Filed August 26, 2025

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

BIOBANKING COMPLIANCE PROGRAM

Licensure of Embryo Storage Facilities

Proposed New Rules: N.J.A.C. 8:77

Authorized By: Jeffrey A. Brown, Acting Commissioner, Department of Health.

Authority: N.J.S.A. 26:2A-23 through 31 (P.L. 2019, c. 268, P.L. 2022, c. 106).

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2025-125.

Submit written comments by November 14, 2025, electronically to http://www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked by November 14, 2025, to:

Kimberly Jenkins, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

On December 4, 2019, the Governor approved P.L. 2019, c. 268, codified in part at N.J.S.A. 26:2A-23 through 31 (the Act), and effective March 1, 2021 (see P.L. 2019, c. 268, § 10). On September 15, 2022, the Governor approved P.L. 2022, c. 106, which amended N.J.S.A. 26:2A-25, and became effective March 14, 2023.

The Act requires the Department of Health (Department) to license and regulate embryo storage facilities (ESF). The Act defines an "embryo storage facility" as "a facility which cryopreserves and stores human egg, pre-embryos, and embryos for later

use in *in vitro* fertilization, embryo transfer, gamete transfer, pronuclear stage transfer and zygote transfer, and other procedures performed to achieve a pregnancy or pregnancies ..." and "include[s] the office of a licensed health care provider which stores human eggs, pre-embryos, or embryos." N.J.S.A. 26:2A-24. The Act prohibits a person from operating an ESF in the State unless the ESF is licensed by the Department. N.J.S.A. 26:2A-25. The Act requires the Department to promulgate rules that promote safety and best practices and prescribe standards for the operation, maintenance, and administration of ESFs. N.J.S.A. 26:2A-26.

The Act requires the Department to conduct on-site inspections of a licensed ESF and authorizes Department staff to inspect all documents, records, files, or other data maintained by the ESF to determine compliance with the Act and Department requirements. *Id.*

The Act directs the Commissioner to promulgate rules to implement the Act. N.J.S.A. 26:2A-26. See also P.L. 2019, c. 268, § 10 (authorizing the Commissioner to take anticipatory administrative action to implement the Act). To implement the rulemaking obligations that the Act establishes, as described above, the Department is proposing new rules at N.J.A.C. 8:77, Licensure of Embryo Storage Facilities.

In developing this rulemaking, the Department solicited input from a group of stakeholders (Embryo Storage Advisory Panel), consisting of individuals with a wide variety of educational and professional expertise, including embryology, biobanking management, legal aspects of assisted reproduction, laboratory operations, reproductive rights, and reproductive medicine. Panel members provided their comments on the standards prescribed by the Act and made rule recommendations.

Subchapter 1 would establish general provisions. Proposed new N.J.A.C. 8:77-1.1, Definitions, would establish definitions of words and terms the chapter uses. Among those definitions is the “Biobanking Compliance Program,” which was recently established by the Department to regulate embryo storage facilities and establishments that handle different biological materials pursuant to other laws that the Department administers. Proposed new N.J.A.C. 8:77-1.2, Waiver, would establish a standard and procedure by which an entity that is subject to the chapter could apply to the Department for waiver of a provision or provisions of the chapter. Proposed new

N.J.A.C. 8:77-1.3, Published professional guidance, would incorporate by reference, certain publications, primarily authored by practice committees for the American Society for Reproductive Medicine and/or the Society for Assisted Reproductive Technology, as amended and supplemented, that includes guidance and sets forth best practices that the Department is referencing as operational standards for personnel, equipment maintenance, emergency preparedness, and quality management for embryo storage facilities.

Subchapter 2, Issuance and Renewal of Licensure; Inspection; Fees, would establish standards for issuance and renewal of licensure, inspection standards, and applicable fees. Proposed new N.J.A.C. 8:77-2.1, Application for licensure of an embryo storage facility, would establish standards by which one may apply to the Department for licensure of an ESF by completing and submitting the application form that is incorporated herein by reference as N.J.A.C. 8:77 Appendix, the required documentation, and fee. Proposed new N.J.A.C. 8:77-2.2, Licensure criteria, would establish the criteria pursuant to which the Department would license an ESF. Proposed new N.J.A.C. 8:77-2.3, Inspection, would establish standards for Department inspection of applicants for licensure as an ESF and renewal of licensure for a licensed embryo storage facility (L-ESF). Proposed new N.J.A.C. 8:77-2.4, License, would reiterate the Act's requirement that any person that intends to operate an ESF must obtain a license, describe the contents of the license, and direct where it must be displayed in the facility. Proposed new N.J.A.C. 8:77-2.5, Renewal of license, would establish the procedure pursuant to which an L-ESF would apply for renewal of its license. Proposed new N.J.A.C. 8:77-2.6, Fees, would establish the fees the Department would impose on an applicant for an initial license and on an L-ESF seeking renewal of its license. Proposed new N.J.A.C. 8:77-2.7, Cessation of operations; change of ownership, would establish standards by which an L-ESF is to notify the Department if it intends to discontinue operations or transfer ownership to another entity, and would identify the procedure by which a proposed new owner is to apply for authorization to obtain licensure of the ESF, and procedures by which the proposed new owner could continue operations without interruption by applying to the Department for advance approval of the license prior to the conclusion of the proposed transfer of ownership. Proposed new N.J.A.C.

8:77-2.8, Provisional licensure, would establish a procedure by which an ESF that is currently operating in the State could apply for provisional licensure without any interruption to its operations upon the effective date of the new rules, to facilitate continuity of services to existing clients of its services, pending the Department's issuance of a final determination on the ESF's application for licensure.

Subchapter 3, Administration; Policies and Procedures, would establish standards for administration of ESFs and identify required policies and procedures. Proposed new N.J.A.C. 8:77-3.1, Required policies and procedures, would establish specific subject areas and criteria that are to be addressed in an ESF's policies and procedures. Proposed new N.J.A.C. 8:77-3.2, Maintenance of records, would establish ESF recordkeeping requirements and require an ESF to maintain records relating to the individuals from whom reproductive tissue is received, its performance of procedures on the reproductive tissue, and the ultimate disposition of the reproductive tissue, and would require that records relating to specific reproductive tissue be mailed for no less than 10 years after release for use in assisted reproductive technology (ART), among other requirements. Proposed new N.J.A.C. 8:77-3.3, Reportable events, would identify occurrences that could negatively impact the viability, safety, or future use of the reproductive tissue, or impact the premises or operational continuity of the L-ESF, or failure of equipment that is critical in cryopreserving or storing reproductive tissue or in ensuring staff safety, which an ESF is to report, and the manner and timeframes by which the report is to be made to the Department, as well as information that must be included in the report.

