

# NAACLS Standards for Accredited and Approved Programs

Adopted 2012, Revised 9/2013, 1/2014, 4/2014, 10/2014, 11/2014,  
10/2015, 4/2016, 6/2016, 11/2016, 11/2017, 5/2018, 11/2018, 5/2019,  
10/2019, 5/2020, 11/2020, 5/2021, 10/2021

The logo for NAACLS features the acronym "NAACLS" in a bold, black, sans-serif font. The letters are set against a light blue, semi-circular gradient background that resembles a rising sun or a lens flare. The letters "N", "A", and "C" have a slight shadow effect, making them appear to float above the blue background.

National Accrediting Agency  
for Clinical Laboratory Sciences

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# STANDARDS FOR ACCREDITED AND APPROVED 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 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 Clinical 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)

#### B. Consortium Sponsor

A separate and distinct entity consisting of two or more members that exists for the purpose of operating an educational program. Where a consortium exists, at least one member of the consortium must meet the requirements of a sponsoring institution specified in I.A. The creation of the consortium must be clearly documented as a formal memorandum of

understanding and signed by all members. This document shall contain the following elements:

1. governance of the consortium
2. lines of authority within the consortium for the educational program
3. responsibilities of each member in the delivery of the educational program

C. Multi-location Sponsor

1. A specified campus location of an entity that controls a system of campuses, which is accredited by an institutional accrediting agency that is recognized by the U.S. Department of Education and given the authority to provide postsecondary education. The specified campus location delivers the educational program in its entirety and awards a minimum of a certificate at the completion of the program.
2. A specified location of an entity that controls a system of hospitals, medical centers, or laboratories accredited by an applicable recognized agency (see Standards Compliance Guide), which awards a minimum of a certificate at the completion of the program.

D. Responsibilities of the Sponsor

1. The sponsor has primary responsibility for:
  - a. supporting curriculum planning and course selection by program faculty and staff
  - b. appointing faculty and staff
  - c. maintaining student transcripts permanently
  - d. granting the degree and/or certificate documenting satisfactory completion of the educational program
  - e. ensuring that appropriate personal safety measures are addressed for students and faculty

- f. ensuring that all provisions of the Standards are met
- g. ensuring that graduates of the program have obtained or will obtain the minimum degree and/or certificate upon completion of the program

Pathologists' Assistant programs: a master's degree or higher, or a certificate for students who hold or complete the required degree

MLS, DMS, HTL, and CG, programs: a baccalaureate degree or higher, or a certificate for students who hold or complete the required degree

MLT and HT programs: an associate degree or higher, or a certificate for students who hold or complete the required degree

Phlebotomy and Clinical Assistant programs: a certificate for the student

- 2. The sponsor must ensure that the activities assigned to students in the clinical setting are educational.
- 3. There must be documented ongoing communication between the sponsor and its affiliates for exchange of information and coordination of the program.
- 4. The sponsor must provide eligible students the opportunity to participate in applied clinical experiences.
- 5. The sponsor must have a formal affiliation agreement with all other entities that are involved in the education of the students, which describes:
  - a. the relationship
  - b. the roles
  - c. the responsibilities of the sponsor 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

A review of the results of the following outcomes measures from the last three active years must be documented, analyzed and used in program assessment and continuous quality improvement of the program to include an annual submission to NAACLS. If outcome measure(s) does/do not meet the stated NAACLS approved benchmarks (see Standards Compliance Guide), then an analysis and action plan must be submitted to correct the deficiency (ies).

1. External certification results
2. Graduation rates
3. Placement rates (i.e., employment positions in the field of study or pursuit of further education)
4. Attrition rates
5. Other (optional): such as results of capstone projects, faculty feedback, exit or final examinations, exit interviews with graduates, student and graduate professional leadership, impact of the program on local and regional healthcare, etc.

### C. Program Assessment and Modification

The results of program outcomes measures and assessment must include findings from graduate and employer feedback and be:

1. Reflected in ongoing curriculum development, resource acquisition/allocation, and program modification.
2. Analyzed to demonstrate the effectiveness of any changes implemented.

### **III. Resources**

#### **A. General Resources**

1. The sponsor must appoint sufficient faculty and staff with the necessary qualifications to perform the functions identified in documented job description
2. Resources assessment must be part of a continuous program evaluation
3. Resources must be sufficient to allow achievement of program goals

#### **B. Financial Resources**

Financial resources for continued operation of the educational program must be sufficient to achieve the program goals.

#### **C. Physical Resources**

Physical resources such as facilities, equipment and supplies, information resources, and instructional resources sufficient to achieve the program goals.

