategy</b> for IT investments	Develops a comprehensive laboratory IT <b>lifecycle management strategy</b>
<b>INF 12.07. Informatics communication strategy</b>	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

Laboratory certifications, accreditations and licensing competencies ensure adherence to local, national and international certification, accreditation and licensing requirements.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 13.01. Certification, accreditation and licensing (CAL) compliance</b>	Explains applicable CAL electronic data <u>requirements</u> related to work area	Verifies the implementation of predefined data processing standards and form management associated with CAL for a <u>laboratory program</u>	Evaluates electronic data processing standards in order to ensure laboratory adherence to current and new CAL <u>requirements</u>	Develops <u>workflows</u> and <u>modules</u> to automate laboratory adherence to data processing standards associated with CAL
<b>INF 13.02. External certification</b>	Enters data into predefined <u>modules</u>	Verifies performance of predefined electronic systems regarding external <u>certifications</u>	Evaluates current capabilities to manage external <u>certifications</u> and future needs	Develops electronic <u>modules</u> to automate the management of external <u>certifications</u>
<b>INF 13.03. Privacy and security</b>	Describes electronic standards for own job classification related to the privacy and security of <u>protected information</u>	Ensures that individual <u>laboratory programs</u> adhere to electronic security and privacy standards	Evaluates individual electronic security and privacy standards that the laboratory must meet	Develops <u>workflows</u> and <u>modules</u> to ensure electronic systems meet security and privacy standards and adhere to regulatory <u>requirements</u>

## INF 14.00: Customer Relationship Management

Customer relationship management competencies ensure management of customer relationships.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>14.01. Tracking customer and staff feedback</b>	Describes predefined <u>modules</u> to record customer and staff feedback	Verifies the implementation of predefined <u>modules</u> 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 <u>workflow</u> and <u>modules</u> that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of customer and staff feedback
<b>INF 14.02. Tracking laboratory errors and information requests</b>	Describes predefined <u>modules</u> to record laboratory errors and <u>information</u> requests	Verifies the implementation of predefined <u>modules</u> to record laboratory errors and <u>information</u> requests	Evaluates current and future needs to track and perform <i>ad hoc</i> queries on laboratory errors and <u>information</u> requests	Develops <u>workflow</u> and <u>modules</u> that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of laboratory errors and <u>information</u> requests
<b>INF 14.03. Tracking corrective actions and reports</b>	Describes predefined <u>modules</u> that summarize reporting and corrective actions	Verifies the implementation of predefined <u>modules</u> to summarize corrective actions and generate reports	Evaluates current and future needs to track, perform <i>ad hoc</i> queries and provide reports regarding corrective actions	Develops <u>workflow</u> and <u>modules</u> that automate the collection of data to track and to perform <i>ad hoc</i> queries and reporting of correction actions

# INF 15.00: Quality Control and Quality Assurance Management

QC and QA management competencies ensure management of quality control and quality assurance processes.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 15.01. QC data associated with sample results</b>	Describes predefined <b>modules</b> that collect <b>QC</b> data associated with <b>sample</b> results	Verifies the electronic set-up, extraction and transmission of <b>QC</b> data using predefined <b>modules</b> and data capture utilities for automated instruments	Evaluates automated systems for <b>QC</b> data set up, extraction and transmission	Develops automated processes for <b>QC</b> data set up, extraction and transmission
<b>INF 15.02. Data review and validation</b>	Lists <b>QC</b> data that are collected electronically to support <b>validation</b> of test results	Performs review and validation of data	Ensures final data are configured using rules-based functionality prior to release to customers	Develops <b>workflows</b> and <b>modules</b> to assist in automating the <b>validation</b> of test results
<b>INF 15.03. Data trending</b>	Enters <b>QC</b> data to support tracking, trending and analysis of method accuracy and precision	Verifies the use of automated software to support analysis of <b>QC</b> 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 <b>workflows</b> and automation processes to support automated tracking, trending and analysis of method accuracy and precision
<b>INF 15.04. QC reporting</b>	Uses predefined <b>modules</b> to produce electronic and paper results that include <b>QC</b> data associated with test runs	Verifies the reporting and evaluation of <b>QC</b> data associated with analytical testing using predefined <b>modules</b>	Evaluates automated reporting of <b>QC</b> data associated with analytical <b>batches</b>	Develops reports that meet method <b>requirements</b> and customer needs to capture and deliver <b>QC</b> data in multiple formats and messages
<b>INF 15.05. QA and QMS</b>	Describes organizational structure, policies, processes, procedures and resources that address <b>QA</b> related to informatics activities	Performs day-to-day oversight of organizational structure, policies, processes, procedures and resources that address <b>QA</b> - and <b>QMS</b> -related to informatics activities	Evaluates organizational structure, policies, processes, procedures and resources that address <b>QA</b> - and <b>QMS</b> -related to informatics activities	Develops informatics <b>workflows</b> and the organizational structure, policies, processes, procedures and resources to address <b>QMS</b> and <b>QA</b> related to informatics activities
<b>INF 15.06. Responses to QC data</b>	Describes data elements needed to support automated auto-alerts, qualifiers or triggering of responses to <b>QC</b> data	Verifies that data to support auto-alerts, qualifiers or triggering of responses to <b>QC</b> data are associated with test results	Validates data elements using configurable rules-based functionality to provide auto-alerts, qualifiers or triggering of responses to <b>QC</b> data	Develops automated <b>workflows</b> to provide auto-alerts, qualifiers and triggering of responses to <b>QC</b> data

## INF 16.00: Laboratory Safety and Accident Investigation

Laboratory safety and accident investigation competencies ensure management of laboratory safety and accident investigations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 16.01. Hazardous materials management</b>	Describes electronic data entry and access to hazardous material locations, <b>safety data sheets (SDS)</b> , procedures, disposal <b>records</b> current practice standards and master <b>records</b>	Verifies the central management of <b>hazardous materials</b> using predefined electronic <b>modules</b> for reporting and tracking	Evaluates the electronic, centralized management of <b>hazardous materials</b>	Develops an electronic, centralized system to manage <b>hazardous materials</b>
<b>INF 16.02. Incident tracking</b>	Describes predefined <b>modules</b> 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 <b>workflows</b> , processes, and procedures to track and manage safety and accident investigations
<b>INF 16.03. Select agent management</b>	Describes national <b>select agents</b>	Ensures staff compliance with regulations associated with national <b>policy</b> for <b>select agents</b>	Evaluates processes to adhere to national <b>policy</b> for <b>select agents</b>	Develops <b>policy</b> for <b>select agents</b>
<b>INF 16.04. Hazardous material alerts</b>	Describes system alerts associated with <b>hazardous materials</b>	Verifies the generation of package and <b>sample</b> labels once an alert is received electronically	Evaluates current and future electronic <b>hazardous material alerts requirements</b>	Develops electronic <b>modules</b> to manage and track activities associated with <b>hazardous material alerts</b>
<b>INF 16.05. Hazardous risk management</b>	Lists electronic central <b>documents</b> 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 <b>workflow</b> analyses to ensure the electronic management of hazardous risks

## INF 17.00: Laboratory Mutual Assistance and Disaster Recovery

Laboratory mutual assistance and disaster recovery competencies ensure management of laboratory mutual assistance and disaster recovery.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 17.01. Continuity of Operations Plan (COOP)</b>	Outlines coverage of informatics and IT services within the laboratory's <b>COOP</b>	Verifies that <b>laboratory program</b> responsibilities are carried out during the implementation of a <b>COOP</b>	Evaluates the informatics and IT aspects of the laboratory <b>COOP</b> to ensure they are complete and up-to-date	Develops informatics <b>COOP work-flows</b> and procedures to restore informatics and IT support
<b>INF 17.02. COOP contractual instruments</b>	Describes <b>COOP</b> formal contractual instruments involving informatics	Verifies the performance of <b>laboratory program</b> informatics responsibilities pertaining to <b>COOP</b> contractual instruments	Manages the documentation supporting existing informatics contractual instruments pertaining to disaster recovery and mutual assistance through drills	Develops work plans and <b>project management</b> processes to ensure that comprehensive informatics contractual instruments are in place
<b>INF 17.03. Electronic catalogue of capacities and services</b>	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 <b>workflows</b> and <b>project management</b> 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

Core IT products and services competencies ensure management of core IT hardware, software and services.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 18.01. Client-side systems and software</b>	Employs client-side computer systems including <b>LIMS</b> access protocols and routine office software	Verifies the correct use of <b>LIMS</b> and advanced use of office software	Evaluates modifications, upgrades and new releases to laboratory instrument software and systems	Evaluates client-side options regarding <b>LIMS</b> installation, management and use
<b>INF 18.02. Electronic communication</b>	Describes communication tools for electronic <b>information</b>	Determines content for electronic <b>information</b> communication tools	Evaluates the use and <b>requirements</b> of electronic <b>information</b> communication tools	Develops the technology to support electronic <b>information</b> communication tools
<b>INF 18.03. Enterprise-wide LIMS availability</b>	Describes <b>LIMS</b> management processes	Verifies <b>LIMS</b> processes for data collection, data processing and reporting for laboratory business needs	Evaluates <b>LIMS</b> functionality to meet laboratory and customer needs	Manages the continuous <b>availability</b> and development of an enterprise-wide <b>LIMS</b> to ensure a fully functional and mature system

