



# **NAACLS Standards for Accredited Programs**

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# Standards For All Accredited Programs

## Core Standards

### I. Sponsorship

#### A. Sponsoring Institution

The sponsor of an educational program must be one of the following:

1. A post-secondary academic institution accredited by an institutional accrediting agency that is recognized by the U.S. Department of Education and given the authority to provide post-secondary education, which awards a minimum of a certificate at the completion of the program.
2. A hospital, medical center, or laboratory accredited or licensed by an applicable recognized agency (see Standards Compliance Guide), which awards a minimum of a certificate at the completion of the program.
3. A secondary or post-secondary institution, recognized by the state in which it is located. (for phlebotomy and medical laboratory assistant programs only).
4. An institution recognized by the national government or a regional/national accrediting agency for higher education of the country in which it is located as a post-secondary academic institution with degree granting authority. (for programs outside of the United States).
5. A Public Health Laboratory or an organization/corporation of member Public Health Laboratories recognized by the state in which it is located and not affiliated with a hospital, medical center or accredited secondary or post-secondary institution.

#### B. Responsibilities of the Sponsor and/or Program Partner

1. The sponsor is responsible for:
  - a. Ensuring that all provisions of the standards are met.
  - b. Curriculum development.
  - c. Maintaining student transcripts permanently.
  - d. Defining its administrative line of authority.
2. The sponsor and/or program partner are responsible for:
  - a. Course selection by program faculty and staff.
  - b. Appointing faculty and staff.
  - c. Granting the degree and/or certificate documenting satisfactory completion of the educational program.
  - d. Ensuring that appropriate personal safety measures are addressed for students and faculty.
  - e. Ensuring that graduates of the program have obtained or will obtain the minimum degree and/or certificate upon completion of the program:
    - i. *Path A programs*: a master's degree or higher, or a certificate for students who hold or complete the required degree.

- ii. *BMS, CG, DMS, HTL, MLM, MLS, and PHM programs*: a bachelor's degree or higher, or a certificate for students who hold or complete the required degree.
  - iii. *HT and MLT programs*: an associate degree or higher, or a certificate for students who hold or complete the required degree.
  - iv. *MLA and PBT programs*: a certificate for the student.
- f. Ensuring that the activities assigned to students in the applied learning experiences setting are educational.
3. There must be documented ongoing communication between the sponsor and/or program partner and its active affiliates for exchange of information and coordination of the program.
  4. The sponsor and/or program partner must provide eligible students with the opportunity to participate in applied learning experiences.
  5. The sponsor and/or program partner must have a formal affiliation agreement or memorandum of understanding (MOU) with affiliates who are involved in the education of the students, which describes:
    - a. the relationship
    - b. the roles
    - c. the responsibilities of the sponsor and/or program partner and that entity

## II. Assessment and Continuous Quality Improvement

### A. Systematic Assessment

There must be a documented plan for continuous and systematic assessment of the effectiveness of the program.

### B. Outcome Measures

The following outcome measures must be documented and submitted to NAACLS annually for use in program assessment and continuous quality improvement.

1. external certification results
2. graduation rates
3. placement rates
4. attrition rates
5. other (optional)

### C. Feedback

The following findings must be collected and used in program assessment and continuous quality improvement.

1. findings from graduate feedback
2. findings from employer feedback

### D. Program Assessment and Modification

All programs must make efforts to continually improve by:

1. Review of required feedback and last three active years of required outcome measures.
2. Analysis of curriculum development, resource acquisition/allocation.

3. Modifications made based on analysis of required feedback and/or outcome measures.
4. Assessment of effectiveness resulting from any changes implemented.

### III. Resources

#### A. General Resources

1. The sponsor must provide sufficient financial resources for the continued operation of the education program to meet documented goals.
2. Resource assessment of personnel and physical resources must be a part of continuous program evaluation.

#### B. Personnel

1. The sponsor must appoint a sufficient number of personnel to achieve program outcomes.

#### C. Physical Resources

1. The sponsor must provide physical resources such as facilities, equipment and supplies, information resources, and instructional resources sufficient to achieve program outcomes.

### IV. Students

#### A. Publications and Disclosures

1. The following must be defined, published, and readily available to prospective and enrolled students:
  - a. Program mission statement.
  - b. Program goals and graduate competencies.
  - c. Programmatic accreditation status including the name, address and contact information for NAACLS.
  - d. Results of external certification outcomes, graduation rates outcomes, placement rates outcomes of the last three active years.
  - e. List of active partners, academic affiliates and clinical/applied learning experiences facilities.
  - f. Admission criteria, including essentials functions, advance placement, transfer of credits and credits for experiential learning.
  - g. List of course descriptions including the number of academic credit hours per course (if appropriate).
  - h. Names and academic rank or title of the program director and faculty (and medical director for pathologists' assistant programs).
  - i. Current tuition and fees including withdrawals and refund policies.
  - j. Policies and processes by which students may perform direct patient and/or reportable work.

- k. Policies and procedures for:
  - i. Advising and guiding students through the program while maintaining confidentiality and impartiality.
  - ii. Obtaining clinical/applied learning experience assignments, specifically addressing if applied learning experiences are not provided through programmatic processes, or cannot be immediately guaranteed.
  - iii. Student grievance and appeals.
  - iv. Program completion, probation, suspension, dismissal, and academic appeals.
- l. Academic calendar.
- m. Rules and regulations governing acceptable personal and academic conduct, including expectations for behavior while completing clinical/applied learning experiences.
- n. A line of authority for administrative personnel including:
  - i. Roles and responsibilities as they apply to enrolled students.
  - ii. Contact information.

## **B. Student Records**

1. The program must maintain student records, conforming to any governmental or sponsor regulations.
2. The student transcript/student record must be retained permanently by the sponsor and contain at least:
  - a. legal name
  - b. grades and credits
  - c. dates of admission and completion

## **C. Health and Safety**

1. Health
  - a. The program must provide evidence that the health and safety of students, faculty, patients, and program specific staff is safeguarded.
2. Safety
  - a. The program must provide evidence that each enrolled student, all faculty members, and program specific staff have received biohazard and safety training.

## **V. Operational Policies**

### **Fair Practices**

- A. Student recruitment and admission must be non-discriminatory in accordance with existing governmental regulations and those of the sponsor.
- B. Faculty recruitment and employment practices must be non-discriminatory in accordance with existing governmental regulations and those of the sponsor.
- C. The granting of the degree or certificate must not be contingent upon any type of external certification or licensure examination.

- D. A general plan must be provided, addressing temporary and permanent program closure. In the event of such closure, a detailed plan which includes provisions for current students to complete their course of study must be submitted to NAACLS within 30 days of the official announcement.
- E. Students must have an assigned preceptor, appropriate for the discipline, who directly oversees their clinical/applied learning experiences.
- F. Students may not be substituted for laboratory employees/personnel to perform direct patient and/or reportable work, during their clinical/applied learning experiences.
- G. Student employment at a clinical/applied learning site must be non-compulsory and must be outside of assigned applied learning experiences/academic hours.

## **VI. Administrative: Maintaining Accreditation**

### **Program/Sponsoring Institution Responsibilities**

Programs are required to comply with administrative requirements for maintaining accreditation including:

- A. Submitting required documentation to NAACLS by the established deadline. These include but are not limited to self-study reports, applications for continuing accreditation and required Progress Reports, Interim Report and Action Plans.
- B. Paying accreditation fees, as determined by NAACLS, by the due date.
- C. Informing NAACLS of relevant administrative and operational changes within 30 days. These include changes in program official names, physical addresses, URL or telephone numbers; status or location, changes in CEO/dean or president/chancellor, and institution name.
- D. Agreeing to a site visit date before the end of the period for which accreditation is awarded.
- E. Submitting an outcomes report on an annual basis to NAACLS addressing major changes, if any, and program assessment standards (Standard II) by the established deadline date.
- F. Verifying compliance with these standards upon request from NAACLS, which may include submitting to an off-cycle site visit.
- G. Protecting the intellectual property of NAACLS materials by:
  - 1. Using proper citations when sharing NAACLS content or materials.
  - 2. Obtaining written approval prior to distributing any content or materials purchased from NAACLS.
- H. Submitting all materials and conducting all NAACLS-accreditation related communication in English.
  - 1. All material translations to be completed by an individual with experience in or knowledge of medical laboratory terminology.



# Unique Standards for the Biomedical Sciences (BMS)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the biomedical sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of biomedical science programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Biomedical Scientist Profession

Several different professionals are encompassed under the NAACLS-defined umbrella of biomedical scientist. The biomedical scientist is qualified by academic and applied science education to provide service and/or research in existing or emerging professions outside of what are considered traditional clinical laboratory environments. Examples may include clinical embryologist or nanotechnologist. The specific scope of practice and entry-level competencies will vary depending on each unique profession, and these professionals may work in industry or specialty clinics and laboratories.