### **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/approval 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 clinical 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 service work must be published
- k. policies and procedures for:
  - 1. advising and guiding students through the program while maintaining confidentiality and impartiality;
  - 2. clinical assignment specifically addressing when placement cannot be immediately guaranteed;
  - 3. student grievance and appeals;
  - 4. criteria for program completion including probation, suspension, and dismissal
- l. academic calendar
- m. rules and regulations governing acceptable personal and academic conduct, including behavior expectations for clinical experience

**B. Student Records**

- 1. The program must maintain student records, conforming to any governmental or sponsor regulations. Records example include admission, evaluation, counseling, advising, grades, credits, etc.

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, and patients during educational activities is safeguarded.
  2. Safety
    - a. The program must provide evidence that each student enrolled has 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 must be submitted to NAACLS within 30 days of the official announcement.
- E. Service work by students in clinical settings outside of academic hours must be noncompulsory.

- F. Students may not be substituted for regular staff during their student experiences.

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

### Program/Sponsoring Institution Responsibilities

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

- A. Submitting required documentation by NAACLS by the established deadline. These include but are not limited to Self-Study Reports, Applications for Continuing Accreditation/Approval, and required Progress Reports, Interim Report and Action Plans;
- B. Paying accreditation/approval 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 (e.g. inactivity, closure) or location, and institution name;
- D. Agreeing to a site visit date before the end of the period for which accreditation/approval 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.

## **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 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 science programs. Paper 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 clinical 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 clinical 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 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 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 clinical 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 entry level, the medical laboratory scientist will have the following basic knowledge and skills in:

- A. Application of safety and governmental regulations and standards as applied to clinical 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 clinical laboratory science;
- E. Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services;
- F. Principles and practices of clinical study design, implementation and dissemination of results.

## 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

- a. has an earned master's or doctoral degree;
- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC generalist certification as a Medical Laboratory Scientist/Medical Technologist.
- c. has three years of teaching experience;
- d. has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

#### 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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinical based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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 Coordinator (required for multi-location programs only; assigned to each participating site)

#### 1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director;
- c. have at least one year of experience in medical laboratory science education.

#### 2. Responsibilities

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

- a. coordinating teaching and clinical education;
- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

### C. Faculty

#### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g., practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

1. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## VIII. MLS Curriculum Requirements

A. Instructional Areas

1. Prerequisite courses in biological sciences, chemistry and mathematics that provide the foundation for course work required in the laboratory science program.
2. The curriculum must address pre-analytical, analytical and post-analytical components of 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 laboratory.

The program curriculum must include the following 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
3. Application of safety and governmental regulations and standards as applied to clinical laboratory science.
  4. Principles and practices of professional conduct and the significance of continuing professional development.
  5. Communications sufficient to serve the needs of patients, the public and members of the health care team.
  6. Principles and practices of administration and supervision as applied to clinical laboratory science.
  7. Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services.
  8. Principles and practices of clinical study design, implementation and dissemination of results.
- B. Learning Experiences
1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
2. 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 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 technician programs. Paper 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 clinical 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; direct and supervise clinical laboratory resources and operations; 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 and other substances, 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 patient 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 clinical 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 entry level, the medical laboratory technician will have the following basic knowledge and skills in:

- A. 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.

## 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

- a. has an earned master's or doctoral degree;
- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC generalist certification as a Medical Laboratory Scientist/Medical Technologist.
- c. has three years of teaching experience;
- d. has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

#### 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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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 Coordinator (required for multi-location programs only; assigned to each participating site)
  - 1. Qualifications
    - a. The site program coordinator must:
    - b. have an academic degree appropriate to the program level;
    - c. hold the same level certification required of a program director;
    - d. have at least one year of experience in medical laboratory science education.
  - 2. Responsibilities
    - a. The site program coordinator, when required, is responsible for:
    - b. coordinating teaching and clinical education;
    - c. evaluating program effectiveness;
    - d. maintaining appropriate communications with the program director.
- C. Faculty
  - 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g., practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

1. Responsibilities

- a. The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## VIII. MLT Curriculum Requirements

A. Instructional Areas

1. Prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program
2. 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, 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 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
  - 3. Application of safety and governmental regulations compliance
  - 4. Principles and practices of professional conduct and the significance of continuing professional development
  - 5. Communications sufficient to serve the needs of patients, the public and members of the health care team
- B. Learning Experiences
  - 1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

- 1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
- 2. The 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. Paper 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**

Histotechnology 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.

Histotechnology 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.

