TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2019
Department:	Mgmt & QA	**Due Date:**	7/31/2019
		Implementation:	**7/23/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Authorization of Personnel and Delegation of Responsibilities SGMC.QA3001 v1

Description of change(s):

This is a 'new' SOP that replaces 2 previous NQA corporate policies; *Policy for Delegation of Responsibilities* and *Policy for Authorization of Personnel*

It is very similar to the old SOPs but has been converted to our local SOP format and info that did not pertain to our labs was deleted

This SOP will be implemented on July 23, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Authorization of Personnel and Delegation of Responsibilities**
Prepared by	Leslie Barrett Date: 6/4/2019
Owner	Cynthia Bowman-Gholston, Robert SanLuis Date: 6/4/0219

Local Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This document describes the policy and process for the CLIA Laboratory Director to:

- Delegate and reapportion certain responsibilities and duties in laboratories on their behalf. This document also provides a standard process that defines, in writing, the authorized designee's responsibilities and duties.
- Authorize individuals to perform their current duties and job responsibilities.

2. SCOPE

This policy applies to all Laboratory personnel.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and any revisions. • Ensures that delegated responsibilities are assigned to qualified individuals. • Authorizes appropriately trained and qualified individuals to perform pre-analytic, analytic, and post-analytic duties. • Ensures test systems and associated records of employee Training and Competency are maintained by delegated individuals • Signs Delegation and Authorization Documents. • Ensures adequate continuing clinical laboratory education programs are available for all personnel.
Laboratory Director or Designee	• Recurring review of this SOP
Technical Supervisor	• Implements this process in the area(s) for which he/she is responsible. • Ensures applicable documentation of education, experience, and certification is on file according to standard practice. • Ensures that each authorized individual successfully completes the appropriate training • Ensures employee training records include the level of supervision required, when applicable. • Ensures each authorized individual demonstrates competency to perform the applicable test systems.
Pre-analytical/Post-analytical Department Manager	• Implements this process in the area(s) for which he/she is responsible. • Ensures applicable documentation of education, experience, and certification is on file according to standard practice. • Ensures that each authorized individual has successfully completed the appropriate training and demonstrates competency to perform the applicable job assignments for pre-analytical or post-analytical processes.
Laboratory Management and Quality Assurance Department	• Ensures that all Delegation and Authorization Documents have Laboratory Director approval signature (electronic or manual) • Ensures the original signed Documents are retained according to document control practice • Ensures retired (inactive) Documents are archived according to record retention policy

4. DEFINITIONS

Term	Definition
Assessor	Qualified individual(s) who is/are delegated to perform competency assessment functions.
Clinical Consultant	Individual(s) qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care.
General Supervisor	Qualified individual(s) who, under the direction of the Laboratory Director and supervision of the Technical Supervisor, provides day-to-day supervision of testing personnel and reporting of test results for **high** complexity testing.
High Complexity Testing	Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health
Laboratory Director	An individual qualified to manage and direct laboratory personnel and the performance of **moderate complexity or high complexity test** performance. This is the individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CLIA and CAP certificate (as applicable).
Moderate Complexity Testing	Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health
Non-testing Personnel	Individuals responsible for performing pre-analytic and/or post-analytic tasks which are not technical in nature.
Pre-analytical/Post-analytical Department Manager	An individual who, under the direction of the Laboratory Director, is primarily responsible for a pre-analytic or post-analytic area or department. The Quest Diagnostics job title may vary and does not have to include the word "manager."
Pre-analytical/Post-analytical Department Supervisor	An individual who, under the direction of the Laboratory Director and/or Pre-analytic/Post-analytic Department Manager, provides day-to-day supervision of personnel performing pre-analytic and post-analytic processes. The Quest Diagnostics job title may vary and does not have to include the word "supervisor."
Post-analytic Process	A process that occurs after testing is complete, such as result reporting.
Pre-analytic Process	A process that occurs prior to testing, such as patient preparation, specimen collection, identification, preservation, transportation and specimen processing
Technical Consultant	Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **moderate** complexity tests or procedures.
Technical Supervisor	Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **high** complexity tests or procedures.

