Summary of changes to Training, Competency and Testing Personnel requirements.

The full document (see the link below) is loaded with good progress for the laboratory industry.

Final Rule, effective Jan 28, 2024

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

TABLE 8: Personnel Requirements by Test Complexity for Proposed Personnel Changes that Require Training or Experience, or Both

CLIA Section	Role	Complexity
§ 493.1405	Laboratory director	Moderate
§ 493.1411	Technical consultant	Moderate
§ 493.1423	Testing personnel	Moderate
§ 493.1443	Laboratory director	High
§ 493.1449	Technical supervisor	High
§ 493.1489	Testing personnel	High

Laboratory training or experience has been defined to include the required skills to perform pre-analytic, analytic and post-analytic phases of testing. This includes positions held by Lab Director, Technical supervisors and Testing personnel in Moderate and High complexity laboratories.

Each individual must have documentation of training or experience applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he or she has the skills required for the proper performance of pre-analytic, analytic, and post-analytic phases of testing.

Example

- Proper specimen collection, handling and labelling;
- Proper test performance according to the laboratory's policies and manufacturer's instructions;
- Verification of performance specifications;
- Calibration and preventive maintenance;
- Proficiency testing; and
- Proper reporting of patient test results

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Acceptable documentation of training or experience has been established to include documentation from previous employment, including itemized job descriptions and competency assessments.

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field;
- On-site or off-site instrument trainings given by a manufacturer;

● Technical training sessions, workshops, or conferences given by a professional laboratory organization; or

● A formal laboratory training program. Documentation may consist of, but is not limited to: ● Letters from training programs or employers;

● Attestation statements of an individual's training and experience by the LD;

● Log sheet(s) initialed by the attendees indicating attendance at a training session or inservice; and

● Certificates from organizations providing the training session, workshop, conference, specialty course.

Letters on letterhead from previous employment, competency assessment, and comprehensive list of job responsibilities may be examples of acceptable documentation.

Exclusions research, forensic labs

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Testing personnel qualifications has been expanded to be more inclusive.

§ 493.1423 Standard; Testing personnel qualifications. * * * * * (b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or

(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or

(3) Meet the requirements in § 493.1405(b)(3)(i)(B), (b)(4)(i)(B) or (C), or (b)(5)(i)(B); or

(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or

(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (

6)(i) Have earned a high school diploma or equivalent; and (ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens.

Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory; (G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

(7) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or

(iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution; and (B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

(8) Notwithstanding any other provision of this section, an individual is considered qualified as a testing personnel under this section if they were qualified and serving as a testing personnel for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. 25. Effective December 28, 2024, amend § 493.1443 by revising paragraph (b) to read as

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Competency for Provider Performed Microscopy has been defined to include all competency elements except “Direct observation of performance of instrument maintenance and function checks”. PPM competency assessment must be performed on the same 6-month, 1-year schedule as other CLIA laboratories

Provider Performed Micrsocopy (PPM) competency assessment

● Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;

● Monitoring the recording and reporting of test results;

● Review of test results or worksheets;

● Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

● Assessment of problem-solving skills.

Excludes “Direct observation of performance of instrument maintenance and function checks” as the only equipment required for PPM testing is limited to bright-field and phase-contrast microscopy.

Same frequency as other CLIA Labs for consistency.

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