Histotechnology 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. Histotechnology 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 Histotechnologist

At entry level, the Histotechnologist will possess the following entry level competencies:

- A. receiving and accessioning tissue specimens;
- B. preparing tissue specimens for microscopic examinations, including all routine procedures;
- C. performing more complex procedures for processing and staining tissues, including enzymes, and immunohistochemistry;
- D. assisting with and/or performing gross examination and frozen section procedures in histopathology as well as cytology specimen preparation methods;
- E. identifying tissue structures, cell components, and their staining characteristics, and relating them to physiological functions;
- F. recognizing factors that affect procedures and results, and taking appropriate action within predetermined limits when corrections are indicated;
- G. developing, testing, implementing, evaluating, and selecting new techniques, procedures, instruments and methods in terms of their usefulness and practicality within the context of a given laboratory's personnel, equipment, space, and budgetary resources;
- H. making decisions concerning the results of quality control and quality assurance measures and instituting proper procedures to maintain accuracy and precision;
- I. confirming abnormal results, verifying quality control procedures, executing quality control procedures, and developing solutions to problems concerning the generation of laboratory data;
- J. establishing and performing preventative and corrective maintenance of equipment or instruments, as well as identifying appropriate sources for repair;
- K. exercising and applying principles of safety, management and supervision;
- L. demonstrating professional conduct and interpersonal communication skills with patients, laboratory personnel, other health care professionals, and with the public;

- M. recognizing and acting upon individual needs for continuing education as a function of growth and maintenance of professional competence;
- N. recognizing the responsibilities of other laboratory and healthcare professionals and interacting with them with respect for their jobs and patient care;
- O. leading supportive personnel and peers in their acquisition of knowledge, skills and attitudes; and providing leadership in educating other health personnel and the community;
- P. applying principles of education methodology;
- Q. applying principles of current information systems;
- R. applying principles of in-situ hybridization, plastic, and electron microscopy.

At entry level, the Histotechnologist will have the following basic knowledge and skills in:

- A. 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. Education techniques and terminology sufficient to train/educate users and providers of laboratory services.

## **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
  - a. has a baccalaureate degree or higher;

- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification as a Histotechnologist. 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. has three years of experience in medical or laboratory education that includes:
  - teaching courses, conducting and managing learning experiences;
  - evaluating student achievement;
  - providing input into curriculum development, policy and procedure formulation;
  - evaluation of program effectiveness;
- d. has knowledge of NAACLS accreditation;
- e. has knowledge of certification procedures;

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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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 Coordinator (required for multi-location programs only; assigned to each participating site)

#### 1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director;
- c. have at least one year of experience in medical laboratory science education.

#### 2. Responsibilities

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

- a. coordinating teaching and clinical education;
- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

### C. Faculty

#### 1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

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

a. Qualifications

The clinical liaison must:

- i. Be a medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

E. Education Coordinator (when required)

2. Qualifications

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

- a. has at least a baccalaureate degree and three years of experience in the program discipline;
- b. holds ASCP-BOC U.S. certification as a Histotechnologist;
- c. has knowledge of NAACLS accreditation and current certification procedures.

3. 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. Prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
2. 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.
3. Concepts and principles of laboratory operations must include:
  - a. Fixation
    - Tissue identification
    - Parameters
    - Reagents
    - Pathology
    - Biochemistry principles and theories
  - b. Processing, to include chemistry principles and theories
    - Decalcification
    - Frozen sections
    - Enzymes
    - Immunohistochemistry
    - Cytology
  - c. Embedding/Microtomy
  - d. Staining
    - Procedures, reagents, and quality control
    - Hematoxylin and Eosin

Special Staining procedures

Immunohistochemistry

Cytology

Pathology

Biochemistry principles and theories

e. Laboratory Operations

Safety

Laboratory mathematics

Instrumentation

Quality control

Management

Education

Regulations

4. Application of safety and governmental regulations and standards as applied to histotechnology.
5. Principles and practices of professional conduct and the significance of continuing professional development.
6. Communications sufficient to serve the needs of patients, the public and members of the health care team.
7. Principles and practices of administration, supervision, and safety as applied to histotechnology.
8. Education techniques and terminology sufficient to train/educate users and providers of laboratory services.

B. Learning Experiences

1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
2. The evaluation systems must serve as a reliable indicator of this 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. Paper 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**

Histotechnology 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.

Histotechnology 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.

Histotechnology 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. Histotechnology 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 Competencies of the Histotechnician

At career entry, the histotechnician will be able to perform routine histologic procedures such as:

- A. Receiving and accessioning tissue specimens;
- B. Preparing tissue specimens for microscopic examinations, including all routine procedures;
- C. Assisting with gross examination and frozen section procedures in histopathology;
- D. Identifying tissue structures and their staining characteristics;
- E. Performing preventive and corrective maintenance of equipment and instruments or referring to appropriate sources for repairs;
- F. Recognizing factors that affect procedures and results, and taking appropriate action within predetermined limits when corrections are indicated;
- G. Performing and monitoring quality control within predetermined limits;
- H. Applying principles of safety;
- I. Demonstrating professional conduct and interpersonal communication skills with patients, laboratory personnel, other health care professionals, and with the public;
- J. Recognizing the responsibilities of other laboratory and healthcare professionals and interacting with them with respect for their jobs and patient care;
- K. Recognizing and acting upon individual needs for continuing education as a function of growth and maintenance of professional competence; and,
- L. Exercising principles of management, safety, and supervision, as the primary analyst making specimen oriented decisions on predetermined criteria, including a working knowledge of criteria values. Communications skills will extend to frequent interactions with members of the healthcare team, external relations, customer service, and patient education. The levels of analysis range from routine tissue processing to complex histopathology laboratory procedures in the various major areas of anatomic pathology. The histotechnician will have diverse functions in

areas of pre-analytic, analytic, and post-analytic processes. The histotechnician will have responsibilities for information processing, training, and quality control monitoring wherever histologic procedures are performed.