Term	Definition
Testing Personnel	Individuals responsible for performing laboratory assays and reporting laboratory results

5. POLICY FOR DELEGATION

5.1. The Laboratory Director is responsible for ensuring all persons performing delegated functions are qualified to do so and that the delegated functions are properly performed.

5.2. The Laboratory Director may NOT delegate the following responsibilities:

Responsibility	Duties That May NOT Be Delegated
Quality Management	Ensures that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing. Examples include but are not limited to: o Signature approval of new method validation packages o Signature approval of pre-analytical, analytical, and post-analytical SOPs and revisions to those SOPs o Signature approval of Individual Quality Control Plans (IQCP) o Participation in Quality Management meetings o Documented annual review of the Quality Management program for effectiveness, including determination and/or approval of quality monitors and improvement activities o Selection and approval of referral testing laboratories o Interacting with government and other agencies as appropriate o Provides for intra-laboratory consultations and clinical consultations regarding the ordering of appropriate tests and the medical significance of laboratory data o Documented review and approval of the content and format of patient reports according to regulatory requirements. * o Documented system for reviewing, approving, and authorizing the use of specimen collection/handling procedures (written or electronic) o For part-time Laboratory Directors, there must be an agreement defining the frequency of on-site visits and documentation of activities performed during the visits. * This function may be performed by a Laboratory Director-qualified designee. The laboratory must develop an appropriate Delegation Document describing how this function is delegated.
Safety	Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biologic hazards.

Responsibility	Duties That May NOT Be Delegated
	Examples include but are not limited to: o Signature approval of safety procedures o Evidence of involvement in the laboratory's safety program (may include: participation in safety meetings, consultation on safety policies and issues, review of incident investigations) o Documented review/approval of corrective actions taken for safety issues.
On-Site Supervision	Ensure that a qualified general supervisor provides on-site supervision of high complexity test performance by testing personnel.
Personnel	Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, proper supervision, accurate performance of tests, and to report test results in accordance with the personnel responsibilities described elsewhere. Examples include but are not limited to: o Establish systems to ensure consultants, supervisors, managers, and testing personnel are qualified to perform their assigned duties o Ensure staffing levels are sufficient for the workload o Ensure that all applicable credentials and certifications are documented and on file.
Responsibilities	Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. Examples include but are not limited to: o Delegating, in writing, the specific responsibilities and duties that are delegated to qualified Technical Consultants, Clinical Consultants, Technical Supervisors, General Supervisors, and Pre-analytical/Post-analytical Department Managers using this standard operating procedure. NOTE: The Laboratory Director or Technical Supervisor or Pre-analytical/Post-analytical Department Manager may delegate to General Supervisors or Pre-analytical/Post-analytical Department Supervisors, as appropriate.
Approval Of Standard Operating Procedures (SOP)	Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic and post-analytic phases of testing. Approval of procedures and changes to procedures must be performed by the director named on the laboratory's CLIA certificate.

Responsibility	Duties That May NOT Be Delegated
	If the Laboratory Director does not meet the qualifications of Technical Supervisor for a specialty or subspecialty, the Technical Supervisor must also sign and approve new and changed procedures. Recurring review of procedures may be delegated to the appropriate Technical Supervisor or Pre-analytic and Post-analytic Department Manager. Examples include but are not limited to: o Signing and approving all testing procedures when initially placed in use. This includes all analytic procedures, as well as procedures that contain pre-analytic and post-analytic processes, such as specimen collection, specimen transport, specimen processing, and reporting of patient results o Signing and approving procedures whenever revisions are made. o If there is a change in Laboratory Director, the new director must review and sign all procedures within a reasonable period of time, not to exceed 6 months.

5.3. The Laboratory Director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, OR delegate the following responsibilities to personnel meeting the qualifications:

5.3.1. The Laboratory Director may delegate responsibilities to the **Technical Consultant** (moderate complexity testing) or to the **Technical Supervisor** (high complexity testing).

