State of Connecticut

Department of Public Health

Statement of Reasons Pursuant to

Connecticut General Statutes § 4-168(e)

Comment and Response Document

September 25, 2024

Concerning

PR2023-039

Source Plasma Donation Centers

Public Comment Period: January 2, 2024 to February 2, 2024

1. Introduction

This comment response concerns the Connecticut Department of Public Health ("the Department") proposed regulation PR2023-039 regarding Source Plasma Donation Centers. The purpose of this proposed regulation is to establish standards to exempt source plasma donation centers, as defined in Conn. Gen. Stat. § 19a-490(u), from the requirements of licensure as clinical laboratories. The proposed regulation establishes standards for such source plasma donation centers to secure licensure by the Department under a separate licensure category, as provided in revised Conn. Gen. Stat. § 19a-565. Separate proposed regulations establish standards for the licensure of blood collection facilities to meet the requirements of Conn. Gen. Stat. § 19a-565 as amended by Public Act 23-31.

Section 1 of these proposed regulations establishes standards for the licensure of source plasma donation centers in Connecticut. Proposed section 19a-36-E2 establishes licensure procedures, including inspection, renewal, waiver, and disciplinary provisions. Proposed section 19a-36-E3 sets minimum standards of operation to be developed and implemented as policies and procedures at each licensed source plasma donation center to ensure health and safety. Proposed section 19a-36-E4 sets standards for donor testing. Section 19a-36-E5 sets standards for the required personnel categories and their respective training, qualifications and competencies. Section 19a-36-E6 establishes record and reporting requirements for donor records, reportable diseases, errors and adverse reactions.

Section 2 of this proposed regulation repeals sections 19a-36-A47 to 19a-36-A55, inclusive, of the Regulations of Connecticut State Agencies, which previously have governed blood collection facilities and plasmapheresis as a registration within the clinical laboratory licensure category.

The Department received twelve written or verbal comments during the public comment period for PR2023-038.

2. Rule-making Process

On September 29, 2023, the Department posted policies and procedures governing the licensure of blood collection facilities pursuant to Public Act 23-31, as authorized by Section 9 of Public Act 23-31, amending Conn. Gen. Stat. § 19a-565. Such policies and procedures were effective October 1, 2023, and shall take the place of regulation until such time as the final regulation (PR2023-039) is adopted.

On January 2, 2024, Notice of Intent to adopt the proposed regulation was posted pursuant to Conn. Gen. Stat. § 4-168(a). On this date, the policies and procedures were continued and remain in effect until such time as the final regulation is adopted.

The public comment period was conducted from January 2, 2024 to February 2, 2024. A public hearing was requested made to the Department in accord with Conn. Gen. Stat. § 4-168(b). On January 18, 2024, public notice of such hearing was posted to the eRegulations system including when, where, and how interested persons may present their views on the proposed regulation in person. The public hearing was conducted in hybrid format on January 25, 2024, with interested parties presenting their views in person and via Zoom. A total of twelve written public comments were submitted to the Department via the eRegulations system, via email, or verbally at the public hearing.

In accordance with Connecticut General Statutes § 4-168(e), this report includes:

1. Principal reasons in support of or in opposition to the proposed regulations, and the Department's reasons for accepting or rejecting such considerations; and
2. The final wording of the proposed regulation.

3. Comments and Responses

The comments responded to below have been submitted to the Department in written form during the statutory public comment period. Language in the comments and responses in quotation marks is directly quoted from public comments.

(A) Comments related to definitions

(1) Comment: One commenter requested the addition of "healthy" to the proposed definition of "donor."

Response: Donors health status may change at any time. No revisions will be made.

(B) Comments related to licensing procedures

(2) Comment: One commenter requested the ability to refer to company-wide policies and procedures on operating standards rather than submit separately for individual license applications.

Response: A source plasma donation center license is not transferable or assignable. Facility licensure applications must be submitted separately and in full for each facility location.

(3) Comment: One commenter requested clarification that clinical laboratories licensed in the state of Connecticut do not require separate and additional licensure as a blood collection facility or source plasma donation center in order to conduct the activities within the statutory definitions of those facilities.