Subchapter 4, Operational Standards, would establish standards for the operations of ESFs. The Act directs that the Department's rules accord with the standards for biorepositories established by the College of American Pathologists (CAP) Biorepository Accreditation Program, the Federal Guidance on Good Tissue Practice, and certain standards of the International Organization for Standardization (ISO). Operational standards for ESFs are addressed at proposed new Subchapter 4, and the Department notes the following requirements of the Act. The Preamble to the CAP Biorepository Accreditation Program Standards of Accreditation states that "[A] biorepository is an entity that receives, stores, processes, and distributes specimens as

needed for research." Embryo storage facilities, as defined by the Act, are not involved in research activities, but rather, are part of the assisted reproductive medicine process. As such, the CAP Accreditation Standards for Biorepositories are not incorporated into the ESF operational standards in the proposed rules.

Similarly, the Act directs that the Department's rule accord with the U.S. Food and Drug Administration (FDA) guidance on Current Good Tissue Practices. Subpart D of 21 CFR 1271, Current Good Tissue Practice. In addition, the FDA issued a guidance document, Guidance for Industry, Current Good Tissue Practice (CGTP), and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (December 2011) (Guidance Document), which sets forth nonbinding recommendations and guidance for complying with certain subparts at 21 CFR 1271. Notably, however, the only provisions at Subpart D that apply to reproductive tissue as defined pursuant to the Act, are paragraph (c) at 21 CFR 1271.150, which provides that establishments need only comply with the requirements of Subpart D and Subpart C that are applicable to the operations of that establishment and 21 CFR 1271.155, Exemptions and alternatives, which sets forth the process to request an exemption from any requirement at Subpart C or D at 21 CFR 1271. Also, as a threshold matter, certain facilities are exempt from the requirements at 21 CFR 1271 pursuant to one of the exceptions set forth in the regulations, particularly at subparagraph (d) at 21 CFR 1271.15. Thus, whether a particular ESF may be required to comply with Federal Current Good Tissue Practice as set forth at Subpart D at 21 CFR 1271 is a case-by-case determination that depends on the particular scope of operations of the facility. Accordingly, these proposed rules do not impose a separate independent requirement that all L-ESFs adhere to the requirements at Subpart D at 21 CFR 1271 or the Guidance Document.

Lastly, the Act requires that the rules accord with ISO 9001- Quality Management, and ISO 20387 Biotechnology — Biobanking — General Requirements for Biobanking. A number of the stakeholders that the Department convened to provide recommendations and input, advised that those ISO standards are tedious, burdensome, costly, and are not the gold standard for the field. Accordingly, the

proposed rules refer to selected parts of these standards concerning quality management that appear to be widely practicable and have general applicability.

In light of the foregoing, proposed new N.J.A.C. 8:77-4.1, Operational standards, would require compliance with the requirements of that subchapter to the extent applicable to an ESF's operations and not in conflict with standards of the accrediting body. Proposed new N.J.A.C. 8:77-4.2, Personnel, would establish personnel requirements for ESFs that are laboratories and for ESFs that are offices of licensed healthcare providers. Proposed new N.J.A.C. 8:77-4.3, Safety and adequacy of physical plant, would establish requirements for the structure, maintenance, and features of the premises of ESFs. Proposed new N.J.A.C. 8:77-4.4, Safety, functionality, and maintenance of equipment, would establish requirements for the use and maintenance of equipment and prescribe safety features that must be implemented by ESFs. Proposed new N.J.A.C. 8:77-4.5, Emergency preparedness and recovery, would require an ESF to develop, document, and periodically review a plan for emergency preparedness and recovery and to establish the minimum components of such a plan. Proposed new N.J.A.C. 8:77-4.6, Quality management, would require an ESF to develop, document, and periodically review a program for quality management and to establish the minimum components of such a program. Proposed new N.J.A.C. 8:77-4.7, Required disclosures, would require an ESF to disseminate, in writing, to its clients its policies regarding disposition of reproductive tissue in certain circumstances.

Subchapter 5, Enforcement Actions and Hearings, would address enforcement actions and hearings. Proposed new N.J.A.C. 8:77-5.1, Enforcement, would establish standards for Department actions against an L-ESF's license or operations for violation of the Act, the proposed new rules, or for good cause. Proposed new N.J.A.C. 8:77-5.2, Hearings, would set forth the effective dates of the various enforcement actions that the Department could take, and the process to be taken by an ESF that chooses to appeal certain of those enforcement actions by submitting a written request for a hearing, in addition to, a response to the charges in the enforcement action.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

According to the Centers for Disease Control and Prevention, which maintains annual data on the number of assisted reproductive technology procedures and birth outcomes in the United States, in 2022, 457 fertility clinics across the country, including 14 in New Jersey, reported performing a total of 251,003 ART procedures. CDC, State-Specific ART Surveillance available at https://www.cdc.gov/art/php/surveillance-state-specific/index.html. Of the 12,975 ART procedures performed in the State in 2022, 11,036 involved embryo transfer. *Id.* Of the ART procedures performed in the State that year, 6,694 pregnancies and 5,540 live birth deliveries were achieved. *Id.*

The proposed new rules would establish standards for premises, equipment, recordkeeping, adverse event reporting, emergency preparedness, and quality management, among other standards, that will help ensure the safety of embryo storage facilities, promote the effective and consistent operation of equipment, and ensure that facilities are prepared for emergencies and natural disasters. As a result, individuals and couples that utilize assisted reproductive technology will have greater confidence in the integrity of stored reproductive tissue and its availability for their future use or benefit. Staff, clients, and visitors to embryo storage facilities will be ensured that the premises and equipment are being optimally maintained, thereby decreasing the likelihood of avoidable equipment failure that could endanger both the health and safety of staff, and the integrity of the stored reproductive tissue. The standards would decrease the probability of avoidable equipment failure that has, in the past resulted in catastrophic storage system failure in facilities located in other states. Accordingly, these proposed rules would have a positive social impact on individuals seeking ART services, as well as staff providing ART procedures at ESFs.

Given the expanding use of ART, the expense involved in pursuing ART, and the vital importance of ensuring the safety and viability of cryopreserved human eggs and embryos, the Department is unaware of individuals or entities that would realize a negative social impact from the proposed new rules.

Economic Impact

The following would incur costs associated with the proposed new rules: the Department, persons seeking to operate an ESF, existing ESFs applying for licensure,

which may include hospitals, specialized clinical laboratories, medical practices, physician's offices, and reproductive clinics.

N.J.S.A. 26:2A-28 provides that the Commissioner shall establish a fee to be paid by each ESF upon application for licensure and upon renewal and the income therefrom be appropriated to the Department to effectuate the purposes of the Act.