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate all of the responsibilities, a single duty, or a combination of duties.
- Delegations must not be ambiguous and must clearly indicate who is responsible for each duty in a particular area.
- Delegations may be restricted by department, shift, or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities if appropriately licensed and qualified in the specialty.

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
Test Methodology	• Ensure that the test methodologies selected have the capability of providing the quality of results required for patient care • Ensure verification procedures are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method • Ensure Laboratory personnel perform tests, as required, for accurate and reliable test results. Examples include but are not limited to: o Submission of complete method validation studies to the

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
	Laboratory Director for approval prior to patient testing o Preparation and submission of a complete Standard Operating Procedure for all new or changed test methods, including submission to the Laboratory Director for review and approval signature o Documented training, prior to performing the test, for all testing personnel for any new or changed test methods. o Ensuring that the CAP Activity Menu is correct and changes are appropriately communicated to the quality assurance department and/or CAP
Proficiency Testing (PT)	• Ensure that the laboratory is enrolled in CMS approved PT programs for the testing performed • Ensure PT samples are tested as required • Sign PT survey attestation statement • Ensure PT results are returned within the timeframes established by the PT program • Ensure all PT results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action, including analysis of trends and bias as applicable. • Ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Examples include but are not limited to: o Documentation that all tests are covered by PT or alternative performance assessment (APA) o Timely and accurate submission of PT results o Documented review of PT results and performance, including documented approval of corrective actions taken in response to PT failures and/or near miss evaluations o Documented steps taken to prevent inappropriate referral of PT samples or inappropriate communication of PT results.
Quality Management/ Quality Control	Ensure that quality control and quality management programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Examples include but are not limited to: o Documented review of Quality Control data, Quality Assurance monitors, and Quality Improvement activities o Ongoing assessment of the department's IQCP (s) o Timely and effective responses to quality failures identified through the laboratory's problem tracking process.

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
Analytic Performance	Ensure the establishment and maintenance of acceptable levels of analytic performance for each test system. Examples include but are not limited to: o Ensuring appropriate QC frequency is defined in each SOP o Establishing appropriate QC ranges prior to performing each test system o Documented monthly review of QC data to monitor analytic bias and/or imprecision.
Corrective Action	Ensure that all necessary corrective actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified; and that patient test results are reported only when the system is functioning properly. Examples include but are not limited to: o Review and approval of corrective actions taken in response to QC failures, revised reports, and Reportable Quality Issues (RQIs) o Review and approval of corrective actions taken in response to quality issues identified through the laboratory's problem tracking process and department Quality Management activities o Review of corrective actions taken in response to major instrument or test system failures.
Training	Ensure that, prior to testing patient specimens, all personnel have the appropriate training for the type and complexities of the services offered and have demonstrated that they can reliably perform all testing operations and report accurate results. Examples include but are not limited to: o Ensuring a complete and documented training program is established for all staff
Competency	Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to assure that they are competent and maintain competency to process specimens, perform test procedures and report test results promptly and proficiently. Whenever necessary, identify needs for remedial training. Examples include but are not limited to: o Establishing a complete and documented competency assessment program for all staff o Ensuring that all employees are assessed by a trained appropriately delegated individual using all applicable tools: direct observation, record review, test performance, and assessment of problem-solving skills. o Ensuring that remedial training is provided (as appropriate).

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
SOPs	Ensure that approved procedures are available to all personnel for all aspect of the testing process. Examples include but are not limited to: o Recurring review of approved SOPs to ensure they are complete, readily available, and reflect current practice.

5.3.2. The Laboratory Director may delegate responsibilities to the **Clinical Consultant.**

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate one or both of the responsibilities,
- Delegation may be restricted by department, shift or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities.

Responsibility	Duties That May Be Delegated To Clinical Consultant
Laboratory Reports	Ensure that reports of test results include pertinent information required for interpretation. Example includes but is not limited to: Explanatory medical interpretations added to laboratory reports.
Consultation	Ensure that consultation is available to laboratory clients on matters relating to the quality of test results and their interpretation concerning specific patient conditions. Example includes but is not limited to: Conversations with clients to discuss test results and possible clinical implications for specific patients or types of patients.