## 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

- a. has a baccalaureate degree or higher;
- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification as a Histotechnologist or Histotechnician. 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. has three years of experience in medical or laboratory education that includes:
  - teaching courses, conducting and managing learning experiences;
  - evaluating student achievement;
  - providing input into curriculum development, policy and procedure formulation;
  - evaluating program effectiveness.
- d. has knowledge of NAACLS accreditation;
- e. has knowledge of certification procedures.

#### 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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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 Coordinator (required for multi-location programs only; assigned to each participating site)

1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director;
- c. have at least one year of experience in medical laboratory science education.



## 2. Responsibilities

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

- a. coordinating teaching and clinical education,
- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

## C. Faculty

### 1. Didactic Instructor Appointments

#### a. Qualifications

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). The program must ensure and document ongoing professional development of the program faculty/instructors.

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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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.

B. Advisory Committee

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

1. Responsibilities

- a. The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

C. Education Coordinator (when required)

1. Qualifications

- a. The education coordinator, when required, must be a medical laboratory professional who:
- b. has at least an associate's degree and three years of experience in the program discipline.;

- c. holds ASCP-BOC U.S. certification as a Histotechnologist or Histotechnician;
  - d. has knowledge of NAACLS accreditation and current certification procedures.
2. Responsibilities
- a. 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. Prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.
  - 2. 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.
  - 3. Concepts and principles of laboratory operations must include:
    - a. Fixation
      - Tissue identification
      - Parameters
      - Reagents
    - b. Processing
      - Decalcification
      - Frozen sections
      - Enzymes
      - Immunohistochemistry
      - Cytology

c. Embedding/Microtomy

d. Staining

Procedures, reagents, and quality control

Hematoxylin and Eosin

Special Staining procedures

Basic Immunohistochemistry

Cytology

e. Laboratory Operations

Safety

Laboratory mathematics

Instrumentation

Quality control

4. Application of safety and governmental regulations and standards as applied to histotechnology.

5. Principles and practices of professional conduct and the significance of continuing professional development.

6. Communications sufficient to serve the needs of patients, the public and members of the health care team.

7. Principles and practices of safety as applied to histotechnology.

B. Learning Experiences

1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately

achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
2. 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. Paper 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 Competencies of the Diagnostic Molecular Scientist

At career entry, the **Diagnostic Molecular Scientists** will be able to demonstrate entry level competencies such as:

- Evaluating and monitoring methods of collection, transport and handling of various specimen types for molecular analysis;
- Applying appropriate advanced principles and techniques to prepare specimens for molecular based testing, as well as troubleshooting and evaluating appropriate actions for problem resolution;
- Applying basic and advanced principles, practices and applications of molecular based testing for clinical laboratory diagnostic purposes;
- Performing appropriate techniques utilizing instrumentation for molecular analysis and correlating results with acquired, inherited and infectious diseases, and pharmacogenomics;
- Utilizing bioinformatic techniques and resources to evaluate genomic information for performing techniques, analyze molecular assays and genomic assays, and correlate assay results;
- Applying the principles and techniques of first, second, and third generation sequencing, correlating results with acquired, inherited, and infectious diseases;
- Complying with and performing preventive and corrective maintenance programs for instruments and equipment, as well as troubleshooting and evaluating appropriate actions for problem resolution;
- Investigating and applying advanced molecular principles, practices, and quality assurance to develop new assays or procedures as a result of studies on new technologies, as well as troubleshooting and evaluating appropriate solutions;
- Applying principles of quality control that evaluate data, including sequencing data, for necessity of repeat analysis, correlation with disease states, organism identification and disease diagnosis;
- Applying principles of quality assurance and performing measurements to assure validity and accuracy of laboratory data generated;

- Complying with laws, regulations and accrediting standards, as well as guidelines of relevant governmental and non-governmental agencies;
- Utilizing resource management strategies to maintain optimal laboratory efficiency;
- Exercising established procedures for general laboratory safety, biohazard containment and waste disposal;
- Demonstrating leadership, professional and ethical conduct and interpersonal skills for patients, clients, healthcare professionals and the public;
- Formulating a short-term and long-term plan for professional career development.



## 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

- a. has an earned master's or doctoral degree;
- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification in Molecular Biology or ABMGG certification in Molecular Biology.
- c. has three years of teaching experience;
- d. has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

#### 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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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 Coordinator (required for multi-location programs only; assigned to each participating site)

1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director;
- c. have at least one year of experience in medical laboratory science education.