Response: Each permanent brick and mortar facility, not otherwise exempt from licensure as a source plasma donation center, requires a separate license. As defined in the Conn. Gen. Stat. § 19a-490(h), a clinical laboratory means a facility "used for microbiological, serological, chemical, hematological, immunohematological, biophysical, cytological, pathological or other examinations of human body fluids, secretions, excretions or excised or exfoliated tissues for the purpose of providing information for the (1) diagnosis, prevention or treatment of any human disease or impairment, (2) assessment of human health, or (3) assessment of the presence of drugs, poisons or other toxicological substances." A source plasma donation center is defined in the Connecticut General Statutes § 19a-490(u), and a blood collection facility is defined in the Connecticut General Statutes in the Connecticut General Statutes § 19a-490(t).

A clinical laboratory is not exempt from licensure as a source plasma donation center or from licensure as a blood collection facility. If the clinical laboratory proposes to conduct activities

beyond the statutory scope of § 19a-490(h) and within the statutory scope of either a source plasma donation center or a blood collection facility, separate licensure is required.

(C) Comments related to personnel requirements

(1) Comment: Multiple commenters requested revisions to proposed section 19a-36-E5(c)(3) of the proposed regulation regarding center director qualifications. Commenters proposed removing the requirement for "one year of specialized training in blood banking" or equivalent experience, and revising this requirement to reflect the standards to mirror 21 CFR 630.5.

(2) Response: The Department will revise the center director qualification to reduce confusion related to the term "blood banking". Legislation passed in the 2024 session, Public Act 24-7, amends Conn. Gen. Stat. § 19a-565(b) to require the Department's regulations to provide for a responsible physician, as defined in 21 CFR 630.3, to serve as director of a blood collection facility or a source plasma donation center. As a result, the proposed regulation will be revised to align the center director's qualifications with the federal definition of "responsible physician" set forth in 21 CFR 630.3.

(3) Comment: Commenters requested clarification of the center director responsibilities to verify that the center director is not directly involved in coordinating training or daily administrative tasks.

Response: As written, the proposed regulation states that the center director is responsible for ensuring staff adhere to all operating policies and procedures, and for ensuring that staff training is conducted in a manner that ensures staff maintain the required skills and knowledge to safely conduct services, not that the director is personally responsible for managing daily administrative and training tasks.

The Department will revise the proposed regulation to clarify that physician responsibilities encompass oversight to ensure clinical standards and public health and safety, and do not encompass direct duties in performing apheresis and training. The Department will revise the term "coordination" to "oversight" in Section 19a-36-E5(c)(4)(B)(ii).

(4) Comment: Multiple commenters requested revisions in the permitted delegation authority of the center director to align with federal standards in 21 CFR 630.5. Specifically, commenters requested the proposed regulations be revised to permit delegation of duties related to donor eligibility and phlebotomy from the center director to trained individuals in addition to permitted delegation to a responsible physician and physician substitute.

Response: The proposed regulation PR2023-039 was drafted to meet the requirements of Conn. Gen. Stat. § 19a-565(b) directing the Department to adopt regulations to include a requirement for a registered nurse or advanced practice registered nurse to be onsite during all hours of operation. Legislation passed in the 2024 session, Public Act 24-7, amends Conn. Gen. Stat. § 19a-565(b) to remove the onsite requirement for a registered nurse or advanced practice registered nurse. As a result, the proposed regulation will be revised to allow the delegation to staff other than the responsible physician or physician substitute of such duties as are permitted by federal regulation.

A responsible physician or physician substitute is required by federal regulation to conduct certain aspects of donor eligibility determinations. The Department will permit delegation to trained persons only for those activities permitted by federal regulation, and will also revise requirements to ensure the licensee can complete any non-delegable activities during all hours of operation in the event donor has a change in status, and to ensure non-delegable activities are performed by a responsible physician or physician substitute.

(5) Comment: Multiple commenters requested the removal of the proposed ratio of staff trained and certified in CPR per donors onsite. These commenters requested revisions to comport with federal standards requiring only one personnel member with CPR certification at the facility during all donation activities.

Response: The Department understands that licensees may be operating at a high volume of donors at any given time. In order to ensure the public health and safety of donors, the CPR requirements will not be revised.

