Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/ Medical Technologist

PREAMBLE

OBJECTIVE

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 laboratory science/medical 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 CLINICAL LABORATORY SCIENCE PROFESSION

The clinical laboratory professional 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. Clinical laboratory professionals 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 clinical laboratory professional has 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 laboratory testing is researched, developed or performed. Clinical laboratory professionals possess skills for financial, operations, marketing, and human resource management of the clinical laboratory. Clinical laboratory 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, 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 CAREER ENTRY OF THE CLINICAL LABORATORY SCIENTIST/MEDICAL TECHNOLOGIST

At career entry, the clinical laboratory scientist/medical technologist will be proficient in performing the full range of clinical laboratory tests in areas such as hematology, clinical chemistry, immunohematology, microbiology, serology/immunology, coagulation, molecular, and other emerging diagnostics, and will play a role in the development and evaluation of test systems and interpretive algorithms. The clinical laboratory scientist/medical technologist 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. The clinical laboratory scientist/medical technologist will also possess basic knowledge, skills, and relevant experiences in:

- A. Communications to enable consultative interactions with members of the healthcare team, external relations, customer service and patient education;
- B. Financial, operations, marketing, and human resource management of the clinical laboratory to enable cost-effective, high-quality, value-added laboratory services;
- C. Information management to enable effective, timely, accurate, and cost-effective reporting of laboratory-generated information, and;
- D. Research design/practice sufficient to evaluate published studies as an informed consumer.

Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/Medical Technologist

REQUIREMENTS FOR ACCREDITATION

I. SPONSORSHIP

1. Institutional Affiliation

The sponsoring institution and affiliates, clinical and/or academic, if any, must be accredited by recognized regional and/or national agencies.

In programs in which the education is provided by two or more institutions, responsibilities of the sponsoring institution and of each affiliate for program administration, instruction, and supervision must be described in writing and signed by both parties. All provisions of the agreement must be active with written documentation of the following items:

- A. General
 - 1. Reason for the agreement
 - 2. Responsibilities of the academic facility
 - 3. Responsibilities of the clinical facility
 - 4. Joint responsibilities
- B. Specific
 - 1. Supervisory responsibilities for the students
 - 2. Student professional liability coverage
 - 3. Student health and safety policies
 - 4. Provision for renewal
 - 5. Termination clause providing for program completion of enrolled students

2. Acceptable Institutions

Educational programs must be established in:

- A. colleges and universities;
- B. hospitals and medical centers;
- C. medical laboratories, and;
- D. other institutions or consortia which meet comparable standards for education in clinical laboratory science.

3. Sponsoring Institution's Responsibilities

Accreditation is granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and applied education, appoints faculty to the program, receives and processes applications for admission, and grants the baccalaureate or higher degree or certificate documenting completion of the program.

- A. The sponsoring institution or consortium must be responsible for providing assurance that the activities assigned to students in the clinical setting are educational.
- B. There must be documented ongoing communication between the sponsoring institution and its affiliates for exchange of information and coordination of the program.

II. RESOURCES

4. General Resources

Resources must support the number of students admitted into the program. The instructor to student ratio must be adequate to achieve the stated program goals.

5. Program Administration

- A. Program Director
 - 1. The program must have a qualified program director.
 - 2. Responsibilities

The program director must be responsible for the organization, administration, periodic review, planning, development, evaluation and general effectiveness of the program. The program director must have input into budget preparation and must be responsible for maintaining NAACLS approval of the program.

3. Qualifications

The program director must be a clinical laboratory scientist/medical technologist who holds nationally recognized generalist certification and who has a master's or doctoral degree and three years of experience in clinical laboratory science education that includes teaching courses, conducting and managing learning experiences, evaluating student achievement, providing input into curriculum development, policy and procedure formulation, and evaluation of program effectiveness. The program director must have a knowledge of education methods and administration as well as current accreditation and certification procedures.

4. 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.

- B. Advisory Committee
 - 1. There must be an advisory committee composed of individual(s) from the community of interest (i.e. pathologists, other physicians, scientific consultants, academic professionals, administrators, practicing clinical laboratory scientists/medical technologists, practicing

clinical laboratory technicians/medical laboratory technicians and other professionals) who have knowledge of clinical laboratory science education.

2. Responsibilities

The advisory committee of the program shall have input into any aspect of the program/curriculum with regard to its current relevancy and effectiveness.

6. Faculty

The program must have qualified faculty (e.g., clinical laboratory scientists/medical technologists, administrators, managers and physicians).

A. Responsibilities

The faculty must participate in teaching courses, supervising applied laboratory learning experiences, evaluating student achievement, developing curriculum, formulating policy and procedures, and evaluating program effectiveness.