Biomedical scientists practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, additional health care professionals, and others in laboratory practice as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the patient are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education.

Biomedical scientists demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

### Description of Career Entry-Level Competencies of the Biomedical Scientist

The biomedical scientist will have diverse responsibilities in areas of analysis and/or clinical decision-making, regulatory compliance with applicable regulations, education, and quality assurance/performance improvement wherever laboratory testing is researched, developed or performed.

At career entry-level, the biomedical scientist will have the following professional competencies.

They will have the ability to:

### **A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## **VII. Professional Education Program Administration**

### **A. Program Director**

The program director must be a laboratory professional who:

#### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. A relevant certification, licensure, or recognition appropriate for the field.
- c. Three years of teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold relevant certification, licensure, or recognition appropriate for the field, a qualified professional who does hold relevant certification, licensure, or recognition appropriate for the field must hold appointment as an accreditation liaison.

#### 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
  - b. Provide evidence that s/he participates in the budget preparation process.
  - c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
  - d. Be responsible for maintaining NAACLS accreditation of the program.
  - e. Have regular and consistent contact with students, faculty, administration, and program personnel.
3. Appointments  
The program director must have a faculty or clinical appointment at the sponsoring institution.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications  
The site program administrator must:
  - a. Have a degree appropriate with the program level:
  - b. Hold the same level certification required of a program director.
  - c. Have at least of one year of experience in laboratory science education to include knowledge of:
    - i. education methods
    - ii. program assessment and administration
2. Responsibilities  
The site program administrator, when required, is responsible for:
  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructor**

1. Didactic Instructor Appointments  
The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.
  - a. Qualifications  
Faculty/instructors designated by the program must:
    - i. Demonstrate adequate knowledge and proficiency in their content areas.
    - ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities  
The responsibilities of the faculty/instructors must include:
    - i. Participation in teaching courses.
    - ii. Evaluation of student achievement.
    - iii. Development of curriculum, policy and procedures.
    - iv. Assessment of program outcomes.
2. Clinical/Applied Learning Experience Liaison

At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/applied learning experiences for students.

a. Qualifications

The clinical/applied learning experience liaison must:

- i. Be a laboratory professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
- ii. Demonstrate knowledge of the program discipline.
- iii. Have at least one year of experience as a health care professional.

b. Responsibilities

The clinical/applied learning experience liaison must be responsible for:

- i. Coordinating clinical instruction at the site.
- ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.
- c. Holds relevant certification, licensure, or recognition appropriate for the field.

2. Responsibilities

The accreditation liaison, when required, must:

- a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty, and program personnel.

## **VIII. BMS Curriculum Requirements**

### **A. Instructional Areas**

1. Prerequisite courses in biological sciences, chemistry and mathematics that provide the foundation for course work required in the professional program.

2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical and post-analytical components of laboratory services. This includes collecting, processing, and analyzing biological specimens and other substances, principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, foundations of laboratory operations and management and continuous assessment of laboratory services for all major areas practiced in the contemporary field and level of practice.
4. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to the field of practice.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.
  - c. Communications sufficient to serve the needs of patients, the public and members of the health care team and/or professional community.
  - d. Principles and practices of administration and supervision as applied to the field of practice.
  - e. Sufficient educational methodologies and terminology to train/educate users and providers of laboratory services.
  - f. Principles and practices of clinical study design, implementation and dissemination of results.
  - g. Interprofessional education and collaborative practice.

## **B. Learning Experiences**

1. Learning experiences must be properly sequenced and include necessary content and activities to enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII.A.2.
2. After demonstrating competency, students, with qualified supervision, may be permitted to perform procedures.

## **C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design

# Unique Standards for the Cytogenetic Technologist (CG)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of cytogenetic technology programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Cytogenetics Profession

Cytogenetic technologist professionals are qualified by academic and applied science education to provide service and research in classical cytogenetics (chromosome analysis) molecular cytogenetics (fluorescent in situ hybridization – FISH), genomic analysis (array comparative genome hybridization) and other related areas in rapidly changing and dynamic healthcare delivery systems. They have diverse and multi-level functions in the areas of chromosome and genome analysis and clinical decision-making, information management, regulatory compliance, education, and quality assurance/performance improvement wherever constitutional or acquired genetics testing is researched, marketed, developed or performed. Cytogenetic technology professionals perform, develop, evaluate, correlate and assure accuracy and validity of laboratory testing and procedures; direct and supervise laboratory resources and operations; and collaborate in the diagnosis and treatment of patients. They possess skills for financial, operations, marketing, and human resource management of the genetics laboratory.

Cytogenetic technologist professionals practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, health care professionals, and others in laboratory practice, as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment to the patient are essential qualities. Communication skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Cytogenetic technologist professionals demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

## Description of Career Entry-Level Competencies of the Cytogenetic Technologist

At career entry-level, the cytogenetic technologist will have the following professional competencies.

They will have the ability to:

### A. Professional Behaviors and Communication

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### B. Safety and Compliance

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### C. Education and Research

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

### D. Laboratory Operations

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.



### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## **VII. CG Program Administration**

### **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### 1. Qualifications

The program director must have:

- a. Earned their master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification in cytogenetics or ABMGG certification in clinical cytogenetics.
- c. Three years of teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation and certification procedures.

- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification in cytogenetics or ABMGG certification in clinical cytogenetics, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification in cytogenetics or ABMGG certification in clinical cytogenetics must hold appointment as an accreditation liaison.
2. Responsibilities  
The program director must:
    - a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
    - b. Provide evidence that s/he participates in the budget preparation process.
    - c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
    - d. Be responsible for maintaining NAACLS accreditation of the program.
    - e. Have regular and consistent contact with students, faculty, and program personnel.
  3. Appointments  
The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited CG program prior to October 1, 2013, remain eligible as a program director.

## **6. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications  
The site program administrator must:
  - a. Have a bachelor's degree.
  - b. Hold the same level certification required of a program director.
  - c. Have at least one year of experience in medical laboratory science education to include knowledge of:
    - i. education methods
    - ii. program assessment and administration
    - iii. certification/licensure procedures
2. Responsibilities  
The site program administrator, when required, is responsible for:
  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

## **7. Faculty/Instructors**

1. Didactic Instructor Appointments  
The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

- a. Qualifications  
Faculty/instructors designated by the program must:
    - i. Demonstrate adequate knowledge and proficiency in their content areas.
    - ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities  
The responsibilities of the faculty/instructors must include:
    - i. Participation in teaching courses.
    - ii. Evaluation of student achievement.
    - iii. Development of curriculum, policy and procedures.
    - iv. Assessment of program outcomes.
2. Clinical/Applied Learning Experience Liaison  
At least one clinical liaison/ applied learning experience, who is employed by the clinical/applied learning site, must be designated at each clinical site affiliated with the program to coordinate clinical experiences for students.
- a. Qualifications  
The clinical liaison must:
    - i. Be a health care professional who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
    - ii. Demonstrate knowledge of the program discipline.
    - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities  
The clinical/applied learning experiences liaison must be responsible for:
    - i. Coordinating clinical/applied learning instruction at the site.
    - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of medical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications  
The accreditation liaison, when required, must be a medical laboratory professional who:
  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification in cytogenetics or ABMGG certification in clinical cytogenetics.
2. Responsibilities  
The accreditation liaison, when required, must:
  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.

- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty and program personnel.

## VIII. CG Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The program curriculum must include the following scientific content:
  - a. Specimen preparation and processing.
  - b. Molecular cytogenetic testing.
  - c. Chromosome analysis and imaging.
  - d. Laboratory operations including safety, professional standards and conduct, quality control, guidelines and regulations.
4. The program curriculum must also include:
  - a. Principles of interpersonal and interdisciplinary communication and team-building skills and the significance of continuing professional development.
  - b. Principles and practices of administration and supervision.
  - c. Educational methodologies and terminology sufficient to train/educator users and providers of laboratory services sufficient for future clinical faculty.
  - d. Principles and practices of clinical study design, implementation and dissemination of results.
  - e. Interprofessional education and collaborative practice.