(6) Comment: One commenter requested the removal of the reference to Centers for Disease Control and Prevention (CDC) standards for infection control in healthcare facilities. The comment asserts that source plasma donation centers, as licensed in the state of Connecticut, are not healthcare facilities.

Response: The Department notes that language pertaining to the CDC standards is in the policies and procedures, not the proposed regulation PR 2023-039 as posted for public comment. The Department notes that pursuant to Conn. Gen. Stat. § 19a-565, and as defined within Conn. Gen. Stat. § 19a-490, source plasma donation centers are now licensed as healthcare facilities in the state of Connecticut. Per the regulatory authority of the Department, the proposed regulations will be revised to ensure appropriate standards for infection control and prevention including references to the CDC standards on hygiene in healthcare settings and requirements to change gloves between donors.

(7) Comment: Some commenters requested revisions lowering the qualification requirements for center administrative managers from a minimum educational requirement of an associates degree and two years of management experience in an equivalent facility, to a minimum educational requirement of a high school diploma and two years of supervisory experience in any setting.

Response: The Department sets minimum staffing qualifications for key personnel as component of the Department's regulatory oversight of healthcare facilities. Administrative managers need sufficient experience and knowledge to ensure, within the scope of the administrative manager's responsibilities, that operations comport with state laws and regulations and protect public health and safety. The Department will not propose revisions to the administrative manager qualifications.

(8) Comment: One commenter requested clarifying revisions regarding the cross-training requirements to require only training in those tasks specific to each staff role at the center.

Response: As drafted in the proposed regulation, Sec. 19a-36-E5(c)(7), a licensee is required to ensure sufficient training across staff in plasmapheresis to ensure safe and appropriate staffing levels of trained staff are maintained in the event of an emergency. The licensee has discretion to implement this across staff members in a manner that meets the operational standards under Sec. 19a-36-E3(d)(3)(E).

(D) Comments related to testing requirements

(1) Comment: One commenter recommended revising the references to federal testing standards to remove references to recovered plasma, which is not collected at source plasma donation centers.

Response: The references to 21 CFR 640.33 and 21 CFR 640.5 will be removed.

(E) Comments related to reporting requirements

(1) Comment: The Department received a comment requesting a change to the reporting requirements for the center director's absence. The proposed change would reduce the reporting requirement for an unplanned director absence of 30 days or more from 24 hours to 30 days.

Response: Standard regulatory requirements for licensed facilities require the Department to receive immediate communication when there is a change of director or absence of key personnel.

(2) Comment: Commenters requested various changes to the adverse event reporting requirements proposed in PR2023-039. Recommendations were made for the Department to require reporting in alignment with the standards of the industry association, or to require only reporting of fatal reactions, not any severe reactions experienced by donors. Separately, requests were made to eliminate all quarterly reporting entirely, or to require reporting only of adverse events and not report the full set of data on donor outcomes currently indicated in proposed section 19a-36-E6(d).

Response: Reporting of severe donor reactions, in addition to the federally required reporting of fatal reactions, is necessary to meet the purposes of the Department in ensuring public health and safety.

The Department proposes revisions to the reporting requirements beyond the adverse event reporting requirements, such that licensees will not be required to report donor denials, deferrals, or total protein results for deferred donors. Instead, the Department will only require annual reporting of donor complaints.

Final proposed wording of the PR2023-039:

State of Connecticut

Department of Public Health

Regulation Concerning

Source Plasma Donation Centers

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 19a-36-E1 to 19a-36-E6 as follows:

(NEW) Sec. 19a-36-E1. Definitions

As used in this section:

