

Template-based Approach to Delegation of Duties in the Clinical Laboratory

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Abstract

Competency assessment is one of the most common deficiencies received in high and moderate complexity clinical laboratories every year. Lab Directors and Managers must understand the roles and responsibilities for all staff, and what may be delegated to whom. Competency assessment is a responsibility that must be delegated in writing to a qualified individual, a huge challenge for larger testing facilities. The authors developed a standardized process for qualifying assessors and documenting delegated responsibilities with role-based templates, including a centralized electronic storage system to house and maintain all documentation. This template-based approach is scalable to any size laboratory or facility.

Background

The Mayo Clinic Department of Laboratory Medicine and Pathology (DLMP) in Rochester, Minnesota is home to over 3,300 allied health staff employees in 63 laboratories performing non-waived patient testing through our intramural and extramural practice. DLMP had a 2017 billable volume of over 25 million tests; 11.2 million in the intramural practice and 14 million in the extramural practice.

Standardizing processes has become essential to our quality management program.

Terminology

DLMP Role	CLIA Role	NYS Role
Department Chair	CLIA Lab Director	NYS Lab Director *PFI specific
Laboratory Section Director	Technical Supervisor (high complexity) Technical Consultant (moderate complexity)	Assistant Director -COQ Holder Moderate Complexity n/a
Consultant	Clinical Consultant	
Supervisor	General Supervisor (high complexity labs only)	NYS Supervisor (high complexity labs only)

Figure 1. The Department of Laboratory Medicine and Pathology (DLMP) utilizes various job positions to fulfill both CLIA and New York State (NYS) roles.

Role Demographics

CLIA Role	# of Personnel
CLIA Lab Directors	5
Staff Pathologists	71
Technical Supervisors	97
Technical Consultants	10
Clinical Consultants	78
General Supervisors	54
Testing Personnel	2,255

Figure 2. Personnel in CLIA defined roles within DLMP

Personnel Roster

Figure 3. A personnel roster template was created to accommodate the content and formatting of various accrediting and regulatory bodies. This allows for easy maintenance and documentation of personnel record requirements.

Letters of Delegation

Figure 4. Templates were created allowing for person specific delegation from the CLIA lab director down to an employee performing direct observation at the bench level.

Qualifications Worksheet

Figure 5. To eliminate ambiguity, worksheets assist laboratory supervisors in determining if personnel are qualified to perform supervisory delegated tasks. It also includes information necessary for the employee's file.

Competency Assessment of Delegated Supervisory Duties

Figure 6. Annual competency assessment is required to be performed on individuals performing supervisory delegated responsibilities. A template was created allowing for customization of the assessment.

- ### Outcomes
- This process allows for a standardized approach to delegation
 - Scalable templates allow for easy use in any sized laboratory.
 - Documentation is maintained electronically in a central location allowing for quick retrieval during inspections and as needed.
 - By using this process DLMP ensures all personnel with supervisor delegated responsibilities are qualified, delegated assigned responsibilities in writing and competency assessed annually.

- ### References
- 42 CFR 493. Clinical Laboratory Improvement Act, 1988 Amendments
 - College of American Pathologists Accreditation and Laboratory Improvement—Accreditation Checklists.
 - New York State Clinical Laboratory Evaluation Program—Laboratory Standards.