B. Qualifications

Faculty designated by the program must demonstrate adequate knowledge and proficiency in their content areas and demonstrate the ability to teach effectively at the appropriate level.

C. Professional Development

The program must assure and document ongoing professional development of the program faculty to assure that the faculty members are able to fulfill their instructional responsibilities.

7. Financial Resources

Financial resources for continued operation of the educational program must be ensured by an adequate, institutionally approved budget or by a statement of continued financial support from an executive officer of the sponsoring institution.

8. Physical Resources

A. Facilities

Classrooms, laboratories, administrative offices and other facilities must be adequate, equipped for safety, and must be in compliance with pertinent governmental laws.

B. Equipment and Supplies

Each student must have reasonable access to and experience with modern equipment and supplies.

C. Information Resources

Each student must have reasonable access to information resources containing current editions of books, periodicals and other reference materials in contemporary formats related to all content areas of the curriculum.

D. Instructional Resources

Adequate instructional resources must be available to facilitate each student's attainment of entry level competencies.

E. Computer Technology

Each student must have access to and experience with contemporary computer technology.

III. CURRICULUM

9. Curricular Requirements

A. Curricular Structure

Instruction must follow a plan which documents a structured curriculum composed of general education, basic sciences, and professional courses including applied (clinical) education. The curriculum must include clearly written program goals and competencies and course syllabi which must include individual course goals and objectives.

The curriculum must include all the major subject areas currently offered in the contemporary clinical laboratory. Behavioral objectives which address cognitive, psychomotor, and affective domains must be provided for didactic and applied (clinical practice) aspects of the program and must include clinical significance and correlation. Course objectives must show progression to the level consistent with entry into the profession.

B. Instructional Areas

The curriculum must include:

- 1. Scientific content (either prerequisite or as an integral part of the curriculum) to encompass areas such as anatomy/physiology, immunology, genetics/molecular biology, microbiology, organic/biochemistry, and statistics.
- 2. Pre-analytical, analytical, and post-analytical components of laboratory services, such as hematology, hemostasis, chemistry, microbiology, urinalysis, body fluids, molecular diagnostics, immunology, phlebotomy, and immunohematology. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting, techniques, interpretation of clinical procedures and results, statistical approaches to data evaluation, and continuous assessment of laboratory services for all major areas practiced in the contemporary clinical laboratory.
- 3. Principles and practices of quality assurance/quality improvement as applied to the preanalytical, analytical, and post-analytical components of laboratory services.

- 4. Application of safety and governmental regulations and standards as applied to laboratory practice.
- 5. Principles of interpersonal and interdisciplinary communication and team-building skills.
- 6. Principles and application of ethics and professionalism to address ongoing professional career development.
- 7. Education techniques and terminology sufficient to train/educate users and providers of laboratory services.
- 8. Knowledge of research design/practice sufficient to evaluate published studies as an informed consumer.
- 9. Concepts and principles of laboratory operations must include:
 - a. Critical pathways and clinical decision making;
 - b. Performance improvement;
 - c. Dynamics of healthcare delivery systems as they affect laboratory service;
 - d. Human resource management to include position description, performance evaluation, utilization of personnel, and analysis of workflow and staffing patterns, and;
 - e. Financial management: profit and loss, cost/benefit, reimbursement requirements, materials/inventory management.
- C. Learning Experiences

The learning experiences needed in the curriculum to develop and support entry level competencies must be properly sequenced and include instructional materials, classroom presentations, discussion, demonstrations, laboratory sessions, supervised practice and experience.

- 1. Student experiences must be educational and balanced so that all competencies can be achieved.
- 2. Student experiences at different clinical sites must be comparable to enable all students to achieve entry level competencies.
- 3. Policies and processes by which students may perform service work must be published and made known to all concerned in order to avoid practices in which students are substituted for regular staff. After demonstrating proficiency, students, with qualified supervision, may be permitted to perform procedures. Service work by students in clinical settings outside of academic hours must be noncompulsory.
- D. Evaluations

Written criteria for passing, failing, and progression in the program must be provided. These must be given to each student at the time of entry into the program. Evaluation systems must be related to the objectives and competencies described in the curriculum for both didactic and applied components. They must be employed frequently enough to provide students and faculty with timely indications of the students' academic standing and progress and to serve as a reliable indicator of the effectiveness of instruction and course design.