(1) "Accreditation organization" means an entity that sets and evaluates quality and performance standards for source plasma donation centers as defined in these regulations including through onsite assessment.
(2) "Adverse event" means an event related to donation, and classified according to nationally recognized classifications, that has a negative effect on donor health or safety.
(3) "Apheresis" has the same meaning as provided in section 2 of Public Act 24-7.
(4) "Blood" means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.
(5) "Blood collection facility" has the same meaning as provided in section 19a-490(t) of the Connecticut General Statutes
(6) "Blood component" means a product containing a part of blood separated by physical or mechanical means.
(7) "Business entity" has the same meaning as provided in section 19a-565(a) of the Connecticut General Statutes.
(8) "Centers for Disease Control" or "CDC" means the Centers for Disease Control and Prevention.
(9) "Certification in CPR" means training and certification in CPR by the American Heart Association, the American Red Cross, the American Safety and Health Institute or an organization using guidelines for cardiopulmonary resuscitation and emergency cardiovascular care published by the American Heart Association and the International Liaison Committee on Resuscitation
(10) "Clinical laboratory" has the same meaning as provided in section 19a-490(h) of the Connecticut General Statutes.
(11) "Clinical Laboratory Improvement Amendments" or "CLIA" means the regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988, set forth in 42 CFR 493 as amended from time to time.
(12) "CLIA certificate" means a certificate of compliance or accreditation as defined in 42 CFR 493.2 as amended from time to time.
(13) "Commissioner" means the Commissioner of the Department of Public Health or the commissioner's designee.
(14) "Department" means the Connecticut Department of Public Health.
(15) "Director" means the person designated by the licensee to be responsible for the daily technical and administrative operations of the source plasma donation center.

(16)"Donor" has the same meaning as provided in section 2 of Public Act 24-7.
(17)"Food and Drug Administration" or "FDA" means the federal Food and Drug Administration.
(18)"Licensee" means a source plasma donation center licensed pursuant to this section.
(19)"Physician substitute" means an advanced practice registered nurse (APRN) licensed pursuant to Chapter 378 of the Connecticut General Statutes, a physician assistant licensed pursuant to Chapter 370, or a registered nurse licensed pursuant to Chapter 378 of the Connecticut General Statutes.
(20) "Plasmapheresis" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
(21) "Reference laboratory" means a laboratory that receives and performs tests on blood or blood components collected by a facility licensed pursuant to this section.
(22) "Responsible physician" has the same meaning as provided in 21 CFR 630.3, as amended from time to time.
(23) "Source plasma" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.
(24)"Source plasma donation center" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes. "Storage" means the holding of blood or blood components related to collection thereof.
(25) "Trained person" means an individual, including a physician substitute, who is adequately instructed and qualified to perform specified functions pertaining to plasmapheresis under the direction of the responsible physician.

(NEW) Sec. 19a-36-E2. Licensure Procedures

(a) No person or business entity shall establish, conduct, operate or maintain a source plasma donation center unless such center holds a license issued by the department in accordance with this section. No source plasma donation center shall operate without the applicable CLIA certificate. Applicants may apply for CLIA certification concurrently with their application for a license pursuant to this section. Prior to operation, the applicant shall secure the applicable CLIA certificate required to establish, conduct, operate or maintain such center and shall present to the department satisfactory evidence that the applicant has retained the services of personnel qualified pursuant to these regulations to collect source plasma by plasmapheresis.
(b) Approval for licensure as a source plasma donation center pursuant to this section shall exempt licensed source plasma donation centers conducting only those functions provided in section 19a-490(u) of the Connecticut General Statutes from requirements for licensure as a clinical laboratory under section 19a-565(b) of the Connecticut General Statutes. Licensed clinical laboratories require separate licensure as a source plasma donation center to conduct those functions provided in section 19a-490(u) of the Connecticut General Statutes.
(c) Application for initial or renewal licensure.
    (1) Application for initial or renewal licensure shall be made by the applicant in a form and manner prescribed by the department. No plasmapheresis shall be conducted until the applicant has been notified by the department that the license is approved and in effect, except at a plasmapheresis center as defined in section 19a-36-A47 registered with the

department before October 1, 2023. No plasmapheresis shall be conducted upon the expiration of licensure or if the license has been suspended, denied or revoked.

(2) Application for the grant of initial licensure or licensure renewal shall include, but not be limited to, the following:
  (A) Name and location of the center;
  (B) Statement of ownership and operation including name and address of the licensee;
  (C) Name, address and qualifications of the director;
  (D) Business identification number issued by the Secretary of State;
  (E) Certificates of malpractice and public liability insurance;
  (F) Current CLIA certificate, as applicable;
  (G) A list of reference laboratories to be used;
  (H) Policies and procedures required under section 19a-36-E3 of the Regulations of Connecticut State Agencies;
  (I) A roster of qualified personnel under section 19a-36-E2(a) and section 19a-36-E5 of the Regulations of Connecticut State Agencies;
  (J) Training curricula and documentation of training provided by the applicant to personnel, including training completed and in progress, as applicable;
  (K) The licensing or renewal fees provided in section 19a-565(f) of the Connecticut General Statutes; and
  (L) Such additional information as the department may require.