The Department has limited knowledge concerning the number of in-State entities that would apply for licensure as embryo storage facilities or the total revenues the Department might realize from licensure fees upon the Department's adoption and implementation of the proposed new rules. The U.S. Food and Drug Administration's Human Cell and Tissue (HCT/P) Establishment Registration public query website (https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm), currently lists 22 registered HCT/P establishments in the State, however, there are facilities that are ESFs pursuant to the Act and the new rules that are not HCT/P establishments as defined in Federal regulation due to the nature of their operations.

The Department would incur ongoing operational and administrative costs associated with filling and retaining four new staff positions; purchasing and ongoing maintenance of infrastructure, such as information technology resources; performing reviews of applications for licensure and renewal of licensure; conducting periodic on-site inspections of ESFs; and conducting ongoing oversight and enforcement activities. The Department estimates that it will cost slightly over $360,560 annually, excluding the cost of inspections, to operate the ESF component of the Biobanking Compliance Program for salaries at current Civil Service Commission rates, infrastructure, and administrative expenses.

Revenues associated with application fees cannot be determined due to uncertainties regarding the implementation of the rules and the number of ESFs that would be subject to the Act and the proposed new rules. However, it is anticipated that revenues received from licensure and renewals would be insufficient to cover the Department's operational costs. Therefore, the proposed fees of $1,500 for initial licensure and $1,500 for annual renewal are proposed as interim figures until the Department has greater certainty as to its annual expenses and revenues. With

experience over time, the Department would then be able to adjust the fees *pro rata* among regulated entities through a future rulemaking.

The Department notes that it is unable to effectively compare the proposed fees with those of other states, because although other states regulate tissue banking, it does not appear that any other state is specifically regulating only egg and embryo storage and cryopreservation, as defined by the Act, at this time.

Other than payment of Department fees for initial licensure and annual renewal, the Department expects than an applicant for licensure as an ESF may not incur measurable costs associated with readying the premises, staff, and equipment of an ESF to comply with the standards of the proposed new rules because it is anticipated that the ESF as it currently operates may be in compliance with many of those standards, particularly if the ESF is currently accredited by either CAP or the Joint Commission.

However, because the proposed new rules would require that an ESF be accredited by one of two accrediting bodies, either CAP or the Joint Commission, an existing ESF will incur additional costs in becoming accredited and maintaining accreditation by an accrediting body, if it is not currently accredited.

Separately, a reproductive laboratory that qualifies as an ESF as defined by the Act is already subject to the requirements of the Federal Clinical Laboratory Improvement Amendments (CLIA), which vary depending on the type of testing performed at the facility. The Federal CLIA requirements apply only to clinical laboratories and are separate and distinct from the requirement imposed by these proposed new rules that an ESF be accredited by either the Joint Commission or CAP.

An ESF that operates without obtaining Department licensure or otherwise fails to comply with the Act or the proposed new rules would incur costs associated with Department enforcement actions, lost income due to suspension, revocation, curtailment, and/or refusal to issue or renew a license and retention of legal services to defend an enforcement action.

Federal Standards Statement

The FDA has established standards to regulate "establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps)," including a

requirement at 21 CFR 1271.10(b) that the establishment register with the FDA and comply with certain other parts at 21 CFR 1271, as applicable to the particular operations of the establishment, primarily in an effort to prevent the transmission or spread of communicable disease by the operations of these establishments. "Manufacture" means "any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor." 21 CFR 1271.3(e). The proposed new rules would require any applicant that is required by FDA regulation to register as an HCT/P establishment to submit proof of such registration with their application for Department licensure. The Department expects that some ESFs, such as reproductive laboratories, will not be subject to any of the requirements at 21 CFR 1271 because they do not meet the threshold definition of "manufacture." Additionally, the Department expects that some IVF facilities will not be subject to any of the requirements at 21 CFR 1271 because they are establishments "that do not recover, screen, test, process, label, package, or distribute, but only receive or store HCT/Ps solely for implantation, transplantation, infusion, or transfer within your facility," pursuant to paragraph (c) at 21 CFR 1271.15. To the extent that some ESFs, due to their particular operations and activities, are required to comply with 21 CFR 1271.150(c) concerning Current Good Tissue Practice requirements and any of the Donor Eligibility requirements at 21 CFR 1271, Subpart C, those are separate and distinct from any standards imposed by these proposed new rules. There are no Federal standards for reproductive tissue that concern a facility's personnel, physical plant, equipment, emergency preparedness, or quality management.

In addition, the Department is proposing this rulemaking pursuant to the authority at N.J.S.A. 26:2A-23 et seq., and not pursuant to the authority of, or to implement, comply with, or participate in, any program established pursuant to Federal law or a State law that incorporates or refers to any Federal law, standard, or requirement. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the proposed new rules would necessarily result in the creation of new jobs by entities seeking to operate ESFs

because ESFs, as defined by the Act, are currently operating in the State in the form of reproductive/IVF clinics, hospitals, reproductive laboratories, and medical practices that specialize in assisted reproduction.

As the Economic Impact describes, the Department's implementation of the Act and the proposed new rules would require the Department to retain staff with administrative and subject matter expertise to perform functions associated with accepting and processing applications for licensure, conducting on-site inspections of licensees, periodically reviewing accreditation standards and the rules, as necessary, to ensure that licensees adhere to current best practices, and pursuing enforcement activities against entities that are not compliant with the Act and the proposed new rules.

The Department does not anticipate that the proposed new rules would result in the loss of jobs in the State.

Agriculture Industry Impact

The Department does not anticipate that the proposed new rules would have an impact on the agriculture industry in the State.

Regulatory Flexibility Analysis

The proposed new rules would impose requirements on entities seeking to apply for and renew Department licensure as an ESF in the State. The Department is unable to estimate the number of entities that would seek to become licensed ESFs in the State or the number of such entities that would be small businesses within the meaning of the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., because the licensure of these facilities is a new State initiative. The U.S. Food and Drug Administration's Human Cell and Tissue (HCT/P) Establishment Registration public query website (https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm), currently lists 22 registered HCT/P establishments in the State, however, there are facilities that are ESFs pursuant to the Act and the new rules that are not HCT/P establishments as defined in Federal regulation due the nature of their operations. Hospitals that the Department licenses pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., are not small businesses within the meaning of the New

Jersey Regulatory Flexibility Act. Laboratories and medical practices may be small businesses as defined by the New Jersey Regulatory Flexibility Act.

