Agency
Department of Public Health
Subject
Reportable Diseases and Laboratory Findings
Inclusive Sections
§§ 19a-36-A1—19a-36-F6

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Reportable Diseases and Laboratory Findings

Sec. 19a-36-A1. Definitions

As used in Sections 19a-36-A1 to 19a-36-A46 of the Regulations of Connecticut State Agencies:

(1) "Authorized agent" means an individual designated by a local director of health to act for him or her in the performance of any of his or her duties.

(2) "Carrier" means an infected person or animal who, without any apparent symptoms of communicable disease, harbors a specific infectious agent and may serve as a source of infection for humans. The state of harboring a specific infectious agent may occur in an individual with an infection that is inapparent throughout its course (asymptomatic carrier), or in an individual during the incubation period, convalescence, and post-convalescence of a clinically recognizable disease (incubatory carrier and convalescent carrier). The carrier state may be of short duration (transient carrier) or long duration (chronic carrier).

(3) "Case" means a person or animal who exhibits evidence of disease.

(4) "Cleaning" means the process of removal of organic matter conducive to growth or maintenance of infectivity of infectious agents by scrubbing and washing as with hot water and soap.

(5) "Commissioner" means the state commissioner of health services.

(6) "Communicable disease" means a disease or condition, the infectious agent of which may pass or be carried directly or indirectly, from the body of one person or animal to the body of another person or animal.

(7) "Communicable period" means any time period during which a specific infectious agent may be transferred directly or indirectly from an infected person or animal to another human or animal.

(8) "Contact" means a person or animal known to have had association with an infected person or animal in such a manner as to have been exposed to a particular communicable disease.

(9) "Contamination" means the presence of undesirable substance or material which may contain an infectious agent on external body surfaces (e.g., skin), articles of apparel, inanimate surfaces or in food or beverages.

(10) "Cultures" mean growths of an infectious agent propogated on selected living or artificial media.

(11) "Date of onset" means the day, month and year on which the case or suspected case experienced the first sign or symptoms of the disease.

(12) "Department" means the Connecticut Department of Health Services.

(13) "Disinfection" means a directly applied chemical or physical process by which the disease producing powers of infectious agents are destroyed. (1) "Concurrent disinfection" means the immediate disinfection and disposal of body discharges, and the immediate disinfection or destruction of all infected or presumably infected materials. (2) "Terminal disinfection" means the process of rendering the personal clothing and immediate physical environment of a patient free from the probability of conveying an infectious agent to others

after removal of the patient or at a time when the patient is no longer a source of infection.

(14) "Epidemic" means the occurrence of cases of illness clearly in excess of normal expectancy over a specific time period in a community, geographic region, building or institution. The number of cases indicating an epidemic may vary according to the causative agent, size and type of population exposed, previous experience with the disease, and time and place of occurrence. An outbreak of disease is an epidemic.

(15) "Epidemiologic investigation" means an inquiry into the incidence, distribution and source of disease to determine its cause, means of prevention, and efficacy of control measures.

(16) "Foodborne outbreaks" means illness in two or more individuals acquired through the ingestion of common-source food or water contaminated with chemicals, infectious agents or their toxic products. Foodborne outbreaks include, but are not limited to, illness due to heavy metal intoxications, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens intoxication and hepatitis A.

(17) "Foodhandler" means a person who prepares, processes, or otherwise handles food or beverages for people other than members of his or her immediate household.

(18) "Health care facility" means any hospital, long term care facility, home health care agency, clinic or other institution licensed under Chapter 368v of the Connecticut General Statutes and also facilities operated and maintained by any state agency for the care or treatment of mentally ill persons or persons with mental retardation or substance abuse problems.

(19) "Health care provider" means a person who has direct or supervisory responsibility for the delivery of health care or medical services. This shall include but not be limited to: licensed physicians, nurse practitioners, physician assistants, nurses, dentists, medical examiners, and administrators, superintendents and managers of health care facilities.

(20) "Incubation period" means the time interval between exposure to a disease organism and the appearance of the first symptoms of the resulting disease.

(21) "Infection" means the entry and multiplication of an infectious agent in the body of a person or animal with or without clinical symptoms.

(22) "Infectious agent" means a microorganism capable of producing infection with or without disease.

(23) "Isolation" means the use of special precautions during the period of communicability to prevent transmission of an infectious agent. Such special precautions may include: physical separation of infected persons or animals from others, or precautions such as blood precautions that do not necessarily result in physical separation of individuals.

(24) "Laboratory" means any facility licensed, or approved by the department in accordance with section 19a-30 of the Connecticut General Statutes.

(25) "Local director of health" means and includes the city, town, borough or district director of health and any person legally authorized to act for the local director of health.

(26) "Medical information" means the recorded health information on an individual who has a reportable disease or who has symptoms of illness in the setting of an outbreak. This

information includes details of a medical history, physical examination, any laboratory test, diagnosis, treatment, outcome and the description and sources of suspected causative agents for such disease or illness.

(27) "Nosocomial infection" means infections that develop within a hospital or other health care facility or are produced by microorganisms acquired while in a hospital or health care facility.

(28) "Outbreak." See "epidemic."

(29) "Quarantine" means the formal limitation of freedom of movement of persons or animals exposed to, or suffering from a reportable disease for a period of time not longer than either the longest incubation period or the longest communicable period of the disease, in order to prevent spread of the infectious agent of that disease.

(30) "Reportable disease" means a communicable disease, disease outbreak, or other condition of public health significance required to be reported to the department and local health directors.

(31) "Reportable laboratory finding" means a laboratory result suggesting the presence of a communicable disease or other condition of public health significance required to be reported to the department and local health directors.

(32) "State epidemiologist" means the person designated by the Commissioner as the person in charge of communicable disease control for the state.

(33) "Surveillance" means the continuing scrutiny of all aspects of occurrence and spread of a disease relating to effective control of that disease, which may include but not be limited to the collection and evaluation of: morbidity and mortality reports; laboratory reports of significant findings; special reports of field investigations of epidemics and individual cases; data concerning the availability, use, and untoward side effects of the substances used in disease control, such as rabies vaccine; and information regarding immunity levels in segments of the population.

(34) "Suspected case" means a person or animal suspected of having a particular disease in the temporary or permanent absence of definitive clinical or laboratory evidence.

(35) "Other condition of public health significance" means a non-communicable disease caused by a common source or prevalent exposure such as pesticide poisoning, silicosis or lead poisoning.

(Effective October 25, 1989; Amended October 10, 2008; Amended March 19, 2025)

Sec. 19a-36-A2. List of reportable diseases and laboratory findings

The commissioner shall issue a list of reportable diseases and laboratory findings within sixty days of the effective date of these regulations, on the next January 1, and annually thereafter. The list shall show it is the current list and shall specify its effective date. This list shall also include but not be limited to the reporting category of each disease, procedures for the reporting, and minimum investigation and control measures for each disease. Listed diseases are declared reportable diseases as of the effective date of approval by the commissioner.

(a) The commissioner in consultation with the state epidemiologist will annually review the existing list and develop recommendations for deletions or additions to the list.

(b) The state epidemiologist or other commissioner designee shall convene and chair an advisory committee to review the recommendations for any changes to the list prior to preparing the final list for that year. This committee shall make recommendations to the commissioner regarding the contents of the list.

(c) The commissioner shall review the advisory committee's recommendations and make final deletions or additions to the list to take effect January 1 of the next year. He will furnish copies of the list before January 1 to the following:

(1) physicians licensed by the department;

(2) directors of clinical laboratories licensed, registered or approved by the department;

(3) local directors of health in Connecticut;

(4) health care facilities licensed under Chapter 368v of the Connecticut General Statutes.

(Effective October 25, 1989)

Sec. 19a-36-A3. Persons required to report reportable diseases and laboratory findings

(a) **Reportable Diseases.**

(1) Every health care provider who treats or examines any person who has or is suspected to have a reportable disease shall report to the local director of health or other health authority within whose jurisdiction the patient resides and to the department such information about the affected person as described in section 19a-36-A4 of these regulations.

(2) If the case or suspected case of reportable disease is in a health care facility, the person in charge of such facility shall ensure that reports are made to the local director of health and the department in the manner specified in section 19a-36-A4 of these regulations. The person in charge shall designate appropriate infection control or record-keeping personnel for this purpose.

(3) If the case or suspected case of reportable disease is not in a health care facility and if a health care provider is not in attendance or is not known to have made a report within the appropriate time specified in section 19a-36-A4, such report of reportable diseases shall be made to the local director of health or other health authority within whose jurisdiction the patient lives and the department in the manner specified in section 19a-36-A4 by:

(A) the administrator serving a public or private school or day care center attended by any person affected or apparently affected with such disease;

(B) the person in charge of any camp;

(C) the master or any other person in charge of any vessel lying within the jurisdiction of the state;

(D) the master or any other person in charge of any aircraft landing within the jurisdiction of the state;

(E) the owner or person in charge of any establishment producing, handling or processing dairy products, other food or non-alcoholic beverages for sale or distribution;

(F) morticians and funeral directors.

(4) Each local director of health shall report or ensure reporting to the department within 24 hours of each case or suspected case of a Category I reportable disease and such additional information of which he has knowledge as described in section 19a-36-A4 of these regulations.

(b) **Reportable laboratory findings.**—The director of a laboratory that receives a primary specimen or sample which yields a reportable laboratory finding shall be responsible for reporting such findings within forty-eight (48) hours to the local director of health of the town in which the affected person normally resides, or, in the absence of such information, of the town from which the specimen originated, and to the department on forms provided by the department.

(1) When a laboratory identifies or presumptively identifies a significant isolate or other finding that requires confirmation by the laboratory as required in the annual list, the director must submit that isolate or specimen from which the finding was made to the department's laboratory division.

(2) Laboratory tests and confirmatory tests for certain reportable diseases as specially indicated in the annual list shall be exempted from any and all fees for the state laboratory services in accordance with Section 19a-26 of the Connecticut General Statutes.

(Effective October 25, 1989)

Sec. 19a-36-A4. Content of report and reporting of reportable diseases and laboratory findings

(a) **Reportable diseases.**

(1) Each report of a case or suspected case of reportable disease shall include the full name and address of the person reporting and of the physician attending; the diagnosed or suspected disease and date of onset; the full name, age, race/ethnicity, sex and occupation of the affected individual and other facts the department or local director of health requires for purposes of surveillance, control and prevention of reportable diseases. The reports shall be sent in envelopes marked "CONFIDENTIAL."

(2) Reports may be written or oral as required by the category of disease as follows:

(A) Category I: diseases of high priority because of need for timely public health action: reportable immediately by telephone on day of recognition or suspicion of disease; on weekdays to both, the local health director of the town in which the patient resides and the department, on weekends to the department. A completed disease report form provided by the department must also be mailed to both the local health director and the department within 12 hours.

(B) Category II: diseases of significant public health importance, usually requiring public health action: reportable by mail to the local director health and the department within 12 hours of recognition or suspicion on a form provided by the department.

(b) **Reportable laboratory findings.**

(1) Each report of reportable findings shall include the name, address, age, sex, and, if

known, race/ethnicity of the person affected, the name and address of the attending physician, the identity of the infectious agent or other reportable laboratory findings, and the method of identification.

(2) Reports shall be mailed to the local director of health of the town in which the patient resides and to the department within 48 hours of making the finding in envelopes marked "CONFIDENTIAL."

(Effective October 25, 1989)

Sec. 19a-36-A5. Confidentiality of data

All epidemiologic information which identifies an individual and which is gathered by the state or local health department in connection with the investigation of reported cases or suspected cases of disease or during the investigation of outbreaks of disease shall be kept in compliance with current confidentiality statutes.

(Effective October 25, 1989)

Sec. 19a-36-A6. Investigation and control of reportable disease and outbreaks by the department

(a) The department, in cooperation with the local director of health, in the investigation and control of reportable disease shall make or cause to be made such investigation as it deems necessary and shall secure all such data as may assist it in establishing adequate control measures.

(b) In order to investigate and control any apparent outbreak or unusual occurrence of reportable disease, the department shall institute such special disease surveillance, follow-up reports and control measures as it deems necessary.

(c) Individual medical information pertaining to cases of reportable disease, persons affected by outbreaks of disease or significant increases in the rate of nonsocomial infection shall be provided when requested to an investigator who presents official identification of the department or the local department of health. Such an investigator may be an employee of the State or local health department.

(Effective October 25, 1989)

Sec. 19a-36-A7. Diseases not enumerated

Diseases not specifically listed pursuant to section 19a-36-A2 and presenting a special problem shall be reported and controlled in accordance with special instructions of the state department of health or, in the absence of such instructions, in accordance with orders and directions of the local director of health.