(3) Inspection.
  (A) Upon determination that the application materials are complete, the department shall notify the applicant of inspection. The applicant shall make the premises, facilities, equipment, policies and procedures required under section 19a-36-E3 of the Regulations of Connecticut State Agencies, and records available for department inspection upon request of the department, and shall make personnel available for interviews.
  (B) The commissioner may, in the commissioner's discretion, waive inspection upon renewal of a license issued under this section, if the commissioner elects to accept a favorable and timely onsite assessment report conducted by an accreditation organization. In the event of any corrective action plan under such accreditation, the department shall review such plan and evidence of remediation.

(4) Issuance and renewal of license.
  (A) The department may issue a license or renewal of a license to operate the source plasma donation center if the department determines following inspection that the source plasma donation center complies with the statutes and regulations pertaining to its licensure.
  (B) The commissioner shall issue a license to the source plasma donation center in the name of the owner of the source plasma donation center or business entity appearing on the application. The license shall not be transferable or assignable.
  (C) The licensee shall post the license in a conspicuous location at the source plasma donation center.

(D) A license issued under this section shall be renewed biennially. Applications for renewal shall be submitted to the department by the end of the twentieth month of the current license.

(d) Denial, suspension or revocation of licensure.

(1) The department may deny an initial or renewal application for licensure for any of the following reasons:

(A) The licensee has failed to comply with applicable federal, state, and local laws;

(B) Failure of the source plasma donation center to permit department inspection of the premises or access to the center's records upon request of the department;

(C) If licensure would pose a threat to the health, safety and well-being of the public; or

(D) There is a material misstatement of fact on the application.

(e) A license issued under this section may be revoked or suspended in accordance with chapter 54, or subject to any other disciplinary action specified in section 19a-17 of the Connecticut General Statutes if the licensed blood collection facility has engaged in fraudulent practices, fee-splitting inducements or bribes or violations of applicable federal and state laws and regulations including but not limited to any provision of section 19a-565 of the Connecticut General Statues, or violations of these regulations.

(f) Change in ownership. Any change in ownership of an entity licensed pursuant to this section shall be made in compliance with section 19a-493 of the Connecticut General Statutes.

(g) Change in facilities. Any entity licensed pursuant to this section proposing an expansion or alteration of its facility shall notify the department at least thirty days prior to enacting any such changes, expansions or alterations.

(h) Change or absence of director. Any entity licensed pursuant to this section proposing a change in director shall notify the department at least thirty days prior to such change. In the event of an unplanned change in director, or the absence of a director for greater than thirty days, the licensee shall notify the department within twenty-four hours of the unplanned change or absence greater than thirty days, and the licensee may designate an interim director who meets the qualifications set forth in section 19a-36-E5(c)(3) of the Regulations of Connecticut State Agencies for a period of up to six weeks.

(i) Waiver.

(1) The commissioner may waive provisions of these regulations as provided in section 19a-495 of the Connecticut General Statutes if the commissioner determines that such waiver would not endanger the health, safety or welfare of any donor. The commissioner may impose conditions upon granting the waiver that assure the health, safety and welfare of donors, and may revoke the waiver upon a finding that the health, safety, or welfare of any donor has been jeopardized.

(2) The licensee requesting a waiver shall do so in a form and manner prescribed by the commissioner. Such request shall include:

(A) The specific regulations for which the waiver is requested;

(B) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the source plasma donation center upon enforcement of the regulations;

(C) The specific relief requested;

(D) Any documentation that supports the request for waiver; and
(E) Alternative policies and procedures proposed.

(3) In consideration of any request for waiver, the commissioner may consider:
(A) The impact of a waiver on services provided; and
(B) Alternative policies or procedures proposed by the source plasma donation center.

(4) The commissioner reserves the right to request additional information before processing the request for waiver.

(NEW) Sec. 19a-36-E3. Minimum standards for operation

(a) Source plasma donation centers licensed pursuant to this section shall comply with applicable federal, state and local laws.