To the extent the proposed new rules might apply to small businesses, the following analysis applies. The proposed new rules would impose reporting, recordkeeping, and other compliance requirements on entities that apply for and maintain licensure in the State. The Summary above describes those requirements. The Economic Impact describes the costs of compliance. Other than payment of Department fees for initial licensure and annual renewal, the Department expects that an applicant for licensure as an ESF may not incur measurable costs associated with readying the premises, staff, and equipment of an ESF to comply with the standards of the proposed new rules because it is anticipated that the ESF as it currently operates may be in compliance with many of those standards, particularly if the ESF is currently accredited by either CAP or the Joint Commission.

However, because the proposed new rules would require that an ESF be accredited by one of two accrediting bodies, either CAP or the Joint Commission, an existing ESF will incur additional costs in becoming accredited and maintaining accreditation by an accrediting body, if it is not currently accredited. The Department does not anticipate that the proposed new rules would require applicants to retain any new staff or professional services if the applicant is already cryopreserving or storing human eggs or embryos in the State pursuant to the CAP or Joint Commission standards. The Department is unable to estimate the costs associated with retaining new staff or professional services if the applicant is not already operating as an ESF in the State. The Department proposes no lesser or differing standards for small businesses because the Department has determined that the proposed new rules would establish minimum standards necessary to ensure the safety of embryo storage facilities and the integrity of human eggs or embryos that are stored and cryopreserved in the State.

Housing Affordability Impact Analysis

The proposed new rules would have no impact on the affordability of housing in New Jersey, and there is an extreme unlikelihood that they would evoke a change in the

average costs associated with housing because the proposed new rules would establish standards for licensure of ESFs and would have no bearing on housing costs.

Smart Growth Development Impact Analysis

The proposed new rules would have no impact on smart growth, and there is an extreme unlikelihood that the proposed new rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed new rules would establish standards for licensure of ESFs and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposed new rules follows:

CHAPTER 77

LICENSURE OF EMBRYO STORAGE FACILITIES

SUBCHAPTER 1. GENERAL PROVISIONS

8:77-1.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Accrediting body" means the College of American Pathologists (CAP), Reproductive Accreditation Program, 325 Waukegan Road, Northfield, IL 60093, www.cap.org, or the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), Laboratory or Office-Based Surgery Accreditation Programs, 1 Renaissance Blvd., Oakbrook Terrace, Illinois, 60181, www.jointcommission.org.

“Act” means N.J.S.A. 26:2A-23 through 31.

"ALIS portal" means the online application website that the Department administers to process applications for licensure of embryo storage facilities.

"Applicant" means an entity seeking issuance or renewal of Department ESF licensure.

"Assisted reproductive technology" or "ART" means *in vitro* fertilization, embryo transfer, gamete transfer, pronuclear stage transfer and zygote transfer, and other procedures involving transfer of reproductive tissue into a human recipient to achieve pregnancy.

"Biobanking Compliance Program" or "BCP" means the Biobanking Compliance Program within the Clinical Laboratory Improvement Services at the Department, for which the contact information is:

Biobanking Compliance Program, CLIS

New Jersey Public Health, Environmental, and Agricultural Laboratory

Mailing address for regular mail delivery:

PO Box 361, Trenton, NJ 08625-0361

Mailing address for courier service or in-person delivery:

3 Schwarzkopf Drive, Ewing, NJ 08628-1620

Electronic mail address: clis.biobanking@doh.nj.gov.

"CDC" means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"Client" means the individual or individuals who provide the reproductive tissue that is stored by an entity subject to this chapter.

"Commissioner" means the Commissioner of the Department.

"Cryopreserve" means cooling reproductive tissue, whether gradually or by vitrification, to a temperature at which biological activity is stopped for purposes of preserving the reproductive tissue for later use in ART.

"Department" means the Department of Health.

"Embryo storage facility" or "ESF" means "embryo storage facility" as the Act defines and describes that term, specifically at N.J.S.A. 26:2A-24.

“Establishment Inspection Report” means the final written report produced by the FDA concerning its inspection of a facility, and typically made available to the facility three to six months after the inspection.

"FDA" means the Food and Drug Administration of the United States Department of Health and Human Services.

“Form 483” means the document issued by the FDA at the conclusion of its inspection of a human cell and tissue (HCT/P) establishment that includes notes about observations made during the inspection and indicates that either no action is indicated, voluntary action is indicated, or official action is indicated.

"Intended recipient" means the client or the human recipient into whom the reproductive tissue will be transferred.

"Licensed embryo storage facility" or "L-ESF" means an entity to which the Department issued a license to operate as an ESF, in accordance with the Act and this chapter.

"Person" means "person" as the Act defines and describes that term, specifically at N.J.S.A. 26:2A-24.

"Plan of correction" means a list or description of the measures the applicant or L-ESF is to undertake to correct BCP-identified deficiencies and the schedule for completion of each aspect of the plan.

"Reproductive tissue" means a human oocyte or embryo.

"Storage" means the act of keeping reproductive tissue, whether cryopreserved or fresh, for later use in ART.

8:77-1.2 Waiver

(a) The BCP may waive any part of this chapter if the BCP determines that a waiver would not:

1. Endanger the life of any person or the viability of any human oocyte or embryo;

2. Endanger public health, safety, or welfare; or

3. Adversely affect the provision of embryo storage services.

(b) A person seeking a waiver of a requirement of this chapter shall apply to the BCP, in writing, in which the person shall state:

1. The nature of the waiver the person is requesting;

2. The specific standard or standards for which the person requests the waiver;

3. The reasons for the waiver request, including a statement of the type and degree of hardship that the person would realize if the BCP were to decline to grant the waiver;

4. A description of how the waiver and any alternative proposal would ensure the safety and integrity of the reproductive tissue stored by the person and the safety of the staff and premises; and

5. Documentation to support the waiver application.

(c) The BCP may request additional information before processing a waiver request.

8:77-1.3 Published professional guidance

(a) The Department incorporates herein by reference, as amended, supplemented, and reaffirmed, the following guidance documents (hereinafter collectively referred to as "Published Professional Guidance"):

1. Practice Committee of the American Society for Reproductive Medicine, "Cryostorage of Reproductive Tissues in the *In Vitro* Fertilization Laboratory: A Committee Opinion," *Fertility and Sterility*, (June 9, 2020) (hereinafter "Cryostorage in IVF Labs"), available at https://doi.org/10.1016/j.fertnstert.2020.06.019;

2. Practice Committees of the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, and the Society of Reproductive Biologists and Technologists, "Development of an Emergency Plan for *In Vitro* Fertilization Programs: A Committee Opinion, in *Fertility and Sterility*, vol. 115, no. 4, April 2021 (hereinafter "Emergency Plan for IVF Programs"), available at https://doi.org/10.1016/j.fertnstert.2021.01.009;