IV. STUDENTS

10. Program Description/Publications

Students must be provided with a clear description of the program and its content and current publications, which must include:

- A. program mission statement;
- B. program goals and competencies;
- C. course objectives;
- D. applied education assignments (if applicable);
- E. admission criteria, both academic and non-academic;
- F. a list of course descriptions;
- G. names and academic rank or title of the program director and faculty;
- H. tuition and fees with refund policies;
- I. causes for dismissal;
- J. rules and regulations;
- K. a listing of clinical facilities (if applicable),
- L. essential functions, and
- M. policies and procedures when applied experience cannot be guaranteed.

11. Admissions

Admission of students, including advanced placement if available, must be made in accordance with the clearly defined and published practices of the institution. Specific academic standards and essential functions required for admission to the program must be clearly defined, published and provided to prospective students and made available to the public. The signature of the student indicating full understanding of the policies for progression in the program and completion of the program must be secured.

12. Acceptable Conduct

Rules and regulations governing acceptable personal and academic conduct must be defined and provided to all students upon entering the program.

13. Student Records

Student records must be maintained for admission, evaluation, and counseling or advising sessions. Individual grades and credits for courses must be recorded and permanently maintained by the sponsoring institution. The program must maintain the student records, conforming to any governmental regulations and the regulations of any other accrediting agencies.

14. Health and Safety

There must be a procedure for determining that each applicant's or student's health will permit the individual to meet the written essential functions of the program. Students must be informed of and have access to the usual student health care services of the institution. The health and safety of students, faculty, and patients associated with educational activities must be safeguarded. Emergency medical care must be available for students while in attendance.

15. Guidance

Guidance must be available to assist students in understanding and observing program policies and practices, for advising on professional and career issues, and for providing counseling or referral for personal and financial problems that may interfere with progress in the program. Confidentiality and impartiality must be maintained in dealing with student problems.

16. Appeal Procedures

Appeal procedures must be distributed to students upon entering the program. They must include provisions for academic and non-academic types of grievances and a mechanism for neutral evaluation that ensures due process and fair disposition.

V. OPERATIONAL POLICIES

17. Fair Practices

- A. Programmatic announcements must accurately reflect the program offered and include NAACLS' name, address and phone number.
- B. Student recruitment and admission must be non-discriminatory in accordance with existing governmental regulations and the regulations of any other accrediting agencies applicable to the institution.
- C. Faculty recruitment and employment practices must be non-discriminatory in accordance with existing governmental regulations and the regulations of any other accrediting agencies applicable to the institution.
- D. Academic credits and costs to the student must be accurately stated, published, and made known to all applicants.
- E. Policies and procedures for student withdrawal and refunds of tuition and fees must be published and made known to all applicants.
- F. If more than one clinical laboratory science program is offered at an institution, the sponsoring institution must demonstrate that each program is being conducted to assure appropriate instruction for the students at the different educational levels.
- G. The program must culminate in at least a baccalaureate degree or higher or in a certificate for the student who enters the program with a baccalaureate degree. The granting of the degree or certificate must not be contingent upon the student's passing any type of external certification or licensure examination. Academic standards for the program must be acceptable to the institution that grants the degree.
- H. A written record of formal student complaints and resolution must be maintained.
- I. Program evaluation information, including graduation, placement and any certification pass rates must be made available to NAACLS upon request.

VI. PROGRAM EVALUATION

18. Systematic Review

There must be a mechanism for continually and systematically reviewing the effectiveness of the program to include survey and evaluation instruments that incorporate feedback from a combination of students, employers, faculty, graduates, exit or final examinations, and accreditation review.

19. Outcome Measures

A review of outcomes measures (e.g. external certifying examination results, results from capstone projects) from the last three active years must be documented, analyzed and used in the program evaluation.

20. Graduation and Placement Rates

A review of graduation rates and placement rates must be documented, analyzed and used in the program evaluation.

21. Program Evaluation and Modification

The results of program evaluations must be documented and reflected in ongoing curriculum development and program modification, followed by an analysis of the effectiveness of any changes implemented.

VII. MAINTAINING ACCREDITATION

22. Program/Sponsoring Institution Responsibilities

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

- A. Submitting the Self-Study Report, an Application for Continuing Accreditation, or a required Progress Report as determined by NAACLS;
- B. Paying accreditation fees, as determined by NAACLS;
- C. Informing NAACLS of relevant administrative and operational changes within 30 days. This includes changes in program official names, addresses or telephone numbers; affiliates, status (e.g., inactivity, closure) or location; and institution name;
- D. Completing an Annual Report prescribed by NAACLS and returning it by the established deadline;
- E. Verifying compliance with these Standards upon request from NAACLS, and;
- F. Agreeing to a site visit date before the end of the period for which accreditation was awarded.