5.3.3. The Laboratory Director may delegate responsibilities to one or more **General Supervisors**.

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate all of the responsibilities, a single duty, or combination of duties.
- If the Laboratory Director delegates responsibilities to one or more General Supervisors, the Delegation Document(s) must be maintained under document control and maintained with other Delegation Documents.
- Overlap in the assignment of General Supervisor duties is acceptable in order to provide adequate supervision.
- The Laboratory Director or Technical Supervisor may reapportion Competency assessment activities to an Assessor.
- Delegation may be restricted by department, shift, or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities.

Responsibility	Duties That May Be Delegated To General Supervisor
Corrective Action	Assure that all corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications. Examples include but are not limited to: o Advise testing personnel on appropriate corrective actions when problems occur o Ensure that corrective action documentation is complete o Consult with and obtain approval of the Technical Supervisor for process improvements implemented in response to major or frequently recurring problems o Document review of quality control, instrument function, preventative maintenance and other laboratory records (monitor QC weekly, other records at least monthly - more often if necessary).
Patient Reporting	Ensures that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Examples include but are not limited to: o Supervisory review of workflow, work practices and test records, as necessary. (It is not required that all test records be reviewed.) o Initial review and approval of corrective action documentation o Advise testing personnel on daily QC practice o Documented weekly review of QC data to monitor analytic bias and/or imprecision.
Orientation / Training	Provides orientation to all testing personnel. Examples include but are not limited to: o Ensures that orientation of all testing personnel is completed and documented (as applicable) o Ensures that employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing patient testing.
Competency	Annually evaluates and documents the performance of all testing personnel. Examples include but are not limited to: o Manage and administer the department competency program o Review and approve completed documentation of competency assessment activities o Address identified performance issues and provide documented follow-up on corrective action.

5.3.4. Certain Laboratory Director responsibilities for pre-analytic and post-analytic phases of testing may be delegated to **Pre-analytic/Post-analytic Department Managers.** These individuals are not required to hold a job title of manager, but must be supervisory level staff members who are primarily responsible for oversight of these departments.

- The Laboratory Director may delegate all of the responsibilities, a single duty, or a combination of duties.

- Delegations must not be ambiguous and must clearly indicate who is responsible for each duty in a particular area.
- Delegation may be restricted by shift or department.

Responsibility	Duties That May Be Delegated To Pre-Analytic/Post-Analytic Department Managers
Quality Management	Ensures that quality management programs are established and maintained to assure that quality pre-analytic and/or post-analytic laboratory services are provided and to identify failures in quality as they occur. Examples include but are not limited to: o Documented monthly review of Quality Assurance monitors and Quality Improvement activities o Timely and effective responses to quality failures identified through the laboratory's problem tracking process and department Quality Management program.
Corrective Action	Ensures that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's pre-analytic and/or post-analytic processes are identified. Examples include but are not limited to: o Review and approval of corrective actions taken in response to revised reports or Reportable Quality Issues (RQIs) o Review and approval of corrective actions taken in response to quality issues identified through the laboratory's problem tracking process and Quality Management activities.
Training	Ensures that, prior to performing pre-analytic and/or post-analytic procedures, all personnel have the appropriate training and have demonstrated that they can perform a specific process, workstation or job assignment correctly. Examples include but are not limited to: o Establishing a complete and documented training program for all staff o Signing/attesting that the department employees are trained.
Competency	Ensures that policies and procedures are established for monitoring individuals who conduct pre-analytic and post-analytic phases of testing, to assure that they are competent and maintain competency to perform these tasks proficiently and, whenever necessary, identify needs for remedial training. Examples include but are not limited to: o Establishing a complete and documented competency assessment program for all staff o Signing/attesting that department employees are competent o Documentation that remedial training and/or continuing education is provided (as appropriate).