3. Practice Committee of the American Society for Reproductive Medicine, "Minimum Standards for Practices Offering Assisted Reproductive Technologies: A Committee Opinion," *Fertility and Sterility*, vol. 115, no. 3, (March 2021) (hereinafter "Minimum Standards for ART Practices"), available at https://doi.org/10.1016/j.fertnstert.2020.12.036;

4. Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology, "Revised Guidelines for Human Embryology and Andrology Laboratories," *Fertility and Sterility*,

vol. 90, suppl 3, (November 2008) (hereinafter “Guidelines for Labs”), available at https://doi.org/10.1016/j.fertnstert.2008.08.099, especially Table 1, Recommended staff according to volume of laboratory cycles at p. S46; and

5. Schiewe MC, Freeman M, and Whitney JB, et al., "Comprehensive Assessment of Cryogenic Storage Risk and Quality Management Concerns: Best Practice Guidelines for ART labs," *Journal of Assisted Reproduction and Genetics* (2019), 36:5-14 (hereinafter “QM for ART Labs”), available at https://doi.org/10.1007/s10815-018-1310-6.

SUBCHAPTER 2. ISSUANCE AND RENEWAL OF LICENSURE; INSPECTION; FEES

8:77-2.1 Application for licensure of an embryo storage facility

(a) A person seeking to operate an ESF in New Jersey shall apply to the BCP for licensure pursuant to the Act by submitting, either electronically through the ALIS portal or by regular mail to the BCP:

1. The information and documentation requested in the application form at N.J.A.C. 8:77 Appendix, incorporated herein by reference; and

2. The nonrefundable fee specified at N.J.A.C. 8:77-2.6.

(b) The BCP shall:

1. Notify an applicant, in writing, if it determines that an application is incomplete;

2. Identify in the written notice, the information or documentation needed to complete the application; and

3. Refrain from processing the application until the applicant submits the information or documentation necessary to complete the application.

i. If the BCP does not receive, within 30 days of issuance of a notice issued pursuant to (b)2 above, the information or documentation that the notice identifies as needed from the applicant to complete the application, the BCP will consider the applicant to have abandoned the application and the nonrefundable fees, without prejudice, to the application being reactivated if the applicant submits the information or documentation indicated in the written notice and absent the BCP granting an extension of the deadline by waiver pursuant to the process at N.J.A.C. 8:77-1.2.

ii. Provisional licensure granted pursuant to N.J.A.C. 8:77-2.8 irrevocably lapses upon abandonment of an application.

(c) Upon finding that an application is complete, and an applicant has paid the applicable fee, the BCP will:

1. Review the application for conformity with the requirements at N.J.A.C. 8:77-2.2;

2. Evaluate the character, competence, and integrity of the applicant, pursuant to N.J.S.A. 26:2A-25.b through the following review:

i. The applicant's record of ESF ownership or operation in this State or in any other jurisdiction, for which N.J.A.C. 8:77-2.2(a)5 and 7 requires an applicant to submit documentation, for evidence of a deficiency representing a serious risk of harm to clients or stored reproductive tissue; and

ii. Records of convictions for crimes or offenses committed by the owner or operator demonstrating a potential risk to client safety and welfare or the integrity of stored reproductive tissue.

(1) A person who is convicted of a crime relating adversely, either directly or indirectly, to the person's capability of owning, managing, or operating an ESF is ineligible to own, manage, or operate an ESF unless the person is rehabilitated pursuant to N.J.S.A. 2A:168A-1 et seq.; and

3. Perform an on-site inspection of the ESF during normal operating hours, at the discretion of BCP.

8:77-2.2 Licensure criteria

(a) An applicant for licensure of an ESF by the Department shall submit the following with its application:

1. The information and documentation requested in the application form at N.J.A.C. 8:77 Appendix;

2. The applicable fee as specified at N.J.A.C. 8:77-2.6;

3. A copy of the applicant's current Certificate of Accreditation issued by the accrediting body, unless the applicant is a licensed health care provider that stores fresh reproductive tissue on site for use in ART;

4. Evidence of current registration with the FDA, if required by Federal regulation, as an HCT/P establishment;

5. If applicable, a copy of the Form 483 and any Establishment Inspection Report issued by the FDA following its most recent inspection of the ESF, as well as documentation of any actions taken or proposed by the ESF in response to Form 483 and the Establishment Inspection Report;

6. A copy of the applicant's lease or deed to the premises, and, if applicable, the certificate of occupancy; and

7. For purposes of track record review, and if applicable, each Form 483 and each Establishment Inspection Report, received for an ESF owned or operated by the applicant and/or a subsidiary or parent of the applicant in the State of New Jersey, and each report of any inspection performed in a jurisdiction outside of New Jersey in which an ESF owned or operated by the applicant and/or a subsidiary or parent of the applicant is located, during the 10 years preceding the date of an application for initial licensure, identifying deficiencies noted, as well as documentation of any actions taken or proposed by the ESF, in response to Form 483 or the Establishment Inspection Report.

(b) The BCP shall consider the following, as applicable, in determining whether to grant an application for L-ESF status:

1. The result of the BCP's inspection of the proposed ESF premises;

2. The applicant's track record at the premises as reflected in the documents provided pursuant to (a)5 and 7 above; and

3. The results of the investigation of the character, competency, and integrity of the applicant pursuant to N.J.A.C. 8:77-2.1(c)2.

(c) The BCP shall license an applicant if:

1. The application demonstrates that the premises, equipment, operational capacity, personnel, and policies and procedures, are fit and adequate;

2. The track record of the applicant's existing facility and that of any other ESF that the applicant, or a subsidiary or parent, owns or operates indicates that the applicant, and/or a subsidiary or parent of the applicant, is in compliance with the Act, this chapter, any applicable Federal, State, and local regulatory standards in New

Jersey and other jurisdictions in which the applicant, and/or a subsidiary or parent of the applicant engages in the storage or cryopreservation of reproductive tissue; and

3. There is reasonable assurance that the applicant will operate the ESF in accordance with the Act and this chapter.

(d) The BCP, upon receipt of an application for licensure of an embryo storage facility, will:

1. Request the appropriate State and local fire, health, and building officials to conduct examinations and inspections to determine compliance with State and local ordinances, codes, and regulations by the ESF; and

2. Request that such inspections be conducted and the results reported to the BCP within 60 days after the request.

8:77-2.3 Inspection

(a) In accordance with N.J.S.A. 26:2A-26, an applicant or an L-ESF shall make available for inspection to the BCP during normal operating hours with or without prior notice, its facility premises, documents, records, electronic files, and other data or materials that the ESF maintains to enable the BCP to assess compliance with the Act and this chapter.