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 18.04. Networking</b>	Describes network access protocols and use of the laboratory network	Verifies laboratory use of pre-defined network protocols	Evaluates the use of networks to support laboratory activities	Manages the administration of network servers
<b>INF 18.05. IT help desk</b>	Describes access to available IT support	Documents the delivery of support to <b>laboratory programs</b>	Evaluates IT support needed for laboratory operations	Develops formal contractual instruments, <b>workflows</b> and <b>project management</b> processes for the delivery of IT support throughout the laboratory
<b>INF 18.06. Software development life cycle (SDLC)</b>	Describes the processes to use and improve electronic laboratory <b>workflows</b> and algorithms	Verifies needs for software process improvements	Evaluates the resources that impact the <b>SDLC</b>	Manages the <b>SDLC</b> at the enterprise-level, including <b>change management</b>
<b>INF 18.07. Enterprise integration engine</b>	Lists predefined functions that use an <b>integration engine</b>	Verifies the use of predefined <b>integration engine modules</b>	Evaluates integration functions with partners and customers	Develops automated <b>workflows</b> and processes regarding data capture and use of an <b>integration engine</b> to message data
<b>INF 18.08. Legacy data systems</b>	Defines legacy data systems	Verifies access to, and use of, legacy data systems	Evaluates the accessibility and searchability of legacy data	Develops <b>workflows</b> and processes to ensure that legacy data are accessible and searchable
<b>INF 18.09. LIMS communication with third-party data systems</b>	Describes predefined <b>modules</b> to support <b>LIMS</b> communication with third-party data systems	Verifies the proper use of pre-defined <b>modules</b> to support <b>LIMS</b> communication with third-party data systems	Evaluates the ability of the <b>LIMS</b> to communicate with third-party data systems	Develops <b>workflows</b> and processes to support <b>LIMS</b> communications with third-party systems
<b>INF 18.10. Access and audit trails</b>	Describes <b>modules</b> that provide a view of audit trails	Verifies staff access to electronic audit trails	Evaluates the ability of the <b>LIMS</b> to manage access and audit trails	Develops protocols to manage access and audit trails
<b>INF 18.11. Instrument analysis software</b>	Describes instrument analysis software systems	Uses instrument analysis software	Evaluates analytical instrument software	Develops analytical instrument software systems
<b>INF 18.12. Computer maintenance and troubleshooting</b>	Identifies basic computer problems	Performs routine computer maintenance and troubleshooting	Performs complex computer maintenance and troubleshooting	Manages the computer maintenance and troubleshooting processes

## INF 19.00: Policies and Procedures

Policies and procedures competencies ensure management of operational, **budgeting** and funding policies and procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>INF 19.01. Informatics policy</b>	Describes existing informatics policies	Ensures <b>laboratory program</b> adherence to existing informatics policies	Evaluates informatics policies	Develops processes for informatics <b>policy</b> making
<b>INF 19.02. Change control</b>	Describes <b>change control</b> processes related to informatics	Ensures <b>laboratory program</b> adherence to the <b>change control</b> processes related to informatics	Evaluates the effectiveness of <b>change control</b> processes related to informatics	Develops informatics <b>policies, processes</b> and <b>procedures</b> to manage <b>change control</b> and ensure staff compliance
<b>INF 19.03. Documentation for standardized laboratory IT processes</b>	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 <b>workflows</b> and processes to ensure paper and electronic documentation is centrally located and accessible
<b>INF 19.04. Operational budgeting strategy</b>	Describes the importance of electronic budgetary processes	Identifies informatics business needs of the <b>laboratory program</b> for operational <b>budgeting</b> strategizing	Evaluates the operational <b>budgeting</b> strategy	Develops a <b>budgeting</b> strategy for the laboratory's informatics systems and services
<b>INF 19.05. Capital budgeting</b>	Describes the <b>capital budgeting</b> processes for informatics-related assets	Provides the listing of <b>capital budget</b> needs regarding laboratory informatics	Evaluates <b>capital budgeting</b> needs regarding laboratory informatics	Develops <b>capital budgets</b> for electronic <b>information</b> systems and services
<b>INF 19.06. Partnership channels</b>	Lists established stakeholders and partnership channels	Presents short- and long-term informatics business needs to management staff	Ensures that laboratory informatics business needs are presented to stakeholders and partnership channels	Develops partnerships to facilitate funding for informatics

# Microbiology Competency Guidelines

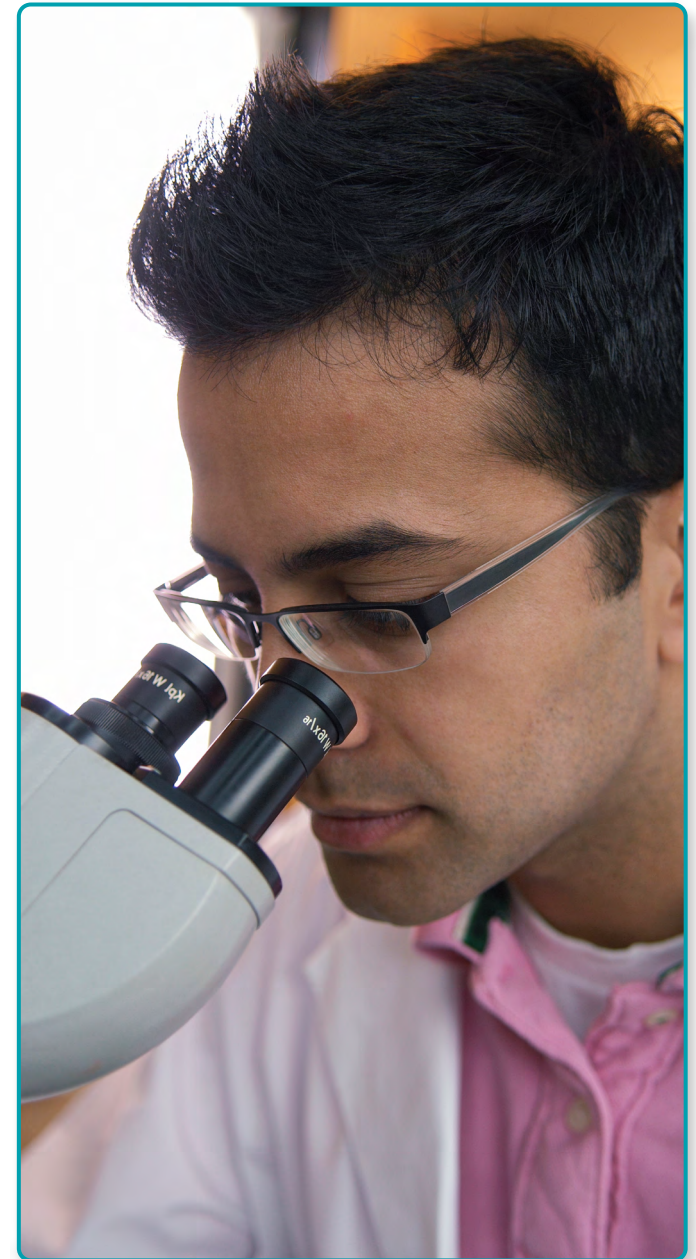
**Purpose:** The competencies in Microbiology address the knowledge, skills and abilities needed to safely and securely detect, identify and report infectious agents of concern to the public while following the laboratory path of workflow.

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, immunology and bacteriology that are encompassed in the disciplines of clinical, food and environmental microbiology.

Microbiology is critical for detecting and identifying **outbreak**, emerging diseases and biological threats. Health laboratories serve many 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, health laboratories provide many specialized tests that are not commercially available.

## Microbiology Domain Notes

*Multiple sources were identified as support documents for this domain<sup>36, 39, 46, 48, 49, 70</sup> 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).*



## MCB 1.00: Concepts and Techniques

Concepts and techniques competencies ensure adherence to policies and principles governing actions and behaviors that are essential when working in a microbiology laboratory.

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

## MCB 2.00: Facilities and Safety

Facilities and safety competencies ensure work with microbiological agents is conducted safely within a laboratory facility.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 2.01. Laboratory hazards related to microbiological agents</b>	Recognizes laboratory hazards and <u>hazard communication</u> related to microbiological agents	Explains laboratory hazards and <u>hazard communication</u> related to microbiological agents	Ensures staff compliance with <u>policies, processes</u> and <u>procedures</u> addressing laboratory hazards related to microbiological agents	Develops <u>policies, processes</u> and <u>procedures</u> regarding hazards related to microbial agents based on risk assessments*
<b>MCB 2.02. Safe work practices</b>	Adheres to <u>policies, processes</u> and <u>procedures</u> regarding safe <u>work practices</u> related to microbiological agents	Explains <u>policies, processes</u> and <u>procedures</u> regarding safe <u>work practices</u> related to microbiological agents	Ensures staff compliance with <u>policies, processes</u> and <u>procedures</u> regarding safe <u>work practices</u> related to microbiological agents	Creates a culture of biosafety by ensuring that <u>policies, processes</u> and <u>procedures</u> regarding safe <u>work practices</u> related to microbiological agents are aligned with current standards and regulatory <u>requirements</u>
<b>MCB 2.03. Personal protective equipment (PPE)</b>	Adheres to <u>policies, processes</u> and <u>procedures</u> regarding <u>PPE</u> use for work related to microbiological agents	Explains <u>policies, processes</u> and <u>procedures</u> regarding <u>PPE</u> use for work related to microbiological agents	Ensures staff compliance with <u>policies, processes</u> and <u>procedures</u> regarding <u>PPE</u> use for work related to microbiological agents	Establishes <u>policies, processes</u> and <u>procedures</u> regarding <u>PPE</u> use for work related to microbiological agents

\* 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.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 2.04. Biosafety cabinets and other engineering controls</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding the use of biosafety cabinets and other <b>engineering controls</b>	Explains use of biosafety cabinets and other <b>engineering controls</b>	Ensures laboratory adherence to biosafety cabinet <b>certification</b> and staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding the use of biosafety cabinets and other <b>engineering controls</b>	Establishes <b>policies, processes</b> and <b>procedures</b> , including training, to ensure implementation and use of biosafety cabinets and other <b>engineering controls</b>
<b>MCB 2.05. Waste management related to microbiological agents</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding waste management related to microbiological agents	Explains waste management <b>policies, processes</b> and <b>procedures</b> related to microbiological agents	Establishes waste management processes and procedures related to microbiological agents	Oversees the <b>waste management plan</b> related to microbiological agents
<b>MCB 2.06. Decontamination</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding <b>decontamination</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding <b>decontamination</b> for different microorganisms	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding <b>decontamination</b>	Develops <b>policies, processes</b> and <b>procedures</b> related to <b>decontamination</b>
<b>MCB 2.07. Storage of microbiological materials</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding storage of microbiological materials	Explains <b>policies, processes</b> and <b>procedures</b> regarding the storage of microbiological materials for different microorganisms	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> that address the storage of microbiological materials	Develops <b>policies, processes</b> and <b>procedures</b> related to the storage of microbiological materials