(b) Source plasma donation centers licensed pursuant to this section shall at minimum comply with all requirements for donor eligibility and screening, blood donation, and donor notification in section 21 CFR 630, as amended from time to time.

(c) Source plasma donation centers licensed pursuant to this section shall comply with all requirements for source plasma in section 21 CFR 640.60 to 21 CFR 640.76, inclusive, as amended from time to time.

(d) Policies and procedures setting forth minimum standards of operation shall be provided to the department for review upon initial application and on request. Such policies and procedures shall be available to facility personnel for use in areas where procedures are performed. Source plasma donation centers shall develop and implement such policies and procedures in writing to include, but not be limited to, the following:

(1) Policies and procedures for donors, including but not limited to:
(A) Donor education including donation process and donation risks;
(B) Donor consent in language that is clear and accessible;
(C) Donor care including privacy, confidentiality, response to adverse events, and the provision of emergency care;
(D) Donor eligibility including health assessment and donation limits;
(E) Post-procedure instructions for donors including potential adverse events;
(F) Donor notification in the event of abnormal findings and test results;
(G) Procedures for donors to file complaints with a source plasma donation center licensed under this section; and
(H) Procedures for donors to file complaints with the department regarding a source plasma donation center licensed under this section.

(2) Documentation and recordkeeping, including confidentiality and retention of donor records.

(3) Staffing including educational and training requirements including but not limited to:

(A) A defined training program to verify the ability of all trained persons in accordance with section 19a-36-E5 of these regulations;
(B) Policies to identify ongoing training and education needs for personnel who perform activities affecting the quality of blood and blood components and the health and safety of donors;
(C) Records of personnel qualifications and training shall be kept verifying the qualifications of staff, and to document ongoing training and continuing education of staff;
(D) Each facility licensed pursuant to this section shall establish and maintain minimum staffing levels; and
(E) Staffing plans to ensure that cross-trained staff are available to maintain minimum levels as established in subdivision (D) above if there is a staffing or donor emergency.

(4) Emergency preparedness.
(5) Medical contingency planning.
(6) Facility maintenance.
(7) Data collection and reporting in accordance with the requirements of section 19a-36-E6.
(8) Quality assurance and infection control in compliance with all federal and state regulatory requirements, including but not limited to:

(A) Quality assurance and process improvement procedures including the competency of personnel, and periodic documented review to assess the effectiveness of such quality assurance and process improvement procedures.
(B) Equipment policies and procedures to ensure appropriate calibration, maintenance and monitoring for health and safety.
(C) Handling and discarding of blood and blood components to meet standards of practice governing safe disposal, including a written procedure for documented review prior to the release and final labeling of blood or blood components.
(D) Labeling, which shall conform with the most recent Food and Drug Administration (FDA) standards.
(E) Contamination. Policies and procedures to prevent contamination and ensure aseptic methods of collection of blood, in accord with CDC standards for infection prevention and control that apply in healthcare settings and which shall include but not be limited to changing gloves between donors when conducting phlebotomy procedures.
(F) Errors and adverse events. Policies and procedures regarding errors and adverse events shall include a list of potential adverse events and plan for response. Such policies and procedures shall ensure the capture, assessment, investigation, documentation, and monitoring of deviations from, or of failure to meet, specified requirements, including adverse donor reactions. The

investigation shall, when applicable, include an assessment of the effect of the deviation on donor eligibility and donor and patient safety. The responsibility for review and authority for the disposition of nonconforming blood, blood components, tissue, derivatives, critical materials, and services shall be defined. Adverse events shall be reported in accordance with section 19a-36-E6 of these regulations and in accordance with federal requirements.

(9) Facilities and equipment.

(A) The management, operation, personnel, equipment, facilities, sanitation and maintenance of the facility shall be such as to ensure the health, comfort and safety of donors, staff and the public at all times.

(B) Facilities, environment, and equipment shall be provided to maintain safe and acceptable standards for handling of human blood and blood components. Source plasma donation center facilities shall consist of at least a pre-donation waiting area, a private donor screening area for confidential donor examinations and questioning, a donor recovery area, lavatory facilities on the same floor, clean and convenient handwashing facilities for personnel, and the proper equipment for conducting testing and plasmapheresis, and for the immediate labeling and storage of blood and blood components until the collections are tested. The facility shall be designed and constructed to ensure accessibility and confidentiality in accordance with state and federal law.