(b) Following a BCP inspection, BCP staff shall meet with representatives of the applicant or L-ESF to perform an inspection summation, which shall describe the BCP's findings, including any deficiencies that the BCP identifies, and subsequently shall issue a written report to the applicant or L-ESF, identifying:

1. The BCP's findings and any deficiencies that the BCP noted during the inspection (deficiency report); and

2. If the BCP found deficiencies:

i. The date by which the applicant or L-ESF must submit to the BCP, a proposed plan of correction to cure the deficiencies; and/or

ii. If the BCP finds that the deficiencies represent an immediate threat to reproductive tissue, the BCP's directed plan of correction, which will require the applicant or L-ESF to undertake specific action to correct the deficiencies and indicate the date by which the applicant must implement the directed plan of correction.

(c) The BCP will review a proposed plan of correction that an applicant or L-ESF submits pursuant to (b)2i above to determine whether the proposed plan would ensure compliance with the Act and this chapter, and thereupon issue written notice to the applicant or L-ESF:

1. Indicating whether the BCP accepts the plan of correction;

2. Directing the applicant or L-ESF to implement the aspects of the plan that the Department accepts;

3. Directing the applicant or L-ESF to submit by a specified date a revised plan of correction, if applicable, for the parts of the plan that the BCP determines to be unacceptable; and/or

4. Issuing a BCP-directed plan of correction and/or taking enforcement action, if applicable.

(d) An applicant or L-ESF shall notify the BCP, in writing, upon completion of its implementation of a plan of correction, indicating the dates upon which it implements each aspect of the plan.

1. Following its receipt of a notice pursuant to (d) above, the BCP may conduct additional inspections, as necessary, to confirm the satisfactory implementation of the plan of correction.

2. Upon the BCP determining that an applicant or L-ESF has timely and satisfactorily implemented an applicable plan of correction, the BCP will issue a written notice to the applicant or L-ESF indicating that the BCP accepts the performance and implementation of the plan as satisfactory.

3. If the BCP determines that an applicant or L-ESF has not timely and/or satisfactorily implemented or maintained compliance with an approved or directed plan of correction or an aspect thereof, the BCP shall issue written notice to the applicant or L-ESF specifying the additional corrective actions needed and the dates by which the applicant or L-ESF is to complete these actions, and may implement immediate enforcement actions, as necessary, to ensure compliance with the Act and this chapter.

8:77-2.4 License

(a) An applicant shall not operate an ESF in the State until the BCP issues an ESF license to the applicant.

(b) A license will indicate:

1. Its expiration date, which will be for a period of no longer than 12 months from issuance; and

2. The address of the licensed premises.

(c) An L-ESF shall prominently display its license at a location on its premises that is readily accessible to public view and inspection.

(d) An applicant shall apply for a separate license for each location in the State at which reproductive tissue is cryopreserved and stored for later use in ART, and for each office of a licensed health care provider that stores reproductive tissue on site for use in ART.

8:77-2.5 Renewal of license

(a) To renew a license, an L-ESF shall submit, either electronically through the ALIS portal or by regular mail to the BCP, at least 45 days before the expiration of its license:

1. The information requested at N.J.A.C. 8:77-2.2(a)3, 4, 5, and 7 issued since the Department's issuance of the L-ESF's current license;

2. The fee set forth at N.J.A.C. 8:77-2.6; and

3. The completed form of application established at N.J.A.C. 8:77 Appendix.

(b) Upon finding that an L-ESF's application for renewal of its license is complete and the L-ESF has paid the applicable fee, the BCP will review the application and supplemental documentation for conformity with the requirements at (a)1 above, and cause an investigation to be made of the applicant to confirm their character, competency, and integrity pursuant to N.J.A.C. 8:77-2.1(c)2, and may perform an on-site inspection of the L-ESF's premises pursuant to N.J.S.A. 26:2A-26 and N.J.A.C. 8:77-2.1(c)3.

8:77-2.6 Fees

(a) The following fees are applicable:

1. Initial license: $1,500; and

2. Annual renewal of license: $1,500.

8:77-2.7 Cessation of operations; change of ownership

(a) An L-ESF shall notify the BCP, in writing, of an intended cessation of operations or proposed transfer of ownership at least 30 calendar days before the intended date of cessation or transfer.

(b) Licensure of an L-ESF is not assignable or transferable and shall be immediately void if the facility ceases to operate, if the facility's ownership changes, or if the facility is relocated to a different site.

(c) A person proposing to own or operate an existing ESF shall apply to the Department for licensure, in accordance with N.J.A.C. 8:77-2.1.

1. To facilitate continuity of operations without interruption of an ESF that the existing owner proposes to transfer, the proposed transferee entity may apply to the BCP for licensure as the new owner of the existing ESF in anticipation of closing or conclusion of a proposed transfer, and the BCP will undertake best efforts to conclude its review before the anticipated closing date, provided the transferee entity submits its application for registration and accreditation at least 45 days prior to the anticipated date of the closing or conclusion of the proposed transfer of ownership; and

2. In the event that the Department has not issued a new license for the operation of the ESF, for any reason, as of the date of the change of ownership, the Department will no longer recognize the ESF as an L-ESF since the prior owner's license will become void pursuant to (b) above; however, the ESF shall be deemed to hold provisional licensure pursuant to N.J.A.C. 8:77-2.8(c).

8:77-2.8 Provisional licensure

(a) The Department shall deem an existing ESF that is fully operational as of (the effective date of this rulemaking) to be a provisionally licensed ESF and thereby authorized to continue existing operations in the State without interruption; provided:

1. The ESF is in good standing with, and currently accredited by, an accrediting body;

2. The ESF is currently registered with the FDA as a human cell and tissue establishment pursuant to 21 CFR 1271.1(b)1, if required by Federal regulation;

3. The ESF submits to the BCP written notice of its intention to apply for licensure as an ESF by (30 days after the effective date of this rulemaking), and submits evidence of its current accreditation by an accrediting body; and

4. The ESF applies to the BCP for licensure pursuant to N.J.A.C. 8:77-2.1 by (60 days after the effective date of this rulemaking).

(b) Upon receipt of an ESF's notice of intention pursuant to (a)3 above, the BCP will issue a document evidencing provisional licensure to the ESF reflecting the ESF's status as a provisionally licensed ESF.

(c) Provisional licensure status shall remain effective until the earlier of either:

1. The BCP's issuance of a final determination on the ESF's application for licensure; or

2. The ESF's abandonment of an application for licensure pursuant to N.J.A.C. 8:77-2.1(b)3i.

(d) An existing ESF as described at (a) above that engages in the cryopreservation or storage of reproductive tissue in the State without having obtained provisional licensure, in accordance with this section, is subject to BCP enforcement action for violation of the Act pursuant to N.J.S.A. 26:2A-29 and this chapter.