## MCB 3.00: Pre-examination

Pre-examination competencies ensure assessment of microbiological **samples** during the pre-examination phase.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 3.01. Sample collection, labeling and handling</b>	Describes routine <b>sample</b> collection, labeling and handling <b>policies, processes</b> and <b>procedures</b> for microbiological <b>examination</b>	Consults on non-routine <b>sample</b> collection, labeling, and handling procedures for microbiological <b>examination</b>	Monitors staff compliance with established <b>policies, processes</b> and <b>procedures</b> regarding microbiological sample collection, labeling and handling	Oversees the <b>policies, processes</b> and <b>procedures</b> for <b>sample</b> collection, labeling and handling for microbiological <b>examination</b>
<b>MCB 3.02. Packaging and shipping</b>	Performs packing and shipping of <b>Category A</b> and <b>Category B infectious substances</b>	Explains packing and shipping of <b>Category A</b> and <b>Category B infectious substances</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding the packing and shipping of <b>Category A</b> and <b>Category B infectious substances</b>	Develops <b>policies, processes</b> and <b>procedures</b> to ensure staff compliance with packing and shipping regulations concerning <b>Category A</b> and <b>Category B infectious substances</b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 3.03. Material transport</b>	Describes the importance of adhering to established <b>policies, processes</b> and <b>procedures</b> regarding microbiological material transport	Explains microbiological material transport <b>policies, processes</b> and <b>procedures</b>	Develops microbiological material transport processes and procedures	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding microbiological material transport
<b>MCB 3.04. Biological threats</b>	Describes <b>policies, processes</b> and <b>procedures</b> for the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing agents of concern
<b>MCB 3.05. Accessioning and receipt</b>	Performs procedures for accessioning and receipt of microbiological samples	Explains <b>policies, processes</b> and <b>procedures</b> regarding accessioning and receipt of microbiological samples	Develops processes and procedures for microbiological sample accessioning and receipt	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding microbiological sample accessioning and receipt
<b>MCB 3.06. Sample tracking</b>	Performs systematic tracking of microbiological samples from receipt to final disposition	Explains <b>policies, processes</b> and <b>procedures</b> 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 <b>policies, processes</b> and <b>procedures</b> for the systematic tracking of microbiological samples from receipt to final disposition
<b>MCB 3.07. Sample evaluation and appropriateness for testing</b>	Assesses <b>sample appropriateness</b> for a particular microbiological <b>examination</b>	Explains appropriateness of routine and non-routine samples for microbiological <b>examination</b>	Develops processes and procedures for <b>assessment</b> of routine and non-routine <b>sample appropriateness</b> for microbiological <b>examination</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding <b>assessment</b> of routine and non-routine <b>sample appropriateness</b> for microbiological <b>examination</b>
<b>MCB 3.08. Testing workflow*</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding testing <b>workflow</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding testing <b>workflow</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> related to testing <b>workflow</b>	Establishes <b>policies, processes</b> and <b>procedures</b> related to testing <b>workflow</b>
<b>MCB 3.09. Nucleic Acid Amplification Tests (NAAT) workflow (facility specific)</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding NAAT <b>workflow</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding NAAT <b>workflow</b> , including pre- and post-amplification areas	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding NAAT <b>workflow</b>	Establishes <b>policies, processes</b> and <b>procedures</b> for NAAT <b>workflow</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 **post-examination** procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 3.10. Sample set-up</b>	Performs sample set-up procedures for microbiological <b><u>examinations</u></b>	Explains sample set-up for microbiological <b><u>examinations</u></b>	Develops processes and procedures regarding sample set-up for microbiological <b><u>examinations</u></b>	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding sample set-up for microbiological <b><u>examinations</u></b>
<b>MCB 3.11. Sample storage and handling</b>	Performs procedures for microbiological sample storage and handling prior to <b><u>examination</u></b>	Explains procedures for microbiological sample storage and handling prior to <b><u>examination</u></b>	Develops processes and procedures for microbiological sample storage and handling prior to <b><u>examination</u></b>	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding microbiological sample storage and handling prior to <b><u>examination</u></b>
<b>MCB 3.12. Epidemiologic collaboration</b>	Describes which microbiological <b><u>examination</u></b> requests require epidemiologic notification and consultation	Reports to epidemiologists when microbiological <b><u>examination</u></b> requests warrant notification	Ensures staff compliance with <b><u>policies, processes</u></b> and <b><u>procedures</u></b> for notification and consultation with epidemiologists regarding microbiological <b><u>examination</u></b> requests	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> for notification and consultation with epidemiologists regarding microbiological <b><u>examination</u></b> requests

## MCB 4.00: Examination

**Examination** competencies ensure assessment of microbiological samples during the examination phase.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 4.01. Preparation of culture media</b>	Prepares culture media according to <b><u>policies, processes</u></b> and <b><u>procedures</u></b>	Explains the preparation of culture media	Ensures staff compliance with <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding quality practices for media preparation	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> for media preparation
<b>MCB 4.02. Selection of media</b>	Selects media according to procedures	Explains the media selection process	Ensures staff compliance with <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding quality practices for media selection	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding media selection
<b>MCB 4.03. Culture inoculation</b>	Performs culture inoculation using aseptic techniques	Explains how to inoculate cultures using aseptic technique	Ensures staff compliance with <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding quality practices for culture inoculation	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding culture inoculation
<b>MCB 4.04. Microscopic examination with morphological characteristics</b>	Recognizes the morphological characteristics of different organisms	Explains morphological identification and differentiating organisms from artifacts	Ensures staff compliance with <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding quality practices for morphological identification	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding morphological identification

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 4.05. Culture growth characteristics</b>	Recognizes growth characteristics of microorganisms	Explains how to identify growth characteristics of microorganisms	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for identifying microorganism growth characteristics	Oversees the <b>policies, processes</b> and <b>procedures</b> for interpretation of microorganism growth characteristics
<b>MCB 4.06. Manual identification and susceptibility testing methods</b>	Performs identification and susceptibility testing using manual methods	Explains the performance of identification and susceptibility testing using manual methods	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for performing identification and susceptibility testing using manual methods	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the performance of identification and susceptibility testing using manual methods
<b>MCB 4.07. Automated identification and susceptibility testing systems</b>	Performs identification and susceptibility testing using automated systems	Explains the performance of identification and susceptibility testing using automated systems, including how to utilize algorithms to determine additional testing	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for performing identification and susceptibility testing using automated systems	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the performance of identification and susceptibility testing using automated systems
<b>MCB 4.08. Agent-specific antigen detection</b>	Performs antigen detection methods	Explains how to perform antigen detection methods	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for antigen detection methods	Oversees the <b>policies, processes</b> and <b>procedures</b> for antigen detection
<b>MCB 4.09. Nucleic acid (NA) sequencing of infectious agents</b>	Performs NA sequencing of infectious agents	Explains the performance of NA sequencing for the identification of infectious agents	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for NA sequencing of infectious agents, including the selection and utilization of databases	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding NA sequencing and sequence-based identification
<b>MCB 4.10. Strain typing methods</b>	Performs <b>strain typing</b>	Explains how to perform <b>strain typing</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding quality practices for <b>strain typing</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding <b>strain typing</b>
<b>MCB 4.11. Rule-out testing for agents of concern</b>	Explains the <b>policies, processes</b> and <b>procedures</b> 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 <b>policies, processes</b> and <b>procedures</b> regarding rule-out testing and referral
<b>MCB 4.12. Quality control (QC) analysis</b>	Performs <b>QC</b> activities	Interprets <b>QC</b> data prior to reporting results	Examines <b>QC</b> data over time to establish <b>QC</b> ranges and limits	Ensures the <b>QC</b> program adheres to regulatory <b>requirements</b>

## MCB 5.00: Post-examination

Post-examination competencies ensure performance of post-examination procedures of microbiological testing.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 5.01.</b> <b>QC evaluation</b>	Assembles <b>QC</b> data for evaluation	Evaluates <b>QC</b> data for a given data reporting period	Ensures staff compliance with established <b>policies, processes</b> and <b>procedures</b> for <b>QC</b> evaluation activities	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>QC</b> evaluation activities
<b>MCB 5.02.</b> <b>Test analysis and results interpretation</b>	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
<b>MCB 5.03. Results reporting and data release</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> related to reporting and release of <b>examination</b> results and <b>notifiable results</b>	Explains the <b>policies, processes</b> and <b>procedures</b> related to reporting and release of <b>examination</b> results and <b>notifiable results</b>	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> related to reporting and release of <b>examination</b> results and <b>notifiable results</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> , related to reporting and release of <b>examination</b> results and <b>notifiable results</b> to partners
<b>MCB 5.04. Quality assurance (QA)</b>	Explains the differences between <b>QA</b> and <b>QC</b>	Collects data for reporting on <b>QA</b> indicators	Evaluates <b>QA</b> indicator data	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>QA</b>

## MCB 6.00: Regulatory Compliance

Regulatory compliance competencies ensure compliance with regulations.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 6.01.</b> <b>Nonconforming event (NCE) tracking</b>	Recognizes <b>NCEs</b> in laboratory processes	Documents <b>NCEs</b> on discovery for implementation of corrective actions	Analyzes <b>NCEs</b> for corrective actions and documentation	Designs a management system for <b>NCEs</b>
<b>MCB 6.02.</b> <b>Proficiency testing (PT) and alternative assessment</b>	Performs <b>PT</b> and <b>alternative assessment</b>	Reviews <b>PT</b> and <b>alternative assessment</b> results	Monitors to ensure the <b>PT</b> and <b>alternative assessment</b> program meets regulatory <b>requirements</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> related to <b>PT</b> and <b>alternative assessments</b>
<b>MCB 6.03.</b> <b>Method validation and performance verification</b>	Participates in performance of method <b>validation</b> and performance <b>verification</b>	Compiles results of method <b>validation</b> and performance <b>verification</b>	Evaluates method <b>validation</b> and performance <b>verification</b> results	Oversees the <b>policies, processes</b> and <b>procedures</b> related to method <b>validation</b> and performance <b>verification</b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>MCB 6.04. Development and validation of laboratory-developed tests (LDTs)</b>	Participates in the collection of <b>LDT</b> data	Evaluates <b>LDT validation</b> data	Creates processes and procedures for the development and <b>validation</b> of <b>LDTs</b>	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the development and <b>validation</b> of <b>LDTs</b>
<b>MCB 6.05. Select agents</b>	Describes the <b>policies, processes</b> and <b>procedures</b> related to <b>select agents</b> , including the securing, safe handling and testing of select agents and the documentation of activities	Complies with <b>policies, processes</b> and <b>procedures</b> related to related to <b>select agents</b> , including the securing, safe handling and testing of select agents and the documentation of activities	Implements <b>policies, processes</b> and <b>procedures</b> regarding <b>select agent</b> security, biosafety, testing and <b>incident</b> response plans	Oversees <b>select agent</b> security, biosafety, testing and <b>incident</b> response plans to ensure alignment with select agent regulations

# Chemistry Competency Guidelines

**Purpose:** 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.

Chemistry is the science of detection, measurement and characterization of chemicals of 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 health laboratories provide a first line of defense in the rapid recognition of toxic chemical exposures and 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.