(Effective October 25, 1989)

Sec. 19a-36-A8. General measures for control of reportable diseases

The local director of health, in instituting measures for the control of reportable diseases:

Investigation

(a) shall make, or cause to be made, such investigations as he may deem necessary and shall secure all such data as may assist him in establishing adequate control measures;

Isolation and orders

(b) shall establish and maintain quarantine, isolation or such other measures for control as are required by statute, the public health code or special instructions of the state department of health, and, when possible, shall issue his instructions and orders in writing or on printed forms;

Removal

(c) shall have the authority to set up proper isolation or quarantine of an affected person or persons, carrier or contact, when, in his opinion or in the opinion of the state commissioner of health, this is not or cannot be effectively maintained on the premises occupied by such person or persons by methods designated in this part; to remove or require the removal of such person or persons to a hospital or other proper place designated by him; or to employ such guards or officers as may be necessary to maintain effective isolation or quarantine;

Instruction

(d) shall provide, by himself or his authorized agent, for the specific instruction of cases, contacts, their attendants and all other persons affected, in the proper methods for the prevention of the spread of the disease and shall supply such information and literature as may be required by law or by the instructions of the state department of health;

Enforcement

(e) shall make, at intervals during the period of communicability, inquiry or investigation to satisfy himself that the measures instituted by him for the protection of others are being properly observed;

Laboratory tests

(f) shall, when the control or release of a case, contact or carrier of a reportable disease is dependent upon laboratory findings, require the specimens upon which such findings are based to be examined by the laboratory division of the state department of health or by a laboratory specifically approved for that purpose by the state department of health and shall, by himself or his authorized agent, secure and submit release cultures or specimens for examination; in cases of enteric diseases all release specimens shall be taken at least one week after specific therapy has been discontinued;

Schools—Isolation

(g) shall, in the event of an outbreak of a communicable disease in any public, private, parochial or church school, make a prompt and thorough investigation; control such an outbreak by individual examination of pupils, teachers and other persons associated with the outbreak; employ such other means as he deems necessary to determine the source of infection or to provide for the segregation of infected persons; in the event of an outbreak of a communicable disease in any school, require school physicians and school nurses to conform to the orders, regulations and restrictions issued by him;

Schools—Readmission

(h) shall, in the case of any school child who has been excluded from school for having been a case, contact or carrier of a communicable disease, by himself or his authorized agent, issue a permit for such child to re-enter school when in his opinion such child is no longer infectious;

Unusual disease

(i) shall, when an unusual or rare disease occurs in any part of the state or when any disease becomes so prevalent as to endanger the state as a whole, contact the state department of health for assistance, and shall cooperate with the representatives of the state department of health acting under the direction of the state commissioner of health;

Other measures

(j) shall introduce such other measures as he may deem advisable.

(Effective October 25, 1989)

Sec. 19a-36-A9. Control of diseases suspected of being reportable

The local director of health, on receiving a report of a disease suspected of being reportable, shall confer with the physician or other person making such report, make further examination or investigation as he deems necessary and advise, recommend or establish such procedures as he may deem necessary to protect the public health until the character of the disease is definitely determined.

(Effective October 25, 1989)

Sec. 19a-36-A10. Presumably exposed persons may be examined and controlled

The local director of health, when he has reasonable grounds to believe that a person or persons may have been exposed to a communicable disease, may control such persons as known contacts and may make such examinations and adopt such measures as he deems necessary and proper for the protection of the public health and the prevention of the spread of disease.

(1) The conviction of any person for any offense involving sexual promiscuity or illicit sex relations shall constitute reasonable grounds for the local director of health to believe that that person may have been exposed to a communicable disease and shall justify the examination and such other measures of control of that individual as are deemed necessary and proper by the state department of health for the protection of public health and the prevention of spreading of disease.

(2) The warden or other person in charge of any prison or jail in the state shall notify the prison or jail physician, in writing, within twenty-four hours upon the receipt of a prisoner who may have been exposed to a communicable disease and of every prisoner who has been convicted of any offense involving sexual promiscuity or illicit sex relations. A routine medical examination shall be made on every prisoner whose conviction involves sexual promiscuity or illicit sex relations. Such routine medical examination shall include the taking of a blood specimen for serological test for syphilis and the taking of three smears for gonococci taken not less than twenty-four hours apart and, if the prisoner is found to be

infected, treatment shall be instituted as necessary. The tests referred to above shall be performed in the bureau of laboratories of the state department of health or in a laboratory specifically approved for these purposes by the state department of health, and they shall be performed in a manner that meets the approval of the state department of health. Upon the expiration of a sentence, any person having syphilis or gonococcal infection, whether in an infectious or non-infectious stage, and in need of further followup treatment shall be reported to the state department of health by the attending physician, who shall give the name, sex, age and marital status and a record of the treatment given while such person was imprisoned.

(Effective October 25, 1989)

Sec. 19a-36-A11. Control of carriers of the infectious agent of communicable disease

Carriers, whether transient, convalescent or chronic, of the infectious agent of any communicable disease shall be maintained under observation until repeated laboratory examinations of appropriate specimens show the absence of the infectious agent. Examination of all such specimens shall be in conformity with subsection (f) of section 19a-36-A8.

(a) Any local director of health or physician who discovers any carrier of an infectious agent shall report the fact to the state department of health giving the full name, age, sex, occupation and address of such carrier. The state department of health shall, upon receipt of such report, notify the local director of health of the town, city or borough wherein the carrier resides. The local director of health concerned shall then communicate the fact to the carrier himself, or his guardian, giving specific instructions regarding the precautions necessary to protect others from infection.

(b) Any privy or latrine used by an enteric disease carrier shall be so constructed as to exclude flies and to meet the approval of the local director of health. The disinfection and disposal of its contents shall be in accordance with instructions given by the local director of health.

(c) A carrier of an infectious agent shall not engage in any occupation involving the handling of any food or beverage intended for the use of others.

(d) Enteric disease carriers shall not work on any public water supply or watershed.

(e) A carrier who changes his residence shall notify the local director of health of the town, city or borough in which he has been residing of the date of his departure, his destination and his new address. The local director of health shall immediately forward this information to the state department of health.

(f) The local director of health shall visit each carrier within his jurisdiction at least once every three months and shall render quarterly reports concerning each such carrier to the state department of health upon forms prescribed for the purpose.

(Effective October 25, 1989)

Sec. 19a-36-A12. Enteric disease carriers

(a) A chronic carrier of enteric disease shall be defined as a person who persists in excreting enteric pathogenic organisms for twelve months or more after onset of illness or probable date of infection or one who, though he may never have been known to have the disease, has been shown to harbor the infectious agent in his body.

(b) All specimens for the release of enteric carriers from supervision shall be collected at least ten days after the cessation of any antibiotic therapy or any therapy directed at the disease.

(c) All specimens for the release of enteric carriers from supervision shall be examined in conformity with subsection (f) of section 19a-36-A8.

(d) Chronic carriers of the organisms causing typhoid fever and paratyphoid fever shall not be released from supervision until six successive specimens of urine and six successive specimens of feces, the last two of which shall be validated by collection of the specimen in a hospital or otherwise under direct supervision, have been found negative. Specimens for such examination shall be so collected that a time interval of not less than one month shall elapse between successive specimens of urine and between successive specimens of feces. The final two specimens of feces to be examined may be validated by the giving of lycopodium or a negative bile culture may be substituted for such validation.

(e) A chronic carrier of enteric disease excreting the organism in discharges other than the feces or urine shall not be released from supervision until negative cultures as outlined by the state department of health for the specific case have been obtained.

(Effective October 25, 1989)

Sec. 19a-36-A13. Control of tuberculosis

(a) When a licensed physician or hospital superintendent has reported a case of tuberculosis and has agreed to assume the responsibility for the proper instruction of the patient and the taking of measures necessary for the protection of others, the local director of health need not take action other than that prescribed by sections 19a-262 to 19a-264, inclusive, of the general statutes.

(b) When such patient, while in an infectious state, neglects or refuses to follow the prescribed instructions or discontinues treatment, the physician or superintendent shall immediately notify the local director of health.

(c) When a physician or hospital superintendent has declined to assume such responsibility, the local director of health shall supply the affected person with printed instructions and take such other action as may be necessary and proper for the protection of the public health.

(Effective October 25, 1989)

Sec. 19a-36-A14. Control of refractory persons affected with tuberculosis

When it comes to the attention of a local director of health that a person is affected with tuberculosis and is a menace to the public health or is likely to jeopardize the health of any

person or persons in or on the premises occupied or frequented by the affected person, he shall immediately investigate and shall take proper measures to prevent the spread of such disease for the protection of the public health and, if necessary, may cause the removal of such person to an isolation hospital or other proper place, there to be received and kept until he is no longer a menace to the public health.

(Effective October 25, 1989)

Sec. 19a-36-A15. Control of venereal disease

(a) When a licensed physician or hospital superintendent has reported a case of gonorrhea or syphilis and has agreed in writing to assume the responsibility for the proper instruction of the patient, the local director of health shall supply such physician or hospital superintendent with printed instructions for such patient.

(b) When such patient, while in an infectious state, neglects or refuses to follow the prescribed instructions or discontinues treatment, the physician or superintendent shall immediately notify the local director of health.

(c) In investigating cases or suspected cases of the above-mentioned diseases, the local director of health shall treat all information as confidential, but such course shall not preclude the making of reports to the state department of health.

(Effective October 25, 1989)

Sec. 19a-36-A16. Control of refractory persons affected with venereal diseases

When it comes to the attention of a local director of health that a person is affected with or presumably affected with gonorrhea or syphilis in any form and is likely to jeopardize the health of any person or persons in or on the premises occupied or frequented by the affected person, the local director of health shall immediately investigate and shall take proper measures to prevent the spread of such disease for the protection of the public health, and he shall direct such person to report regularly for treatment to a licensed physician or to a public clinic, there to be treated until such person is free from infectious discharges. If such person, in the opinion of the local director of health, is a menace to the public health, the local director of health shall order the removal of such person to an isolation hospital or other proper place, there to be received and kept until he no longer is a menace to the public health; or the local director of health shall adopt such other measures as he may deem necessary to protect the public health.

(Effective October 25, 1989)

Sec. 19a-36-A17. Observance of quarantine and instructions

Every person who is affected with a communicable disease, who is a carrier or who is suspected of having come in contact, directly or indirectly, with a case of communicable disease shall strictly observe and comply with all orders, quarantine regulations and restrictions given or imposed by the local health authority or the state commissioner of

health in conformity with law.

(Effective October 25, 1989)

Sec. 19a-36-A18. Control of quarantine area

No person other than the attending physicians and authorized attendants shall enter or leave, and no one except the local director of health or his representative shall permit any other person to enter or leave, any room, apartment or premises quarantined for a communicable disease, nor shall any person needlessly expose a child or other person to a communicable disease. No person shall remove any article from a quarantined area without permission of the local director of health. The local director of health shall report immediately to the state commissioner of health, by telegraph or telephone, the name, address, probable destination and route of departure of any person who was under control for a reportable disease and who has left his jurisdiction without his consent.

(Effective October 25, 1989)

Sec. 19a-36-A19. Duty of local director of health to quarantined persons in need

When a person under quarantine is, in the opinion of the local director of health, unable to obtain medical care, food or other actual necessities, the local director of health shall report his findings to the proper town, city or borough authority. If such town, city or borough authority fails to supply at once the needed care, the local director of health shall supply such quarantined person with medical attention, food or other actual necessities, and the expense incurred in performing such duty shall constitute a legal expense of the local director of health and shall be paid according to state statute.

(Effective October 25, 1989)

Sec. 19a-36-A20. Preventing spread of disease by common carriers

In the event of the epidemic prevalence of a communicable disease, when a written declaration to that effect has been made by the state commissioner of health, any person, firm or corporation operating any common carrier within the state, or in the waters thereof, shall comply strictly with any order issued by the state commissioner of health for the purpose of preventing the introduction into the state, or the transmission from one point to another within the state, of any person or persons, animals, insects or materials likely to convey the disease.

(Effective October 25, 1989)

Sec. 19a-36-A21. Food and food handlers restricted

When a case of any of the reportable diseases listed pursuant to section 19a-36-A2 occurs on the premises where milk or food is produced, kept, handled or sold, the local director of health shall institute such measures as he deems necessary to prevent the spread of such disease and to protect such foods from being contaminated; and he shall require all uninfected persons who reside in an apartment or dwelling where any such disease exists,

and who handle milk or food elsewhere, to remain away from such abode as long as the disease is present.

(Effective October 25, 1989)

Sec. 19a-36-A22. Use of milk, food and water containers restricted

The local director of health in charge of a case or a suspected case of a communicable disease that may be conveyed by milk, food or water shall forbid the return of any container to the distributor when such container has been within a quarantined area, or has been handled or presumably handled by anyone in attendance upon a person affected or believed to be affected with such disease, until such empty container has been sterilized by boiling water or by live steam, or in any other manner satisfactory to the local director of health.