(C) Any areas of the facility where procedures are performed or blood or blood components are collected shall be kept clean, adequately lit and ventilated, and shall be of adequate size to ensure the health and safety of donors and staff.

(D) Source plasma donation centers licensed pursuant to this section shall maintain appropriate facilities and equipment for record keeping in accordance with this section.

(E) Equipment shall be adequate and in good order at all times as considered necessary for the proper handling of work for which licensure may be granted. Equipment shall be validated for installation, operation and performance, maintained and repaired, and qualified for its intended use according to the manufacturer's written instructions, and monitored for compliance with requirements according to a documented schedule. Source plasma donation centers licensed pursuant to this section shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

(F) Source plasma donation centers licensed pursuant to this section shall ensure their facilities comply with applicable federal, state and local laws.

(e) Source plasma donation centers shall maintain written documentation that each staff person employed is fully trained in the policies and procedures setting forth minimum standards of operation as required pursuant to this section.

(NEW) Sec. 19a-36-E4. Examinations and laboratory tests

(a) Source plasma donation centers licensed pursuant to this section shall only perform donor eligibility tests. The performance of any other laboratory testing shall require a clinical laboratory license pursuant to section 19a-565(b) of the Connecticut General Statutes as amended by section 9 of Public Act 23-31.

(b) Blood and blood components collected shall be tested according to the requirements of 21 CFR 610.40, as amended from time to time. If the source plasma donation center refers specimens to a reference lab located in the state of Connecticut, the reference lab shall require a clinical laboratory license pursuant to section 19a-565(b) of the Connecticut General Statutes . Reference labs located outside of the state of Connecticut shall comport with applicable state and federal licensing requirements.

(c) All donor testing shall be conducted by personnel licensed and authorized as required in the state where testing occurs.

(d) Source plasma donation centers licensed pursuant to this section shall meet the requirements of 42 CFR 493, Subpart H, as amended from time to time, regarding enrollment in an approved proficiency testing program under the source plasma donation center's CLIA certificate for each non-waived donor eligibility test conducted.

(e) If proficiency testing is required by federal regulation, records of proficiency testing shall be maintained for two years, including results and interpretations.

(f) All reference laboratories utilized by a source plasma donation center licensed pursuant to this section shall hold an applicable federal certificate or license, and state license as applicable.

(NEW) Sec. 19a-36-E5. Personnel requirements and qualifications

(a) A source plasma donation center licensed pursuant to this section shall ensure a minimum of two personnel with current certification in CPR is onsite for every ten donors present, with a minimum of one personnel with current certification in CPR onsite for less than ten donors. No blood shall be drawn unless personnel so certified in CPR and trained in donor emergency response protocols is present onsite.

(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 source plasma donation center director and qualified technical staff as follows:

(1) The licensee shall be responsible for ensuring that a qualified director supervises operations of a source plasma donation center licensed pursuant to this section at all times unless delegated pursuant to this section. If so required under the licensee's current CLIA certificate, the licensee shall also be responsible for ensuring 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 30 days or more, the licensee shall report such absence to the department in writing.

(2) Qualifications and responsibilities of 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 performing tests categorized as moderate complexity 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 source plasma donation center director.

(A) The director of the source plasma donation center shall be a responsible physician as defined in section 19a-36-E1 of the Regulations of Connecticut State Agencies. The director shall be responsible for ensuring compliance with the requirements for plasmapheresis set forth in 21 CFR 630 and 21 CFR 640, as amended from time to time. The director and the licensee shall be responsible for compliance with the rules set forth in this chapter, and all applicable state and federal statutes and regulations.

(B) The director shall be responsible for ensuring compliance with all procedures and policies as required under section 19a-36-E3 of the Regulations of Connecticut State Agencies.

(C) The director shall not individually serve as director of more than five licensed source plasma donation centers including those located out of state. If the director serves as director of any facility located outside of Connecticut, the director shall notify the department thereof.