## Chemistry Domain Notes

Sources were identified as support documents for this domain.<sup>47, 71</sup> 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).

## CHM 1.00: Concepts and Techniques

Concepts and techniques competencies ensure application of knowledge of **chemical concepts** and techniques to studies of biological and environmental matrices.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 1.01. Chemical properties</b>	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 health issues
<b>CHM 1.02. Chemical concepts</b>	Describes <b>chemical concepts</b>	Applies <b>chemical concepts</b> to analyses	Differentiates <b>chemical concepts</b> in analyses	Formulates new <b>chemical concepts</b> to improve determinations
<b>CHM 1.03. Laboratory statistics</b>	Explains statistical concepts and practices	Collects data for and performs statistical analyses	Evaluates summarized data for statistical analyses	Oversees the development and use of statistical programs
<b>CHM 1.04. Equations and calculations</b>	Performs chemical calculations	Explains 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
<b>CHM 1.05. Measurements</b>	Performs measurements and unit conversion calculations	Explains measurements and unit conversion calculations	Determines the needed accuracy and precision of measurements	Develops <b>processes</b> and <b>procedures</b> to maximize the accuracy and precision of measurements and techniques

## CHM 2.00: Facilities and Safety

Facilities and safety competencies ensure work with hazardous materials is conducted safely within a laboratory facility.

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

## CHM 3.00: Pre-examination

Pre-examination competencies ensure performance of chemistry pre-examination procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 3.01. Sample collection, labeling, and handling</b>	Describes routine sample collection, labeling, and handling <b>policies, processes</b> and <b>procedures</b> for chemical <b>examination</b>	Consults on non-routine sample collection, labeling, and handling procedures for chemical <b>examination</b>	Monitors staff compliance with established <b>policies, processes</b> and <b>procedures</b> regarding chemical sample collection, labeling, and handling	Oversees the <b>policies, processes</b> and <b>procedures</b> for the collection and handling of samples for chemical <b>examination</b>
<b>CHM 3.02. Packaging and shipping</b>	Performs the packing and shipping of hazardous samples	Explains packing and shipping of hazardous samples	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding the packing and shipping of hazardous samples	Develops <b>policies, processes</b> and <b>procedures</b> to ensure staff compliance with packing and shipping regulations concerning hazardous samples
<b>CHM 3.03. Material transport</b>	Practices and adheres to established <b>policies, processes</b> and <b>procedures</b> regarding transport of materials for chemical <b>examination</b>	Explains material transport <b>policies, processes</b> and <b>procedures</b>	Develops material transport processes and procedures	Oversees the <b>policies, processes</b> and <b>procedures</b> for the transport of materials for chemical <b>examination</b>
<b>CHM 3.04. Chemical threats</b>	Describes the <b>policies, processes</b> and <b>procedures</b> for the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Ensures staff compliance with <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern	Oversees the <b>policies, processes</b> and <b>procedures</b> regarding the identification, handling, safety, appropriateness and triage of samples containing chemical agents of concern
<b>CHM 3.05. Accessioning and receipt</b>	Performs procedures for sample accessioning and receipt	Explains <b>policies, processes</b> and <b>procedures</b> regarding sample accessioning and receipt	Manages the <b>policies, processes</b> and <b>procedures</b> for sample accessioning and receipt	Designs <b>policies, processes</b> and <b>procedures</b> regarding sample accessioning and receipt
<b>CHM 3.06. Sample tracking</b>	Performs systematic tracking of samples from receipt to final disposition	Explains <b>policies, processes</b> and <b>procedures</b> for the systematic tracking of samples from receipt to final disposition	Manages the <b>policies, processes</b> and <b>procedures</b> for the systematic tracking of samples from receipt to final disposition	Designs <b>policies, processes</b> and <b>procedures</b> for the systematic tracking of samples from receipt to final disposition
<b>CHM 3.07. Sample evaluation and appropriateness for testing</b>	Assesses appropriateness of routine samples for chemical <b>examination</b>	Explains appropriateness of routine and non-routine samples for chemical <b>examination</b>	Manages the <b>policies, processes</b> and <b>procedures</b> for <b>assessment appropriateness</b> for chemical <b>examination</b>	Establishes <b>policies, processes</b> and <b>procedures</b> regarding the <b>assessment</b> of routine and non-routine <b>sample appropriateness</b> for chemical <b>examination</b>

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 3.08. Testing workflow*</b>	Adheres to <b>policies, processes</b> and <b>procedures</b> regarding testing <b>workflow</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding testing <b>workflow</b>	Ensures laboratory processes and procedures include use of testing <b>workflow</b>	Develops <b>policies, processes</b> and <b>procedures</b> related to testing <b>workflow</b>
<b>CHM 3.09. Sample processing</b>	Performs sample processing procedures for routine chemical <b>examinations</b>	Performs sample processing for complex chemical <b>examinations</b>	Instructs staff on sample processing for routine and complex chemical <b>examinations</b>	Develops <b>policies, processes</b> and <b>procedures</b> regarding sample processing for routine and complex chemical <b>examinations</b>
<b>CHM 3.10. Pre-examination sample storage and handling</b>	Performs procedures for sample storage and handling prior to <b>examination</b>	Explains procedures for sample storage and handling prior to <b>examination</b>	Manages processes and procedures for sample storage and handling prior to <b>examination</b>	Designs <b>policies, processes</b> and <b>procedures</b> regarding sample storage and handling prior to <b>examination</b>
<b>CHM 3.11. Epidemiologic collaboration</b>	Describes which chemical <b>examination</b> requests require epidemiologic notification and consultation	Reports to epidemiologists when chemical <b>examination</b> requests warrant notification	Manages the <b>policies, processes</b> and <b>procedures</b> for notification and consultation with epidemiologists regarding chemical <b>examination</b> requests	Designs <b>policies, processes</b> and <b>procedures</b> regarding notification and consultation with epidemiologists regarding chemical <b>examination</b> requests

## CHM 4.00: Examination

**Examination** competencies ensure performance of chemistry examination procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 4.01. Examination</b>	Performs chemistry <b>examination</b> procedures	Explains chemistry <b>examination</b> procedures	Monitors staff compliance with chemistry <b>examination policies, processes</b> and <b>procedures</b>	Oversees chemistry <b>examination policies, processes</b> and <b>procedures</b>
<b>CHM 4.02. Chemical extractions</b>	Performs routine chemical extraction methods	Performs non-routine chemical extractions	Selects chemical extractions for an identified purpose	Develops new and improved types of chemical extractions
<b>CHM 4.03. Quality control (QC) analysis</b>	Performs <b>QC</b> activities	Interprets <b>QC</b> data prior to reporting results	Examines <b>QC</b> data over time to establish <b>QC</b> ranges and limits	Ensures the <b>QC</b> program adheres to regulatory <b>requirements</b>
<b>CHM 4.04. Equipment troubleshooting</b>	Identifies basic laboratory equipment problems	Performs routine equipment maintenance and minor repairs	Monitors equipment functioning over lifecycle and coordinates non-routine maintenance, complex repairs	Develops equipment troubleshooting processes and procedures and plans for equipment retirement and replacement

\* 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 **post-examination** procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 4.05. Sample storage and handling after examination</b>	Performs procedures for sample storage and handling after <u>examination</u>	Explains procedures for sample storage and handling after <u>examination</u>	Manages processes and procedures for sample storage and handling after <u>examination</u>	Designs <u>policies, processes</u> and <u>procedures</u> for sample storage and handling after <u>examination</u>

## CHM 5.00: Post-examination

Post-examination competencies ensure performance of chemistry post-examination procedures.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 5.01. QC evaluation</b>	Assembles <u>QC</u> data for evaluation	Evaluates <u>QC</u> data for a given data reporting period	Ensures staff compliance with established <u>policies, processes</u> and <u>procedures</u> for <u>QC</u> evaluation activities	Oversees the <u>policies, processes</u> and <u>procedures</u> related to <u>QC</u> evaluation activities
<b>CHM 5.02. Test analysis and results interpretation</b>	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
<b>CHM 5.03. Results reporting and data release</b>	Adheres to <u>policies, processes</u> and <u>procedures</u> related to reporting and release of <u>examination</u> results and <u>notifiable results</u>	Explains <u>policies, processes</u> and <u>procedures</u> related to reporting and release of <u>examination</u> results and <u>notifiable results</u>	Ensures staff compliance with <u>policies, processes</u> and <u>procedures</u> related to reporting and release of <u>examination</u> results and <u>notifiable results</u>	Oversees the <u>policies, processes</u> and <u>procedures</u> , related to reporting and release of <u>examination</u> results and <u>notifiable results</u> to partners
<b>CHM 5.04. Quality assurance (QA)</b>	Explains the differences between <u>QA</u> and <u>QC</u>	Collects data for reporting on <u>QA</u> indicators	Evaluates <u>QA</u> indicator data	Oversees the <u>policies, processes</u> and <u>procedures</u> related to <u>QA</u>