(Effective October 25, 1989)

Sec. 19a-36-A23. Regulation of traffic in psittacine birds

(a) As used in this section: "Psittacine birds" means, unless otherwise specified, all birds commonly known as parrots, macaws, cockatoos, lovebirds, parakeets, cockatiels and all birds of the order psittaciformes.

(b) Any person or entity that imports, purchases, breeds, sells, exchanges, barters, gives away or otherwise deals in psittacine birds shall keep records of such transactions embodying information required by the Department of Public Health. For each bird, records shall include:

(1) The date of bird's arrival on premises;

(2) A description of the bird (i.e.: species, common name, variety);

(3) The unique identifier consistent with the leg band or microchip;

(4) The name, address and phone number of the prior owner of the bird; and

(5) The date and a description of the final disposition. If the final disposition is a change of ownership, the records shall also include name, address and phone number of the person accepting ownership of the bird.

Such records shall be open for inspection by the local director of health, a representative of the Department of Public Health, a local animal control officer, or a representative of the state Department of Agriculture. The records shall be kept for the period of time commencing on the date of the bird's arrival on the premises and continuing until two years following the date of final disposition of such bird.

(c) Except as provided for in subsection (d) of these regulations, all psittacine birds, except parakeets, that are imported, purchased, sold, exchanged, bartered or given away shall be banded with a metal leg band that has a diameter adequate for the species. Said band shall contain a unique identifier for each individual psittacine bird. The leg band design may be closed, or opened (seamed) provided that it is tamper evident. This subsection shall not prohibit the use of a unique identifier for parakeets.

(d) A microchip that includes the unique identifier for each individual psittacine bird may be used in place of a leg band. An appropriate microchip reader shall be available at

any pet shop licensed pursuant to section 22-344 of the Connecticut General Statutes where a psittacine bird is normally kept.

(e) Any psittacine bird imported into Connecticut shall be accompanied by a health certificate signed by a veterinarian licensed in the state or country of origin certifying that such psittacine bird was healthy before shipment and had no known exposure to avian chlamydiosis in the 60 days preceding the date of issuance of the health certificate. The certificate shall include the date of veterinary inspection, and for each psittacine bird the description (i.e. species, common name, variety), and source including name, address, and phone number of the prior owner. The unique identifier as it appears on the leg band as described in subsection (c) of these regulations or the microchip as described in subsection (d) of these regulations shall be present on either the health certificate accompanying the psittacine bird or a document attached to the health certificate. If the unique identifier is located on a document attached to the health certificate, the health certificate shall indicate where on the attached document the unique identifier is located.

(f) The breeder of any parakeet imported, purchased, sold, exchanged, bartered or given away shall be indicated on either:

(1) A metal leg band that has a diameter adequate for the species that may be closed, or opened (seamed) provided that it is tamper evident; or

(2) A microchip provided that an appropriate microchip reader shall be available at any pet store licensed pursuant to section 22-344 of the Connecticut General Statutes where a parakeet is normally kept.

Such breeder shall also be identified on records required pursuant to subsection (b) of this section and the health certificate required pursuant to subsection (e) of this section except that on any document where said subsections require a unique identifier the name of the breeder shall be included in lieu thereof.

(Effective October 25, 1989; Amended January 3, 2011)

Sec. 19a-36-A24. Distribution and use of microbial agents for control of animal life

Microbial agents capable of producing disease in man shall not be sold, distributed or used for the control or destruction of any form of animal life.

(Effective October 25, 1989)

Sec. 19a-36-A25. Laboratories to register

Any person, firm or corporation, or the duly authorized agent thereof, operating or maintaining a laboratory in which there is made any examination, determination or test specified in section 19a-36-A26, shall register such laboratory with the state department of health before any such examination, determination or test is made. The carrying on of any of the examinations, determinations or tests specified in said section shall be deemed the operating or maintaining of a laboratory.

(Effective October 25, 1989)

Sec. 19a-36-A26. Registration required when. Exemptions

(a) Except for laboratory work of the types hereinafter exempted, registration is required for any of the following laboratory procedures:

(1) Those which utilize any living agent capable of causing human infections or reportable disease of man, or which are used to secure evidence bearing upon the presence or absence of such living agents or the illnesses caused;

(2) those used to determine the sanitary quality of water or the amount of pollution therein or to control and evaluate the effectiveness of water treatment;

(3) those performed on sewage, sewage effluent or sewage sludge in connection with investigation of sources of pollution, problems of sewage disposal or effectiveness of sewage treatment;

(4) any examination, determination or test performed on any sample of milk, cream, frozen dessert, milk product or milk beverage or of any container or package used or intended to be used for holding any such product;

(5) those used to determine the sanitary quality of any substance used as a food, or as an ingredient of food or as a container for food, or to determine whether or not such substance may be harmful to health;

(6) those performed on any material or substance for the purpose of determining the effectiveness of sanitation in the establishment serving food or beverages to the public;

(7) those performed on air or materials contributing substances to the air which may be prejudicial to health, except those performed for routine operational control or maintenance purposes.

(b) Laboratories performing any of the work specified above shall be exempt from the requirements of this section only when all such work is done under one or more of the following conditions:

(1) When laboratory findings are obtained in a laboratory facility and service maintained by a licensed practitioner of a healing art exclusively for the examination of his own patients within the scope of his license to practice;

(2) when the laboratory has been established as an agency of the state or federal government for the purpose of providing data for state or federal officials in the enforcement of the dairy and pure food and drug laws;

(3) when laboratory work is confined to butter fat tests on milk and cream for use in determining payment to producers of such products under provisions of the general statutes;

(4) repealed, March 23, 1976;

(5) when laboratory findings are obtained on materials derived from animals in a laboratory facility and service maintained by a veterinarian licensed to practice in Connecticut performing laboratory examinations exclusively on animals under his or her care and treatment.

(c) When the laboratory work consists solely of those tests necessary to control the operation of water treatment plants under the supervision of operators whose qualifications have been approved by the state department of health or of sewage treatment plants under

the supervision of operators whose qualifications have been approved by the state department of environmental protection, upon recommendation of the division of environmental health services in the former case or the state department of environmental protection in the latter case, the department shall grant registration without approval as provided in section 19a-36-A33 solely for the purpose of allowing such operators to perform those tests as shall be required for the control of treatment. Such granting of limited registration or renewal thereof may be made by the department without prior inspection or investigation of facilities, personnel, equipment and proficiency.

(Effective October 25, 1989)

Sec. 19a-36-A27. Application for registration or reregistration

(a) Application for registration shall be made on forms provided for the purpose by the state department of health and shall set forth clearly essential information concerning the laboratory, including its name, its location, the name of the person, firm or corporation owning or operating it, and such additional information as the state department of health may at any time deem necessary regarding the tests to be made, the housing, equipment and personnel of the laboratory. As part of the application for registration, the owner of the laboratory, or his duly authorized agent, shall designate a person to be in charge of the laboratory and shall agree to notify the state department of health in writing before any change in status of the person in charge or removal of the laboratory to new quarters is made.

(b) In a similar manner, application for reregistration of such laboratory shall be made (1) biennially within thirty calendar days prior to expiration of the registration then current, (2) before the laboratory is moved to new quarters, (3) whenever a change in status of the person designated to be in charge is about to be made or (4) whenever registration has lapsed for any cause.

(Effective October 25, 1989)

Sec. 19a-36-A28. Conditional permission to operate laboratory

The state department of health may extend conditional permission to operate an unregistered laboratory for a period not to exceed thirty days pending completion of investigation or carrying out of conditions imposed prior to registration or reregistration.

(Effective October 25, 1989)

Sec. 19a-36-A29. Granting of registration

Registration or reregistration of a laboratory will be granted only after the state department of health has determined by inspection and investigation that no condition or circumstance exists which would, in the opinion of the state department of health, cause the laboratory to be operated in a manner prejudicial to the health of the public.

(Effective October 25, 1989)

Sec. 19a-36-A30. Suspension or revocation of registration

Registration of a laboratory may be suspended at any time when investigation has shown that the registration agreement has been violated or that the laboratory is being operated in a manner which may be prejudicial to the health of the public. Registration may be revoked for such cause after notice to and hearing of the parties interested.

(Effective October 25, 1989)

Sec. 19a-36-A31. Inspections and investigation by state department of health

Representatives of the state department of health shall be granted reasonable access to laboratory quarters and records for inspection and investigation. Whenever necessary to evaluate the accuracy of any type of laboratory work done in a laboratory which is registered or has applied for registration, said department will require technical reviews of procedures used or submit a reasonable number of suitable specimens or samples and require reports thereon.

(Effective October 25, 1989)

Sec. 19a-36-A32. Prohibition of transmission of material to unregistered laboratory

No person, firm or corporation shall, without approval in writing from the state department of health, maintain, conduct or operate a station or office for the reception from the public of materials to be transmitted to a laboratory for the making of any clinical, medical, or sanitary laboratory examination, determination or test except when the laboratory in which the work is to be done is currently registered with the state department of health or is exempt from registration requirements, as provided for in section 19a-36-A26.

(Effective October 25, 1989)

Sec. 19a-36-A33. Requirements and standards for approval

(a) The department of Public Health will approve registered laboratories only under the following circumstances:

(1) When such approval is sought in order to comply with provisions of the general statutes or the public health code of Connecticut making approval a prerequisite for the performance of laboratory tests for the purposes specified therein;

(2) When laboratory tests for the diagnosis of reportable diseases of man are to be made in a laboratory serving a hospital, or

(3) Whenever the department of Public Health deems that the application of standards for approval of a laboratory would be in the interests of the public health. When any of the foregoing conditions exist, the person in whose name a laboratory is registered may apply to the department of Public Health for approval of such laboratory to perform one or more examinations, determinations or tests specified in section 19a-36-A26 of the Regulations of Connecticut State Agencies. If after inspection and investigation such laboratory is found to conform to the requirements and standards for approval that are required by said

department, the laboratory may be designated as an approved laboratory to perform examinations, determinations or tests specified. In recognition thereof the department shall issue a certificate of approval in the name of the individual who is designated by the owner of the laboratory, or by his authorized agent, to be the individual in charge of the work for which approval is requested.

(b) Requirements and standards for approval of laboratories shall be based upon the ability and qualifications, as determined by investigation or examination, of the individual designated by the owner to be in charge of the laboratory and to the extent deemed necessary at any time of persons performing the examinations, determinations or tests; upon the standards and agreements set forth in section 19-4-1 of the Regulations of Connecticut State Agencies; and upon agreement on the part of the individual in charge to adhere to the standards upon which approval is based for making the specified examinations, determinations or tests. Approval shall lapse at any time that registration has expired or approval may be revoked or suspended at the discretion of the department of Public Health if at any time the standards of performance are found to be below that required. Certificates of approval shall expire at the end of each registration period and shall be returned at any time if revoked or suspended.

(c) Environmental laboratories, as defined in section 19a-29a (a) of the Connecticut General Statutes, located outside of the geographical boundaries of Connecticut must be approved to test samples that have originated in the state of Connecticut. For the purposes of this section:

(1) "Matrix" means the component or substrate (e.g. drinking water, wastewater, soil) which contains the analyte of interest.

(2) "Analyte" means the substance being measured in an analytical procedure.

(3) "Primary accrediting authority" means the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting approval for determination of a given analyte in a given matrix for an environmental laboratory.

(A) In order to obtain approval, an applicant shall complete an application for registration in accordance with section 19a-36-A27 of the Regulations of Connecticut State Agencies, remit a biennial fee of $1000.00 as specified in section 19a-29a (c) of the Connecticut General Statutes, and it must be established that:

(i) The laboratory is certified or approved by its primary accrediting authority for the analytes and matrices for which approval is requested, and the certification standards of the primary accrediting authority are equivalent to or exceed Connecticut's standards, and;

(ii) The requirements of section 19a-36-A62 of the Regulations of Connecticut State Agencies regarding qualifications of the director are complied with.

(B) For analytes and/or matrices for which the primary accrediting authority does not have a Connecticut equivalent certification, the Department of Public Health may approve the laboratory based on its certification or approval in a Territory, Federal, State or other nationally recognized program whose standards are equivalent to, or exceed Connecticut's

standards, such as, but not limited to, the National Environmental Laboratory Accreditation Program.

(C) An approval shall automatically expire:

(i) Upon a change in the ownership of the laboratory, unless 30 days in advance of the transfer, a new completed application is received by the department. In such case the Department of Public Health shall grant conditional permission to operate the laboratory for 30 days or until the department either approves or disapproves the new application, whichever is sooner, in accordance with section 19a-36-A28 of the Regulations of Connecticut State Agencies.