(e) An ESF remains responsible to submit reportable events to the Department pursuant to N.J.A.C. 8:77-3.3 during the pendency of its provisional licensure status, notwithstanding its anticipated or actual submission of an application for licensure of the ESF.

SUBCHAPTER 3. ADMINISTRATION; POLICIES AND PROCEDURES

8:77-3.1 Required policies and procedures

(a) An L-ESF shall establish, document, in writing, implement, and annually review and revise, as necessary, policies and procedures that address:

1. The safety, traceability, and integrity of the reproductive tissue entrusted to it;

2. The safe and effective functioning of all equipment and instrumentation;

3. The safety and competency of its staff;

4. The cryopreservation, storage, and destruction of reproductive tissue; and

5. Ensuring the confidentiality of all client and intended recipient records, including all protected health information pursuant to the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, S. 264, as amended and supplemented, and its implementing regulations.

(b) An L-ESF shall make its written policies and procedures readily accessible to its staff and, upon request, to the Department.

(c) An L-ESF's policies and procedures shall address, at a minimum, the following, as applicable to the cryopreservation, storage, and destruction of reproductive tissue that is performed at the facility, consistent with any requirements of the accrediting body:

1. Staff training and evaluation, including implementation of periodic training and assessment relevant to each staff member's job functions to ensure competency and compliance with applicable safety and quality improvement standards;

2. Positive identification of reproductive tissue at each step in the handling process, as well as tracking and attendant recordkeeping from the point of receipt or accession to:

i. The transfer to an intended recipient; or

ii. Other disposition;

3. Temperature criteria for storage of reproductive tissue;

4. Use of equipment and instruments in accordance with the manufacturer's instructions, regular physical inspection and maintenance of all tanks, dewars, sensors, and alarms, and the maintenance of records documenting these activities;

5. The L-ESF's policies concerning disposition of stored reproductive tissue in the event of:

i. The L-ESF's inability to communicate with a client or intended recipient;

ii. An emergency, natural disaster, or other occurrence that renders the reproductive tissue nonviable for reproductive purposes;

iii. Divorce, dissolution of relationship, or the inability of all individuals having a legal interest in the reproductive tissue to agree on disposition;

iv. Death or incapacity of the client or intended recipient;

v. Contracted duration of storage has been surpassed or storage fees have not been paid; and

vi. Cessation of the L-ESF's operations for any reason;

6. Emergency preparedness and recovery including the operational standards set forth at N.J.A.C. 8:77-4.5;

7. Quality control and management including the standards set forth at N.J.A.C. 8:77-4.6;

8. Recordkeeping, including the standards set forth at N.J.A.C. 8:77-3.2; and

9. Informed consent of the client and, if known, the intended recipient for all services to be provided to that client or intended recipient by the embryo storage facility.

8:77-3.2 Maintenance of records

(a) In accordance with the policies and procedures that an L-ESF establishes pursuant to N.J.A.C. 8:77-3.1, an L-ESF shall maintain records relating to the individuals from whom reproductive tissue is received, its performance of procedures on the reproductive tissue, including cryopreservation and storage, and the ultimate disposition of the reproductive tissue, including, at a minimum, the following:

1. An acquisition log or other similar record indicating, at a minimum, the following information, with the author of each entry identified:

i. The client's unique identifying code or number;

ii. The unique identifying code(s) or number(s) corresponding to the specific reproductive tissue;

iii. Confirmation of the client's written informed consent for all services provided to that client by the L-ESF;

iv. The date of accession of the reproductive tissue by the L-ESF;

v. Confirmation of positive identification of reproductive tissue at each step in the facility's handling;

vi. The specific location within the facility where the reproductive tissue is stored;

vii. The specific location within the storage tank or chamber where the reproductive tissue is stored; and

viii. The name and address of the facility or physician that will be utilizing the oocyte or embryo for ART, if known;

2. A disposition log or other similar record indicating for each reproductive tissue:

i. The proper identification of the reproductive tissue;

ii. The name of the facility and physician who will ultimately receive the reproductive tissue for use in ART;

iii. The date and method of transport of the reproductive tissue to that facility and physician;

iv. The intended recipient's name, if the name has been provided to the L-ESF, or the intended recipient's identification code, if known;

v. The date and method of disposition of any reproductive tissue stored by the L-ESF, and documentation of consent obtained; and

vi. The date, destination, and method of transport of any reproductive tissue that is transported to another facility for purposes of storage;

3. Individual files with respect to each reproductive tissue, to include, as applicable:

i. The name of the client or the client’s unique identifying number;

ii. The unique identifying number of the particular reproductive tissue;

iii. The name of the physician who performed retrieval of the oocytes and the facility name and contact information, if known;

iv. The name of the technical staff that manipulated the reproductive tissue in any way;

v. The name of the intended recipient, if known;

vi. The date of accession by the L-ESF;

vii. The anticipated duration of storage pursuant to written agreement with the client;

viii. The ultimate disposition; and

ix. Any comments deemed relevant by technical staff of the facility; and

4. Records that demonstrate positive identification of the reproductive tissue has been verified at each stage in the L-ESF’s handling of the reproductive tissue, from receipt to disposition, by either:

i. Separate confirmation of proper identification of the reproductive tissue at each stage by a second member of staff; or

ii. An implemented plan or system that reduces the risk of misidentification of reproductive tissue by staff.

(b) An L-ESF shall not disclose or release the following to any person or entity, except upon the written consent of the individual who is the subject of the information, to authorized employees of the Department, or as permitted by law:

1. The client's name, address, and any other information that would directly or indirectly identify the client; and

2. The intended recipient's name, address, and any other information that would directly or indirectly identify the intended recipient.

(c) An L-ESF shall keep records relating to specific reproductive tissue for no less than 10 years after release for use in ART.

(d) An L-ESF shall keep all other (quality control and equipment, maintenance, staff training) records on site for no less than two years.

(e) An L-ESF shall maintain a duplicate set of all records required pursuant to (a) above, shall store this set of records separately from the original records, and shall make this set of records accessible to staff at all times.

(f) An L-ESF shall ensure that its records are open to inspection by the Department.