## CHM 6.00: Compliance

Compliance competencies ensure compliance with national or international standards or guidelines.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>CHM 6.01.</b> <b><u>Nonconforming event (NCE) tracking</u></b>	Recognizes <b><u>NCEs</u></b> in laboratory processes	Documents <b><u>NCEs</u></b> on discovery for implementation of corrective actions	Analyzes <b><u>NCEs</u></b> for corrective actions and documentation	Designs a management system for <b><u>NCEs</u></b>
<b>CHM 6.02.</b> <b><u>Proficiency testing (PT) and alternative assessment</u></b>	Performs <b><u>PT</u></b> and <b><u>alternative assessment</u></b>	Reviews <b><u>PT</u></b> and <b><u>alternative assessment</u></b> results	Monitors to ensure the <b><u>PT</u></b> and <b><u>alternative assessment</u></b> program meets regulatory <b><u>requirements</u></b>	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> related to <b><u>PT</u></b> and <b><u>alternative assessments</u></b>
<b>CHM 6.03.</b> <b><u>Method validation and performance verification</u></b>	Participates in performance of method <b><u>validation</u></b> and performance <b><u>verification</u></b>	Compiles results of method <b><u>validation</u></b> and performance <b><u>verification</u></b>	Evaluates method <b><u>validation</u></b> and performance <b><u>verification</u></b> results	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> related to method <b><u>validation</u></b> and performance <b><u>verification</u></b>
<b>CHM 6.04.</b> <b><u>Development and validation of laboratory-developed tests (LDTs)</u></b>	Participates in the development of <b><u>LDTs</u></b>	Evaluates <b><u>LDT validation</u></b> data	Creates processes and procedures for the development and <b><u>validation</u></b> of <b><u>LDTs</u></b>	Oversees the <b><u>policies, processes</u></b> and <b><u>procedures</u></b> regarding the development and <b><u>validation</u></b> of <b><u>LDTs</u></b>

# Bioinformatics Competency Guidelines

**Purpose:** 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.

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 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.

## Bioinformatics Domain Notes

Sources were identified as support documents for this domain.<sup>72,73</sup> This domain is intended for all laboratory scientists in addition to bioinformatics specialists.



## BIO 1.00: Biology and Computer Science Knowledge

Biology and computer science knowledge competencies ensure integration of knowledge of biology and computer science.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>BIO 1.01. Domain-specific biology principles</b>	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
<b>BIO 1.02. Domain-specific computer science principles</b>	Identifies <u>computer science domains</u> to apply to biological problems	Applies <u>computer science domains</u> to biological problems	Evaluates <u>computer science domains</u> to apply to biological problems	Develops new understandings of <u>computer science domains</u> to apply to biological problems

## BIO 2.00: Statistical Methods Knowledge

Statistical methods knowledge competencies ensure application of knowledge of statistical methods for analysis of biological data.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>BIO 2.01. Statistical analysis</b>	Prepares data for processing	Uses simple statistical analysis to analyze trends and patterns and to draw conclusions related to the biological data	Compares findings to any related data sets	Oversees selection of advanced statistical methods applicable to specific bioinformatics analyses

## BIO 3.00: Data Analysis

Data analysis competencies ensure analysis of biological data.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>BIO 3.01. Data analysis</b>	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
<b>BIO 3.02. Data interpretation</b>	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
<b>BIO 3.03. Data visualization and representation</b>	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

Subcompetency	Beginner	Competent	Proficient	Expert
<b>BIO 3.04. Communication</b>	Discusses bioinformatics with other scientists within their institution	Initiates bioinformatics collaborations with colleagues	Facilitates knowledge-sharing with stakeholders	Contributes to new findings and meaningful advancements in bioinformatics through the evaluation and sharing of knowledge

## BIO 4.00: Data Management

Data management competencies ensure conduct of data management, storage and retrieval.

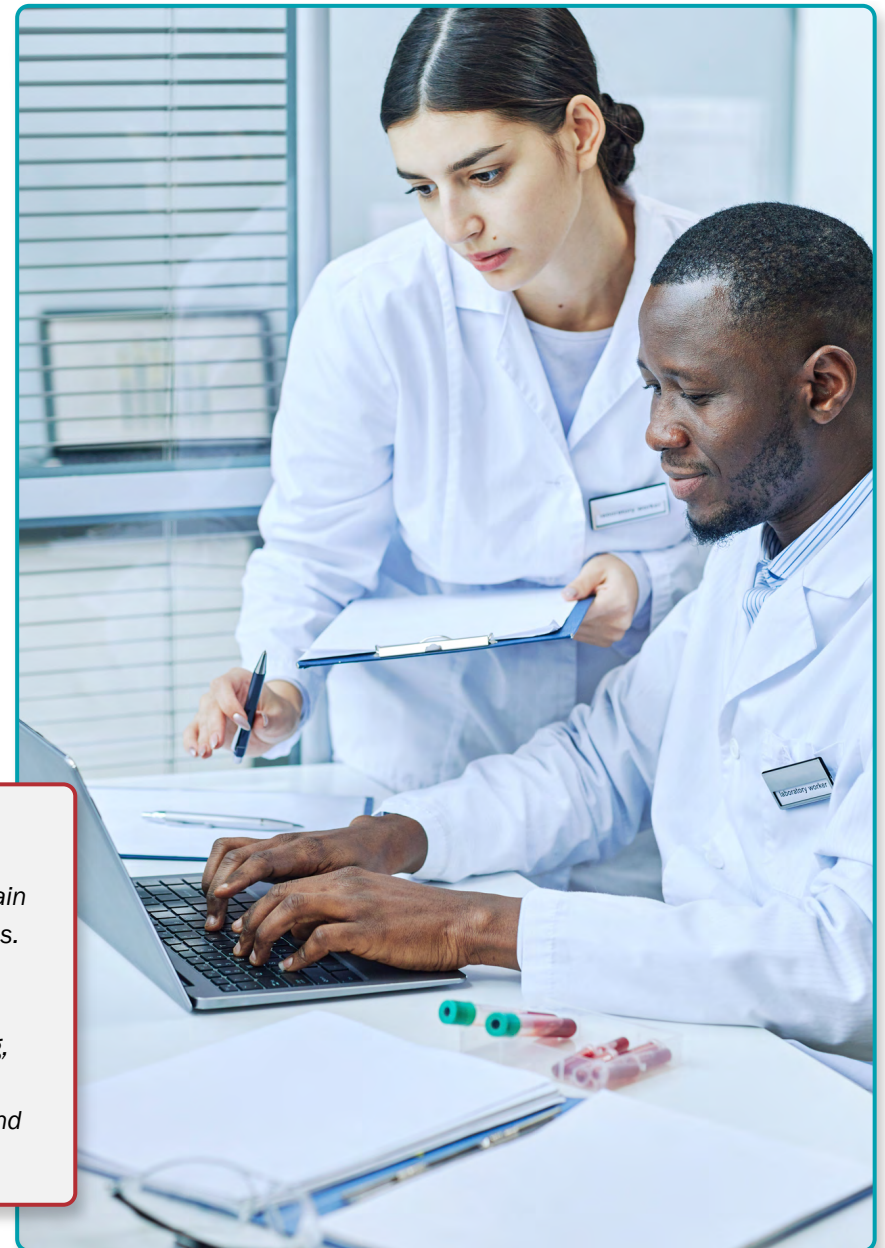
Subcompetency	Beginner	Competent	Proficient	Expert
<b>BIO 4.01. Data structures</b>	Demonstrates basic knowledge of <b>data structures</b>	Applies knowledge of <b>data structures</b> to relevant problems	Manipulates <b>data structures</b> to address biological problems	Develops new <b>data structures</b>
<b>BIO 4.02. Data management</b>	Describes data management techniques	Applies knowledge of data management techniques to relevant problems	Evaluates data management techniques	Develops new data management techniques
<b>BIO 4.03. Data storage and retrieval</b>	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
<b>BIO 4.04. Allocation of computing resources</b>	Describe available computing resources and capacity	Allocates computing resources	Manages allocation of multiple computing resources	Develops new methods for allocation of computing resources

# Research Competency Guidelines

**Purpose:** 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 and health knowledge, methods and/or practice.

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 and health enterprise, as communities are continually challenged with new diseases and unknown environmental health threats. The 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.



## Research Domain Notes

Multiple sources were identified as support documents for this domain.<sup>19, 22, 74, 75</sup> 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.

## RES 1.00: Research Programs

Research program competencies ensure development of research programs.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 1.01. Research objectives and agenda</b>	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
<b>RES 1.02. Research funding</b>	Describes general funding mechanisms that support public health and 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
<b>RES 1.03. Funding proposal reviews</b>	Describes basics of the proposal review <u>process</u>	Reviews internal proposals to verify adherence to guidelines and recommended principles	Serves as an ad hoc reviewer for research proposal reviews	Serves on research proposal review committees
<b>RES 1.04. Research staffing needs</b>	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
<b>RES 1.05. Research resource management</b>	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
<b>RES 1.06. Requirement for guidelines or standards</b>	Complies with guidelines and standards <u>requirements</u> in the performance of research	Identifies noncompliance with standards and guidelines <u>requirements</u> pertaining to the performance of research	Manages processes regarding staff compliance with standards and guidelines <u>requirements</u> concerning the performance of research	Ensures that <u>laboratory programs</u> operate consistent with standards and guidelines <u>requirements</u> concerning the performance of research

## RES 2.00: Ethical Conduct

Ethical conduct competencies ensure the ethical and responsible conduct of research.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 2.01. Ethical conduct in research</b>	Complies with <b>policies, processes</b> and <b>procedures</b> related to <b>ethical conduct in research</b>	Explains <b>policies, processes</b> and <b>procedures</b> regarding <b>ethical conduct in research</b>	Ensures staff compliance to policies and procedures related to ethical research practices	Oversees the <b>policies, processes</b> and <b>procedures</b> for implementing and maintaining ethical research practices
<b>RES 2.02. Human and nonhuman subjects</b>	Complies with <b>policies, processes</b> and <b>procedures</b> related to doing research in human and nonhuman subjects	Explains <b>policies, processes</b> and <b>procedures</b> 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 <b>policies, processes</b> and <b>procedures</b> for implementing and maintaining <b>ethical practices</b> related to doing research in human and nonhuman subjects
<b>RES 2.03. Collaboration</b>	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
<b>RES 2.04. Sharing research data</b>	Complies with established agreements pertaining to research data sharing and the use of intellectual property	Describes issues that might arise pertaining to data ownership and the sharing of data	Ensures staff compliance with established agreements regarding data sharing	Establishes guidelines for sharing research data