(ii) Upon any change in the information in the laboratory application, unless within two weeks of said change, a new appropriately updated application is received by the department. In such case the department shall grant the laboratory conditional permission to operate for 30 days or until the department either approves or disapproves the new application, whichever is sooner, in accordance with section 19a-36-A28 of the Regulations of Connecticut State Agencies.

(iii) Upon a change in the director of the laboratory, unless a new director is hired by the laboratory owner and approved by the department within 30 days after the termination of the previous director.

(D) If the certification of the laboratory, upon which the department bases its approval, is suspended or revoked, the approval of the department is automatically and immediately likewise suspended or revoked. An out of state laboratory must notify the department in writing of any changes in its certification within 14 days of said change.

(E) The owner shall maintain the current address of its laboratory with the department. Any notice with respect to the operation of the laboratory sent to the owner at the laboratory address on file is effective notice. Service of process by the department upon the owner shall be effective when made on the Connecticut Secretary of State's Office.

(Effective October 25, 1989; Amended October 10, 2006)

Sec. 19a-36-A34. Serologists to be certified

Before any serological test for syphilis may be reported for use or used as an aid to the diagnosis or the exclusion of syphilis, any person performing such test shall have demonstrated a standard of proficiency in performing such test which will fulfill the requirements of the state department of health and such person shall hold an unexpired certificate to perform such test which shall be issued by the state department of health subject to revocation for cause and to annual renewal. Serological tests performed entirely for instructional, research or experimental purposes and serological tests performed by a physician for use only in his private practice are exempted from this requirement.

(Effective October 25, 1989)

Sec. 19a-36-A35. Standard tests for syphilis

A standard laboratory blood test or a standard serological test for syphilis as required

under the provisions of the general statutes or the public acts shall be a serological test approved by, and performed in a manner that meets the approval of the state department of health. The following types of tests are so approved: VDRL slide flocculation, fluorescent treponemal antibody absorption (FTA-ABS), automated reagin (ART) and rapid plasma reagin (RPR) circle card tests.

(Effective October 25, 1989)

Sec. 19a-36-A36. Funeral directors to report deaths of reportable communicable diseases

Within twelve hours after being called to take charge of a human body dead of a communicable disease listed pursuant to section 19a-36-A2, the funeral director shall report the case to the local director of health and the body shall be prepared for burial in accordance with section 19a-36-A39.

(Effective October 25, 1989)

Sec. 19a-36-A37. Funerals of persons dead of reportable communicable diseases

Funerals of persons dead of any communicable disease listed pursuant to section 19a-36-A2 shall be conducted in such a manner that the family and public shall have no opportunity to come into contact with the body.

(Effective October 25, 1989)

Sec. 19a-36-A38. Definitions

The intent and meaning of certain words and phrases as used in sections 19a-36-A39, 19a-36-A40, 19a-36-A41 and 19a-36-A42 are as follows:

(a) **Washed.** A dead human body shall be considered as washed when the entire surface of the body has been bathed with a disinfecting solution.

(b) **Embalmed.** A body shall be considered embalmed when it has had injected into the circulatory system embalming fluid in an amount not less than five per cent of the body weight and when such cavities have been injected as may be necessary to properly preserve the body and render it sanitary.

(c) **Wrapped.** A body shall be considered as wrapped when it has been bandaged with five thicknesses of cloth saturated with a disinfecting solution, provided, when a body has been embalmed, the face, arms and hands need not be so bandaged.

(d) **Embalming fluid.** For the purposes mentioned in section 19a-36-A40, an embalming fluid shall be a fluid containing not less than four per cent formaldehyde gas by weight.

(e) **Disinfecting solution.** A disinfecting solution shall be an aqueous solution containing not less than five per cent of phenol by weight, a 1-500 solution of bichloride of mercury or such other solution as shall be equivalent to five per cent phenol in germicidal action when tested in the presence of organic matter by a method and in a laboratory that has met the approval of the state department of health for that purpose, provided such other solution shall have been approved in writing by the commissioner of health. The active ingredients

shall be named on the label of any package or container in which a disinfecting solution is offered for sale.

(Effective October 25, 1989)

Sec. 19a-36-A39. Preparation for burial of persons dead of reportable communicable diseases

Human bodies dead of any communicable disease listed pursuant to section 19a-36-A2 shall be prepared for burial by being washed with a disinfecting solution or embalmed or wrapped.

(Effective October 25, 1989)

Sec. 19a-36-A40. Transportation of dead bodies

(a) Dead human bodies to be transported by common carrier shall be embalmed or wrapped and then enclosed in a casket, and outside box or, in lieu of such double container, be enclosed in an impervious container acceptable to the commissioner of health.

(b) Dead human bodies to be removed from the place of death to another location for preparation shall be temporarily prepared by enclosing in an impervious container. The licensed embalmer having charge of such a body may sign the certificate required in section 7-62 of the general statutes, but in so doing, such licensed embalmer obligates himself to further prepare the body as required by section 19a-36-A39 as soon as practicable after arrival at his regular place of business.

(c) The impervious containers mentioned in subsections (a) and (b) of this section shall be cleansed and washed with a disinfecting solution after each use.

(Effective October 25, 1989)

Sec. 19a-36-A41. Disinterment permits

Embalmed bodies which have been placed in receiving vaults shall not be regarded the same as disinterred bodies until after the expiration of thirty days. All bodies remaining in a receiving vault over thirty days shall be treated the same as disinterred bodies. The above shall not apply during winter months to embalmed bodies which are to be buried in any cemetery in Connecticut before the first of June following the date in which they are placed in such receiving vault, but permits may be granted for removal and burial the same as if burial were made immediately after death.

(Effective October 25, 1989)

Sec. 19a-36-A42. Care in handling bodies dead of a communicable disease

Any licensed embalmer who has in charge the preparation of a body dead of a communicable disease shall take the necessary precautions to prevent the spread of infection, and such licensed embalmer shall instruct the owner of the building or the family in which the death occurs, or both, that it is unlawful to remove any infectious material, clothing, instrument or thing until thoroughly disinfected by combustion, by boiling for at

least ten minutes or by thorough saturation or immersion in a disinfecting solution for at least two hours.

(Effective October 25, 1989)

Sec. 19a-36-A43. Sanitation of buildings, equipment and instruments

All buildings occupied or used and all equipment and instruments used or owned by funeral directors or licensed embalmers shall be kept in a sanitary condition acceptable to the state department of health.

(Effective October 25, 1989)

Sec. 19a-36-A44. Inspection of buildings, equipment and instruments

The state department of health may, at any time, make an inspection of the buildings occupied or used or the equipment or instruments owned or used by funeral directors or licensed embalmers in the discharge of their business. When such buildings, equipment or instruments are found to be in such an insanitary condition as to be detrimental to the public health, and when it also is found that such buildings, equipment or instruments are owned or used by a licensed embalmer, such fact shall be reported to the state board of examiners of embalmers and funeral directors with the recommendation that the license be not renewed to the licensed embalmer who owns or operates such insanitary place of business.

(Effective October 25, 1989)

Sec. 19a-36-A45. Repealed

Repealed April 20, 1995.

Sec. 19a-36-A46. Sale of turtles

(1) No live turtle shall be sold in Connecticut until examination in the laboratory of the state department of health of three specimens of water from the tank in which the turtle is kept, taken not less than forty-eight hours apart by a representative of either a local health department or state department of health fails to show the presence of salmonella organisms. (2) Should a single such examination show the presence of salmonella organisms all turtles in the tank shall be destroyed. (3) Persons who import, purchase, sell, exchange, barter, give away or otherwise deal in turtles shall keep records of such transactions embodying information required by the state department of health for a mininum period of two years, which records shall be open for inspection by a representative of the local director of health or the state department of health. (4) In any location where turtles are offered for sale the vendor shall post warnings which adequately inform the public that the transmission of salmonella disease by turtles is possible.

(Effective October 25, 1989)

Sec. 19a-36-A47. Plasmapheresis centers and blood collection facilities: Definitions (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A48. Registration of a plasmapheresis center and/or blood collection facility (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A49. Denial, suspension or revocation of registration (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A50. Qualifications of director (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A51. Responsibilities of registrant and director (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A52. Minimum standards for operation of centers (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A53. Standards for plasmapheresis and blood collection (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A54. Maintenance of records and reports (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A55. Laboratory tests (Repealed)

Repealed March 19, 2025.

(Effective October 25, 1989; Repealed March 19, 2025)

Sec. 19a-36-A56. Repealed

Repealed October 10, 2008.

Environmental Laboratories

Sec. 19a-36-A57. Definitions

As used in sections 19a-36-A57 through 19a-36-A63:

(1) "Advisory committee" means a group of consultants, appointed by the commissioner and serving in a voluntary capacity, to advise the commissioner on matters relating to the regulation of environmental laboratories.

(2) "Commissioner" means the Commissioner of Public Health.

(3) "Department" means the Connecticut Department of Public Health.

(4) "Environmental laboratory" means any facility or other area defined in subsection (a) of Section 19a-29a of the Connecticut General Statutes.

(Adopted effective November 29, 1995)

Sec. 19a-36-A58. Identification and tracking of samples

Every sample received in an environmental laboratory for testing shall be numbered or otherwise marked so that it may be identified and related to the source from which it was derived. A dated record of its receipt, disposition and examination and of the findings obtained shall be made and kept on file for a minimum of two (2) years after receipt.

(Adopted effective November 29, 1995)

Sec. 19a-36-A59. Examination of samples

An environmental laboratory shall have available at all times in the immediate bench area of personnel engaged in examining samples and performing related procedures within a speciality (e.g., minerals, nutrients, volatile organics, trace metals) current laboratory manuals or other complete written descriptions and instructions related to the analytical methods used by those personnel, designated and dated to reflect the most recent supervisory review. Such manuals shall also contain information concerning preparation and storage or reagents, standards and calibration procedures, and pertinent literature references.

(Adopted effective November 29, 1995)

Sec. 19a-36-A60. Referral of samples

(a) An environmental laboratory shall refer samples for testing only to an environmental laboratory that is registered or approved by the department.

(b) An environmental laboratory shall perform at least seventy (70) percent of those tests for which it has approval and refer out those tests for which approval has not been granted.

(c) When samples have been referred, reports shall be done by one of the following:

(1) The testing environmental laboratory, with permission from the referring environmental laboratory, may send test results directly to the person who ordered the tests.

(2) The referring environmental laboratory shall indicate on the report to the person who ordered the test the name and address of each environmental laboratory at which a test was performed.

(Adopted effective November 29, 1995)

Sec. 19a-36-A61. Proficiency testing

(a) An environmental laboratory shall enroll in a proficiency testing program approved by the department.

(b) An environmental laboratory shall successfully participate in an approved program for each analyte or test for which it has approval.

(c) The proficiency testing samples shall be examined or tested with the environmental laboratory's regular workload by personnel who routinely perform the testing in the environmental laboratory, using methods approved by the department.

(Adopted effective November 29, 1995)

Sec. 19a-36-A62. Qualifications of director

No person shall be a director of an environmental laboratory unless one (1) of the following qualifications are met.

(a) When microbiology is performed, the director shall have at least:

(1) a baccalaureate degree from an accredited institution including a minimum of eight (8) semester hours of microbiology; and

(2) a minimum of one (1) year of pertinent experience in environmental microbiology.

(b) When chemical analyses are performed, the director shall have at least:

(1) a baccalaureate degree from an accredited institution including a minimum of eight (8) semester hours of inorganic and/or organic chemistry; and

(2) a minimum of one (1) year of pertinent experience in environmental chemistry.

(Adopted effective November 29, 1995)

Sec. 19a-36-A63. Advisory committee

The advisory committee shall consist of:

(a) two (2) private environmental laboratory directors;

(b) two (2) public environment laboratory directors;

(c) two (2) members from public water utilities;

(d) one (1) specialist in microbiology from a registered or approved environmental laboratory;

(e) one (1) specialist in inorganic chemistry from a registered or approved environmental laboratory;

(f) one (1) specialist in organic chemistry from a registered or approved environmental laboratory;

(g) one (1) person who is not a laboratory director and has no financial interest in any laboratory registered with the department; and

(h) one (1) person who is the owner of an environmental laboratory.

(Adopted effective November 29, 1995)

Public Swimming Areas

Sec. 19a-36-B61. Public swimming areas

(a) **Definitions.** As used in this section:

(1) "Public swimming area" means a designated location, together with any buildings, toilet facilities, the water and the land area used in connection therewith, at any natural or artificial pond, lake, stream, tidal water or other body of fresh or salt water that is advertised as a place for swimming and is accessible to the public. Public swimming area does not include: (A) swimming areas in connection with or appurtenant to single family dwellings and used solely by persons residing in such dwellings and such person's guests, including but not limited to those swimming areas accessible only as part of a lake association, beach association or condominium; (B) any state owned or operated swimming areas; and, (C) public swimming pools that are regulated under Section 19-13-B33b of the Regulations of Connecticut State Agencies.