Responsibility	Duties That May Be Delegated To Pre-Analytic/Post-Analytic Department Managers
SOPs	Ensures that approved procedures are available to all personnel for all aspects of the testing process. Examples include but are not limited to: o Recurring review of approved pre-analytic and/or post-analytic SOP's to ensure they are complete, readily available and reflect current practice.

5.3.5. The Laboratory Director or Pre-analytical/Post-analytical Department Manager may delegate the following responsibilities to one or more **Pre-analytical/Post-analytical Department Supervisors.**

- The Laboratory Director or department manager may delegate all of the responsibilities, a single duty, or a combination of duties.
- If a Pre-analytical/Post-analytical Department Manager delegates responsibilities to one or more Department Supervisors, the Delegation Document(s) must be maintained under document control and maintained with other Delegation Documents.
- Overlap in the assignment of Pre-analytical/Post-analytical Department Supervisor duties is acceptable in order to provide adequate supervision.
- Delegation may be restricted by shift or department.

Responsibility	Duties That May Be Delegated To Pre-analytic/Post-analytic Department Supervisor
Corrective Action Instrumentation	Ensure that all corrective actions are taken whenever pre-analytical or post-analytical systems deviate from the laboratory's established performance specifications. Examples include but are not limited to: o Advise personnel on appropriate corrective actions when problems occur o Ensure that corrective action documentation is complete o Consult with and obtain approval of the department manager for major or frequently recurring problems o Review instrument function, preventative maintenance and other department records (at least monthly).
Corrective Action Procedures / Processes	Ensure that pre-analytic/post-analytic corrective actions are taken in accordance with policies and procedures established by the Laboratory Director. Examples include but are not limited to: o Supervisory review of workflow, work practices, and department records (such as route sheets, accuracy of data entry from patient requisitions, documentation of client calls, etc.) o Initial review and approval of corrective action documentation o Advise pre-analytic/post-analytic personnel on daily problem-solving actions.

Responsibility	Duties That May Be Delegated To Pre-analytic/Post-analytic Department Supervisor
Orientation / Training	Provide orientation to all pre-analytic/post-analytic personnel; Examples include but are not limited to: o Ensure that orientation of all pre-analytic/post-analytic personnel is completed and documented (as applicable) o Ensure employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing job assignments
Competency	Annually evaluate and document the performance of all pre-analytical/ post-analytical personnel. Examples include but are not limited to: o Manage and administer the department competency program o Ensure that all employees are assessed by a trained individual (does not have to be a supervisor) using all applicable tools o Review and approve competency assessment activities. o Address identified performance issues and provide documented follow-up on corrective action.

5.3.6. The Laboratory Director or Technical Supervisor may delegate competency assessment responsibilities to an **Assessor**.

- For **Moderate Complexity** testing, Assessor duties may only be delegated by the Laboratory Director
  - The Assessor must meet the qualifications of a Technical Consultant
- For **High Complexity** testing, Assessor duties may be delegated by either the Laboratory Director or Technical Supervisor.
  - The Assessor must meet the qualifications of a General Supervisor.

Responsibility	Duties That May Be Delegated To an Assessor

Competency Assessment Observes employees as they perform all steps of procedure(s) and/or Test Systems	• Observe employees as they perform all steps of procedure(s) and/or Test Systems using the following methods:
	  • Review of all records associated with procedure(s) and/or Test Systems
	  • Evaluate Test Performance
	  • Evaluate Problem Solving Skills
	• Review must include documentation of evidence used to evaluate the employee's performance

5.3.7. The Laboratory Director may delegate responsibilities for Proficiency Testing to the **Quality Assurance Director/Manager.**

Responsibility	Duties That May be Delegated to the Quality Assurance Specialist
PT activities	Manage proficiency testing activities within the laboratory Examples include but are not limited to:

Responsibility	Duties That May be Delegated to the Quality Assurance Specialist
	o Annual review of laboratory enrollment in an HHS approved PT program for all testing performed. o Review of PT performance by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. o Review approved corrective action plan when PT results are found to be unacceptable or unsatisfactory.