### B. Learning Experiences

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

### C. Evaluations

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Diagnostic Molecular Scientist (DMS)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of diagnostic molecular science programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Diagnostic Molecular Scientist Profession

Diagnostic molecular scientist professionals are qualified by academic and applied science education to provide service and research in the molecular diagnosis of acquired, inherited, and infectious diseases. They have diverse and multi-level functions in the areas of analysis and clinical decision-making, information management, regulatory compliance, education, and quality assurance/performance improvement. Diagnostic molecular scientists perform, develop, evaluate, correlate, and assure accuracy and validity of laboratory testing and procedures; direct and supervise laboratory resources and operations; and collaborate in the diagnosis and treatment of patients. They possess skills for financial, operations, marketing, and human resource management of the molecular pathology laboratory. Diagnostic molecular scientists practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, health care professionals, and others in laboratory practice, as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment to the patient are essential qualities. Communication skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Diagnostic molecular scientists demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community. An attitude of respect for the patient and confidentiality of the patient's record and/or diagnosis must be maintained.

### Description of Career Entry-Level Competencies of the Diagnostic Molecular Scientist

At career entry-level, the diagnostic molecular scientist will have the following professional competencies.

They will have the ability to:

**A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

**B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

**C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

**D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

**E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

## F. Analytical Competencies

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

## G. Post-Analytical Competencies

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

# VII. DMS Program Administration

## A. Program Director

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification in Molecular Biology or ABMGG certification in Molecular Biology.
- c. Three years of teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification in Molecular Biology or ABMGG certification in Molecular Biology, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification in Molecular Biology or ABMGG certification in Molecular Biology must hold appointment as an accreditation liaison.

## 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process.
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program.
- e. Have regular and consistent contact with students, faculty, and program personnel.

## 3. Appointments

The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited DMS program prior to October 1, 2013, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

### 1. Qualifications

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. education methods
  - ii. program assessment and administration
  - iii. certification/licensure procedures

### 2. Responsibilities

The site program administrator, when required, is responsible for:

- a. Coordinating teaching and clinical/applied learning experiential education.
- b. Evaluating program effectiveness.
- c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

#### a. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

#### b. Responsibilities



The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
  - ii. Evaluation of student achievement.
  - iii. Development of curriculum, policy and procedures.
  - iv. Assessment of program outcomes.
2. Clinical/Applied Learning Experience Liaison
- At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical site affiliated with the program to coordinate clinical experiences for students.
- a. Qualifications
 

The clinical liaison must:

    - i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
    - ii. Demonstrate knowledge of the program discipline.
    - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities
 

The clinical/applied learning experience liaison must be responsible for:

    - i. Coordinating clinical/ applied learning experience instruction at the site.
    - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of medical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications
 

The accreditation liaison, when required, must be a medical laboratory professional who:

  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification in Molecular Biology or ABMGG certification in Molecular Biology.
2. Responsibilities
 

The accreditation liaison, when required, must:

  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

## VIII. DMS Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite courses in biological sciences including genetics, chemistry and mathematics that provide the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical and post-analytical components of diagnostic molecular laboratory services covering diagnostic molecular tests used to detect or diagnose acquired (infectious and noninfectious) diseases and genetic predisposition or disorders. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services.
4. The program curriculum must include the following scientific content:
  - a. Organic and/or biochemistry, genetics, cell biology, microbiology, immunology, and diagnostic molecular biology.
  - b. Principles, methodologies, and applications of molecular microbiology (infectious diseases), molecular pathology (hematology/oncology), and molecular genetics.
  - c. Techniques of molecular science must include current techniques in each of separation and detection, amplification, and sequence analysis, for example sanger sequencing.
  - d. Clinical significance of laboratory procedures in diagnosis and treatment.
5. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to diagnostic molecular science.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.
  - c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
  - d. Principles and practices of administration, supervision, and quality management as applied to diagnostic molecular science.
  - e. Sufficient educational methodologies and terminology to train/educate users and providers of laboratory services.
  - f. Principles and practices of applied study design, implementation and dissemination of results.
  - g. Interprofessional education and collaborative practice.

**B. Learning Experiences**

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

**C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Histotechnician (HT)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of histotechnician programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Histotechnology Profession

Histotechnician professionals are qualified by academic and applied science education to provide service and research in histotechnology and related areas in rapidly changing and dynamic healthcare delivery systems. They have diverse and multi-level functions in the areas of analysis and clinical decision-making, information management, regulatory compliance, education, and quality assurance/performance improvement wherever anatomic pathology testing is researched, marketed, developed or performed.

Histotechnician professionals perform, develop, evaluate, correlate and assure accuracy and validity of laboratory testing and procedures; direct and supervise anatomic pathology laboratory resources and operations; and collaborate in the diagnosis and treatment of patients. They possess skills for financial, operations, marketing, and human resource management of the histopathology laboratory.

Histotechnician professionals work independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, health care professionals, and others in laboratory practice, as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment to the patient are essential qualities. Communication skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Histotechnician professionals demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

### Description of Career Entry-Level Competencies of the Histotechnician

At career entry-level, the histotechnician will have the following professional competencies.

They will have the ability to:

**A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

**B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

**C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

**D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

**E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

## F. Analytical Competencies

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

## VII. HT Program Administration

### A. Program Director

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### 1. Qualifications

The program director must have:

- a. A bachelor's degree or higher.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist or histotechnician.
  - i. If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist or histotechnician, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist or histotechnician must hold appointment as education coordinator.
- c. Three years teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist or histotechnician, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist or histotechnician must hold appointment as an accreditation liaison.

#### 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
  - b. Provide evidence that s/he participates in the budget preparation process.
  - c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
  - d. Be responsible for maintaining NAACLS accreditation of the program.
  - e. Have regular and consistent contact with students, faculty, and program personnel.
3. Appointments
- The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited HT program prior to October 1, 2013, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications
 

The site program administrator must:

  - a. Have a bachelor's degree
  - b. Hold the same level certification required of a program director
  - c. Have at least one year of experience in medical laboratory science education to include knowledge of:
    - i. education methods
    - ii. program assessment and administration
    - iii. certification/licensure procedures
2. Responsibilities
 

The site program administrator, when required, is responsible for:

  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

1. Didactic Instructor Appointments
 

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

  - a. Qualifications
 

Faculty/instructors designated by the program must:

    - i. Demonstrate adequate knowledge and proficiency in their content areas.
    - ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities
 

The responsibilities of the faculty/instructors must include:

    - i. Participation in teaching courses.

- ii. Evaluation of student achievement.
  - iii. Development of curriculum, policy and procedures.
  - iv. Assessment of program outcomes.
- 2. Clinical/Applied Learning Experiences Liaison
 

At least one clinical liaison, who is employed by the clinical/applied learning experiences site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical experiences for students.

  - a. Qualifications
 

The clinical liaison must:

    - i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
    - ii. Demonstrate knowledge of the program discipline.
    - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities
 

The clinical/applied learning experience liaison must be responsible for:

    - i. Coordinating clinical/applied learning experience instruction at the site.
    - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of medical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications
 

The accreditation liaison, when required, must be a medical laboratory professional who:

  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist.
2. Responsibilities
 

The accreditation liaison, when required, must:

  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

#### **F. Education Coordinator (when required)**

1. Qualifications
 

The education coordinator, when required, must be a medical laboratory professional who:

  - a. Has a bachelor's degree and three years of experience in the program discipline.



- b. Holds ASCP BOC U.S. certification as a histotechnologist or histotechnician.
  - c. Has knowledge of NAACLS accreditation and current certification procedures.
2. Responsibilities  
The education coordinator, when required, must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

## VIII. HT Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry –level competencies of the program discipline.
3. Applications of histology, immunohistochemistry, enzyme histochemistry, cytology specimen preparation, electron microscopy and light microscopy. This includes principles and methodologies, problem-solving, and troubleshooting, for all major areas practiced in the contemporary histopathology laboratory.
4. Concepts and principles of laboratory operations must include:
  - a. accessioning
  - b. gross examination
  - c. frozen sectioning
  - d. fixation
  - e. processing
  - f. embedding/microtomy
  - g. staining principles, procedures, reagents and quality control
  - h. laboratory operations including safety, instrumentation, quality control, laboratory mathematics
5. Identifying tissue structures and staining characteristics.
6. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to histotechnology.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.
  - c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
  - d. Principles and practices of safety as applied to histotechnology.
  - e. Interprofessional and collaborative practice.

### B. Learning Experiences

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.

2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

**C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. Evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Histotechnologist (HTL)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of histotechnologist programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Histotechnology Profession

Histotechnologist professionals are qualified by academic and applied science education to provide service and research in histotechnology and related areas in rapidly changing and dynamic healthcare delivery systems. They have diverse and multi-level functions in the areas of analysis and clinical decision-making, information management, regulatory compliance, education, and quality assurance/performance improvement wherever anatomic pathology testing is researched, marketed, developed or performed.

Histotechnologist professionals perform, develop, evaluate, correlate and assure accuracy and validity of laboratory testing and procedures; direct and supervise anatomic pathology laboratory resources and operations; and collaborate in the diagnosis and treatment of patients. They possess skills for financial, operations, marketing, and human resource management and leadership of the histopathology laboratory.