(D) The director shall be responsible for ensuring the source plasma donation center personnel's in-service training delivers the required skills and knowledge to safely conduct donor and plasmapheresis services, and shall be responsible for 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 source plasma donation center to a properly qualified and trained responsible physician who shall be a physician licensed in the state of Connecticut under Chapter 370 of the Connecticut General Statutes, or to a physician substitute who shall meet the qualifications of subdivision (4) of this section. The director may delegate the specific activities with the corresponding levels of medical supervision to a trained person in accordance with requirements of 21 CFR 630.5, as amended from time to time. If the director delegates any responsibilities, the director shall be responsible for the proper performance of all such delegated duties.

(F) The director shall be on site during hours of operation except when the director has delegated his or her responsibilities to a physician substitute qualified pursuant to this

section. The director, a responsible physician or a physician substitute shall be on site as required under 21 CFR 630.5, as amended from time to time.

(4) Qualification and responsibilities of a physician substitute.

(A) A physician substitute may be a registered nurse, a physician assistant, or an advance practice registered nurse as defined for the purposes of this section.

(B) The responsible physician or physician substitute shall be responsible for the following:

(i) Ensuring the health and safety of donors and the performance of plasmapheresis during all hours of operation;

(ii) Oversight of the clinical training of all trained persons;

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

(iv) The performance of all duties delegated to them by the director.

(5) Qualifications and responsibilities of center managers.

(A) The director shall remain responsible for quality and compliance in all technical operations, but may delegate administrative duties related to the daily operation of a source plasma donation center licensed pursuant to this section to a center manager.

(B) The minimum qualification for each center manager conducting such administrative duties shall be an associate's degree and two years documented management experience at a source plasma donation center or equivalent facility.

(6) Qualifications and responsibilities of trained persons.

(A) Trained persons include phlebotomists, plasmapheresis technicians, or other persons duly qualified under this section.

(B) The department shall review training curricula and documentation of training provided by the licensee upon application. Training for all trained persons shall comply with federal requirements. Training shall be documented and shall include direct observations. All training related to the use of plasmapheresis devices shall include documentation of education and ability specific to the device and in accord with federal requirements.

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

(i) Venipuncture;

(ii) Specimen processing;

(iii) Emergency response; and

(iv) Plasmapheresis.

(D) Trained persons shall be supervised by the director, or a responsible physician or physician substitute to whom the director has delegated responsibility, during all hours of operation of a source plasma donation center licensed pursuant to this section.

(7) A source plasma donation center licensed under this section shall ensure sufficient staff are cross-trained in conducting plasmapheresis specific to the device, 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-E3(d)(3)(E) of the Regulations of Connecticut State Agencies.

(NEW) Sec. 19a-36-E6. Records, data collection and reporting requirements

(a) Records. Donor records shall be maintained in accordance with applicable federal and state law including in accordance with the federal requirements in 21 CFR 606.160 and 21 CFR 640.72, as amended from time to time. Quality control records of total protein determinations shall be maintained to ensure that no donor shall donate source plasma if the total protein determination is outside normal limits.

(b) Confidentiality. Source plasma donation centers licensed under this section shall comply with the requirements of section 36a-701b of the Connecticut General Statutes, and with all applicable federal and state laws regarding the confidentiality, privacy and security of donor records and personal information including health information.

(c) Adverse events. Records of donor reactions occurring onsite at the source plasma donation center licensed pursuant to this section, or reported to the center after the donor has left the facility, shall be kept in a manner that complies with the requirements of 21 CFR 640.72, as amended from time to time. Severe reactions that require the provision of medical attention and fatal reactions shall be reported to the department within twenty-four hours.

(d) Reporting. Source plasma donation centers licensed under this section shall comply with all requirements in section 21 CFR 640.73, as amended from time to time, governing reporting of adverse reactions. Source plasma donation centers licensed under this section shall submit annual reports to the department of all donor complaints filed including documentation of the complaint resolution. Reportable diseases. Source plasma donation centers licensed under this section shall comply with the reporting requirements under section 19a-215 of the Connecticut General Statutes.

(e) If an error or accident occurs and any blood or blood component or source plasma not suitable for any or the intended use is released for use, immediate effort shall be made to locate and destroy all components. All actions taken to address an error or accident shall be documented in writing.

Sec. 2. Sections 19a-36-A47 to 19a-36- A55, inclusive, of the Regulations of Connecticut State Agencies are repealed.