

# **Unique Standards and Documentation Required for Accredited CLS/MT Programs**

## **UNIQUE STANDARDS AND THE REQUIRED DOCUMENTATION**

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### **Clinical Laboratory Scientist/Medical Technologist**

#### **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 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.

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## **20. 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.

## 21. 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.

### D. Consortium Education Coordinator (when required, one at each participating entity in a consortium or joint venture)

#### 1. Responsibilities

The Consortium Education Coordinator, when required, is responsible for coordinating classroom teaching and applied education, evaluating program effectiveness, and must have appropriate communications with the Program Director.

## 2. Qualifications

The education coordinator, when required, must hold an appropriate nationally recognized certification required of a program director as stated in Standard 20, an academic degree appropriate to the program level, and at least one year of experience in clinical laboratory science education, including teaching courses, conducting and managing learning experiences, evaluation student achievement, and evaluating instructional effectiveness.

## 22. 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 immunoematology. 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 pre-analytical, 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.

<b>Documentation Required for CLS/MT Unique Standards</b>			
	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 20A1	<u>No Narrative Required</u>	Submit a completed Faculty Fact Sheet for the program director.  <i>The Faculty Fact Sheet is located in the appendix of the Guide.</i>	
Standard 20A2	<u>No Narrative Required</u>	Submit a position description which describes the responsibilities of the program director.	Verify that the program director is responsible for the required aspects of the program.
Standard 20A3	<u>No Narrative Required</u>	Submit the curriculum vita for the program director  Indicate the date that NAACLS approved the program director.  Indicate how knowledge of education, administration and current accreditation/certification procedures was obtained.	Verify that the program director meets the qualifications listed in Standard 20A1-3.
Standard 20A4	<u>No Narrative Required</u>	Document the faculty appointment for the program director at each affiliated academic institution.	Verify documentation (e.g., notice of appointments, academic catalogs, faculty listings) of faculty appointments for the program director at each affiliated academic institution.

### Documentation Required for CLS/MT Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 20B1	<u>No Narrative Required</u>	Submit the name(s) comprising the advisory committee.  Indicate the relationship of the advisory committee member(s) to the program.	
Standard 20B2	Describe the responsibilities of the advisory committee.	Submit a copy of the advisory committee meeting minutes.	Verify the responsibilities of the advisory committee.
Standard 21	<u>No Narrative Required</u>	List the <b>major</b> clinical/didactic faculty for each laboratory discipline.	
Standard 21A	Describe the responsibilities of the program faculty.	<u>No Documentation Required</u>	Verify that faculty are responsible for the required aspects of the program.
Standard 21B	Describe how faculty are evaluated relative to appropriate qualifications.	Submit completed Faculty Fact Sheets for the major didactic faculty for each laboratory discipline. List details of major clinical faculty on Clinical Faculty Fact Sheets.	Verify that faculty have adequate knowledge and proficiency in their content areas.  Verify that major clinical/didactic faculty have the ability to teach effectively at the appropriate level.  Review faculty evaluations.

<b>Documentation Required for CLS/MT Unique Standards</b>			
	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 21C	Describe how the program ensures ongoing professional development of its' clinical and didactic faculty.	Submit sample documentation of ongoing professional development of the clinical and didactic faculty to fulfill instructional abilities.	Verify that the program assures and documents the ongoing professional development of clinical and didactic faculty.
<b><i>IN CASES OF CONSORTIA OR JOINT VENTURES, SUBMIT INFORMATION FOR STANDARDS 21D1 AND 21D2.</i></b>			
Standard 21D	<u><i>No Narrative Required</i></u>	Submit a completed Faculty Fact Sheet for the consortium education coordinator.	
Standard 21D1	<u><i>No Narrative Required</i></u>	Submit a position description which describes the responsibilities of the consortium education coordinator.	Verify that the consortium education coordinator is responsible for the required aspects of the program
Standard 21D2	<u><i>No Narrative Required</i></u>	Submit a curriculum vita for the consortium education coordinator.  Indicate how knowledge of educational methods and current accreditation/certification procedures was obtained.	Verify that the consortium education coordinator meets the qualifications listed in Standard 20AA2.