(2) "Department" means the Department of Public Health.

(3) "Director of Health" means the director of a local health department or district health department approved by the commissioner as specified in sections 19a-200 and 19a-242 of the Connecticut General Statutes.

(4) "Face mask or shield" means a device constructed so as to prevent the return flow of air from a victim to the rescuer.

(5) "Notification system" means a public information system used to notify the public regarding lifeguard status and the opening or closing of a public swimming area, including but not limited to, signs or flags.

(b) **General requirements.** No city, town, borough, institution, person, firm, corporation or other entity shall designate or construct a public swimming area until the director of health for the municipality in which the public swimming area is located has approved the location of such public swimming area. A city, town, borough, institution, person, firm, corporation or other entity operating or maintaining a public swimming area shall comply with the following requirements:

(1) Every public swimming area shall be provided with on-site toilet facilities unless the director of health determines that adequate toilet facilities are already provided elsewhere. Separate toilets for men and women shall be provided, with at least one toilet for every two hundred women and at least one toilet for every three hundred men, and at least one handwashing sink or hand sanitation station shall be provided with each required toilet. All toilet facilities and restroom accommodations shall be constructed and located so that no contamination of the waters used by the swimmers will occur. Toilets shall be installed with the approval of the director of health so as not to create any health or safety issues. Toilets shall be kept in good repair and maintained at all times in a sanitary condition. The location

of all toilet facilities shall be plainly indicated by signs.

(2) The dressing rooms, hallways, toilet rooms, shower rooms or other rooms to which swimmers have access shall be kept clean, well ventilated, and in good repair. The floors shall also be treated daily with a 0.5% chlorine solution, or other equivalent disinfectant.

(3) The area open for authorized swimming shall be clearly designated.

(4) Swimming in public swimming areas shall be restricted to designated areas and during assigned hours of operation.

(5) Diving shall be permitted only off a diving board. No diving boards greater than sixteen feet in length shall be permitted. The owner of the property shall ensure that the diving area is in compliance with the required water depths at all times.

(A) For diving boards of a height of no greater than one meter above the water surface, the diving area shall meet the following requirements:

(i) Not have any submerged or overhead obstructions;

(ii) Have a minimum water depth at all times of eleven feet for at least sixteen feet linear beyond the plummet of the diving board; and

(iii) Have a minimum water depth at all times of eleven feet for at least eight feet horizontal on each side of the plummet of the diving board.

(B) For diving boards of a height greater than one meter above the water surface, the diving area shall meet the following requirements:

(i) Not have any submerged or overhead obstructions;

(ii) Have a minimum water depth at all times of twelve feet for at least sixteen feet linear beyond the plummet of the diving board; and

(iii) Have a minimum water depth at all times of twelve feet for at least eight feet horizontal on each side of the plummet of the diving board.

(C) When no diving board is present, a sign stating the following shall be conspicuously posted: “No diving is permitted”.

(6) Lifeguard services.

(A) When no lifeguard service is provided, one or more warning signs shall be posted in one or more visible locations. The warning sign shall state “Warning – No Lifeguard on Duty” with letters that are legible and at least four inches high.

(B) During the period when the swimming area is open for use, when lifeguard service is provided, the owner of the property shall provide the following:

(i) A notification system to alert swimmers as to where and when lifeguard services are available;

(ii) Appropriate lifesaving equipment, including, but not limited to, infant, child, and adult face masks or shields; appropriate receptacles or holders in proximity to the lifeguard duty stations; and a rescue tube, to each lifeguard on duty, which the lifeguard has been trained to use;

(iii) A telephone or equivalent emergency communication device for emergency use when the area is staffed by a lifeguard; and

(iv) A raised stand at least four feet in height for the lifeguard, placed such that all areas

of the public swimming area are visible from the stand to the one or more lifeguards on duty. The director of health may approve an appropriate alternative to the four foot high raised stand if the director of health determines that all points of the public swimming area can still be visible to the lifeguard on duty.

(7) All public swimming areas shall have a sign posted in one or more visible locations, with signage not less than a half-inch type in size, containing the following information:

(A) Hours of lifeguard coverage if applicable;

(B) Emergency phone information indicating whether a phone is available; and

(C) Location of the nearest first aid unit if one is provided on the premises.

(8) Whenever a public swimming area is closed or reopened pursuant to the provisions of this subsection, the director of health shall comply with the following requirements:

(A) Closure: immediately have put in place a notification system, in one or more conspicuous locations, including the immediate swimming area, notifying swimmers of the sections of the public swimming area that are closed.

(B) Reopening: have removed all closure notifications.

(9) The following shall be prohibited in all public swimming areas: (A) boats, unless used for rescue purposes; (B) washing of persons and articles; (C) littering; and (D) glass containers.

(10) Domestic animals shall be prohibited in the water and on the immediate shoreline associated with the water of a public swimming area when the public swimming area is open for use.

(11) The director of health may:

(A) Inspect all public swimming areas to determine compliance with the provisions of this section.

(B) Issue an order which may result in a closure of the public swimming area, in part or in whole, to the owner of the public swimming area, when the director of health determines: The public swimming area shall remain closed until such time as the director of health determines that the cause for closure has been corrected.

(i) There is a violation of the provisions of this section; or

(ii) The public swimming area is not being maintained in acceptable sanitary conditions; or

(iii) A condition is found that constitutes a public health hazard, safety hazard or a health nuisance to the swimmers; or

(iv) There is evidence of communicable disease being transmitted in order to end the transmission of the disease.

The public swimming area shall remain closed until such time as the director of health determines that the cause for closure has been corrected.

(Effective March 17, 2014; Amended September 8, 2023)

Clinical Laboratories

Sec. 19a-36-D1—19a-36-D19. Reserved

Sec. 19a-36-D20. Definitions

As used in sections 19a-36-D20 through 19a-36-D39:

(1) "Advisory committee" means a group of consultants, appointed by the commissioner and serving in a voluntary capacity, to advise the department on matters relating to the regulation of clinical laboratories. The advisory committee shall consist of two hospital laboratory directors who are certified by the American Board of Pathology in both clinical and anatomic pathology; two private clinical laboratory directors; and four laboratory specialists specializing in the fields of cytopathology, clinical chemistry, hematology, and microbiology of which two shall represent laboratories in hospitals licensed in accordance with chapter 368v of the general statutes and two shall represent private clinical laboratories; and a physician who is not a pathologist and who has no financial interests in any laboratory licensed and/or registered with this department.

(2) "CLIA" means the Federal Clinical Laboratory Improvement Amendments of 1988, Title 42 Part 493 of the code of federal regulations.

(3) "Commissioner" means the commissioner of public health.

(4) "Department" means the department of public health.

(5) "Director" means the person designated by the licensee to be responsible for the daily technical and scientific operations of the laboratory, including choice and application of methods, supervision of personnel and reporting of findings.

(6) "Examination" means an investigation, all or any part of which is necessary to obtain an accurate result, which includes the process of instructing the patient, preparing the specimen collection site, choosing the appropriate collection technique, obtaining a valid specimen, assuring the patient's well being, the judicious handling, transporting and processing of the specimen, and reporting the results in a clear and concise manner to the practitioner whose order initiated the process.

(7) "High complexity tests" means laboratory tests categorized as high complexity in accordance with CLIA.

(8) "Laboratory" means any clinical laboratory as defined in Section 19a-30 of the Connecticut General Statutes or other area, except those specifically exempted by the Connecticut General Statutes, where any type of specimen or material derived from a human being or body is examined to obtain findings bearing upon the presence, absence, prognosis or treatment of disease or upon susceptibility thereto.

(9) "Licensee" means the person or persons in whose name licensure of a laboratory has been sought and granted; this shall be the owner if an individual, the owners if a partnership of two, or a responsible officer of any other group, firm or corporation owning the laboratory.

(10) "Moderate complexity tests" means laboratory tests categorized as moderate complexity in accordance with CLIA.

(11) "Non-waived laboratory tests" means moderate and high complexity tests which are not included in the waived tests as set forth in Title 42 Part 493 of the code of federal regulations.

(12) "Owner" means any individual, partnership, group, firm or corporation holding or claiming ownership of or title to a laboratory.

(13) "Specimen" refers only to materials derived from a human being or body.

(Adopted effective June 4, 1996)

Sec. 19a-36-D21. Licensure required

The owner shall apply to the department for licensure of the laboratory or renewal thereof on forms provided for that purpose. No clinical laboratory tests or examinations shall be performed therein until the licensee has been notified by the department that licensure is in effect. No such tests or examinations shall be made after licensure has been suspended or revoked as provided in section 19a-36-D26 of the regulations of Connecticut State Agencies or after the licensee has voluntarily surrendered its license, until such licensure is renewed or reinstated.

(Adopted effective June 4, 1996)

Sec. 19a-36-D22. Application for licensure

(a) In applying for licensure, the applicant shall set forth the name and location of the laboratory, a complete statement of its ownership including the names and addresses of all owners and the agent for service of process and the agent's address, the name of the director, a list of laboratory tests and examinations for which licensure is sought and such other information as to ownership, quarters, facilities, personnel and proposed operations as the department may require. Application for renewal of licensure shall delineate changes made in the preceding licensure period. When applying for renewal of licensure under this section, the applicant shall simultaneously apply for renewal of any additional registration required by sections 19a-36-A25 through 19a-36-A33 of the regulations of Connecticut State Agencies, and such renewal, when granted, shall be considered to be in force for the issuance of such certificates of approval as are required by section 19a-36-A33 of the regulations of Connecticut State Agencies. The applicant shall, as part of each application, agree to abide by such standards of operation as are made a part thereof.

(b) The following clinical laboratories are exempt from licensure:

(1) laboratories owned and operated by the United States or any agency of the federal government;

(2) laboratories that perform tests or examinations for research purposes only;

(3) laboratories that perform tests or examinations for forensic purposes only; and

(4) laboratories that perform tests or examinations that are exempt for CLIA purposes.

(Adopted effective June 4, 1996)

Sec. 19a-36-D23. Inspection and investigation

The owner shall cause the quarters, facilities and records of the laboratory to be made immediately available for inspection upon request of a representative of the department and shall cooperate with such representative by furnishing information in any pertinent investigation. Failure to allow the Department to inspect constitutes cause for revocation of the laboratory's license.

(Adopted effective June 4, 1996)

Sec. 19a-36-D24. Terms of licensure

The duration of each license shall be set at the discretion of the department, for a period of not less than twenty-four (24) nor more than twenty-seven (27) months from its effective date. The terms of licensure or renewal thereof may restrict the scope of laboratory operations or establish a time limit for the owner to carry out recommendations based upon inspection and investigation. Initial licensure shall not be in force until notice of its effective date and term has been sent to the applicant. Application for renewal of licensure shall be made as follows:

(a) biennially within thirty calendar days prior to expiration of the license then current;

(b) thirty (30) days before any change in ownership that will result in an actual change of the licensee of the laboratory or a planned change of director is made; or

(c) thirty (30) days prior to any major expansion or alteration in quarters, which includes expanding the quarters through construction or relocating the laboratory testing area to another floor, building or location.

(Adopted effective June 4, 1996)

Sec. 19a-36-D25. Denial of licensure

Whenever inspection and investigation pursuant to an application for licensure yield evidence leading to a reasonable presumption that requirements of sections 19a-36-D20 through 19a-36-D38 of the Regulations of Connecticut State Agencies, or of any applicable statute would not or could not be fulfilled, licensure shall be denied.

(Adopted effective June 4, 1996)

Sec. 19a-36-D26. Suspension or revocation of licensure

(a) Licensure may be suspended or revoked whenever in the judgment of the commissioner any one of the following conditions exists:

(1) the laboratory has operated in violation of any applicable statute or regulation or has failed to implement a plan of correction as submitted to the department;

(2) the findings of the laboratory are found, after investigation, to be inaccurate or unreliable beyond the limits of error inherent in the method and such condition is not corrected forthwith;

(3) findings have been reported on specimens that were not tested or examined;

(4) the owner has failed to comply with instructions from the commissioner for the

correction of conditions adversely affecting the quality of work;

(5) CLIA certification has been suspended or revoked; or

(6) any other condition of the laboratory that is deemed prejudicial to the public health.

(b) At the discretion of the commissioner, the licensee may be directed by written notice to appear not less than five days thereafter at a hearing before the commissioner or the commissioner's designee to show cause why licensure should not be suspended or revoked. When, in the judgment of the commissioner, conditions so warrant, suspension of licensure may be invoked without prior hearing. Revocation of a suspended license shall become effective within thirty days after suspension unless otherwise ordered by the commissioner. Prior to revocation, the owner may request a hearing, stating upon what grounds such petition is based.