## RES 3.00: Research Foundation

Research foundation competencies ensure integration of scientific and technical knowledge for use as a foundation for research.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 3.01. Literature searches</b>	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
<b>RES 3.02. Critique of scientific literature</b>	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
<b>RES 3.03. Statistical concepts and tests</b>	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

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 3.04. Study designs</b>	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
<b>RES 3.05. Scientific and technical concepts and procedures</b>	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
<b>RES 3.06. Emerging trends</b>	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

## RES 4.00: Testing Methodology Development

Testing methodology development competencies ensure development of new testing methodology.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 4.01. New testing methodologies</b>	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
<b>RES 4.02. Pilot testing, method validation and performance verification</b>	Contributes to pilot testing, method <b>validation</b> or performance <b>verification</b>	Performs pilot testing, method <b>validation</b> or performance <b>verification</b>	Designs strategies for pilot testing, method <b>validation</b> or performance <b>verification</b>	Oversees pilot testing, method <b>validation</b> and performance <b>verification</b> studies
<b>RES 4.03. New methodology application</b>	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

Research project execution competencies ensure conduct of research to address a public health or health issue or answer a public health or health question.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 5.01. Research project design</b>	Explains how own tasks and activities support specific research projects	Summarizes the health issues and research questions addressed by specific research projects	Designs research projects	Oversees research projects to address the identified health issues or questions
<b>RES 5.02. Experimental strategy and design</b>	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
<b>RES 5.03. Conduct of experiments</b>	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

Research data management, analysis and application competencies ensure conduct of research according to professional standards of data management, analysis and application.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 6.01. Data collection and quality</b>	<b>Records</b> experimental procedures and data	Monitors quality and <b>integrity</b> of recorded information and data	Designs data collection and entry methods that meet data quality standards	Develops <b>policies, processes</b> and <b>procedures</b> to ensure data quality and <b>integrity</b>
<b>RES 6.02. Data management</b>	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
<b>RES 6.03. Data analysis and results interpretation</b>	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
<b>RES 6.04. Data summaries</b>	Describes data tables and graphs	Summarizes experimental data using multiple formats	Develops outlines and formats for data summaries	Critiques data summaries
<b>RES 6.05. Application of research findings to current research</b>	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

\* A detailed plan for conducting a scientific **procedure**.

## RES 7.00: Dissemination of Research Findings

Dissemination of research findings competencies ensure dissemination of research findings.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 7.01. Meeting and conference presentations</b>	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
<b>RES 7.02. Manuscript preparation</b>	Assists in manuscript drafting and editing	Drafts sections of research manuscripts	Publishes as first author or senior author in journals of the discipline	Publishes as senior author for multi-laboratory or multi-institutional research projects or in high-impact interdisciplinary journals
<b>RES 7.03. Manuscript peer review <u>process</u></b>	Reads drafts of manuscripts submitted for peer review	Informally critiques manuscripts submitted for peer review	Participates in the peer review <u>process</u> as a formal reviewer	Participates in the manuscript peer review <u>process</u> as member of the editorial board

## RES 8.00: Translation

Translation competencies ensure translation of research findings to medical and scientific health practice.

Subcompetency	Beginner	Competent	Proficient	Expert
<b>RES 8.01. Translation of research findings into medical and scientific health practice</b>	States research findings as they relate to current health practices	Describes implications of research findings on health practices	Directs translation of research findings to health practices	Oversees translation of research discoveries into meaningful changes in health practices

# Conclusion

---

These competency guidelines outline the knowledge, skills and abilities needed by the laboratory workforce to fulfill the responsibilities of, and demands on, the laboratory system. They were developed with consideration of the variety and complexity of laboratories. 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 laboratory workers, which has been identified as a significant barrier to worker recruitment and retention.<sup>32, 76, 77, 78</sup>

APHL recognizes 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 laboratories 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. 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.

# Appendix

---

## Laboratory Proficiency Tier Definitions\*

The definitions for the levels of proficiency reflect a continuum of knowledge, skills and experience from a beginner through an expert. The distinction between the middle two tiers, competent and proficient, may be slight and may vary somewhat based on specific tasks and settings.

**Beginner:** A beginner is one who demonstrates an elementary level of performance. The beginner might have sufficient subject matter knowledge but has limited practical experience needed to perform a task, behavior or function. The beginner requires on-going supervision and has not passed competency evaluation.

**Competent:** A competent person is one with sufficient training and experience in a task to reliably conduct the task according to established standardized operating **procedures** and with a defined level of **quality**. Competency of an individual is assessed periodically via external **validation** and assessments. As directed by proficient professionals, the competent professional may participate in the **mentoring**/training of beginner level staff and of other competent level staff in learning new tasks.

**Proficient:** The proficient person is competent in conducting complex tasks unsupervised and can identify and resolve non-routine problems. This individual has a high level of organizational understanding and decision-making skills and experience. The proficient level laboratory professional designs, conducts, oversees and evaluates the training of beginner and competent laboratory professionals and conducts and assesses competency of laboratory personnel.

**Expert:** The expert laboratory professional has substantial experience, knowledge, and can operate from a deep understanding of laboratory systems both inside and outside of the organization. The expert, who may be a specific subject matter expert, or a general laboratory systems expert, can form collaborative relationships, and is able to manage available resources to achieve the laboratory's mission. Expert laboratory professionals have mastered the skills of **critical thinking**, problem solving and decision making and are involved in planning, operations and monitoring and evaluation of **laboratory programs**.

---

\* Sources:

- Benner, P. From novice to expert: promoting excellence and power in clinical nursing practice. Menlo Park, CA: Addison-Wesley; 1984.
- Dreyfus SE, Dreyfus HL. A five-stage model of the mental activities involved in directed skill acquisition. Berkeley, CA: University of California–Berkeley; 1980.
- Definitions were developed by two CDC/APHL Steering Committee members by adopting Dreyfus's Model of Skill Acquisition and modifying Benner's Stages of Clinical Competence. Tiers do not correspond directly to grade levels or job titles.

## Glossary of Terms

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

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

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

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

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

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

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

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

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

**Assets:** the resources of an organization or facility (e.g., staff, equipment, instruments, computers, materials, including **select agents** and toxins, and controlled chemicals and other **chemical materials**).

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

**Automated susceptibility testing system:** an automated, computerized system developed for the detection of the sensitivity of organisms to one or more antimicrobial agents. Basic scientific and laboratory concepts and theories: concepts and theories applied by staff during the performance of **sample** analyses. Examples include the effects of temperature on samples and organisms; the principles of acids, bases and pH; molarity; accuracy and precision; sensitivity and specificity; the different wavelengths of light (and uses in the laboratory); the concepts behind different kinds of microscopy; the science behind distillation, filtration, extraction, and chromatography; and the principles of polymerase chain reaction (PCR), sequencing, enzyme-linked immunosorbent assay (ELISA), whole genome sequencing (WGS) and other techniques.

**Auxiliary data:** data from an external source

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

**Biohazardous materials:** infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA; organisms and viruses infectious to humans, animals or plants (e.g., parasites, viruses, bacteria, fungi, prions and rickettsia); and biologically active agents (e.g., toxins, allergens and venoms) that can cause disease in living organisms or cause significant impact to the environment genetically modified organisms or microorganisms, viruses or prions). These materials are not necessarily pathogenic or hazardous. Examples include, but are not limited to, cellular lines, DNA materials, tissues, organs, body fluids, cultured cells, allergens, and **select agents** and toxins.

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

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

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

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

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

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

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

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

**Change management:** a **process** to support moving from a current state through a transition state to a future state. From a **process** perspective, it is a structured method of revising any **policy**, **process** or **procedure** (also referred to as **Change Control**). This includes activities such as transition planning and the design of

hardware and software. It also includes revisions to all associated **documents** and **records**. From a personnel perspective, it is an approach to transitioning persons, teams and organizations to a desired future state.

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

**Chemical hygiene plan:** a written program developed and implemented by the organization that outlines **procedures**, equipment, **personal protective equipment** and **work practices** that are capable of protecting staff from the health hazards presented by **hazardous chemicals** used in that particular workplace.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Data verification:** a **process** during which data entered or stored in a system are checked to ensure accuracy, completeness and consistency with source date.

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

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

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

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

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

**Emergency preparedness and response networks:** international, national, regional and local networks that collaborate to provide emergency preparedness and response capabilities.

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

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

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

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

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

**Ethical conduct in research:** the application of rules and professional codes of conduct that promote the aims of research, encourage essential collaborations, ensure researchers are accountable and promote moral and social values. These principles include honesty in conducting and reporting research, objectivity,

integrity, carefulness, openness, respect for intellectual property, **confidentiality**, responsible authorship and peer review, social responsibility, nondiscrimination, competence, legality, animal welfare and protection of human subjects.

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

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

**Exchange networks:**

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

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

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

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

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

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

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

**Hazardous chemical:** any chemical which is classified as a health hazard

**Hazard communication:** a written program that conveys **information** concerning hazards. Hazard communication includes, but is not limited to, use of **safety signage**, **Safety Data Sheets (SDS)** and other written sources describing hazards of a material or space.

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

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

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

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

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

**Incident Management System (IMS):** The standardized structure and approach that WHO has adopted to manage its response to public health events and emergencies, and to ensure that the organization follows best practice in emergency management. WHO has adapted the IMS to consist of six critical

functions: Leadership, Partner Coordination, **Information** and Planning, Health Operations and Technical Expertise, Operations Support and Logistics, and Finance and Administration

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

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

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

**Instructional design:** the systematic development of instructional specifications using learning and instructional theory to maximize the **quality** of instruction, making the acquisition of knowledge and skill more efficient, effective and appealing. Instructional design is the entire **process** of analysis of learning needs and goals and the development of a delivery system to meet those needs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**MALDI-TOF:** matrix-assisted laser desorption/ionization-time of flight. An analytical technique used to detect and characterize mixtures of organic molecules.

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

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

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

**Medical surveillance program:** the ongoing, systematic collection of health data that signal either biomarkers of exposure or early signs of adverse health outcomes from known biologic, chemical and **radiological materials** and toxicants in persons working with those materials. This includes a program for pre-employment screening, ongoing monitoring and postexposure management.