6. PROCESS FOR DELEGATING DUTIES

Step	Action
1	Choose the appropriate Delegation Form for the responsibilities to be delegated. Refer to Related Documents for a list of Delegation Forms.
2	Forms are maintained on the lab's electronic document control system (EDCS).
3	Complete the "Laboratory Name and Location" section of the form.
4	For each form, list the name(s) of all individuals to whom the specified duties (listed on the form) are delegated. **Note**: Personnel listed must be the qualified individuals who actually perform these duties. Do not list personnel who are qualified to perform these duties but do not actually perform them as part of their regular job functions.
5	List the appropriate CLIA specialty(s) or subspecialty(s) for each person responsible for an analytical area. (Refer to Appendix A) **Note**: The individual must be qualified under CLIA, state, and local regulations to perform the delegated duties.
6	List the department names or areas for which this person has responsibility.
7	List the shift(s) during which the person has responsibility. (Refer to Addendum B "**Standard Abbreviations for Shifts")**
8	List the actual duties (by number on each form) that are delegated. If all, use the word ALL. NOTE: The person to whom duties have been delegated must qualify for the position but does not need to hold that specific job title. For example, a Lead Tech who qualifies as a General Supervisor may be delegated the responsibilities of reviewing corrective action, ensuring staff is trained and managing competency assessment on the night shift as part of her/his duties. The person's actual job title or job description must convey some degree of responsibility and/or supervisory authority over others, but does not have to include the word "supervisor."
9	Each form must be restricted to a single page signed by the individual who is delegating the duties (usually the Laboratory Director but may be the Technical Supervisor or Pre-analytic/Post-analytic Department Manager). Multiple delegated individuals may appear on one form. • If one person on a form changes, the entire form must be updated and re-approved. The prior form will be archived and retained in the EDCS. • If all individuals will not fit on a single form, multiple forms must be used. For example, a laboratory with 16 Technical Supervisors would require at least 3 Technical Supervisor forms. These forms should be numbered in a sequential manner (e.g., TS-1, TS-2, TS-3).

Step	Action
10	Documents must be signed (electronically or manually) as follows: • The Laboratory Director must sign and date the Technical Supervisor, Technical Consultant, General Supervisor, Clinical Consultant, Pre-analytic/Post-analytic Department Manager delegation documents. • Either the Laboratory Director or Pre-analytic/Post-analytic Department Manager may sign a Pre-analytic/Post-analytic Department Supervisor delegation document. • The Laboratory Director must sign and date the Assessor delegation documents for Moderate Complexity testing. • The Laboratory Director or Technical Supervisor must sign and date the Assessor delegation documents for High Complexity Testing.
11	The delegation documents are available in the electronic document control system.
12	Update delegation documents: • Whenever the individuals listed on the form, CLIA designations, or delegated duties change from what is on the current form. • Whenever there is a change in directorship.
13	Archive retired (original) delegation documents according to standard record retention guidelines.

7. POLICY FOR AUTHORIZATION OF PERSONNEL

The laboratory director is responsible for the overall operation and administration of the laboratory. This includes the employment of personnel who are competent to perform test procedures, record and report test results, and for assuring compliance with all applicable regulations.

The laboratory director ensures sufficient numbers of personnel with appropriate educational qualifications, experience, training and competency to meet the needs of the laboratory.

- Each Laboratory Director must document that testing and non-testing personnel involved in pre-analytic, analytic, and post-analytic phases of testing are authorized to perform their assigned duties and responsibilities in the laboratory for which he/she holds a CLIA license and/or CAP certificate.