Histotechnologist professionals work independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, health care professionals, and others in laboratory practice, as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment to the patient are essential qualities. Communication skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Histotechnologist professionals demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

### Description of Career Entry-Level Competencies of the Histotechnologist

At career entry-level, the histotechnologist will have the following professional competencies.

They will have the ability to:

**A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

**B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

**C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

**D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

**E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

## F. Analytical Competencies

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

## G. Post-Analytical Competencies

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

# VII. HTL Program Administration

## A. Program Director

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist.
  - i. If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist must hold appointment as education coordinator.
- c. Three years of teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist, a qualified professional who

does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist must hold appointment as an accreditation liaison.

## 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process.
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program.
- e. Have regular and consistent contact with students, faculty, and program personnel.

## 3. Appointments

The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited HTL program prior to October 1, 2013, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

### 1. Qualifications

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. education methods
  - ii. program assessment and administration
  - iii. certification/licensure procedures

### 2. Responsibilities

The site program administrator, when required, is responsible for:

- a. Coordinating teaching and clinical/applied learning experiential education.
- b. Evaluating program effectiveness.
- c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

#### a. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.

- ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities
    - The responsibilities of the faculty/instructors must include:
      - i. Participation in teaching courses.
      - ii. Evaluation of student achievement.
      - iii. Development of curriculum, policy and procedures.
      - iv. Assessment of program outcomes.
- 2. Clinical/Applied Learning Experience Liaison
 

At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical experience for students.

  - a. Qualifications
    - The clinical/applied learning experience liaison must:
      - i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
      - ii. Demonstrate knowledge of the program discipline.
      - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities
    - The clinical/applied learning experience liaison must be responsible for:
      - i. Coordinating clinical/applied learning instruction at the site.
      - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications
 

The accreditation liaison, when required, must be a medical laboratory professional who:

  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist.
2. Responsibilities
 

The accreditation liaison, when required, must:

  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

## F. Education Coordinator (when required)

### 1. Qualifications

The education coordinator, when required, must be a medical laboratory professional who:

- a. Has at least a bachelor's degree and three years of experience in the program discipline.
- b. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a histotechnologist.
- c. Has knowledge of NAACLS accreditation and current certification procedures.

### 2. Responsibilities

The education coordinator, when required, must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

## VIII. HTL Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. Applications of histology, immunohistochemistry, enzyme histochemistry, cytology specimen preparation, electron microscopy, light microscopy, management, education, and regulations. This includes principles and methodologies, performance of tests, problem-solving, troubleshooting, techniques, interpretation of procedures and results of laboratory services for all major areas practiced in the contemporary histopathology laboratory.
4. Concepts and principles of laboratory operations must include:
  - a. accessioning
  - b. gross examination
  - c. frozen sectioning
  - d. fixation
  - e. processing, to include chemistry principles and theories
  - f. embedding/microtomy
  - g. staining principles, procedures, reagents and quality control
  - h. laboratory operations including safety, instrumentation, quality control, and regulations
5. Identification of tissue structures, cell components, and their staining characteristics and relating them to physiological functions.
6. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to histotechnology.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.



- c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
- d. Principles and practices of administration, supervision, and safety as applied to histotechnology.
- e. Sufficient education techniques and terminology to train/educate users and providers of laboratory services.
- f. Interprofessional education and collaborative practice.

## **B. Learning Experiences**

1. Learning experiences must be properly sequenced and include necessary content and activities to enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

## **C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Medical Laboratory Assistant (MLA)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of medical laboratory assistant programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Medical Laboratory Assistant Profession

Medical laboratory assistants are qualified by academic and practical education to perform multiple skills to support medical laboratory professionals. Medical laboratory assistants collect, transport, and process blood and non-blood specimens for analysis. They prepare and reconstitute reagents, standards and controls, perform waived and point of care test (POCT) procedures using standard protocols and follow established quality control protocols.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment are essential qualities. Medical laboratory assistants consider age specific and psycho-social factors that may impact specimen collection. Communication skills involve direct interaction with the patient, family members of the patient, fellow members of the laboratory team, and other members of the healthcare team. Medical laboratory assistant professionals display ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

### Description of Career Entry-Level Competencies of the Medical Laboratory Assistant

At career entry-level, the medical laboratory assistant will have the following professional competencies.

They will have the ability to:

#### A. Professional Behaviors and Communication

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

## **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

## **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

## **D. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

# **VII. MLA Program Administration**

## **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

### 1. Qualifications

The program director must have:

- a. A bachelor's degree or higher.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist or medical laboratory technician.
- c. Three years of experience in medical laboratory science education
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist or medical laboratory technician, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist or medical laboratory technician, must hold appointment as an accreditation liaison.

Program directors who have been approved as a program director of a NAACLS approved MLA program prior to October 1, 2013, remain eligible as a program director.

## 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program.
- e. Have regular and consistent contact with students, faculty, and program personnel.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

### 1. Qualifications

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. education methods
  - ii. program assessment and administration
  - iii. certification/licensure procedures

### 2. Responsibilities

The site program administrator, when required, is responsible for:

- a. Coordinating teaching and clinical/applied learning experiential education.
- b. Evaluating program effectiveness.
- c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

#### 1. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content area.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

#### 2. Responsibilities

The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
- ii. Evaluation of student achievement.

- iii. Development of curriculum, policy and procedures.
  - iv. Assessment of program outcomes.
- 2. Clinical/Applied Learning Experience Liaison
 

At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical experiences for students.

  - a. Qualifications
 

The clinical liaison must:

    - i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
    - ii. Demonstrate knowledge of the program discipline.
    - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities
 

The clinical/applied learning experience liaison must be responsible for:

    - i. Coordinating clinical/applied learning instruction at the site.
    - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications
 

The accreditation liaison, when required, must be a medical laboratory professional who:

  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist or medical laboratory technician.
1. Responsibilities
 

The accreditation liaison, when required, must:

  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

## **VIII. MLA Curriculum Requirements**

### **A. Instructional Areas**

1. The program curriculum must include instruction and experiences in the following:

- a. 100 hours of clinical experiences.
  - b. Core module competencies must be completed.
  - c. Instruction in a variety of skills including: blood collection, preparation/reconstitution of reagents, standards and controls, perform tests at the medical laboratory assistant level and follow established quality control protocols.
  - d. Curriculum in any module(s) beyond the core module must meet the minimum required standards as stated for the core module. These modules include, but are not limited to: chemistry, donor room, hematology, immunology, microbiology and/or urinalysis.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
  3. The program curriculum must also include:
    - a. The application of safety and governmental regulations compliance.
    - b. Principles and practices of professional conduct, working with diverse stakeholders, and the significance of continuing professional development.
    - c. Communicating effectively with a range of audiences; sufficient to serve the needs of patients, the public, and members of the health care team.
    - d. Interprofessional education and collaborative practice.

## **B. Learning Experiences**

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

## **C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design

# Unique Standards Medical Laboratory Microbiologist (MLM)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of medical laboratory microbiology programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Medical Laboratory Microbiologist Profession

The medical laboratory microbiologist is qualified by academic and applied science education to provide service and research in clinical laboratory science and related areas in rapidly changing and dynamic healthcare delivery systems. Medical laboratory microbiologists perform, develop, evaluate, correlate and ensure accuracy and validity of laboratory information, direct and supervise clinical laboratory resources and operations, and collaborate in the diagnosis and treatment of patients, specifically in the area of medical microbiology. This practitioner has diverse and multi-level functions in the principles, methodologies and performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services for all major areas practiced in the public health, and research microbiology laboratory. Medical laboratory microbiologists possess the skills necessary for financial, operations, marketing, and human resource management of the medical microbiology laboratory.

Medical laboratory microbiologists practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, and other health care professionals, as well as the public, in laboratory operations.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the patient are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education.

Medical laboratory microbiologists demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

## Description of Entry-Level Competencies of the Medical Laboratory Microbiologist

At entry-level, the medical laboratory microbiologist will possess the entry-level competencies to perform the full range of clinical laboratory tests in clinical Microbiology, Molecular Diagnostics, Laboratory Management and Operations, and other emerging diagnostics. The medical laboratory microbiologist will play a role in the development and evaluation of test systems and interpretive algorithms.

The medical laboratory microbiologist will have diverse responsibilities in areas of analysis and clinical decision-making, regulatory compliance with applicable regulations.

Entry-level practitioners will also be responsible for quality assurance and performance improvement wherever laboratory testing is researched, developed, or performed.

At career entry-level, the medical laboratory microbiologist will have the following professional competencies.

