Sec. 19a-36-F5. Personnel requirements and qualifications

(a) A blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall ensure a minimum of two members of the personnel with current certification in CPR are on-site for every ten donors present and a minimum of one member of the personnel with current certification in CPR is on-site if fewer than ten donors are present. No blood shall be drawn or collected, including through apheresis, unless personnel so certified in CPR and trained in emergency response protocols for donor adverse events is present on-site.

(b) The licensee shall be responsible for ensuring an adequate number of suitably qualified personnel is available during all hours of operation to ensure the health and safety of donors and staff.

(c) The licensee shall be responsible for obtaining a qualified director and qualified technical staff as follows:

(1) The licensee shall ensure that a qualified director supervises operations of the blood collection facility and shall ensure the performance of all said director's duties set forth in this section at all times unless such responsibility is delegated pursuant to this section. If so required under the licensee's current CLIA certificate the licensee shall ensure that supervision of testing is designated to a qualified laboratory director at all times. The roles of director and laboratory director may be performed by the same person if duly qualified for both roles. If the director will be absent for thirty days or more, the licensee shall report such absence to the department in writing in accordance with section 19a-36-F2(k) of the Regulations of Connecticut State Agencies.

(2) Qualifications and responsibilities of a laboratory director.

(A) If so required under the licensee's current CLIA certificate, the licensee shall designate a laboratory director. The laboratory director shall meet the qualification standards for directors of clinical laboratories in accordance with CLIA requirements.

(B) The laboratory director shall be responsible for ensuring compliance with the requirements of 42 CFR 493, as amended from time to time.

(3) Qualifications and responsibilities of a director.

(A) The director shall be a physician licensed to practice in Connecticut, and shall have one of the following qualifications:

(i) A minimum of one year of specialized clinical experience which shall include blood banking, blood collection, or pathology; or

(ii) Qualification as a responsible physician.

(B) The director shall be responsible for ensuring compliance with all procedures and policies required under Section 19a-36-F3 of the Regulations of Connecticut State Agencies.

(C) The director shall not individually serve as director of more licensed blood collection facilities than permitted by applicable CLIA requirements. If the director serves as director of any blood collection facility located out of the state, the director shall notify the department thereof.

(D) The director shall be responsible for the following:

(i) Oversight of the blood collection facility personnel's in-service training to ensure personnel acquire and maintain the required skills and knowledge for their responsibilities; and

(ii) All personnel's adherence to established policies and procedures.

(E) The director may delegate his or her responsibilities for administering the licensed activities of the blood collection facility to a responsible physician or to a physician substitute. The director may delegate the specific activities with the corresponding levels of medical supervision to a trained person in accordance with the medical supervision requirements of 21 CFR 630.5, as amended from time to time. If the director delegates any responsibilities or activities, the director shall be responsible for the proper performance of all such delegated responsibilities or activities.

(F) The director shall be on-site during hours of operation except when the director has delegated his or her responsibilities pursuant to this section and when a responsible physician, physician substitute, or trained person is permitted under 21 CFR 630.5, as amended from time to time, to be on-site without a director.

(4) Responsibilities of a physician substitute and responsible physician. A responsible physician or physician substitute shall be responsible for the following, as delegated by the director:

(A) Ensuring the health and safety of donors and the performance of apheresis, as applicable, during all hours of operation;

(B) Oversight of the clinical training of all trained persons, except that a physician substitute shall only be responsible for the oversight of clinical training for a less experienced physician substitute or a person with a lower level of professional credentials;

(C) Assurance that each trained person has completed the training program and has demonstrated competency in all technical and theoretical areas; and

(D) The performance of all responsibilities delegated to them by the director.

(5) Qualification, responsibilities, training and supervision of a trained person.

(A) The minimum qualification for each trained person conducting donor screening, blood collection and apheresis activities, as applicable, shall be a high school diploma or equivalent and documented experience and proficiency of skills and knowledge specific to the equipment and facility. Training shall include but not limited to the following:

(i) Venipuncture;

(ii) Specimen collection and labeling;

(iii) Emergency response; and

(iv) Apheresis, as applicable.

(B) Trained persons shall work under the direction of the director, or a responsible physician, physician substitute, or a trained person as permitted under 21 CFR 630.5, as amended from time to time, to whom the director has delegated responsibility, during all hours of operation of a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(d) A blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall ensure sufficient personnel are cross-trained in blood collection specific to the equipment and facility to maintain safe staffing levels in the event of staff or donor emergency pursuant to the minimum standards for operation in section 19a-36-F3(d)(3)(E) of the Regulations of Connecticut State Agencies.

(Effective March 19, 2025)