2. Responsibilities

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

- a. coordinating teaching and clinical education,
- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

C. Faculty

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## VIII. DMS Curriculum Requirements

A. Instructional Areas

1. 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 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.

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. Techniques of molecular science must include current techniques in each of separation and detection, amplification, and sequence analysis, for example Sanger sequencing;

c. Clinical significance of laboratory procedures in diagnosis and treatment

3. Application of safety and governmental regulations and standards as applied to diagnostic molecular science.
4. Principles and practices of professional conduct and the significance of continuing professional development.
5. Communications sufficient to serve the needs of patients, the public and members of the health care team.
6. Principles and practices of administration, supervision, and quality management as applied to diagnostic molecular science.
7. Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services.
8. Principles and practices of applied study design, implementation and dissemination of results.

B. Learning Experiences

1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
2. 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. Paper 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 Entry Level Competencies of the Cytogenetic Technologist**

At entry level, the Cytogenetic Technologist will possess and be able to perform the following entry level competencies under supervision:

- A. Recommend and instruct in appropriate specimen collection, transport and storage conditions for each specimen type and testing modality;
- B. Receive, accession and evaluate for appropriateness each specimen type;
- C. Process specimens for each culture type, fixation or DNA extraction based on reason for referral;
- D. Set-up, maintain and select cultures for harvest while maintaining aseptic conditions;
- E. Perform harvest of all culture types;
- F. Manipulate environmental and slide conditions to prepare specimen slides for chromosome banding, and FISH probing;
- G. Perform chromosome banding, staining, and FISH;
- H. Perform analysis by G-banding, FISH or aCGH;
- I. Apply principles of brightfield, phase contract and fluorescent microscopy;
- J. Apply principles of computer imaging for case documentation and to produce analyzable images;
- K. Identify and interpret chromosome and genomic abnormalities as correlated to clinical conditions/referral request and differentiate from polymorphism/CNV;
- L. Recognize appropriate concepts and principles of laboratory reporting mechanisms;
- M. Perform and monitor quality control indicators recognizing factors that affect procedures and results, take appropriate action within predetermined limits when corrections are indicated, and notify when appropriate the chain of command;



- N. Recognize and apply principles of laboratory safety;
- O. Demonstrate professional conduct, interpersonal and communication skills when dealing with co-workers, other health care professionals, patients and the public;
- P. Recognize and act upon individual needs for continuing education to maintain certification and competencies as a function of continued growth and development.

At entry level, the Cytogenetic Technologist will have the following basic knowledge and skills in:

- A. Application of safety and governmental regulations and standards as applied to cytogenetics;
- B. Principles of interpersonal and interdisciplinary communication and team-building skills and the significance of continuing professional development;
- C. Principles and practices of administration and supervision;
- D. Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services;
- E. Principles and practices of clinical study design, implementation and dissemination of results.

## **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
  - a. has an earned master's or doctoral degree;
  - b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification in cytogenetics or ABMGG certification in clinical cytogenetics;
  - c. has three years of teaching experience;

- d. has knowledge of education methods and administration as well as current NAACLS accreditation and certification procedures.

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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic 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.

B. Site Program Coordinator (required for multi-location programs only; assigned to each participating site)

1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director;
- c. have at least one year of experience in medical laboratory science education.

2. Responsibilities

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

- a. coordinating teaching and clinical education;
- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

C. Faculty

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## VIII. CG Curriculum Requirements

A. Instructional Areas

1. Prerequisite content in biological sciences, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.

2. The program curriculum must include the following scientific content:

Specimen Preparation (sample acquisition, transport/storage, preparation, culture, harvest, slide preparation, and staining);

Molecular Cytogenetic Testing (utilize appropriate techniques for preparation and analysis of molecular cytogenetic specimens, including array analysis);

Chromosome Analysis and Imaging (selection, analysis, and description of suitable metaphase or interphase cells using microscopy and imaging);

Laboratory Operations (general laboratory skills, guidelines/government regulations, safety, quality assurance/control and professional standards and conduct).

3. Principles of interpersonal and interdisciplinary communication and team-building skills and the significance of continuing professional development;

4. Principles and practices of administration and supervision;

5. Educational methodologies and terminology sufficient to train/educator users and providers of laboratory services sufficient for future clinical faculty);

6. Principles and practices of clinical study design, implementation and dissemination of results.

B. Learning Experiences

1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

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

## **Unique Standards for the Pathologists' Assistant (PathA)**

### **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. Paper 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 (PA) is a highly trained allied health professional who provides various services under the direction and supervision of a pathologist. Pathologists' assistants interact with pathologists in a manner similar to physician's assistants in surgical and medical practice, carrying out their duties under the direction of their physicians. PAs are academically and practically trained to provide accurate and timely processing of a variety of laboratory specimens, including the majority of pathological specimens. PAs are key components to helping make a pathologic diagnosis, but 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, PAs 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 PAs are even self-employed business owners providing their pathology expertise via long- and short-term contract.