(Adopted effective June 4, 1996)

Sec. 19a-36-D27. Connecticut license number

A Connecticut license number, which will be assigned to the laboratory by the department upon initial licensure, shall be inscribed on all reports, lists of tests, fee schedules and advertisements of the laboratory.

(Adopted effective June 4, 1996)

Sec. 19a-36-D28. List of tests and fee schedules

A copy of each list of tests and each fee schedule issued by a laboratory shall be maintained on file at the laboratory and be available to the department upon its request.

(Adopted effective June 4, 1996)

Sec. 19a-36-D29. Acceptance and collection of specimens

(a) No specimen shall be accepted for analysis or collected by an owner or an employee of the laboratory except when requested by a licensed physician or other licensed person authorized by law to make diagnoses.

(b) No person shall be given any parenteral injection for the collection of a specimen except by a licensed physician or other person so authorized by the Connecticut General Statutes.

(c) This section shall not prohibit the transmission of specimens collected as specified in subsection (a) to another licensed laboratory or to a qualified laboratory exempt from licensure requirements nor shall it prohibit the acceptance of specimens submitted by a representative of the department for evaluation of testing procedures.

(d) Except for specimens collected by a practitioner of the healing arts or an employee working under such practitioner's direction or by an employee of a hospital or other health care facility licensed in accordance with chapter 368v of the Connecticut General Statutes, no specimen requiring venipuncture shall be accepted for analysis unless taken by an employee of a laboratory licensed in accordance with sections 19a-36-D20 through 19a-36-D38 of the regulations of Connecticut State Agencies. Any blood collection facility other

than the actual laboratory facility that is used for the collection of specimens by venipuncture shall be inspected prior to use and a written certificate of approval shall be issued by the department. The licensee or director of a laboratory shall notify the department in writing immediately when the operations of an approved blood collection facility are about to terminate.

(e) An approved blood collection facility shall meet all the requirements set forth in subsection (b) of section 19a-36-D38 and shall possess as a minimum, a blood drawing chair or cot acceptable to the department, a telephone, adequate hand washing and toilet facilities for employees and patients located on the same floor as the blood drawing facility and a written procedure manual detailing the steps to be followed in the event of any emergency. Approved blood collection facilities shall be identified by signs and advertising in a manner which will not suggest that the facility is a laboratory. No laboratory examinations shall be performed in a blood collection facility other than the separation of plasma and serum and the preparative procedures necessary for the blood collection.

(f) The director of the laboratory of which the approved blood collection facility is a part shall be responsible for all aspects of the blood collection facility, including without limitation, physical plant, personnel and processing and transporting specimens. The director or supervisor of the laboratory of which the approved blood collection facility is a part shall be available to blood collection facility personnel at all times during operation of the facility for personal or telephone consultation and shall make on-site monthly inspections of the facility to ensure suitable handling of patients and specimens and to instruct the employees in such matters and in the most recent improvements. The director of the laboratory of which the approved blood collection facility is a part shall establish a protocol for action in cases of emergency which shall include, without limitation, the immediate availability of a physician or emergency medical service. Any technical employee of a blood collection facility shall be proficient in venipuncture, specimen processing as limited by sections 19a-36-D20 through 19a-36-D38 of the regulations of Connecticut State Agencies, and emergency procedures required to aid a distressed patient. Each licensed laboratory shall be limited to six (6) blood collection facilities.

(g) Out-of-state laboratories obtaining specimens in blood collection facilities located in Connecticut shall meet all applicable requirements in this section. In accordance with Sections 19a-36-A25 through 19a-36-A33 of the regulations of Connecticut State Agencies, blood collection facilities shall receive written approval from the department before any specimens are collected. Said approval may be revoked by the department at any time in accordance with Section 19a-36-D26 of the regulations of Connecticut State Agencies.

(Adopted effective June 4, 1996)

Sec. 19a-36-D30. Identification of specimens

Every specimen received for testing shall be numbered or otherwise marked so that it may be identified definitely and related to the submitting physician and the patient from whom it was derived. An appropriate, dated record of its receipt, disposition and

examination and of the findings obtained shall be made and kept on file for a minimum of one (1) year after receipt or in accordance with the CLIA regulations, Title 42 part 493 of the code of federal regulations, whichever is more stringent.

(Adopted effective June 4, 1996)

Sec. 19a-36-D31. Examination of specimens

(a) No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and examination when applicable, or other reasons sufficient to render the findings of doubtful validity.

(b) No specimen of excised tissue shall be subjected to pathological examination except by a physician who is licensed to practice medicine in the state in which the laboratory is located and is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or meets all of the education, training or experience requirements to take the examination but has not actually taken and successfully completed the examination. Physicians qualified under these requirements may delegate the responsibility for examination and interpretation of histopathology specimens to an individual who is a resident in a training program leading to certification in anatomic pathology.

(c) No specimen of exfoliated tissue or cells shall be examined except under the supervision and review of a physician who is licensed to practice medicine in the state in which the laboratory is located and meets the personnel qualification standards specified in the CLIA regulations, Title 42 part 493 of the code of federal regulations, as applicable. The Commissioner or the Commissioner's designee may deem a Connecticut licensed physician who is not certified in anatomic pathology to be qualified if said physician possesses qualifications that are equivalent to those required for such certification.

(d) There shall be available at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a specialty (e.g., clinical chemistry, hematology, bacteriology) current laboratory manuals or other complete written descriptions and instructions relating to the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews. Such manuals shall also contain information concerning preparation and storage of reagents, control and calibration procedures, and pertinent literature references. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof. Technical procedures employed in the laboratory for the processing and examination of specimens shall be performed according to directions detailed in the laboratory manual. Each laboratory shall verify or establish performance specifications for any new test method being utilized including accuracy, precision, reportable range or any other performance characteristic requirements for test performance. If the department deems it necessary, it shall review the laboratory's verification or performance specifications on new methodology to ensure its accuracy, precision, reportable range or other performance characteristic

requirements for test performance.

(Adopted effective June 4, 1996)

Sec. 19a-36-D32. Reports of findings

(a) Laboratory findings on a specimen shall be reported directly to the licensed provider who ordered the testing pursuant to authority granted to such provider by chapter 370, 372, 373, 375, 377, 378, 379, 380 or 400j of the Connecticut General Statutes, and may be provided by laboratories other than the department's laboratory to lay persons upon the written request of the provider who ordered the testing. Laboratories other than the department's laboratory may also provide findings upon the written request of providers who did not order the testing, so long as the requesting provider is also statutorily authorized to order such testing pursuant to chapter 370, 372, 373, 375, 377, 378, 379, 380 or 400j of the Connecticut General Statutes, and is providing care to the patient who is the subject of the testing. Nothing in this section shall prohibit the issuance of reports of laboratory findings to town, city or state health officials as required by the Regulations of Connecticut State Agencies or the inspection or impounding of records of such reports by a representative of the department.

(b) No report shall be worded to convey or simulate a diagnosis or prognosis or to specify or suggest specific medication, surgical manipulation or other form of treatment unless signed by a physician licensed to practice in Connecticut or in the state in which the laboratory performing the examinations is located. This subsection shall not prohibit the laboratory from furnishing the normal ranges for the methods of analysis employed in such laboratory nor shall it prohibit the laboratory from identifying patient values that are outside the normal ranges for the methods of analysis employed. When the specimen has been referred for examination to an out-of-state laboratory, the report shall bear or be accompanied by a clear statement that such findings were obtained in such laboratory and shall specify its name and location.

(Adopted effective June 4, 1996; Amended October 3, 2005)

Sec. 19a-36-D33. Qualifications of director

No person shall be the director of a clinical laboratory unless he meets the educational, training and/or experiential requirements identified in this section.

(a) For laboratories performing tests categorized as high complexity, the director shall:

(1) be a physician licensed to practice medicine in Connecticut who is certified in anatomic and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or meets all of the education, training or experience requirements to take the examination but has not actually taken and successfully completed the examination; or

(2) hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and:

(A) be certified by the American Board of Medical Microbiology, the American Board

of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by the Commissioner; or

(B) have at least two (2) years of laboratory training or experience, or both, and at least two (2) years of experience directing or supervising high complexity testing; or

(3) have a combination of education, training and experience in the clinical laboratory specialty, which, in the judgment of the commissioner, qualifies the individual to direct a laboratory whose services are limited to that specialty.

(b) For laboratories performing tests categorized as moderate complexity, the director shall:

(1) meet the qualification standards identified in subsection (a) of this section; or

(2) hold an earned doctoral degree in medicine or dentistry or in chemical, physical or biological sciences from an accredited institution and have at least one (1) year of experience directing or supervising non-waived laboratory testing; or

(3) have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution and have at least one (1) year of laboratory training or experience, or both, in non-waived testing and at least one (1) year of supervisory laboratory experience in non-waived testing; or

(4) have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution and have at least two (2) years of laboratory training or experience, or both, in non-waived testing and at least two (2) years of supervisory laboratory experience in non-waived testing.

(Adopted effective June 4, 1996)

Sec. 19a-36-D34. Qualifications of other personnel

Clinical laboratory personnel other than the director shall meet the educational, training and/or experiential requirements identified in this section.

(a) For laboratories performing tests categorized as moderate complexity, personnel shall meet the following requirements.

(1) A technical consultant shall:

(A) be a physician licensed to practice medicine in Connecticut who is certified in anatomic and/or clinical pathology by the Board of Pathology or the American Osteopathic Board of Pathology or meets all of the education, training or experience requirements to take the examination but has not actually taken and successfully completed the examination; or

(B) hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution and have at least one (1) year of laboratory training or experience, or both in non-waived testing, in the designated specialty areas of service for which the technical consultant is responsible; or

(C) have earned a bachelor's degree in chemical, physical or biological science or medical technology from an accredited institution and have at least two (2) years of

laboratory training or experience, or both in the designated specialty or sub-specialty areas of services for which the technical consultant is responsible.

(2) A clinical consultant shall be qualified to consult with and render opinions to the laboratory's clients concerning diagnosis, treatment and management of patient care and shall:

(A) be qualified as a laboratory director in accordance with Section 19a-36-D33(a) (1) or (2) (A); or

(B) be a physician licensed to practice medicine, osteopathy or podiatry in Connecticut.

(3) Testing personnel shall:

(A) be a physician licensed to practice medicine or osteopathy in Connecticut or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; or

(B) have earned an associate degree in chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(C) have earned a high school diploma or equivalent and have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

(b) For laboratories performing tests categorized as high complexity, personnel shall meet the requirements identified in subsection (a) of this section or the requirements identified in CLIA, Title 42, Part 493 of the code of federal regulations, whichever are more stringent.

(Adopted effective June 4, 1996)

Sec. 19a-36-D35. Responsibilities of licensee and director

(a) The licensee shall ensure that the laboratory is at all times under the direction of a director who meets the qualification standards identified in Section 19a-13-D33 of the regulations of Connecticut State Agencies. Whenever the designated director is to be on leave for more than thirty (30) calendar days, the licensee shall so notify the department in advance and shall designate an interim supervisor of the laboratory who meets the qualifications identified in subsection (c) of this section. The licensee shall notify the department at least thirty (30) days in advance of any proposed change of ownership or major expansion or alteration in quarters. At such time that the director severs connection with the laboratory, the department may grant permission for the continued operation of the laboratory under an interim supervisor for not more than six (6) weeks. In extenuating circumstances, permission to operate longer without a permanent director may be granted subject to conditions specified in writing by the department.

(b) The licensee and director, if different persons, shall be jointly and severally responsible for the operation of the laboratory in compliance with sections 19a-36-D20 through 19a-36-D38 of the regulations of Connecticut State Agencies, and with other pertinent regulatory and statutory requirements. They shall advise the department within seven (7) days of changes in operations or personnel. They shall submit to the department an annual report on forms provided for the purpose which shall relate to the numbers and

types of laboratory examinations performed during the preceding year.

(c) The director shall be responsible for the work of subordinates, the proper management of patient test specimens and records, the proper performance of all tests in the laboratory, and the continual application of quality control procedures to the work in accordance with recommendations and directives of the department. In the absence of the director for any cause, the interim supervisor shall assume the director's responsibilities. Such interim supervisor shall meet the qualification requirements identified in Section 19a-36-D34 of the regulations of Connecticut State Agencies.

(d) Except for illness, vacation or other justifiable leave, the director shall be responsible for the overall operation of the laboratory. No person shall act as director of more than five (5) laboratories.

(Adopted effective June 4, 1996)

Sec. 19a-36-D36. Unethical practices prohibited

(a) **Definitions.** As used in this section:

(1) "Bribe" means any valuable consideration given or promised by a laboratory providing service with a view to influence the behavior of a requester of laboratory services.

(2) "Fee-splitting inducement" means offering or implying a division of payment in any manner between a requester of laboratory services and the laboratory providing the service.