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

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

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

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

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

**Model laboratory practices:** activities and processes integral to the provision of laboratory testing services that optimize the **quality** of the result. These practices are guided by certain industry standards and are adopted by a laboratory to maximize safety, effectiveness, efficiency, timeliness and public health/community outcomes. These practices are usually independent of the test or measurement techniques employed. In the recent past, these practices were referred to as “best practices,” but it is now acknowledged that there is not one collection of best practices for each laboratory or situation.

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

**National Select Agent Program:** a program that oversees the possession, use and transfer of biological **select agents** and toxins.

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

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

**Occupational Safety and Health Administration:** the national agency charged with the enforcement of safety and health legislation.

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

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

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

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

**Personnel security program:** a system for addressing insider threats to ensure that only trusted persons are given authorized access to restricted areas. The program includes policies and **procedures** to ensure that persons that work within an organization are trustworthy and competent to carry out an organization’s mission. This includes conducting interviews of applicants, evaluating positions and verifying applicant suitability

**Physical hazards:** unsafe conditions in the workplace that can cause injury or illness. Examples include ergonomic hazards; electrical shock hazards; loud noises; slip, trip and fall hazards; exposure to hot and cold temperatures; compressed gas cylinders; and **sharps** (i.e., items capable of cutting or piercing human skin such as hypodermic needles, syringes [with or without attached needles], Pasteur pipettes, scalpel blades, suture needles, blood vials, needles

with attached tubing and culture dishes [regardless of the presence of infectious agents]; and other types of broken or unbroken glassware [e.g., microscope slides and cover slips]).

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

**Physical security infrastructure:** the aggregate collection of physical elements, such as locks, access controls, alarms, closed-circuit television monitoring systems, fences and other barriers, sign-in logs and security guards, designed to protect and safeguard the physical components of a facility, including staff and other **assets**.

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

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

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

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

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

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

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

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

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

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

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

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

**Protected information:** any **information** about a person that is maintained by an organization that relates to issues of privacy (the right of a person to keep his or her information private) and **confidentiality** (ensuring that information is accessible only to those authorized to have access). Protected information includes any information that can be used to distinguish or trace a person’s identity and any other personal, health or medical information that is linked or linkable to a person.

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

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

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

**Quality assurance (QA):** planned and systematic activities implemented in a quality system so that quality **requirements** and goals for a product, service or activity will be fulfilled. From a quality-improvement viewpoint, it is a system for ensuring a desired level of quality in the development, production or delivery of products and services. From a bench-level viewpoint, it is the practice of

assessing performance in all steps of the laboratory testing cycle including pre-analytical, analytical and postanalytical phases to promote excellent outcomes in health.

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

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

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

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

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

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

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

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

**Regulated waste:** liquid or semi-liquid blood or other potentially infectious materials, contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed, items that are caked with dried blood or other potentially infectious materials and are capable of

releasing these materials during handling, contaminated **sharps**, and pathological and microbiological wastes containing blood or other potentially infectious materials.

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

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

**Risk assessment:** the stepwise **process** in which the risk(s) arising from working with a hazard(s) are evaluated and the resulting **information** is used to determine whether risk control measures can be applied to reduce those risks to acceptable risks. Risk is the combination of the probability that a hazard will cause harm and the severity of harm that may arise from contact with that hazard.

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

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

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

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

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

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

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

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

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

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

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

**Scientific ethics:** principles, rules and standards guiding the performance of persons and the conduct of laboratory testing that include values and standards such as scientific credibility, scientific accountability, objectivity, assurance of **scientific integrity**, responsible collaboration, responsible authorship and peer review, adhering to intellectual property laws, and adhering to **chain of custody** rules and policies.

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

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

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

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

**Select agents:** a subset of biological agents and toxins having the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products.

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

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

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

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

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

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

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

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

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

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

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

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

**Training report:** a document produced during the development of, and following, the delivery of a training activity. Reports might include training program evaluation summaries, attendance and continuing education credits awarded summaries or statement of deliverables and outcomes realized through a training activity included in a funding reconciliation report.

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

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

**Verification:** the ongoing process that confirms specified requirements (predetermined by validation) are fulfilled. Verification is needed when the laboratory replaces a test system or instrument; adds a new test; or changes the manufacturer of a test kit. The laboratory must verify the manufacturer's performance specifications are substantiated.

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

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

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

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

# References

- 1 Brown, S. The Importance of Laboratories to Global Health, Lablogatory; Sept 5 2016. Accessed April 17, 2025: [labmedicineblog.com/2016/09/05/the-importance-of-laboratories-to-global-health/](http://labmedicineblog.com/2016/09/05/the-importance-of-laboratories-to-global-health/)
- 2 Rasmussen SA and Goodman RA, Ed, The CDC Field Epidemiology; Chapter 22: Natural and Human-Made Disasters, Ronald Waldman, Available from: [www.cdc.gov/field-epi-manual/php/chapters/natural-human-disasters.html](http://www.cdc.gov/field-epi-manual/php/chapters/natural-human-disasters.html).
- 3 Beck AJ, Boulton ML. Predictors of capacity in public health, environmental, and agricultural laboratories. *J Public Health Manag Pract* 2014;20:654–61.
- 4 World Health Organization, One Health [website]. Accessed April 17, 2025 from: [www.who.int/europe/initiatives/one-health](http://www.who.int/europe/initiatives/one-health)
- 5 Nkengsong JN, Mesele T, Orloff S, Kebede Y, Funjongo PN, Timperi R, Birs D. Critical Role of Developing National Strategic Plans as a Guide to Strengthen Laboratory Health Systems in Resource-Poor Settings, *Am J Clin Path* 2009;131:852-857
- 6 Onyebujoh PC, Thirumala AK, Ndiokubwayo JB, Integrating laboratory networks surveillance systems and public health institutes in Africa, *Afr J Lab Med.* 2016;5(3)a431.
- 7 Koo D, Miner K. Outcome-based workforce development and education in public health. *Annu Rev Public Health* 2010;31:253–69, 1, 269.
- 8 Dreyfus SE, Dreyfus HL. A five-stage model of the mental activities involved in directed skill acquisition. Berkeley, CA: University of California–Berkeley; 1980.
- 9 Bloom BS. Taxonomy of educational objectives; Handbook I: The Cognitive Domain. New York, NY, David McKay Co Inc. 1956:
- 10 Anderson LW, Krathwohl DR, Airasian PW, et al. A taxonomy for learning, teaching, and assessing: a revision of Bloom’s taxonomy of educational objectives. New York, NY: Pearson; 2000.
- 11 Clinical and Laboratory Standards Institute. Quality management system: a model for laboratory services: approved guideline. 4th ed. CLSI document QMS01-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
- 12 Centers for Medicare and Medicaid Services, Department of Health and Human Services. Laboratory requirements, 42 CFR. Chapter IV. Part 493. Available at <https://www.govinfo.gov/content/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml>.
- 13 Clinical Laboratory Management Association. Body of knowledge for medical laboratory management. Chicago, IL: CLMA; 2012.
- 14 Clinical and Laboratory Standards Institute. Training and competence assessment: approved guideline. 3rd ed. CLSI document QMS03-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
- 15 Clinical and Laboratory Standards Institute. Laboratory personnel management. CLSI guideline QMS16–Personnel. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
- 16 International Organization for Standardization and International Electrotechnical Commission. International Standard, ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. Geneva, Switzerland: ISO/IEC; 2005.
- 17 Westcott RT. The certified manager of quality/organizational excellence handbook. 3rd ed. Milwaukee, WI: American Society of Quality, Quality Press; 2005.
- 18 World Health Organization. Laboratory quality management system: handbook. Version 1.1, Lyon, France: World Health Organization; 2011. Available at [https://iris.who.int/bitstream/handle/10665/44665/9789241548274\\_eng.pdf](https://iris.who.int/bitstream/handle/10665/44665/9789241548274_eng.pdf)
- 19 Institute of Medicine. Integrity in scientific research: creating an environment that promotes responsible conduct. Washington, DC: The National Academies Press; 2002. Available at <https://nap.nationalacademies.org/catalog/10430/integrity-in-scientific-research-creating-an-environment-that-promotes-responsible>
- 20 Jones NL. A code of ethics for the life sciences. *Sci Eng Ethics* 2007;13:25–43.
- 21 Public Health Leadership Society. Principles of the ethical practice of public health. New Orleans, LA: Public Health Leadership Society; 2002. Available at <https://stacks.cdc.gov/view/cdc/5595/>
- 22 Resnick DB. What is ethics in research & why is it important? Research Triangle Park, NC: NIH National Institute of Environmental Health Sciences; 2011. Available at <https://www.niehs.nih.gov/research/resources/bioethics/whatis>
- 23 Slomka J, Quill B, desVignes-Kendrick M, Lloyd LE. Professionalism and ethics in the public health curriculum. *Public Health Rep* 2008;123(Suppl 2):27–35.
- 24 Bennis W. On becoming a leader. 1st ed. Cambridge, MA: Perseus Publishing; 1989.
- 25 CDC, Association of Public Health Laboratories. Core functions and capabilities of state public health laboratories: A report of the Association of Public Health Laboratories. *MMWR Recomm Rep* 2002;51(No. RR-14):1–8.
- 26 Association of Public Health Laboratories. The core functions of public health laboratories. Silver Spring, MD: Association of Public Health Laboratories; 2024. Available at <https://www.aphl.org/aboutAPHL/publications/Documents/PHL-Core-Functions.pdf>
- 27 Association of Public Health Laboratories. Who will run America’s public health labs? Educating future laboratory directors. Silver Spring, MD: Association of Public Health Laboratories; 2002. Available at [https://www.aphl.org/aboutAPHL/publications/Documents/Who\\_Will\\_Run\\_Americas\\_PHL\\_2002.pdf](https://www.aphl.org/aboutAPHL/publications/Documents/Who_Will_Run_Americas_PHL_2002.pdf)

