

(a) The general supervisor must possess a current license issued by the state in which the laboratory is located, if such licensing is required; and

§ 493.1443(b)(3) or § 493.1449(c)(4) or (5).

(c)(4) Notwithstanding

any other provision of this

considered qualified as a

general supervisor under

qualified and serving as a

general supervisor as of

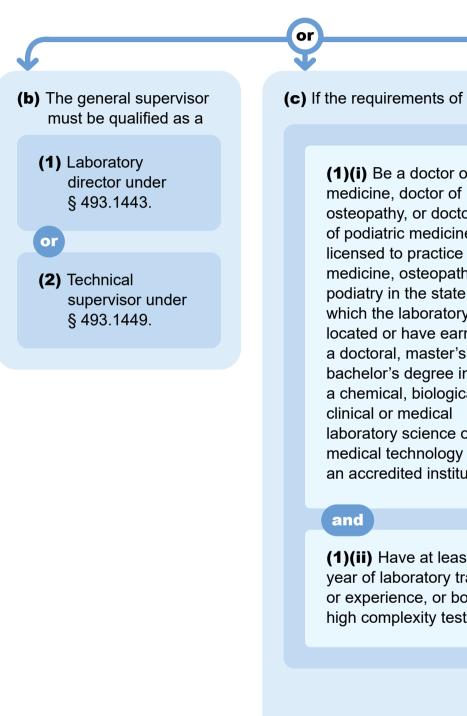
December 28, 2024, and

have done so continuously

since December 28, 2024.

this section if they were

section, an individual is



(1)(i) Be a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, o podiatry in the state in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, laboratory science or medical technology from an accredited institution. (1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing.

(c) If the requirements of paragraph § 493.1461(b)(1) or (2) are not met, the individual functioning as the general supervisor must

or (2)(i) Qualify

as testing

personnel under

(3) which states

at 1489(b)(3)(i)

have earned an

associate degree

medical laboratory

technology from

an accredited

institution.

in a laboratory

science or

§ 493.1489(b)

or (2)(i) Qualify as testing personnel or (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states at 1489(b)(3)(ii) have education and training equivalent to that specified in paragraph § 493.1489(b)(2)(i) that includes:

- (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum,
- (1) Twenty-four (24) semester hours of medical laboratory technology courses.

(1) completion of a clinical

(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.

laboratory training program approved or accredited by the ABHES or the CAAHEP. This training may be included in the 60 semester hours listed in § 493.1489(b)(3)(ii)(A).

under § 493.1489(b)(3) which states at 1489(b)(3)(ii) have education and training equivalent to that specified in paragraph § 493.1489(b)(2)(i) that

technology courses.

- (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:
 - (iii) Twelve (12) semester hours of chemistry, biology, (1) Twenty-four (24) semester or medical laboratory technology in any combination. hours of medical laboratory

- **(B)** Have laboratory training that **(B)** Have laboratory training that

(2) At least 3 months of documented laboratory training in each specialty in which the individual performs high complexity testing.

(B) Have laboratory training that includes: (1) completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or the Commission on Accreditation of Allied Health Education Programs (CAAHEP). This training may be included in the 60

that include

(A) At least 60 semester hours, or equivalent, from an

(i) Six (6) semester hours of chemistry:

(ii) Six (6) semester hours of biology; and

semester hours listed in § 493.1489(b)(3)(ii)(A).

accredited institution that, at a minimum, includes: (2)

Twenty-four (24) semester hours of science courses

(2)(i) Qualify as testing personnel under § 493.1489(b)(3) which or (2)(i) Qualify as testing personnel under § 493.1489(b)(3) or (c)(3) Meet the requirements of states at 1489(b)(3)(ii) have education and training equivalent to which states at 1489(b)(3)(ii) have education and training that specified in paragraph § 493.1489(b)(2) (i) that includes: equivalent to that specified in paragraph § 493.1489(b)(2) (i) that includes:

- (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum.
- (2) Twenty-four (24) semester hours of science courses that include
- (i) Six (6) semester hours of chemistry;
- (ii) Six (6) semester hours of biology; and
- (iii) Twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination.

- **(B)** Have laboratory training that includes:
- (2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(d) For blood gas analysis, the individual providing general supervision must

(1) Be qualified under § 493.1461(b)(1) or (2), or § 493.1461(c).

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution.

(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis.

(3)(i) Have earned an associate's degree related to pulmonary function from an accredited institution.

(3)(ii) Have at least two years of training or experience, or both, in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations must be performed:

(1) In histopathology, by an individual who is qualified as a technical

supervisor under

§ 493.1449(b) or

under § 493.1449(b)

or (2) In dermatopathology, or (3) In ophthalmic by an individual who is qualified as a technical supervisor

pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b)

or (f)(3).

or (4) In oral pathology

bv an individual

who is qualified

as a technical

supervisor under

§ 493.1449(b) or

Resources

- 1. Code of Federal Regulations. Title 42, Part 493 Subpart M- Personnel for Nonwaived Testing
- 2. CMS Quality Safety & Oversight memoranda, guidance, clarifications, and instructions. Policy & Memos to States and CMS Locations I CMS
- 3. CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. Interpretive Guidelines for Laboratories | CMS



v25209 Amendments (CLIA) Personnel Qualifications and Responsibilities: High Complexity Testing." Find the course at reach.cdc.gov/training

Refer to Job Aids disclaimer at reach.cdc.gov/disclaimers#ui-id-6. This job aid is a component of the free, on-demand CDC training course "Clinical Laboratory Improvement