(3) "Fraudulent practice" means one that involves deceit, trickery or cheating.

(4) "Requester of laboratory services" means any person, firm, corporation or other entity that submits specimens, refers specimens for laboratory services or requests or prescribes laboratory tests.

(b) **Permitted practices**

(1) Discounts that represent a reduction in rates due to an actual saving to the laboratory resulting from volume, cost or functional differences may be allowed by the laboratory. If such discount is allowed, it must be available equally to all users of the laboratory's services. A statement of discount policy, if any, shall be clearly indicated on any and all price lists provided to any user of the laboratory's services. A copy of all price lists and fiscal, operating and other business records shall be submitted to the department upon request and at the time of the biennial renewal licensing application.

(2) Competitive bids for laboratory services are exempt from the provisions of subsection (b) (1) of this section. Any agreement resulting from such bidding must be in the best interest of the patient or consumer.

(c) **Prohibited practices**: Bribes and fee-splitting inducements are prohibited

(1) The following practices are prohibited as bribes: offering or providing to a requester of laboratory services office equipment or services of any kind, including, but not necessarily limited to receptionists, nurses or any other employees, except as provided in subdivision (2) of this subsection. Also prohibited are cars, trips, credit cards, or similar favors, free or discounted services to private patients of such requester of laboratory services to a greater extent than is provided by such requester.

(2) The following practices are excluded from the prohibitions identified in subdivision (1) of this subsection: the provision of phlebotomists to collect specimens to be sent to the laboratory for analysis, the provision of equipment or supplies that are used solely to collect, transport, process or store specimens or order or communicate the results of tests or procedures for the laboratory or the provision of specimen collection supplies needed by a physician to obtain and forward specimens for testing, or goods needed by phlebotomists to service institutions such as nursing facilities, or to make house calls or visits to other locations as directed by the requester of laboratory services.

(3) The following are prohibited as fee splitting inducements:

(A) payments of cash by a laboratory to a requester of laboratory services for referring patients or specimens;

(B) cash rebates for volume of business referred or for a period of time of referral except as permitted in subsections (b) (1) and (b) (2) of this section;

(C) payments by a laboratory to rent or lease a portion of the facilities of a requester of laboratory services not related to fair market value of the space or facilities utilized;

(D) payment of excessive fees to a requester of laboratory services for consultation, filing forms, providing standby emergency services to laboratory and blood collection facilities, or other services;

(E) payment of excessive interest by a laboratory on deposits collected for the loan of laboratory equipment;

(F) the sale of coupons, tickets or booklets, or other variations of prepayments by requesters of laboratory services that do not result in lower charges to the actual patient or recipient of laboratory services; and

(G) the purchase of corporation stock, or the purchase or rental of equipment or other tangible assets at more than fair market value by a laboratory.

(4) The following are prohibited as fraudulent practices:

(A) any written or oral agreement between a clinical laboratory and a requester of laboratory services that results in utilization of laboratory services in excess of that needed to provide information for diagnosis, prevention, treatment, or assessment of health of the patient or recipient of such services or excessive charges for these services;

(B) any system of billing or accepting payment for laboratory services that does not accurately identify the laboratory, the requester, the patient or recipient and the cost of such laboratory services; and

(C) any system of billing for laboratory services or issuance of receipts for payment that does not accurately indicate the amount and the recipient of such payment.

(Adopted effective June 4, 1996)

Sec. 19a-36-D37. Referral of specimens to out-of-state laboratories

(a) A Connecticut licensed laboratory may refer specimens for testing to an out-of-state clinical laboratory if the out-of-state laboratory is CLIA certified and is licensed, certified, registered, or approved in the state in which the laboratory is located, if applicable.

(b) The Connecticut licensed clinical laboratory shall maintain documentation which verifies that the out-of-state clinical laboratory, to which specimens are referred from Connecticut, meets the specimen collection, identification, examination, and reporting requirements specified in Sections 19a-36-D29 through 19a-36-D32; the referral requirements specified in subsection (a) of this section; the specimen collection, identification, urine drug testing, and reporting requirements specified in sections 31-51t through 31-51z of the Connecticut General Statutes; and the informed consent, HIV confirmation testing and confidentiality requirements specified in sections 19a-581 through 19a-590 of the Connecticut General Statutes if applicable. This documentation shall be verified as correct on a yearly basis.

(c) The laboratory shall maintain a list of out-of-state laboratories to which specimens are referred, stating the types of tests or examinations for which such specimens are submitted, which list shall be available to the department upon its request.

(Adopted effective June 4, 1996)

Sec. 19a-36-D38. Minimum standards for the operation of private clinical laboratories

(a) The laboratory shall be operated in compliance with all applicable state and federal laws and regulations, including but not necessarily limited to CLIA Title 42 Part 493 of the code of federal regulations and with all reasonable administrative directives pursuant thereto.

(b) Quarters in which laboratory work is performed or specimens collected shall be kept free from filth, excessive dirt or litter or other objectionable condition, shall be adequately lighted and ventilated, shall be equipped with utilities adequate for the work, shall be of adequate size and arrangement for the proper conduct of the work and shall be free from unnecessary safety hazards. Smoking and the consumption of food or beverages shall be prohibited in those areas where the examination of specimens is being carried out. No food or beverage shall be stored in a refrigerator or freezer used for storing patient specimens or potentially infectious materials.

(c) 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.

(d) The laboratory shall at all times be operated under the supervision of a director or other qualified person acceptable to the department.

(e) No misrepresentation of the scope of laboratory services or of the qualifications or special abilities of persons associated with the laboratory shall be permitted.

(Adopted effective June 4, 1996)

Source Plasma Donation Centers

Sec. 19a-36-E1. Definitions

As used in this section, and sections 19a-36-E2 to 19a-36-E6, inclusive, of the

Regulations of Connecticut State Agencies:

(1) "Accreditation organization" means an entity that sets and evaluates quality and performance standards for source plasma donation centers, including through on-site 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) "Blood" means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

(4) "Blood collection facility" has the same meaning as provided in section 19a-490(t) of the Connecticut General Statutes.

(5) "Business entity" has the same meaning as provided in section 19a-565(a) of the Connecticut General Statutes.

(6) "Centers for Disease Control" or "CDC" means the Centers for Disease Control and Prevention.

(7) "Certification in CPR" means training and certification in cardiopulmonary resuscitation by the American Heart Association, the American Red Cross, the American Safety and Health Institute or an organization that uses guidelines for cardiopulmonary resuscitation and emergency cardiovascular care published by the American Heart Association and the International Liaison Committee on Resuscitation.

(8) "Clinical laboratory" has the same meaning as provided in section 19a-490(h) of the Connecticut General Statutes.

(9) "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.

(10) "CLIA certificate" means a certificate of compliance or accreditation as defined in 42 CFR 493.2, as amended from time to time.

(11) "Commissioner" means the Commissioner of Public Health or the commissioner's designee.

(12) "Department" means the Department of Public Health.

(13) "Director" means a person designated by a licensee to be responsible for the daily technical and administrative operations of a source plasma donation center, including oversight of all other personnel.

(14) "Donor" has the same meaning as provided in Section 19a-918 of the Connecticut General Statutes.

(15) "Licensee" means a holder of source plasma donation center license issued pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.

(16) "Physician substitute" means an advanced practice registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes, a physician assistant licensed pursuant to chapter 370 of the Connecticut General Statutes, or a registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes.

(17) "Plasmapheresis" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(18) "Reference laboratory" means a laboratory that receives and performs tests on blood or blood components collected by a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.

(19) "Responsible physician" means an individual who has the qualifications provided in 21 CFR 630.3, as amended from time to time, and, unless serving as director, reports to the director.

(20) "Source plasma" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(21) "Source plasma donation center" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(22) "Storage" means the holding of blood or blood components related to collection thereof.

(23) "Trained person" has the same meaning as provided in 21 CFR 630.3, as amended from time to time.

(Effective March 19, 2025)

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 person or business entity holds a license issued by the department in accordance with section 19a-36-E2 of the Regulations of Connecticut State Agencies. No source plasma donation center shall operate without the applicable CLIA certificate. Applicants may apply for a CLIA certificate concurrently with their application for a license as a source plasma donation center. Prior to issuance of such license, the applicant shall secure the applicable CLIA certificate required to establish, conduct, operate or maintain such center.

(b) A source plasma donation center licensed pursuant to this section that conducts only those functions described in section 19a-490(u) of the Connecticut General Statutes shall be exempt 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 described 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. No plasmapheresis shall be conducted after the expiration of licensure or if a license has been suspended, denied or revoked.

(2) Each application for initial or renewal licensure shall include, but not be limited to, the following:

(A) Name and address of the center;

(B) Statement of ownership and operation, including name and address of the applicant

or licensee;

(C) Name, address and qualifications of the source plasma donation center director;

(D) Business identification number issued by the Secretary of the 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 as described in section 19a-36-E3 of the Regulations of Connecticut State Agencies;

(I) A roster of qualified personnel to be employed or under contract to meet the personnel requirements as described in 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 licensure or renewal licensure 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 this section if the commissioner elects to accept a favorable and timely on-site assessment report conducted by an accreditation organization. In the event of any corrective action plan issued by such accreditation organization, the department shall review such plan and evidence of remediation and may require completion of the implementation of the plan before a license will be granted.

(4) Issuance or renewal of license.

(A) The department may issue a license or renew a license to operate the source plasma donation center if the department determines following inspection that the source plasma donation center is in compliance 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 applicant. 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 not later than four months prior to the expiration of the current license.

(d) Denial of a license. The department may deny an initial or renewal application for a license for any of the following reasons:

(1) The applicant or licensee has failed to comply with applicable federal, state, or local laws;

(2) 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;

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

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

(e) Change in ownership. Any change in ownership of a source plasma donation center licensed pursuant to this section shall be made in compliance with section 19a-493 of the Connecticut General Statutes.

(f) Change in facilities. Any source plasma donation center 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 expansions or alterations.

(g) Change or absence of director. Any source plasma donation center 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 a period of more than thirty days, the licensee shall notify the department in writing within twenty-four hours of the date the licensee receives notice of such unplanned change or absence greater than thirty days. In the event of an unplanned change or absence greater than thirty days 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.

(h) Waiver.

(1) The commissioner may waive provisions of sections 19a-36-E2 to 19a-36-E6, inclusive, of the Regulations of Connecticut State Agencies, as provided in section 19a-495 of the Connecticut General Statutes.

(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 determining whether to grant or deny any request for a 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 may request additional information before determining whether to grant or deny a request for a waiver.

(Effective March 19, 2025)

Sec. 19a-36-E3. Minimum standards for operation

(a) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with applicable federal, state and local laws.

(b) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies 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 section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with all requirements for source plasma in 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 or renewal 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 licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies 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 or test results;

(G) Procedures for donors to file complaints with a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies; and

(H) Procedures for donors to file complaints with the department regarding a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.

(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 qualifications and ability of all trained persons in accordance with section 19a-36-E5(c)(7) of the Regulations of Connecticut State Agencies;

(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 personnel, and to document ongoing training and continuing education of personnel;

(D) Establishment and maintenance of minimum staffing levels; and

(E) Staffing plans to ensure that personnel cross-trained in conducting plasmapheresis specific to the device, equipment and facility are available to maintain safe staffing levels in the event of a personnel or donor emergency and to maintain minimum staffing levels established pursuant to subparagraph (D) of this subdivision.

(4) Emergency preparedness.

(5) Medical contingency planning.

(6) Data collection and reporting in accordance with the requirements of section 19a-36-E6 of the Regulations of Connecticut State Agencies.

(7) 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.

(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 plans for responding to such events. Such policies and procedures shall ensure the identification, 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 or failure 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 the Regulations of Connecticut State Agencies and in accordance with federal requirements.

(8) Facilities and equipment.

(A) The management, operation, personnel, equipment, 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, physical environment, and equipment shall be maintained to provide safe and acceptable standards for handling of human blood and blood components. Source plasma donation centers shall maintain at a minimum 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 such blood and blood components 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 section 19a-36-E2 of the Regulations of Connecticut State Agencies shall maintain appropriate facilities and equipment for record keeping in accordance with section 19a-36-E6 of the Regulations of Connecticut State Agencies.

(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 section 19a-36-E2 of the Regulations of Connecticut State Agencies shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

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

(Effective March 19, 2025)

Sec. 19a-36-E4. Examinations and laboratory tests

(a) Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall only perform donor eligibility tests. The performance of any other laboratory testing shall require a clinical laboratory license effective pursuant to section 19a-36-D21 of the Regulations of Connecticut State Agencies.

(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 laboratory located in the state of Connecticut, the reference laboratory shall have a clinical laboratory license effective pursuant to 19a-36-D21 of the Regulations of Connecticut State Agencies. Reference laboratories located outside of the state of Connecticut shall comply with applicable state and federal licensing requirements.