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."

(American Association of Pathologists' Assistants Web Site, 2011)

## **DESCRIPTION OF ENTRY LEVEL COMPETENCIES OF THE PATHOLOGISTS' ASSISTANT**

At entry level, the Pathologists' Assistant will possess the following entry level competencies:

### **A. Surgical Pathology:**

The ability to prepare, grossly describe and dissect human tissue surgical specimens encompassing:

1. Assurance of appropriate specimen accessioning;
2. Chronicle pertinent clinical information and history, including scans, x-rays, laboratory data etc.;
3. Description of gross anatomic features of surgical specimens, preparation of tissues for histological processing, collection of biological samples such as blood, tissue and toxicological material for studies such as flow cytometry, image analysis, immunohistochemistry, etc., and performing special procedures including faxitron imaging and tumor triage;
4. Preparation and submission of appropriate tissue sections for light microscopy (routine processing) as well as special procedures such as frozen section, electron microscopy and immunofluorescence microscopy;
5. Photographing all appropriate gross specimens and microscopic slides;
6. Performance of duties relating to the administrative maintenance of surgical pathology protocols, reports and data, including the submission of reports, protocols, photographic data or slides, assisting in the completion of specimen coding and billing;
7. Assurance of proper maintenance of equipment, provision of adequate supplies and cleanliness of the surgical pathology suite;
8. Assisting in the organization and coordination of anatomic pathology conferences.

### **B. Autopsy Pathology:**

The ability to perform human postmortem examination, including:

1. Ascertaining proper legal authorization for autopsy;



2. Obtaining patient's medical record/chart(s) and other pertinent data for review with the attending pathologist;
3. Conferring with the attending pathologist(s) to identify any special techniques and procedures to be utilized in the completion of examination (e.g. cultures smears; histochemical, immunofluorescence, toxicological, viral or electron microscopic studies, etc.), and notifying all personnel directly involved;
4. Notifying the physician in charge, the funeral home, and all other appropriate authorities prior to the beginning of the autopsy; and coordinating any requests for special specimen sampling (e.g. organ transplantation, research, etc.);
5. Performing postmortem examinations which may include: external examination; in situ organ inspection; evisceration; dissection and dictation or recording of data such as organ weights, presence of body fluids, gross anatomic findings, etc.;
6. Selecting, preparing and submitting appropriate gross tissue sections for frozen section analysis as well as for light, electron and immunofluorescent microscopy;
7. Obtaining biological specimens such as blood, tissue and toxicological material for studies including flow cytometry, image analysis, immunohistochemistry, etc.; and performing special procedures such as coronary artery perfusion, central nervous system perfusion, enucleation, inner ear bone dissection, spinal cord removal, etc.;
8. Photographing the body, organs, microscopic slides and other pertinent materials;
9. Gathering and organizing clinical information and data pertinent to the preparation of the preliminary summarization of the clinical history;
10. Preparing the body for release, (including indicating the presence of biohazards such as contagious diseases, radiation implants, etc.) and releasing the body to the appropriate mortuary or funeral home representative;
11. Performing duties related to administrative maintenance of anatomic pathology protocols; photographic and microscopic slides; and assuring the completion of coding;

12. Assisting in the organization and coordination of anatomic pathology conference;
13. Assuring the proper maintenance of equipment, the provision of adequate supplies

C. Administrative Duties

Performance of administrative, budgetary, supervisory, teaching, and other such duties as may be appropriate and assigned.

(Reference: American Association of Pathologists' Assistants Bylaws, January, 2010)

At entry level, the Pathologists' Assistant will have the following basic knowledge and skills in:

- A. Anatomy and Basic Microanatomy
- B. General and Systemic Human Pathology
- C. Anatomic Pathology
  1. Surgical Pathology Techniques
  2. Autopsy Techniques
    - a. Toxicology Collection Techniques
  3. Histological Methods and Techniques
    - a. Concepts of Immunohistochemistry
  4. Concepts of Molecular Diagnostics
- D. Microbiology/Immunology
- E. Clinical Pathology
- F. Embryology
- G. Laboratory Safety
- H. Laboratory Information Systems
- I. Laboratory Management
- J. Medical Ethics

- K. Medical Terminology
- L. General Biology
- M. General and Organic Chemistry
- N. College-level Mathematics, through Algebra
- O. Educational Methodologies

## **VII. PathA 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**

- a. is a graduate of a NAACLS-accredited (AAPA approved prior to 1995) pathologists' assistant educational program with an advanced degree (masters or doctoral), currently holds ASCP-BOC certification as a Pathologists' Assistant, or a board-certified pathologist. 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. has 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. has practical knowledge of educational methods, and current accreditation and certification procedures, demonstrate adequate knowledge and proficiency in their content areas, demonstrate the ability to teach effectively at the appropriate level.