- 28 Wright K, Rowitz L, Merkle A, et al. Competency development in public health leadership. *Am J Public Health* 2000;90:1202–7.
- 29 Czabanowska K, Smith T, Könings KD, et al. In search for a public health leadership competency framework to support leadership curriculum—a consensus study. *Eur J Public Health* 2014;24:850–6.
- 30 Council on Linkages Between Academia and Public Health Practice. Core competencies for public health professionals. Washington, DC: Public Health Foundation; 2010. Available at <https://phf.org/programs/core-competencies-for-public-health-professionals/>
- 31 CDC, Council of State and Territorial Epidemiologists. Competencies for applied epidemiologists in governmental public health agencies. Atlanta, GA: CDC, Council of State and Territorial Epidemiologists; 2008. Available at <https://stacks.cdc.gov/view/cdc/45859>
- 32 DeBoy J, Luedtke P, Warren N, Wichman M. Toolkit for ensuring a future workforce of qualified public health laboratory scientist-managers and directors. Chapel Hill, NC: Public Health Leadership Institute; 2006.
- 33 CDC. Public health preparedness capabilities: National standards for state and local planning, Capability 6: Information Sharing. Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at <https://stacks.cdc.gov/view/cdc/60062>
- 34 Mind Tools Ltd. Active listening. Wiltshire, UK: Mind Tools Ltd. Available at <https://www.mindtools.com/az4wxv7/active-listening>.
- 35 National Research Council (US) Committee on Prudent Practices in the Laboratory. Laboratory security. In: Prudent practices in the laboratory: handling and management of chemical hazards, updated version. Washington, DC: National Academies Press; 2011:255–64. Available at <https://www.ncbi.nlm.nih.gov/books/NBK55881/>
- 36 US Department of Health and Human Services, CDC, National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 6th ed. Washington, DC: US Department of Health and Human Services. HHS Publication No. (CDC) 2020. Available at [https://www.cdc.gov/labs/pdf/SF\\_19\\_308133-A\\_BMBL6\\_00-BOOK-WEB-final-3.pdf](https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)
- 37 World Health Organization. Biorisk management: laboratory biosecurity guidance. Geneva, Switzerland: WHO; 2006. Available at <https://www.who.int/publications/i/item/biorisk-management-laboratory-biosecurity-guidance>
- 38 World Health Organization. Health Emergency and Disaster Risk Management Framework. Geneva, Switzerland: WHO; 2019. Available at <https://iris.who.int/bitstream/handle/10665/326106/9789241516181-eng.pdf>
- 39 CDC, Association of Public Health Laboratories. Guidelines for biosafety laboratory competency. *MMWR Suppl* 2011;2011:60.
- 40 CDC. Emergency preparedness and response: laboratory information. Atlanta, GA: US Department of Health and Human Services, CDC; 2015. Available at <http://emergency.cdc.gov/labissues/index.asp>.
- 41 Integrated Consortium of Laboratory Networks. Integrated Consortium of Laboratory Networks web portal. Available at <https://www.icln.org>.
- 42 Federal Emergency Management Agency. National preparedness goal. Washington, DC: US Department of Homeland Security, FEMA; 2015. Available at <http://www.fema.gov/national-preparedness-goal>
- 43 Federal Emergency Management Agency. National incident management system. Washington, DC: US Department of Homeland Security, FEMA; 2015. Available at <https://www.fema.gov/national-incident-management-system>
- 44 Occupational Safety and Health Administration. 29 CFR 1910.38: emergency action plans. Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2002. Available at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.38>
- 45 American Society for Training and Development (ASTD). The ASTD training and development handbook: a guide to human resource development. 4th ed. New York, NY: The McGraw-Hill Companies; 1996.
- 46 American Society for Microbiology. Manual of clinical microbiology. 10th ed. Washington, DC: ASM Press; 2011.
- 47 Burtis CA, Brunts DE. Tietz fundamentals of clinical chemistry and molecular diagnostics. 7th ed. Philadelphia, PA: Elsevier Health Sciences; 2014.
- 48 Animal and Plant Health Inspection Service, CDC. Select agent requirements, 42 CFR part 73, 7 CFR part 331 and 9 CFR part 121. Available at <https://www.selectagents.gov/sat/exclusions/index.htm>
- 49 CDC. Guidelines for safe work practices in human and animal medical diagnostic laboratories. *MMWR Surveill Summ* 2012;61(No. Suppl 1).
- 50 Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections: approved guideline. 4th ed. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
- 51 Fleming DO, Hunt D. Biological safety: principles and practices. 4th ed. Washington, DC: ASM Press; 2006.
- 52 Heymann DL. Control of communicable diseases manual. 19th ed. Washington, DC: American Public Health Association; 2008.
- 53 International Air Transport Association. Dangerous goods regulations. 56th edition requirements. IATA; 2015. Available at <http://www.iata.org/whatwedo/cargo/dgr/pages/download.aspx>
- 54 International Organization for Standardization. Medical laboratories: particular requirements for quality and competence, second edition (ISO 15189); 2007. Available at <https://www.iso.org/standard/76677.html>
- 55 National Research Council of the National Academies. Guide for the care and use of laboratory animals. 8th ed. Washington, DC: National Academies Press; 2011. Available at <http://oacu.od.nih.gov/regs/guide/guide.pdf>

- 56 US Department of Labor. Toxic and hazardous substances: Hazard communication (OSHA 29 CFR 1910.1200 [Final Rule]). Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2013. Available at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200>
- 57 US Department of Labor. Toxic and hazardous substances: Bloodborne pathogens (OSHA 20 CFR 1910.1030). Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2012. Available at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>
- 58 US Department of Labor. Toxic and hazardous substances: Occupational exposure to hazardous chemicals in laboratories (OSHA 29 CFR 1910.1450). Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2012. Available at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1450>
- 59 US Department of Labor. Personal protective equipment: general requirements (OSHA 20 CFR 1910.132). Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2011. Available at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.132>
- 60 US Department of Labor. Laboratory safety guidance. Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2011. Available at <https://www.osha.gov/sites/default/files/publications/OSHA3404laboratory-safety-guidance.pdf>
- 61 US Department of Labor. OSHA Record Keeping Handbook. Washington, DC: US Department of Labor, Occupational Safety and Health Administration; 2005. Available at: <https://www.osha.gov/sites/default/files/enforcement/directives/CPL-02-00-172.pdf>
- 62 Thacker SB, Berkelman RL. History of public health surveillance. In: Halperin W, Baker EL, Monson RR, eds. Public health surveillance. New York, NY: Van Nostrand Reinhold; 1992.
- 63 Dicker RC, Coronado F, Koo D, Parrish RG. Principles of epidemiology in public health practice. 3rd ed. Atlanta, GA: US Department of Health and Human Services, CDC; 2006. Available at <https://stacks.cdc.gov/view/cdc/6914>
- 64 World Health Organization, Department of Communicable Disease Surveillance and Response. WHO recommended surveillance standards. 2nd ed (WHO/CDS/CSR/ISR/99.2). Geneva, Switzerland: World Health Organization. Available at <https://www.who.int/publications/i/item/who-recommended-surveillance-standards>
- 65 CDC, University of Washington School of Public Health and Community Medicine's Center for Public Health Informatics. Competencies for public health informaticians. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at [http://www.cdc.gov/InformaticsCompetencies/downloads/PHI\\_Competencies.pdf](http://www.cdc.gov/InformaticsCompetencies/downloads/PHI_Competencies.pdf)
- 66 APHL/CDC. Informatics self-assessment tool for public health laboratories. Silver Spring, MD: APHL; 2013. Available at <https://www.aphl.org/programs/informatics/Pages/Informatics-Self-Assessment-Tool.aspx>
- 67 APHL/Public Health Informatics Institute (2003). Requirements for public health laboratory information management systems. Available at <https://www.aphl.org/aboutAPHL/publications/Documents/INFO-2003-PHL-Requirements-16-Business-Processes.pdf>
- 68 APHL (2011). The brave new world of consolidated and shared IT services: a guide for laboratories. Available at [https://www.aphl.org/aboutAPHL/publications/Documents/COM\\_2011\\_ITConsolidatedandSharedServices.pdf](https://www.aphl.org/aboutAPHL/publications/Documents/COM_2011_ITConsolidatedandSharedServices.pdf)
- 69 O'Carroll PW; Public Health Informatics Competencies Working Group. Informatics competencies for public health professionals. Seattle, WA: Northwest Center for Public Health Practice, University of Washington School of Public Health and Community Medicine; 2002. Available at <https://www.cphi.washington.edu/resources/2002%20Competencies.pdf>
- 70 Murray PR. Manual of clinical microbiology. 6th ed. Washington, DC: ASM Press; 1995.
- 71 National Research Council (US) Committee on Prudent Practices in the Laboratory. Prudent practices in the laboratory: handling and management of chemical hazards, updated version. Washington, DC: National Academies Press; 2011. Available at <http://www.ncbi.nlm.nih.gov/books/NBK55878>
- 72 National Center for Biotechnology Information, US National Library of Medicine. Welcome to NCBI. Bethesda, MD: National Library of Medicine; 2009. Available at <http://www.ncbi.nlm.nih.gov>.
- 73 Welch L, Lewitter F, Schwartz R, et al. Bioinformatics curriculum guidelines: toward a definition of core competencies. PLoS Comput Biol 2014;10:e1003496.
- 74 National Postdoctoral Association. The NPA postdoctoral core competencies toolkit. New York, NY: National Postdoctoral Association; 2009. Available at <https://www.nationalpostdoc.org/page/CoreCompetencies>.
- 75 Steneck NH/CDC Office of Research Integrity. Introduction to the responsible conduct of research. Washington, DC: US Department of Health and Human Services; 2007. Available at <http://ori.hhs.gov/sites/default/files/rcrintro.pdf>
- 76 Institute of Medicine of the National Academies. Who will keep the public healthy? Educating public health professionals for the 21st century. Washington, DC: The National Academies Press; 2003.
- 77 Association of Schools of Public Health. Master's degree in public health core competency development project, version 2.3. Washington, DC: Association of Schools of Public Health; 2006.
- 78 University of Michigan Center of Excellence in Public Health Workforce Studies, Association of Public Health Laboratories. National laboratory capacity assessment, 2011. Ann Arbor, MI: University of Michigan; 2012.



## Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 | 240.485.2745 | [www.aphl.org](http://www.aphl.org)

© Copyright 2025, Association of Public Health Laboratories. All Rights Reserved.

This project was 100% funded with federal funds from a federal program of \$4.46 million. This publication was supported by Cooperative Agreement #NU2HGH000080 from the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.