## Documentation Required for CLS/MT Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
<p>Standard 22A</p> <p><i>See appendix for Guidelines to Standard 22.</i></p>	<p><u><i>No Narrative Required</i></u></p>	<p>Submit a structured curriculum plan (or sequence of courses).</p> <p>Submit the program goals and competencies.</p> <p>Submit course syllabi with course goals and behavioral objectives for <b>ONE SAMPLE UNIT OF INSTRUCTION</b>. The sample unit should have both lecture and laboratory/clinical components.</p> <p>Submit objectives in the cognitive, psychomotor and affective domains for <b>ONE SAMPLE UNIT OF INSTRUCTION</b>.</p>	<p>Verify that students progress through the program as indicated in the Self-Study Report.</p> <p>Verify that the program has clearly written goals and competencies.</p> <p>Review course objectives for each subject area.</p> <p>Verify that the program has appropriate objectives in the cognitive, psychomotor and affective domains.</p> <p>Verify that the course objectives show progression to the level consistent with entry into the profession.</p>

### Documentation Required for CLS/MT Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22B	<p>Describe the coursework required for completion of the program and indicate whether the course work is addressed as part of the professional program or prior to admission to the program.</p> <p>Identify where the items described in Standard 22B1-9 are included in the curriculum.</p>	<p>Submit brief summaries or course descriptions for each unit of instruction or course in the program.</p> <p>Matrices are provided in the appendix to assist you in identifying where units of instruction are located in the program's curriculum.</p> <p><i>*Use of the matrices is optional.</i></p>	<p>Verify that the curriculum includes the required areas described in Standard 22B1-9.</p> <p>Verify that course work includes all instructional areas.</p>
Standard 22C	<p>Briefly describe how the required material and activities listed in Standard 22B are used in the program to develop entry-level competencies.</p>		<p>Verify that instruction provides sequenced learning experiences</p> <p>Verify that the required materials and activities found in Standard 22B are used in the program to develop entry-level competencies</p>

### Documentation Required for CLS/MT Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22C (continued)	If applicable, describe how student experiences at different clinical sites are ensured as comparable.	Submit a brief summary of the types of laboratory tests performed in each clinical area.	Review the laboratory tests performed in each clinical area.  If applicable, verify that student experiences at different clinical sites are ensured as comparable.
	Justify learning experiences during hours other than the normally scheduled clinical experience.	Submit objectives and evaluation instruments for any learning experiences during hours other than the normally scheduled clinical experience.	Review the justification, objectives and evaluation instruments for any learning experiences during hours other than the normally scheduled clinical experience.  Verify that clinical training is sufficiently balanced to assure that all objectives and competencies are achieved.

### Documentation Required for CLS/MT Unique Standards

	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22C (continued)	Describe how policies and procedures regarding service work are distributed to students and clinical facilities.	Submit policies and procedures explaining when students may perform service work.	<p>Verify that policies and procedures explaining when students may perform service work are published, distributed to students and distributed to clinical affiliates.</p> <p>Verify that service work by students in the clinical settings outside of regular academic hours is non-compulsory.</p>
Standard 22D	<u><i>No Narrative Required</i></u>	Submit the criteria for passing, failing and progression in the program.	Verify that the criteria for passing, failing and progression in the program are established and given to students at the time of entry into the program.

<b>Documentation Required for CLS/MT Unique Standards</b>			
	<i>Narrative</i>	<i>Documentation</i>	<i>Site Visitor Role</i>
Standard 22D (continued)		<p>Indicate when the criteria for passing, failing and progression in the program are given to students.</p> <p>Submit evaluation systems for <b>ONE SAMPLE UNIT OF INSTRUCTION. Evaluation systems must correlate with objectives and competencies submitted for Standard 22A.</b></p> <p>Indicate the frequency of student evaluation in lectures and student and/or clinical laboratories.</p>	<p>Review the evaluation systems for each subject.</p> <p>Review the evaluation systems in the affective domain.</p> <p>Verify that the evaluation systems are employed frequently enough to provide faculty and students with timely indications of a student's academic standing and progress, and to serve as a reliable indicator of the effectiveness of instruction and course design.</p>