8. PROCESS FOR AUTHORIZATION OF PERSONNEL DUTIES

8.1 Personnel Documentation

Step	Action
1	According to standard practice, file and maintain documentation of education, experience, certification (if applicable) and training for each employee involved in pre-analytic, analytic or post-analytic processes.
2	Choose the appropriate Authorization Form for each employee. For testing personnel, select according to level of test complexity. Refer to Related Documents.
3	Enter the printed name of the employee and the printed name of the Laboratory Director on the form.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4</td><td>The Laboratory Director evaluates and verifies that each employee has appropriate education, experience, training, and certification (if applicable) for the level of testing and / or duties.</td></tr>
<tr><td>5</td><td>The Laboratory Director signs and dates the Authorization Form, indicating the employee is authorized to perform either:
the duties and responsibilities of testing personnel or
the pre-analytic or post-analytic duties associated with their job
Note: This is a one time approval by the Laboratory Director and it may be completed at the time of hire.</td></tr>
<tr><td>6</td><td>Employee signs and dates the Authorization Form as confirmation that they understand their duties and responsibilities.</td></tr>
<tr><td>7</td><td>Place the original signed and dated Authorization Form in the employee personnel file. Controlled copies specific to the applicable department must be available to each department.</td></tr>
<tr><td>8</td><td>Update the form <u>only</u> when or if an employee’s responsibilities and/or duties change Example:<table><tr><th>If</th><th>Then</th></tr><tr><td>The employee is authorized to perform high complexity testing and is trained on a new test / bench</td><td>No new authorization is required</td></tr><tr><td>The employee is authorized to perform moderate complexity testing and is trained on a new high complexity test / bench</td><td>A new authorization is required</td></tr></table></td></tr>
<tr><td>9</td><td>Retire Authorization forms:
When an employee form is updated (see step 8)
When an employee leaves the company</td></tr>
<tr><td>10</td><td>Archive retired delegation documents according to standard record retention guidelines.</td></tr>
</table>

8.2 Job Authorization Summary

Step	Action
1	The Job Authorization Summary is a tool used as a quick aid to track which staff are trained for benches or areas. The summary includes • Employee names • Test systems / Training modules (must match the Training Plan) • Key for performance levels • Signature space for supervisor / manager
2	The summary is updated at least every 4 months

Step	Action
3	Signed and dated Job Authorization Summaries are scanned and retained electronically on a shared drive.

9. RELATED DOCUMENTS

- Delegation Documents (AG.F405)
- Competency Assessor Delegation Documents (AG.F407)
- Job Authorization Summary (AG.F353)
- Competency Assessment Policy
- Training Verification Policy

10. REFERENCES

1. Code of Federal Regulations CLIA Public Health 42 CFR Part 493
2. College of American Pathologists Laboratory Accreditation Checklists

11. DOCUMENT HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA738v4.1 and SGAHQDNQA739v1.2		

12. ADDENDA

Addendum	Title
A	Standard Abbreviations for CLIA Specialties and Subspecialties
B	Standard Abbreviations for Shifts

ADDENDUM A

Standard Abbreviations for CLIA Specialties and Subspecialties

CLIA Specialties and Subspecialties	
All - All specialties performed in lab	**IH** – Immunohematology
All ex – All performed in lab except	**ABO** – ABO and Rh
	ADT – Antibody Detection Transfusion
CH - Chemistry	**ADN** – Antibody Detection Nontransfusion
CHR – Routine Chemistry	**ABID** – Antibody Identification
UR – Urinalysis	**COMP** – Compatibility Testing
ENDO - Endocrinology	**MIC** – Microbiology
TOX – Toxicology	**BAC** - Bacteriology
HEM – Hematology	**MBAC** – Mycobacteriology
IMM – Diagnostic Immunology	**MYCO** – Mycology
SYPH – Syphilis Serology	**PARA** - Parasitology
IMMG – General Immunology	**VIR** - Virology

ADDENDUM B

Standard Abbreviations for Shifts

Shift Abbreviations	
ALL – All shifts	**SU** - Sundays
D – Day shift	**MO** - Mondays
E – Evening shift	**TU** - Tuesdays
N – Night shift	**WD** - Wednesdays
DE – Day and evening shifts	**TH** - Thursdays
NE – Night and evening shifts	**FR** - Fridays
DN – Day and night shifts	**SA** - Saturdays
M-F – Monday through Friday only	
WE – Weekends only	
H – Holidays only	