They will have the ability to:

### A. Professional Behaviors and Communication

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### B. Safety and Compliance

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### C. Education and Research

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.



Evaluate clinical research studies and data sets to assess applicability and validity.

#### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

#### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

#### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

#### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## VII. MLM Program Administration

### A. Program Director

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist or categorical ASCP BOC certification in Microbiology.
  - i. If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a generalist certification as a medical laboratory scientist or categorical ASCP BOC certification in Microbiology, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist must hold appointment as education coordinator.
- c. Three years of teaching experience in medical microbiology or related area
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist or categorical ASCP BOC certification in Microbiology, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist or categorical ASCP BOC certification in Microbiology must hold appointment as an accreditation liaison.

#### 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process.
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program
- e. Have regular and consistent contact with students, faculty, and program personnel.

#### 3. Appointments

The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited MLS program prior to October 1, 2013, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

### **1. Qualifications**

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. education methods
  - ii. program assessment and administration
  - iii. certification/licensure procedures

### **2. Responsibilities**

The site program administrator, when required, is responsible for:

- a. Coordinating teaching and clinical/applied learning experiential education.
- b. Evaluating program effectiveness.
- c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

### **1. Didactic Instructor Appointments**

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

#### **a. Qualifications**

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

#### **b. Responsibilities**

The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
- ii. Evaluation of student achievement.
- iii. Development of curriculum, policy and procedures.
- iv. Assessment of program outcomes.

### **2. Clinical/Applied Learning Experience Liaison**

At least one clinical/ applied learning experience liaison, who is employed by the clinical/ applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/ applied learning experiences for students.

#### **a. Qualifications**

The clinical/ applied learning experience liaison must:

- i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical experiences of the students.
- ii. Demonstrate knowledge of the program discipline.
- iii. Have at least one year of experience as a health care professional.

#### **b. Responsibilities**

The clinical liaison must be responsible for:

- i. Coordinating clinical instruction at the site.
- ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

##### 1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.
- c. Holds ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist or categorical ASCP BOC certification in Microbiology.

##### 2. Responsibilities

The accreditation liaison, when required, must:

- a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty and program personnel.

#### **F. Education Coordinator (when required)**

##### 1. Qualifications

The education coordinator, when required, must be a medical laboratory professional who:

- a. Has at least a bachelor's degree and three years of experience in the program discipline.
- b. Holds ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist.
- c. Has knowledge of NAACLS accreditation and current certification procedures.

##### 2. Responsibilities

The education coordinator, when required, must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

### **VIII. MLM Curriculum Requirements**

#### **A. Instructional Areas**

1. The program must identify prerequisite courses in biological sciences, chemistry and mathematics that provide the foundation for course work required in the medical microbiology program.

2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical and post-analytical components of microbiology laboratory services. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services for all major areas practiced in the contemporary clinical microbiology laboratory.
4. The program curriculum must include the following scientific content:
  - a. immunology/serology
  - b. clinical bacteriology
  - c. antimicrobial susceptibility testing and resistance
  - d. molecular microbiology
  - e. mycology
  - f. parasitology
  - g. mycobacteriology and nocardia
  - h. virology
  - i. microbiology laboratory operations and management
5. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to the medical microbiology laboratory.
  - b. Principles and practices of professional conduct, working with diverse stakeholders, and the significance continuing professional development.
  - c. Communicating effectively with a range of audiences; sufficient to serve the needs of patients, the public and members of the health care team.
  - d. Principles and practices of administration and supervision as applied to medical microbiology.
  - e. Educational methodologies and terminology sufficient to train/educate users and providers of microbiology laboratory services.
  - f. Principles and practices of clinical study design, implementation and dissemination of results.
  - g. Interprofessional education and collaborative practice.

## **B. Learning Experiences**

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

## **C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.

2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards Medical Laboratory Scientist (MLS)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the medical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of medical laboratory science programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Medical Laboratory Scientist Profession

The medical laboratory scientist is qualified by academic and applied science education to provide service and research in medical laboratory science and related areas in rapidly changing and dynamic healthcare delivery systems. Medical laboratory scientists perform, develop, evaluate, correlate and assure accuracy and validity of laboratory information; direct and supervise medical laboratory resources and operations; and collaborate in the diagnosis and treatment of patients. The medical laboratory scientist has diverse and multi-level functions in the principles, methodologies and performance of assays; problem-solving; troubleshooting techniques; interpretation and evaluation of clinical procedures and results; statistical approaches to data evaluation; principles and practices of quality assurance/quality improvement; and continuous assessment of laboratory services for all major areas practiced in the contemporary clinical laboratory.

Medical laboratory scientists possess the skills necessary for financial, operations, marketing, and human resource management and leadership of the clinical laboratory.

Medical laboratory scientists practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, other health care professionals, and others in laboratory practice as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the patient are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education.

Medical laboratory scientists demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

## **Description of Career Entry-Level Competencies of the Medical Laboratory Scientist**

At entry-level, the medical laboratory scientist will possess the entry-level competencies necessary to perform the full range of medical laboratory tests in areas such as Clinical Chemistry, Hematology/Hemostasis, Immunology, Immunohematology/Transfusion medicine, Microbiology, Urine and Body Fluid Analysis and Laboratory Operations, and other emerging diagnostics, and will play a role in the development and evaluation of test systems and interpretive algorithms.

The medical laboratory scientist will have diverse responsibilities in areas of analysis and clinical decision-making, regulatory compliance with applicable regulations, education, and quality assurance/performance improvement wherever laboratory testing is researched, developed or performed.

At career entry-level, the medical laboratory scientist will have the following professional competencies.

They will have the ability to:

### **A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.



Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

#### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

#### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

#### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

#### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## VII. MLS Program Administration

### A. Program Director

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist.
- c. Three years of teaching experience.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist must hold appointment as an accreditation liaison.

#### 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process.
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program.
- e. Have regular and consistent contact with students, faculty and program personnel.

#### 3. Appointments

The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited MLS program prior to October 1, 2013, remain eligible as a program director.

### B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)

#### 1. Qualifications

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. education methods

- ii. program assessment and administration
  - iii. certification/licensure procedures
- 2. Responsibilities
 

The site program administrator, when required, is responsible for:

  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

### C. Faculty/Instructors

1. Didactic Instructor Appointments
 

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

  - a. Qualifications
 

Faculty/instructors designated by the program must:

    - i. Demonstrate adequate knowledge and proficiency in their content areas.
    - ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities
 

The responsibilities of the faculty/instructors must include:

    - i. Participation in teaching courses.
    - ii. Evaluation of student achievement.
    - iii. Development of curriculum, policy and procedures.
    - iv. Assessment of program outcomes.
2. Clinical/Applied Learning Experiences Liaison
 

At least one clinical/applied learning experiences liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/applied learning experiences for students.

  - a. Qualifications
 

The clinical/applied learning experience liaison must:

    - i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
    - ii. Demonstrate knowledge of the program discipline.
    - iii. Have at least one year of experience as a health care professional.
  - b. Responsibilities
 

The clinical/applied learning experience liaison must be responsible for:

    - i. Coordinating clinical/applied learning experiences instruction at the site.
    - ii. Maintaining effective communication with the program director or designee.

### D. Advisory Committee

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of medical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

## E. Accreditation Liaison (when required, for international programs only)

### 1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.
- c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist.

### 2. Responsibilities

The accreditation liaison, when required, must:

- a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty and program personnel.

## VIII. MLS Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite courses in biological sciences, chemistry and mathematics that provide the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical, and post-analytical components of laboratory services. This includes principles and methodologies including collection, processing, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services in the following current medical laboratory scientific content areas:
  - a. clinical chemistry
  - b. hematology/hemostasis
  - c. immunology
  - d. immunohematology/transfusion medicine
  - e. microbiology
  - f. urine and body fluid analysis
  - g. laboratory operations and management
4. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to medical laboratory science.

- b. Principles and practices of professional conduct and the significance of continuing professional development.
- c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
- d. Principles and practices of administration and supervision as applied to medical laboratory science.
- e. Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services.
- f. Principles and practices of clinical and research study design, implementation, and dissemination of results.
- g. Interprofessional education and collaborative practice.

### **B. Learning Experiences**

1. Learning experiences must be properly sequenced and include necessary content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII.A.
2. After demonstrating competency, students, with qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

### **C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards Medical Laboratory Technician (MLT)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the medical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of medical laboratory technician programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Medical Laboratory Technician Profession

The medical laboratory technician is qualified by academic and applied science education to provide service in medical laboratory science and related areas in rapidly changing and dynamic healthcare delivery systems. Medical laboratory technicians perform, evaluate, correlate, and assure accuracy and validity of laboratory information; and collaborate in the diagnosis and treatment of patients. The medical laboratory technician has diverse and multi-level functions in the areas of collecting, processing, and analyzing biological specimens, principles and methodologies, performance of assays, problem solving, troubleshooting techniques, significance of clinical procedures and results, principles and practices of quality assessment, for all major areas practiced in the contemporary clinical laboratory.