#### **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 3 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 appointment at the sponsoring institution or must have a faculty appointment in each affiliated academic institution. In the case of a clinically based program, the program director's appointment at affiliated academic institutions may be a regular one, a non-salaried clinical or courtesy appointment, or an adjunct appointment, depending upon the regulations of the academic institution.

Program Directors who have been approved as a program director of a NAACLS accredited Pathologists' Assistant program prior to May 1, 2018 remain eligible as a program director.

### B. Site Program Coordinator (required for multi-location programs only; assigned to each participating site)

#### 1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director.

#### 2. Responsibilities

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

- a. coordinating teaching and clinical education;

- b. evaluating program effectiveness;
- c. maintaining appropriate communications with the program director.

C. Faculty

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

E. Education Coordinator (when required)

2. 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.

3. 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.

- F. Medical Director

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

2. Qualifications

The medical director must:

- a. have a faculty appointment in the sponsoring institution
- b. be a licensed, board-certified anatomic pathologist.

3. Responsibilities

The medical director must provide continuous medical direction for clinical instruction. 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. PathA Curriculum Requirements**

- A. Instructional Areas

1. Prerequisite courses in biology, chemistry and mathematics that provide the foundation for course work required in the Pathologists' Assistant program.
2. 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. 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
  - i. Surgical Pathology Techniques
    - a) Adult
    - b) Pediatric
  - ii. Autopsy Techniques
    - a) Medical Autopsy Techniques
      - 1 Adult
      - 2 Pediatric
    - b) Forensic Autopsy Techniques
      - 1 Adult
      - 2 Pediatric
      - 3 Toxicology Collection Techniques
  - iii. Histological Methods and Techniques
    - a) Concepts of Immunohistochemistry
  - iv. Concepts of Molecular Diagnostics
  - v. Microbiology/Immunology
  - vi. Clinical Pathology
  - vii. Embryology
  - viii. Laboratory Safety
  - ix. Laboratory Information Systems
  - x. Laboratory Management
  - xi. Medical Ethics



xii. Medical Terminology

xiii. Biomedical Photography

3. Application of laboratory safety governmental regulations and standards as applied to anatomic pathology.
  - a. Principles and practices of professional conduct.
  - b. Principles of interpersonal and interdisciplinary communication and team-building skills.
  - c. Principles and practices of administration and supervision as applied to clinical laboratory science.
  - d. Educational methodologies.

B. Learning Experiences

1. Learning experiences (courses, practica, other required activities) 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

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.
2. 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. Paper reviewers and site visit teams assist in the evaluation of the program's compliance with the Standards. Lists of approved programs are published for the information of students, employers, and the public.

### **DESCRIPTION OF THE PHLEBOTOMY PROFESSION**

Phlebotomy professionals are qualified by academic and practical education to collect, transport, and process blood specimens for analysis. They select the appropriate equipment and technique based on a thorough understanding of the anatomy and physiology of the patient, as well as the psycho-social factors that may impact specimen collection. Phlebotomy professionals perform venipunctures and capillary (dermal) punctures adhering to all standards governing patient and employee safety.

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 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 demonstrate 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 Entry Level Competencies of the Phlebotomist**

At entry level, the phlebotomist will possess the following entry level competencies:

- A. Demonstrate knowledge of the health care delivery system and medical terminology;
- B. Demonstrate knowledge of infection control and safety;
- C. Demonstrate basic understanding of the anatomy and physiology of body systems and anatomic terminology in order to relate major areas of the clinical laboratory to general pathologic conditions associated with the body systems;
- D. Demonstrate basic understanding of age specific or psycho-social considerations involved in the performance of phlebotomy procedures on various age groups of patients;
- E. Demonstrate understanding of the importance of specimen collection and specimen integrity in the delivery of patient care;
- F. Demonstrate knowledge of collection equipment, various types of additives used, special precautions necessary and substances that can interfere in clinical analysis of blood constituents;
- G. Follow standard operating procedures to collect specimens via venipuncture and capillary (dermal) puncture;
- H. Demonstrate understanding of requisitioning, specimen transport and specimen processing;
- I. Demonstrate understanding of quality assurance and quality control in phlebotomy;
- J. Communicate (verbally and nonverbally) effectively and appropriately in the workplace.

## **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
  - a. has a baccalaureate degree or higher;

- b. holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification as a Medical Laboratory Scientist/Medical Technologist, Medical Laboratory Technician, or holds certification in phlebotomy from an applicable recognized certification agency (see Standards Compliance Guide).
- c. has 6 months experience in phlebotomy education institution;
- d. has knowledge of educational methods and administration as well as current approval and certification procedures.

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 3 years;
- d. be responsible for maintaining NAACLS approval of the program;
- e. have regular and consistent contact with students, faculty, and program personnel.

