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Standards for Accredited Doctorate In Clinical Laboratory Science (DCLS) Programs

I. Sponsorship

A. Primary 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 doctoral education, with access to a teaching hospital with diagnostic diversity and health care expertise

2. 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 doctoral degree granting authority. The institution must have access to a teaching hospital with diagnostic diversity and health care expertise (for programs outside of the United States)

B. Consortium Sponsor

A consortium is 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 doctoral 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 documenting satisfactory completion of the educational program
   e. receiving and processing applications for admission
   f. ensuring that appropriate personal safety measures are addressed for students and faculty
   g. ensuring that all provisions of the Standards are met
   h. ensuring that graduates of the program have obtained or will obtain an earned doctoral degree, or, for students who hold or complete the required degree, a comparable certificate that meets competencies in cases where the doctoral degree is not a DCLS
   i. supervising of research efforts

2. The sponsor must ensure that the activities assigned to students in the clinical setting support doctoral level studies

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 complete 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

6. The sponsor must have adopted a statement of mission that:
   a. supports the purpose of the institution(s) sponsoring the program
   b. provides for a doctoral program and the conduct of research and service activities.

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

   Programs must define a set of outcomes as they relate to the sponsor’s mission. Outcome measures must be documented, analyzed and used in program evaluation. Outcome measures must be used for ongoing curriculum development and demonstrate the effectiveness of any changes implemented.

III. Resources

A. General Resources

   1. The program must demonstrate that the faculty cohort possesses the depth and diversity of expertise and experience necessary to structure, deliver and assess the effectiveness of the program

   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.

D. Institutional Resources

Adequate resources must be available to facilitate each student’s attainment of doctoral level competencies as defined in the program’s 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. program accreditation status including the name, address and contact information for NAACLS
   d. results of the program outcome measures as identified in Standard II.B
   e. list of affiliated facilities
   f. admission criteria, including essential 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
   i. current tuition and fees including withdrawals and refund policies
   j. policies and processes by which students may perform service work
   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; academic calendar

I. 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. Examples of records 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.

D. Admissions
All admitted students must have:

1. a minimum of a baccalaureate degree, or foreign equivalent
2. generalist certification as a Medical Laboratory Scientist/Medical Technologist

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. A written record of any formal student complaints and their resolution must be maintained

D. The granting of the degree must not be contingent upon the student passing any type of external certification or licensure examination

E. 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

F. Extracurricular work by students must be noncompulsory

G. Trainee experiences must be educational and balanced so that all competencies can be achieved. Learning must not be compromised by reliance on trainees to fulfill staffing obligations

VI. Administrative: Maintaining Accreditation

Program/Sponsoring Institution Responsibilities

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

A. Submitting required documentation determined 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. This includes changes in program official names, physical addresses, program landing page address or telephone numbers; affiliates, 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 is awarded

E. Submitting an assessment report on an annual basis to NAACLS addressing major changes, if any, and program assessment standards (Standard II) by the established deadline date

F. Completing reports required by NAACLS and returning them by the established deadlines

G. Verifying compliance with these Standards upon request from NAACLS, which may include submitting to an off cycle site visit

VII. Program Administration

A. Program Director

1. Qualifications

   The program director must be a medical laboratory professional who has

   a. a doctoral degree from an accredited institution

   b. ASCP-BOC or ASCPi-BOC generalist certification as a Medical Laboratory Scientist/Medical Technologist

   c. three years of teaching experience

   d. appropriate graduate level teaching experience

   e. 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 of participation 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 continuing faculty appointment(s) at the sponsoring institution(s).

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. 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 must be designated at each clinical site affiliated with the program to coordinate clinical experience for students.

a. Qualifications

   The clinical liaison must:

   i. Demonstrate the ability to effectively oversee clinical experiences of the students

   ii. demonstrate knowledge of advanced level practice

b. Responsibilities
The clinical liaison must be responsible for:

i. coordinating clinical instruction at the site

ii. communicating with the program director

D. Advisory Committee

There must be an advisory committee composed of individuals from the communities of interest.

1. Responsibilities

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

VIII. Curriculum Requirements

A. Instructional Areas

1. Graduate-level coursework that includes an appropriate mix of didactic, clinical practice and research must be assured.

2. The program curriculum must include advanced theory and clinical correlation at the graduate level. The curriculum must address pre-analytical, analytical, and post-analytical components of laboratory services.

The program curriculum must contain the following advanced content:

a. Clinical Chemistry

b. Hematopathology/Hemostasis

c. Immunology

d. Immunohematology and Transfusion Services

e. Microbiology and Infectious Disease

f. Molecular Diagnostics and Medical Genetics

g. Laboratory Operations
3. The program curriculum must include scientific and medical information sufficient to provide a foundation for graduate-level work including:

   a. Research Design and Statistics
   b. Epidemiology
   c. Clinical Pharmacology
   d. Pathophysiology
   e. Health Assessment
   f. Health System Operations

4. The program curriculum must include principles and practices of:

   a. patient-centered care to provide and coordinate care as related to laboratory services including disease prevention, wellness promotion, and public health initiatives
   b. healthcare policy including governance and policy development
   c. leadership and management as applied to healthcare services
   d. quality improvement as related to the clinical laboratory and the healthcare team
   e. informatics as related to laboratory stewardship.
   f. professionalism and ethics as they apply to protection of human subjects clinical and research settings
   g. communication and interprofessional collaboration for improving patient and population health outcomes
   h. educational methodologies and terminology sufficient to educate the public, patients, and healthcare team on laboratory related services
   i. grant proposal development
5. An applied or translational research project, final treatise, thesis or capstone project must be required.

B. Experiential Areas

1. Providing patient-centered care including education, consultation, clinical rounding and diagnostic management

2. Applying interpersonal and communication skills with inter-professional teams, diverse communities of patients, and family members

3. Engaging in professionalism and ethics in clinical and research environments

4. Designing, conducting and applying evidence-based clinical research or health outcomes studies

C. Evaluations

1. Written criteria for passing, failing, and progression in the program must be provided to each student at the time of entry into the program.

2. Evaluations of student performance must be related to the objectives and competencies for both instructional and experiential components. They must be employed frequently enough to provide students and faculty with timely indications of the student’s academic standing and progress.

3. Students learning outcomes must be evaluated for the effectiveness of instruction and course design.