Medical laboratory technicians practice independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, other health care professionals, and others in laboratory practice as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the stakeholders are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Laboratory professionals demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

### Description of Entry-Level Competencies of the Medical Laboratory Technician

At entry-level, the medical laboratory technician will possess the entry-level competencies necessary to perform routine medical laboratory tests in areas such as Clinical Chemistry, Hematology/Hemostasis, Immunology, Immunohematology/Transfusion medicine, Microbiology, Urine and Body Fluid Analysis, and Laboratory Operations.

The level of analysis ranges from waived and point of care testing to complex testing encompassing all major areas of the clinical laboratory. The medical laboratory technician will have diverse functions in areas of pre-analytical, analytical, post-analytical processes. The medical laboratory technician will have responsibilities for information processing, training, and quality control monitoring wherever clinical laboratory testing is performed.

At career entry-level, the medical laboratory technician will have the following professional competencies.

They will have the ability to:

### **A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## **VII. MLT Program Administration**

### **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### 1. Qualifications

The program director must have:

- a. An earned master's or doctoral degree.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC generalist certification as a medical laboratory scientist.
- c. Three years of teaching experience.



- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.
  - e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist must hold appointment as an accreditation liaison.
2. Responsibilities
- The program director must:
- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
  - b. Provide evidence that s/he participates in the budget preparation process.
  - c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
  - d. Be responsible for maintaining NAACLS accreditation of the program.
  - e. Have regular and consistent contact with students, faculty, and program personnel.
3. Appointments
- The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited MLT program prior to October 1, 2013, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications
- The site program administrator must:
- a. Have a bachelor's degree.
  - b. Hold the same level certification required of a program director.
  - c. Have at least one year of experience in medical laboratory science education to include knowledge of:
    - i. education methods.
    - ii. program assessment and administration
    - iii. certification/licensure procedures
2. Responsibilities
- The site program administrator, when required, is responsible for:
- a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

a. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

b. Responsibilities

The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
- ii. Evaluation of student achievement.
- iii. Development of curriculum, policy and procedures.
- iv. Assessment of program outcomes.

2. Clinical/Applied Learning Experience Liaison

At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/applied learning experiences for students.

a. Qualifications

The clinical/applied learning experience liaison must:

- i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
- ii. Demonstrate knowledge of the program discipline.
- iii. Have at least one year of experience as a health care professional.

b. Responsibilities

The clinical/applied learning experience liaison must be responsible for:

- i. Coordinating clinical instruction at the site.
- ii. Maintaining effective communication with the program director or designee.

#### D. Advisory Committee

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### E. Accreditation Liaison (when required, for international programs only)

1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.
- c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist.

2. Responsibilities

The accreditation liaison, when required, must:

- a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty and program personnel.

## VIII. MLT Curriculum Requirements

### A. Instructional Areas

1. The program must identify prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical and post-analytical components of laboratory services. This includes principles and methodologies including collection, processing, performance of assays, problem-solving, troubleshooting techniques, significance of clinical procedures and results, principles and practices of quality assessment, for all major areas practiced in the contemporary clinical laboratory. The program curriculum must include the following medical laboratory scientific content:
  - a. clinical chemistry
  - b. hematology/hemostasis
  - c. immunology
  - d. immunohematology/transfusion medicine
  - e. microbiology
  - f. urine and body fluid analysis
  - g. laboratory operations
4. The program curriculum must also include:
  - a. The application of safety and governmental regulations compliance.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.
  - c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
  - d. Interprofessional education and collaborative practice.

### B. Learning Experiences

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

**C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Pathologists' Assistant (Path A)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of pathologists' assistant programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Pathologists' Assistant Profession

A pathologists' assistant (Path A) is a highly trained allied health professional who provides various services under the direction and supervision of a pathologist. Path As are academically and clinically trained to provide accurate and timely processing of a variety of laboratory specimens. Path As are integral in assisting in the diagnostic processes. It is the sole province of the pathologist to render a diagnosis.

Pathologists' assistants perform in a wide scope of clinical practices. Although the majority of pathologists' assistants work in academic and community hospitals, Path As can also be employed in other areas such as private pathology laboratories, forensic pathology laboratories and morgues, reference laboratories, government healthcare systems, and medical teaching facilities. Some Path As are even self-employed business owners providing their pathology expertise via long- and short-term contracts.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the patient are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education. Pathologist's assistant professionals demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

Pathologists' assistants contribute to the overall efficiency of the laboratory or pathology practice in a cost-effective manner. With increased pressure on healthcare systems to control costs, the demand for qualified Pathologists' Assistant is growing every year.

### Description of Career Entry-Level Competencies of the Pathologists' Assistant

At career entry-level, the pathologists' assistant will have the following professional competencies.

They will have the ability to:

### **A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## **VII. Path A Program Administration**

### **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### **1. Qualifications**

The program director must:

- a. Be a graduate of a NAACLS accredited (AAPA approved prior to 1995) pathologists' assistant educational program with an advanced degree (master's or doctoral), currently hold ASCP BOC certification as a Pathologists' Assistant, or a board-certified pathologist.
- i. If the program director is a pathologist, there must be an ASCP certified, NAACLS Accredited program educated pathologists' assistant employed as the educational coordinator/clinical coordinator.
- b. Have a faculty appointment in the sponsoring institution and meet all requirements specified by the institution responsible for providing the didactic

portion of the educational program and maintaining the overall operation of the program.

- c. Have practical knowledge of educational methods and administration as well as current NAACLS accreditation and professional certification procedures, demonstrates adequate knowledge and proficiency in their content areas, demonstrates the ability to teach effectively at the appropriate level.
  - d. (for international programs only) If the program director does not hold ASCP BOC certification as a Pathologists' Assistant, or a board-certified pathologist, a qualified professional who does hold ASCP BOC certification as a Pathologists' Assistant, or a board-certified pathologist must hold appointment as an accreditation liaison.
2. Responsibilities
- The program director must:
- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
  - b. Provide evidence that s/he participates in the budget preparation process.
  - c. Engage in a minimum of 60 hours of documented continuing professional development every three years.
  - d. Be responsible for maintaining NAACLS accreditation of the program
  - e. Have regular and consistent contact with students, faculty, and program personnel.
3. Appointments
- The program director must have a faculty or clinical appointment at the sponsoring institution.

Program directors who have been approved as a program director of a NAACLS accredited PathA program prior to May 1, 2018, remain eligible as a program director.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications
 

The site program administrator must:

  - a. Have a bachelor's degree.
  - b. Hold the same level certification required of a program director.
  - c. Have at least one year of experience in medical laboratory science education to include knowledge of:
    - i. education methods
    - ii. program assessment and administration
    - iii. certification/licensure procedures
2. Responsibilities
 

The site program administrator, when required, is responsible for:

  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.



### C. Faculty/Instructors

#### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.

##### a. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

##### b. Responsibilities

The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
- ii. Evaluation of student achievement.
- iii. Development of curriculum, policy and procedures.
- iv. Assessment of program outcomes.

#### 2. Clinical/Applied Learning Experience Liaison

At least one clinical/applied learning experience liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/applied learning experiences for students.

##### a. Qualifications

The clinical/applied learning experience liaison must:

- i. Be a health care professional staff member of the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
- ii. Demonstrate knowledge of the program discipline.
- iii. Have at least one year of experience as a health care professional.

##### b. Responsibilities

The clinical/applied learning experiences liaison must be responsible for:

- i. Coordinating clinical/applied learning instruction at the site.
- ii. Maintaining effective communication with the program director or designee.

### D. Advisory Committee

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

### E. Accreditation Liaison (when required, for international programs only)

#### 1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.

- c. Holds ASCP BOC certification as a Pathologists' Assistant, or a board-certified pathologist.
2. Responsibilities  
The accreditation liaison, when required, must:
  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

## **F. Education Coordinator (when required)**

1. Qualifications  
The education coordinator, when required, must be a medical laboratory professional who:
  - a. Has maintained 60 credit hours (completed within a three-year time period) of CME related to pathology.
  - b. Holds ASCP BOC U.S. Certification as a Pathologists' Assistant.
  - c. Has knowledge of NAACLS accreditation and current certification procedures.
2. Responsibilities  
The education coordinator/clinical coordinator, when required, must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

## **G. Medical Director**

The Program must have a qualified medical director who does not also serve as the program director.