(c) All donor eligibility 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 section 19a-36-E2 of the Regulations of Connecticut State Agencies 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 such testing, including results and interpretations, shall be maintained for two years.

(f) All reference laboratories utilized by a source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall hold a federal certificate or license, or state license, or both, as applicable.

(Effective March 19, 2025)

Sec. 19a-36-E5. Personnel requirements and qualifications

(a) A source plasma donation center licensed pursuant to section 19a-36-E2 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 plasmapheresis, 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 source plasma donation center 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 also 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-E2(h) 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 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 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 the requirements for plasmapheresis set forth in 21 CFR 630 and 21 CFR 640, as amended from time to time.

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

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

(E) 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.

(F) The director may delegate his or her responsibilities for administering the licensed activities of the source plasma donation center 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 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.

(G) The director shall be on-site during hours of operation except when the director has delegated his or her responsibilities, pursuant to this section, to a responsible physician, physician substitute, or trained person, and when a responsible physician, physician substitute or a 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 a 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 plasmapheresis 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 clinical and theoretical areas; and

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

(5) Qualifications and responsibilities of a center manager.

(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 section 19a-36-E2 of the Regulations of Connecticut State Agencies 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. Such equivalent facility may include any institution, as defined in section 19a-490 of the Connecticut General Statutes, or any facility requiring a CLIA certificate.

(6) Qualifications, responsibilities, training and supervision of a trained person.

(A) The department shall review training curricula and documentation of training provided by the licensee upon application. 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.

(B) 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.

(C) Trained persons shall work under the direction of the director, 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 source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies.

(7) A source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall ensure sufficient personnel are cross-trained in conducting plasmapheresis specific to the device, equipment and facility to maintain safe staffing levels in the event of personnel 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.

(Effective March 19, 2025)

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 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 pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies 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 on-site at the source plasma donation center licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies, 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 pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with all requirements in 21 CFR 640.73, as amended from time to time, governing reporting of adverse events. Source plasma donation centers licensed pursuant to pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall submit annual reports to the department of all donor complaints filed including documentation of the complaint resolution.

(e) Reportable diseases. Source plasma donation centers licensed pursuant to section 19a-36-E2 of the Regulations of Connecticut State Agencies shall comply with the reporting requirements under section 19a-215 of the Connecticut General Statutes.

(f) 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 such blood or blood components or source plasma. All actions taken to address an error or accident shall be documented in writing.

(Effective March 19, 2025)

Blood Collection Facilities

Sec. 19a-36-F1. Definitions

As used in this section, and sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Accreditation organization" means an entity that sets and evaluates quality and performance standards for blood collection facilities, including through on-site 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 19a-918 of the Connecticut General Statutes.

(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 cardiopulmonary resuscitation by the American Heart Association, the American Red Cross, the American Safety and Health Institute or an organization that uses 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) "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 Public Health or the commissioner's designee.

(14) "Department" means the Department of Public Health.

(15) "Director" means a person designated by a licensee to be responsible for the daily technical and administrative operations of a blood collection facility, including oversight of all other personnel.

(16) "Donor" has the same meaning as provided in section 19a-918 of the Connecticut General Statutes.

(17) "Licensee" means a holder of a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(18) "Physician substitute" means an advanced practice registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes, a physician assistant licensed pursuant to chapter 370 of the Connecticut General Statutes, or a registered nurse licensed pursuant to chapter 378 of the Connecticut General Statutes.

(19) "Plasmapheresis" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(20) "Reference laboratory" means a laboratory that receives and performs tests on blood or blood components collected by a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(21) "Responsible physician" means an individual who has the qualifications provided in 21 CFR 630.3, as amended from time to time, and unless serving as director, reports to the director.

(22) "Source plasma" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(23) "Source plasma donation center" has the same meaning as provided in section 19a-490(u) of the Connecticut General Statutes.

(24) "Storage" means the holding of blood or blood components related to collection thereof.

(25) "Trained person" has the same meaning as provided in 21 CFR 630.3, as amended from time to time.

(Effective March 19, 2025)

Sec. 19a-36-F2. Licensure Procedures

(a) No person or business entity shall establish, conduct, operate or maintain a blood collection facility unless such person or business entity holds a license issued by the department in accordance with section 19a-36-F2 of the Regulations of Connecticut State Agencies. Prior to issuance of such license, the applicant shall secure the applicable CLIA certificate, or a CLIA certificate of waiver, if applicable, required to establish, conduct, operate or maintain such facility.

(b) A source plasma donation center shall not be required to obtain a blood collection facility license pursuant to this section if such center is not performing the function of a blood collection facility as provided in section 19a-490(t) of the Connecticut General Statutes.

(c) A hospital licensed under chapter 368v of the Connecticut General Statutes shall not be required to obtain a license as a blood collection facility for blood component collection activities that take place on the hospital campus, as defined in section 19a-508c of the Connecticut General Statutes.

(d) Approval for licensure as a blood collection facility pursuant to this section shall exempt such facility that collects and sells for secondary use any single donor products, including blood components that do not meet the definition of source plasma, from requirements for additional licensure as a source plasma donation center.

(e) Approval for licensure as a blood collection facility pursuant to this section shall exempt such facility that conducts solely waived tests and has a current CLIA certificate of waiver from requirements for licensure as a clinical laboratory. A licensed clinical laboratory shall require separate licensure as a blood collection facility to conduct those functions provided in section 19a-490(t) of the Connecticut General Statutes.

(f) A mobile or temporary blood collection facility shall not require additional licensure provided that the person or business entity operating said facility is otherwise licensed in this state as a blood collection facility in accordance with this section.

(g) 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 blood collection shall be conducted until the applicant has been notified by the department that the license is approved and in effect. No

blood collection shall be conducted after the expiration of a license or if a license has been suspended, denied or revoked.

(2) Each application for initial or renewal licensure shall include, but not be limited to, the following:

(A) Name and address of the facility;

(B) Statement of ownership and operation, including name and address of the applicant or licensee, and name and address of legal operating entity, parent organization, or both, as applicable;

(C) Name, address and qualifications of the director;

(D) Business identification number issued by the Secretary of the State;

(E) Certificates of malpractice and public liability insurance;

(F) Current CLIA certificate or CLIA certificate of waiver;

(G) A list of proposed services offered;

(H) A list of reference laboratories to be used;

(I) Policies and procedures required as described in section 19a-36-F3 of the Regulations of Connecticut State Agencies;

(J) A roster of qualified personnel to be employed or under contract to meet the personnel requirements as described in section 19a-36-F5 of the Regulations of Connecticut State Agencies;

(K) The licensure or renewal licensure 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-F3 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 accreditation 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 and may require completion of the implementation of the plan before a license will be granted.

(4) Issuance or renewal of license.

(A) The department may issue a license or renew a license to operate a blood collection facility if the commissioner determines following inspection that the facility is in compliance with the statutes and regulations pertaining to its licensure.

(B) The commissioner shall issue a license to the blood collection facility in the name of the applicant. The license shall not be transferable or assignable.

(C) A licensee operating a blood collection facility licensed pursuant to this section with

more than one permanent location shall require a separate license for each permanent location.

(D) The licensee shall post the license in a conspicuous location at each location of the blood collection facility.

(E) A license issued under this section shall be renewed biennially. Applications for renewal shall be submitted to the department not later than four months prior to the expiration of the current license.

(h) Denial of a license. The commissioner may, in the commissioner's discretion, deny an initial or renewal application for licensure for any of the following reasons:

(1) The applicant or licensee has failed to comply with applicable federal, state or local laws;

(2) Failure of the blood collection facility to permit department inspection of the premises or access to the facility's records upon request of the department;

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

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

(i) Change in ownership. Any change in ownership of a blood collection facility licensed pursuant to this section shall be made in compliance with section 19a-493 of the Connecticut General Statutes.

(j) Change in facilities. Any blood collection facility 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 expansions or alterations.

(k) Change or absence of director. Any blood collection facility 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 a period of more than thirty days, the licensee shall notify the department in writing within twenty-four hours of the date the licensee receives notice of such unplanned change or absence greater than thirty days. In the event of an unplanned change or absence greater than thirty days the licensee may designate an interim director who meets the qualifications set forth in section 19a-36-F5(c)(3) of the Regulations of Connecticut State Agencies for a period of up to six weeks.

(*l*) Waiver.

(1) The commissioner may waive provisions of sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies as provided in section 19a-495 of the Connecticut General Statutes.

(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 blood collection facility 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 determining whether to grant or deny a waiver, the commissioner may consider:

(A) The impact of a waiver on services provided; and

(B) Alternative policies or procedures proposed by the blood collection facility.

(4) The commissioner may request additional information before determining whether to grant or deny the request for a waiver.

(Effective March 19, 2025)

Sec. 19a-36-F3. Minimum standards for operation

(a) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with applicable federal, state and local laws.

(b) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with the requirements of 21 CFR 607.7, as amended from time to time, and all requirements for donor eligibility, blood donation including apheresis, and donor notification in 21 CFR 630 and 21 CFR 640, as amended from time to time.

(c) All reference laboratories utilized by a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall hold a CLIA certificate or state license or both, as applicable, and shall comply with the requirements of 21 CFR 607.7, 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 or renewal application and on request. Such policies and procedures shall be available to facility personnel for use in areas where procedures are performed. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies 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 blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies; and

(H) Procedures for donors to file complaints with the department regarding a blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies.

(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 qualifications and ability of all trained persons in accordance with section 19a-36-F5(c)(5) of the Regulations of Connecticut State Agencies;

(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 personnel, and to document ongoing training and continuing education of personnel;

(D) Establishment and maintenance of minimum staffing levels; and

(E) Staffing plans to ensure that personnel cross-trained in blood collection, specific to the equipment and facility, are available to maintain safe staffing levels in the event of a personnel or donor emergency and to maintain minimum staffing levels established pursuant to subparagraph (D) of this subdivision.

(4) Emergency preparedness including an emergency communications plan to include notification of the director. If the facility operates temporary or mobile locations, the emergency plan shall include such locations.

(5) Medical contingency planning.

(6) Data collection and reporting in accordance with the requirements of section 19a-36-F6 of the Regulations of Connecticut State Agencies.

(7) 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.

(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 plans for responding to such events. Such policies and procedures shall ensure the identification, 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 or failure 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-F6 of the Regulations of Connecticut State Agencies and in accordance with federal requirements.

(8) Facilities and equipment.

(A) The management, operation, personnel, equipment, 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, physical environment, and equipment shall be maintained to provide safe and acceptable standards for handling of human blood and blood components. Blood collection facilities shall maintain at a minimum 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 apheresis, and for the immediate storage and labeling of blood and blood components until such blood and blood components are tested and qualified as suitable for labeling. 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 lighted and ventilated, and shall be of adequate size to ensure the health and safety of donors and staff.

(D) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain appropriate facilities and equipment for record keeping in accordance with section 19a-36-F6 of the Regulations of Connecticut State Agencies.

(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. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain, at a minimum, emergency equipment for resuscitation and defibrillation.

(e) Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall maintain written documentation that each person employed is fully trained in the policies and procedures setting forth minimum standards of operation as required pursuant to this section.

(Effective March 19, 2025)

Sec. 19a-36-F4. Examinations and laboratory tests

(a) Blood collection facilities licensed pursuant to section 19a-36-F2 shall conduct all donor testing at a duly licensed clinical laboratory.

(b) Blood and blood components collected shall be tested according to the requirements of 21 CFR 610.40 and 21 CFR 640.5, as amended from time to time.

(c) All donor eligibility testing conducted at a reference laboratory shall be conducted by personnel licensed as required in the state where testing occurs.

(Effective March 19, 2025)

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)

Sec. 19a-36-F6. Record and reporting requirements

(a) Records. Donor records shall be maintained in accordance with applicable federal and state law, including 21 CFR 606.160 and 21 CFR 640.72, as amended from time to time. Blood collection facilities shall comply with the requirements of Section 36a-701b of the Connecticut General Statutes.

(b) Confidentiality. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies 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 on-site at the blood collection facility licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies, or reported to the facility 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.

(d) Reporting. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with all requirements in 21 CFR 640.73, as amended from time to time, governing reporting of adverse events. Fatalities confirmed to be caused by blood donation shall be reported to the department, and to the United States Food and Drug Administration in accordance with 21 CFR 606.170(b), as amended from time to time.

(e) Reportable diseases. Blood collection facilities licensed pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies shall comply with the reporting requirements under section 19a-215 of the Connecticut General Statutes.

(f) If an error or accident occurs and any blood or blood component not suitable for any use is released for use, immediate effort shall be made to locate and destroy all such blood

or blood components. All actions taken to address an error or accident shall be documented in writing.

(Effective March 19, 2025)