## B. Site Program Coordinator (required for multi-location programs only; assigned to each participating site)

### 1. Qualifications

The site program coordinator must:

- a. have an academic degree appropriate to the program level;
- b. hold the same level certification required of a program director
- c. have at least one year of experience in medical laboratory science education.

2. Responsibilities

- a. The site program coordinator, when required, is responsible for:
  - b. coordinating teaching and clinical education;
  - c. evaluating program effectiveness;
  - d. maintaining appropriate communications with the program director.

C. Faculty

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## **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. Contact with various patient types in a variety of settings such as health fairs, donor or pheresis centers, nursing homes, in addition to the typical inpatient and outpatient settings;
3. The curriculum must include a minimum of 100 hours of clinical experiences and a minimum of 100 successful unaided collections;
4. 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.

### **B. Learning Experiences**

1. Learning experiences (courses, practica, other required activities) 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. After demonstrating competency, students, with qualified supervision, may be permitted to perform procedures.

### **C. Evaluations**

Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standard II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.

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



## **Unique Standards for the Clinical Assistant (CA)**

### **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 clinical assistant programs. Paper reviewers and site visit teams assist in the evaluation of the program's compliance with the Standards. Lists of approved programs are published for the information of students, employers, and the public.

### **DESCRIPTION OF THE CLINICAL ASSISTANT PROFESSION**

Clinical Assistant is the term NAACLS uses to designate a formally prepared multi-skilled healthcare provider. The Clinical Assistant Competencies define the required skills with a laboratory focus. The Clinical Assistant Standards are used to evaluate educational programs for the Clinical Assistant. For information regarding the level of laboratory testing appropriate for the Clinical Assistant, contact the Center for Disease Control or the United States Health Care Financing Administration.

In accordance with its mission, NAACLS provides leadership in fostering innovative educational approaches and actively supporting cooperative efforts with other agencies. NAACLS encourages employers to formalize training programs for the Clinical Assistant using this approval process. NAACLS also supports the addition of this approved Clinical Assistant program to the competencies of other accredited health service programs.

### **Description of Entry Level Competencies of the Clinical Assistant**

At entry level, Clinical Assistants are able to:

- A. Define the role of the clinical assistant in the healthcare delivery system;
- B. Use common medical terminology;
- C. Demonstrate knowledge of infection control and safety practices;

- D. Follow standard operating procedures to collect specimens;
- E. Prepare blood and body fluid specimens for analysis according to standard operating procedure;
- F. Prepare/reconstitute reagents, standards and controls according to standard operating procedure;
- G. Perform appropriate tests at the clinical assistant level, according to standard operating procedures;
- H. Perform and record vital sign measurements;
- I. Follow established quality control protocols;
- J. Communicate (verbally and non-verbally) effectively and appropriately in the workplace;
- K. Use information systems necessary to accomplish job functions;
- L. Identify and report potential pre-analytical errors that may occur during specimen collection, labeling, transporting and processing.

## **VII. CA 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
  - a. Has a baccalaureate degree or higher;
  - b. Holds ASCP-BOC or ASCP<sup>i</sup>-BOC certification as a Medical Laboratory Scientist/Medical Technologist or Medical Laboratory Technician.

- c. Has three years of experience in medical laboratory science education;

Program Directors who have been approved as a program director of a NAACLS approved CA 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 3 years;
- d. Be responsible for maintaining NAACLS approval of the program;
- e. Have regular and consistent contact with students, faculty, and program personnel.

B. Site Program Coordinator (required for multi-location programs only; assigned to each participating site)

1. Qualifications

The site program coordinator must:

- a. Have an academic degree appropriate to the program level;
- b. Hold the same level certification required of a program director;
- c. Have at least one year of experience in medical laboratory science education

2. Responsibilities

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

- a. Coordinating teaching and clinical education;
- b. Evaluating program effectiveness;
- c. Maintaining appropriate communications with the program director.

C. Faculty

1. Didactic Instructor Appointments

The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). 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 area;
- 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 Liaison

At least one clinical liaison, who is employed by the clinical 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 medical laboratory professional 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 experience as a medical laboratory 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

There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, public member) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

## VIII. CA 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 Clinical 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. Application of safety and governmental regulations compliance
  - 3. Principles and practices of professional conduct and the significance of continuing professional development.
  - 4. Communications sufficient to serve the needs of patients, the public, and members of the health care team.
- B. Learning Experiences
- 1. Learning experiences (courses, practica, other required activities) 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.1.
  - 2. After demonstrating competency, students, with qualified supervision, may be permitted to perform procedures.
- C. Evaluations
- Evaluation systems must relate to course content and support program competencies. If there is evidence that competencies are not adequately achieved (through feedback mechanisms as described in Standards II.B) then course objectives will be examined in detail to assure that the objectives are behavioral, include all domains and relate directly to the evaluations used.
- 1. These evaluation systems must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress.

2. The evaluation systems must serve as a reliable indicator of the effectiveness of instruction and course design.