1. Qualifications  
The medical director must:
  - a. Have a faculty appointment in the sponsoring institution.
  - b. Be a currently licensed or board-certified anatomic pathologist.
2. Responsibilities
  - a. The medical director must provide continuous medical direction for clinical instruction.
  - b. The medical director must actively elicit the understanding and support of practicing physicians and must participate in the clinical instruction of pathology within the program.

## **VIII. Path A Curriculum Requirements**

### **A. Instructional Areas**

1. The program must identify prerequisite courses in biology, chemistry and mathematics that provide the foundation for course work required in the pathologists' assistant program.

2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must provide a comprehensive knowledge of practices in Anatomic Pathology encompassing surgical and autopsy pathology. This includes principles and methodologies, performance of procedures, correlation of clinical information and gross pathology with proper technique, problem solving, troubleshooting techniques, principles and practices of quality assurance/quality improvement, and laboratory management.
4. The program curriculum must include the following scientific and academic content:
  - a. anatomy and basic microanatomy
  - b. human physiology
  - c. general and systemic human pathology
  - d. anatomic pathology
  - e. surgical pathology techniques
    - i. adult
    - ii. pediatric
  - f. autopsy techniques
  - g. medical autopsy techniques
    - i. adult
    - ii. pediatric
  - h. forensic autopsy techniques
    - i. adult
    - ii. pediatric
  - i. toxicology collection techniques
  - j. histological methods and techniques
  - k. concepts of immunohistochemistry
  - l. concepts of molecular diagnostics
  - m. microbiology/immunology
  - n. clinical pathology
  - o. embryology
  - p. laboratory safety
  - q. laboratory information systems
  - r. laboratory management
  - s. medical ethics
  - t. medical terminology
  - u. biomedical photography
5. The program curriculum must also include:
  - a. The application of laboratory safety governmental regulations and standards as applied to anatomic pathology.
  - b. Principles and practices of professional conduct.
  - c. Principles of interpersonal and interdisciplinary communication and team-building skills.
  - d. Principles and practices of administration and supervision as applied to clinical laboratory science.

- e. Educational methodologies.
- f. Interprofessional education and collaborative practice.

**B. Learning Experiences**

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

**C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards for the Phlebotomist (PBT)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of phlebotomy programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Phlebotomy Profession

Phlebotomist professionals are qualified by academic and practical education to collect, transport, and process blood and non-blood specimens for analysis. Phlebotomy professionals collect and instruct patients to collect non-blood specimens such as urine, stool, sputum, throat or other. They select the appropriate phlebotomy equipment, technique and collection site based on a thorough understanding of human anatomy and physiology. Phlebotomy professionals perform venipunctures and capillary (dermal) punctures adhering to all standards governing patient and employee safety. Phlebotomists perform waived and point of care test (POCT) procedures using standard protocol.

The ability to relate to people, a capacity for calm and reasoned judgment, and a demonstration of commitment are essential qualities. Phlebotomists consider age specific and psycho-social factors that may impact specimen collection. Communication skills involve direct interaction with the patient, family members of the patient, fellow members of the laboratory team, and other members of the healthcare team. Phlebotomy professionals display ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the community.

Upon graduation and initial employment, the phlebotomist will be able to demonstrate entry-level competencies in the above areas of professional practice. Refer to the NAACLS Phlebotomist Competencies.

### Description of Career Entry-Level Competencies of the Phlebotomist

At career entry-level, the phlebotomist will have the following professional competencies.

They will have the ability to:

#### A. Professional Behaviors and Communication

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

## **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

## **C. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

# **VII. PBT Program Administration**

## **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

### **1. Qualifications**

The program director must have:

- a. A bachelor's degree or higher.
- b. An ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, medical laboratory technician, or holds certification in phlebotomy from an applicable recognized certification agency.
- c. One year of teaching experience.
- d. Knowledge of educational methods and administration as well as current accreditation and certification procedures.
- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, medical laboratory technician, or holds certification in phlebotomy from an applicable recognized certification agency, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, medical laboratory technician,

or holds certification in phlebotomy from an applicable recognized certification agency must hold appointment as an accreditation liaison

Program directors who have been approved as a program director of a NAACLS approved PBT program prior to October 1, 2013, remain eligible as a program director.

## 2. Responsibilities

The program director must:

- a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
- b. Provide evidence that s/he participates in the budget preparation process.
- c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
- d. Be responsible for maintaining NAACLS accreditation of the program.
- e. Have regular and consistent contact with students, faculty, and program personnel.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

### 1. Qualifications

The site program administrator must:

- a. Have a bachelor's degree.
- b. Hold the same level certification required of a program director.
- c. Have at least one year of experience in medical laboratory science education to include knowledge of:
  - i. Education methods.
  - ii. Program assessment and administration.
  - iii. Certification/licensure procedures.

### 2. Responsibilities

The site program administrator, when required, is responsible for:

- a. Coordinating teaching and clinical/applied learning experiential education.
- b. Evaluating program effectiveness.
- c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors

#### a. Qualifications

Faculty/instructors designated by the program must:

- i. Demonstrate adequate knowledge and proficiency in their content areas.
- ii. Demonstrate the ability to teach effectively at the appropriate level.

#### b. Responsibilities

The responsibilities of the faculty/instructors must include:

- i. Participation in teaching courses.
- ii. Evaluation of student achievement.
- iii. Development of curriculum, policy and procedures.
- iv. Assessment of program outcomes.

2. Clinical/Applied Learning Experiences Liaison

At least one clinical/applied learning experiences liaison, who is employed by the clinical/applied learning site, must be designated at each clinical/applied learning site affiliated with the program to coordinate clinical/applied learning experiences for students.

a. Qualifications

The clinical/applied learning experience liaison must:

- i. Be a health care professional staff member from the facility who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
- ii. Demonstrate knowledge of the program discipline.
- iii. Have at least one year of experience as a health care professional.

b. Responsibilities

The clinical/applied learning experiences liaison must be responsible for:

- i. Coordinating clinical/applied learning instruction at the site.
- ii. Maintaining effective communication with the program director or designee.

#### D. Advisory Committee

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### E. Accreditation Liaison (when required, for international programs only)

1. Qualifications

The accreditation liaison, when required, must be a medical laboratory professional who:

- a. Has knowledge of NAACLS accreditation.
- b. Has at least a master's degree and three years of experience in the program discipline.
- c. Holds ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, medical laboratory technician, or holds certification in phlebotomy from an applicable recognized certification agency.

2. Responsibilities

The accreditation liaison, when required, must:

- a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
- b. Provide input into the curriculum and continuous program assessment and improvement.
- c. Have regular contact, program director, faculty and program personnel.



## VIII. PBT Curriculum Requirements

### A. Instructional Areas

The program curriculum must include instruction and experiences in the following:

1. A variety of collection techniques including evacuated tube collection devices, syringe collection, and capillary/dermal puncture methods.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must include a minimum of 100 hours of clinical experiences and a minimum of 100 successful unaided collections.
4. The application of safety and governmental regulations and standards as applied to phlebotomy.
5. Principles and practices of professional conduct.
6. Principles of interpersonal and interdisciplinary communication and team building skills.
7. Interprofessional education and collaborative practice.

### B. Learning Experiences

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

### C. Evaluations

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.

# Unique Standards Public Health Microbiologist (PHM)

## PREAMBLE

### Objectives

The purpose of these standards and the Description of the Profession is to establish, maintain, and promote standards of quality for educational programs in the clinical laboratory sciences and to provide recognition for educational programs which meet or exceed the minimum standards outlined in this document.

The standards are to be used for the development and evaluation of public health microbiologist programs. Self-study reviewers and site visit teams assist in the evaluation of the program's compliance with the standards. Lists of accredited programs are published for the information of students, employers, and the public.

### Description of the Public Health Microbiologist Profession

The public health microbiologist is qualified by academic and applied science education to provide service and research in public health microbiology. Public health microbiologists practice laboratory science as it relates to the investigation of microorganisms and diagnosis of infectious diseases that pose a threat to the public.

Public health microbiologists function independently and collaboratively, being responsible for their own actions, as defined by the profession. They have the requisite knowledge and skills to educate laboratory professionals, additional health care professionals, and others in laboratory practice as well as the public.

The ability to relate to people, a capacity for calm and reasoned judgment and a demonstration of commitment to the patient and the public are essential qualities. Communications skills extend to consultative interactions with members of the healthcare team, external relations, customer service and patient education.

Public health microbiologists demonstrate ethical and moral attitudes and principles that are necessary for gaining and maintaining the confidence of patients, professional associates, and the public.

### Description of Entry-Level Competencies of the Public Health Microbiologist

At entry-level, the public health microbiologist (PHM) will possess the entry-level competencies to perform the full range of clinical laboratory tests in Public Health Microbiology, Molecular Diagnostics, Laboratory Management and Operations, and other emerging diagnostics, and will play a role in the development and evaluation of test systems and interpretive algorithms.

The public health microbiologist (PHM) will have diverse responsibilities in areas of analysis and clinical decision-making, regulatory compliance with applicable regulations, education, and quality assurance/performance improvement wherever laboratory testing is researched, developed or performed.

At career entry-level, the public health microbiologist will have the following professional competencies.

They will have the ability to:

### **A. Professional Behaviors and Communication**

Demonstrate professional and ethical behavior along with effective interpersonal communication skills when engaging with various stakeholders.

Establish effective interprofessional working relationships with other health care professionals, demonstrating comprehension of and respect for their roles and patient welfare.

Recognize and appreciate the importance of engaging with an inclusive workforce through collaboration.

Value and advocate for a workplace environment that fosters inclusivity, diversity, equity, and accessibility.

### **B. Safety and Compliance**

Comply with government regulations and accreditation standards relevant to the respective discipline.

Adhere to prescribed protocols for overall laboratory safety, biohazard containment, and waste disposal.

Implement quality assurance principles to ensure the validity and accuracy of laboratory-generated data.

### **C. Education and Research**

Acknowledge and respond to individual requirements for continuing education and development to foster growth and maintain professional competence.

Provide instruction to users of laboratory services regarding appropriate procedures, test utilization and interpretation.

Evaluate clinical research studies and data sets to assess applicability and validity.

### **D. Laboratory Operations**

Employ a logical and systematic problem-solving approach when identifying errors and/or technical issues with laboratory procedures and instrumentation.

Apply principles of data security to safeguard laboratory and hospital information systems.

Apply principles of quality assurance to ensure validity and accuracy of laboratory data.

Recognize principles and practices of laboratory management as applied to clinical laboratory science.

### **E. Pre-Analytical Competencies**

Evaluate specimen collection, processing, and storage procedures in accordance with standard operating procedures.

Ensure specimen integrity is maintained throughout the sample procurement process.

### **F. Analytical Competencies**

Adhere to written policies, processes, and procedures for analytical testing, analysis, and instrumentation maintenance.

Evaluate and provide rationale for troubleshooting protocols in analytical testing when appropriate.

Perform routine procedures in accordance with standard operating procedures.

Apply quality control principles to analytical testing procedures, including instrument calibration, statistical analyses of control results, Westgard rules, and verification of reference ranges.

Perform basic calculations, dilutions, and statistical analyses for procedures and analytical testing in the respective discipline.

Apply theoretical principles of instrumentation to current methods of analysis.

### **G. Post-Analytical Competencies**

Perform all post-analytical procedures in accordance with quality assurance protocols and regulatory standards.

Evaluate results for accuracy relative to quality control, patient history, specimen integrity, and overall clinical correlation.

Report test results, including abnormal, STAT, and critical values, in accordance with the laboratory's standard operating procedures.

## **VII. PHM Program Administration**

### **A. Program Director**

The program must have a NAACLS approved medical laboratory professional serving as program director who meets the following qualifications and executes all required responsibilities.

#### **1. Qualifications**

The program director must have:

- a. An earned master's or doctoral degree.
- b. A relevant certification, licensure, or recognition appropriate to the field.
- c. Three years of teaching experience in public health microbiology or related area.
- d. Knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

- e. (for international programs only) If the program director does not hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist, a qualified professional who does hold ASCP BOC or ASCP<sup>i</sup> BOC certification as a medical laboratory scientist must hold appointment as an accreditation liaison.
2. Responsibilities  
The program director must:
    - a. Be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program.
    - b. Provide evidence that s/he participates in the budget preparation process.
    - c. Engage in a minimum of 36 hours of documented continuing professional development every three years.
    - d. Be responsible for maintaining NAACLS accreditation of the program.
    - e. Have regular and consistent contact with students, faculty and program personnel.
  3. Faculty Appointments  
The program director must have a faculty or clinical appointment at the sponsoring institution.

## **B. Site Program Administrator (required for programs with sponsors and partners; assigned to each participating site)**

1. Qualifications  
The site program administrator must:
  - a. Have a bachelor's degree
  - b. Hold the same level certification, licensure, or recognition required of a program director
  - c. Have at least one year of experience in medical laboratory science education to include knowledge of:
    - i. education methods
    - ii. program assessment and administration
    - iii. certification/licensure procedures
2. Responsibilities  
The site program administrator, when required, is responsible for:
  - a. Coordinating teaching and clinical/applied learning experiential education.
  - b. Evaluating program effectiveness.
  - c. Maintaining appropriate communications with the program director.

## **C. Faculty/Instructors**

1. Didactic Instructor Appointments  
The program must have qualified faculty/instructors who hold appointments within the educational program. The program must ensure and document ongoing professional development of the program faculty/instructors.
  - a. Qualifications  
Faculty/instructors designated by the program must:
    - i. Demonstrate adequate knowledge and proficiency in their content areas.

- ii. Demonstrate the ability to teach effectively at the appropriate level.
  - b. Responsibilities
    - The responsibilities of the faculty/instructors must include:
      - i. Participation in teaching courses.
      - ii. Evaluation of student achievement.
      - iii. Development of curriculum, policy and procedures.
      - iv. Assessment of program outcomes.
- 2. Clinical/Applied Learning Experience Liaison
 

At least one liaison, who is employed by the applied laboratory experience providing site, must be designated at each applied laboratory experience site affiliated with the program to coordinate applied laboratory experiences for students.

  - a. Qualifications
    - The liaison must:
      - i. Be a public health professional who demonstrates the ability to effectively coordinate clinical/applied learning experiences of the students.
      - ii. Demonstrate knowledge of the program discipline.
      - iii. Have at least one year of experience as a public health laboratory professional.
  - b. Responsibilities
    - The liaison must be responsible for:
      - i. Coordinating clinical instruction at the applied laboratory experience site.
      - ii. Maintaining effective communication with the program director or designee.

#### **D. Advisory Committee**

1. There must be an advisory committee composed of individuals from the community of interest who have knowledge of clinical laboratory science education.
2. The advisory committee of the program shall have input into the program and curriculum to maintain current relevancy and effectiveness.

#### **E. Accreditation Liaison (when required, for international programs only)**

1. Qualifications
 

The accreditation liaison, when required, must be a medical laboratory professional who:

  - a. Has knowledge of NAACLS accreditation.
  - b. Has at least a master's degree and three years of experience in the program discipline.
  - c. Holds relevant certification, licensure, or recognition appropriate to the field.
2. Responsibilities
 

The accreditation liaison, when required, must:

  - a. Provide guidance and assistance in NAACLS accreditation requirements, policies and procedures.
  - b. Provide input into the curriculum and continuous program assessment and improvement.
  - c. Have regular contact, program director, faculty and program personnel.

## VIII. PHM Curriculum Requirements

### A. Instructional Areas

1. Prerequisite courses in biological sciences, chemistry and mathematics that provide the foundation for course work required in the public health microbiology program.
2. The program must deliver instruction utilizing cognitive, psychomotor, and affective learning domains that enable the student to meet entry-level competencies of the program discipline.
3. The curriculum must address pre-analytical, analytical and post-analytical components of public health microbiology laboratory services. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of laboratory procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of public health microbiology services for all major areas practiced in the contemporary public health microbiology laboratory.
4. The program curriculum must include the following scientific content:
  - a. anaerobic bacteriology
  - b. food and water bacteriology
  - c. gram positive and negative bacteriology
  - d. molecular microbiology
  - e. mycology
  - f. parasitology
  - g. mycobacteriology
  - h. serology
  - i. sexually transmitted infections
  - j. virology
  - k. public health microbiology
  - l. laboratory operations and management.
5. The program curriculum must also include:
  - a. The application of safety and governmental regulations and standards as applied to the public health microbiology laboratory.
  - b. Principles and practices of professional conduct and the significance of continuing professional development.
  - c. Communications sufficient to serve the needs of patients, the public and members of the health care team.
  - d. Principles and practices of administration and supervision as applied to the public health microbiology laboratory.
  - e. Educational methodologies and terminology sufficient to train/educate users and providers of public health microbiology laboratory services.
  - f. Principles and practices of research design, implementation and dissemination of results.
  - g. Interprofessional education and collaborative practice.

**B. Learning Experiences**

1. Learning experiences must be properly sequenced and include content and activities that enable students to achieve entry-level competencies in each major discipline as listed in Standard VIII Instructional Areas.
2. After demonstrating competency, students, under qualified supervision, may be permitted to perform procedures as defined in Standard V.E.

**C. Evaluations**

1. Evaluation systems must relate to course content and align with program and course competencies.
2. Evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
3. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.