8:77-3.3 Reportable events

(a) An L-ESF shall notify the BCP, in writing, through the ALIS portal, or by electronic mail, within seven business days of its discovery of:

1. An error or incident, including human error, that occurs in the course of the L-ESF’s manipulation, handling, cryopreservation, or storage of reproductive tissue that could negatively impact the viability, safety, or future use of the reproductive tissue.

i. The notice of error or incident shall identify the circumstances, the quantity of reproductive tissue affected, the actions the ESF is undertaking to address the error or incident, and any other notifications made concerning the failure, if applicable;

2. The occurrence of an event that impacts the premises or operational continuity of the L-ESF, including, but not limited to, fire, flood, outbreak of illness, HVAC failure, or utility outage.

i. The L-ESF shall include in the notice of the event it issues pursuant to this paragraph, a description of the event, whether the Emergency Preparedness and Recovery Plan required pursuant to N.J.A.C. 8:77-4.5 was implemented in response, the actions the L-ESF is undertaking to address or remediate the event, and, if applicable, any other notifications made concerning the event; and

3. The failure, for any reason, of any equipment that is critical in cryopreserving or storing reproductive tissue or in ensuring the safety of staff.

i. The notice of failure shall identify the specific equipment involved, the duration of the failure, the actions the ESF is undertaking to remediate the failure, and, if applicable, any other notifications made concerning the failure.

SUBCHAPTER 4. OPERATIONAL STANDARDS

8:77-4.1 Operational standards

(a) An L-ESF shall, to the extent applicable to its operations, and not in conflict with standards of the accrediting body, comply with the operational standards detailed in this subchapter.

(b) Nothing in this subchapter shall be construed to limit the ability of an L-ESF to establish operational standards that are more stringent than those set forth in this subchapter.

8:77-4.2 Personnel

(a) An L-ESF that is a laboratory shall comply with the personnel recommendations set forth in "Guidelines for Labs," specifically Table 1, Recommended staff according to volume of laboratory cycles at p. S46 in the Published Professional Guidance.

(b) An L-ESF that is the office of a licensed healthcare provider shall comply with the personnel standards set forth in “Minimum Standards for ART Practices” in the Published Professional Guidance.

8:77-4.3 Safety and adequacy of physical plant

(a) The premises of an L-ESF shall:

1. Be maintained in a clean and orderly manner;

2. Be of suitable size, construction, and design to facilitate maintenance, repair, and sanitary operations;

3. Provide sufficient space for the safe placement of all equipment and for its use by staff, and storage of all required materials, as well as sufficient back-up supplies and equipment;

4. Include heating, ventilation, and air conditioning systems that:

i. Are appropriate for the services provided and equipment used; and

ii. Are regularly maintained according to the manufacturer's recommendations;

5. Be configured, when possible, so that rooms used for storage of reproductive tissue are situated on the premises, so as to:

i. Prevent unauthorized access;

ii. Facilitate the delivery of liquid nitrogen (LN_2) supplies;

iii. Facilitate the removal of cryostorage tanks or other equipment used for storage in the event of an emergency; and

iv. Allow visual surveillance and monitoring of the equipment used in the room through glass windows or doors;

6. Be equipped with a back-up power system; and

7. Maintain an alarmed oxygen sensor in each room in which LN_2 is used.

8:77-4.4 Safety, functionality, and maintenance of equipment

(a) An L-ESF shall ensure that:

1. All equipment and instrumentation used in cryostorage is used in compliance with the manufacturer's recommendations, including with regard to maintenance, lifespan, and monitoring;

2. Oxygen sensors are regularly monitored, and periodically inspected, and their alarms tested, consistent with the manufacturer's recommendations;

3. Remote alarm systems for cryostorage are installed, utilized, maintained, and regularly tested; and

4. An L-ESF that is a laboratory shall adhere to the minimum requirements for best practices in “Cryostorage in IVF Labs” in the Published Professional Guidance.

8:77-4.5 Emergency preparedness and recovery

(a) An ESF shall develop and document, in writing, and review and update, as necessary, but no less frequently than annually, an Emergency Preparedness and Recovery Plan, which shall set forth the actions to be taken to prepare for and respond to an emergency or natural disaster, as well as the actions to be taken following an emergency or natural disaster in order to return to normal operations.

(b) The Emergency Preparedness and Recovery Plan shall be informed by the elements and resources described in “Emergency Plan for IVF Programs” in the Published Professional Guidance, and shall, at a minimum, include:

1. A systematic enterprise-wide assessment of all possible risks to operations, staff, and the facility that an emergency or natural disaster presents, and the actions necessary to mitigate the risks and recover from the emergency or natural disaster;

2. An outline of actions to be taken by staff according to the designated role or title to address those risks in advance of an emergency or natural disaster, when practicable;

3. A communication plan, such as a call tree, to allow for communications between staff, administration, clients, emergency services, and other contacts during the emergency or natural disaster;

4. An evacuation plan to ensure the safety of all staff, clients, and visitors;

5. A plan to ensure the safety, integrity, and maintenance of constant temperature of stored reproductive tissue, including sufficient back-up supplies and storage capacity, which addresses how storage equipment may be relocated to an appropriate off-site location, when deemed necessary, pursuant to the assessment required at (b)1 above; and

6. A recovery plan that outlines actions to be taken by staff according to a designated role or title after the emergency or natural disaster in order to return to

normal operations, as deemed necessary, pursuant to the assessment required at (b)1 above, and which prioritizes the restoration of critical equipment and systems, assesses all damage sustained, confirms the integrity of reproductive tissue, and ensures that the premises are safe for the return of staff, clients, and visitors.

(c) An L-ESF shall provide training to each staff member concerning that individual's assigned responsibilities in the event of an emergency or natural disaster.

(d) An L-ESF shall periodically conduct drills to ensure staff are familiar with the actions to be taken in advance of, during, and following an emergency or natural disaster.

8:77-4.6 Quality management

(a) An L-ESF shall develop, document, implement, and maintain a quality management program that is informed by those elements of the International Organization for Standardization (ISO) ISO 9001 and 20387 that are applicable given the operations of the facility, its personnel, resources, and, as appropriate, to the particular activities of an ESF, and the practices described in "QM for ART Labs" in the Published Professional Guidance.

(b) The quality management program shall be an integrated process-focused system of activities to ensure the consistent quality and suitability of the reproductive tissue for its intended use in ART and the reliability and accuracy of associated data that addresses each stage of the ESF's handling of the reproductive tissue, and shall, at a minimum, include the following:

1. An assessment of all risks that could impact the reproductive tissue or any process or manipulation to which it is subject;

2. Identification of essential criteria or specifications that must be met to ensure consistent outcomes or results;

3. Specification of the appropriate quality control activities, and interval or frequency, needed to:

i. Address the risks identified at (b)1 above; and

ii. Ensure that essential criteria and specifications identified at (b)2 above are consistently met;

4. Documentation of results obtained from implementing the quality control activities;

5. Analysis of the results obtained from implementing the quality control activities, including any limitations, and aggravating or mitigating factors, identification of any nonconforming output, and corrective and/or preventive actions that could be implemented to address problems;

6. Implementation of corrective and preventive action to be taken to address problems, results, and/or nonconforming output;

7. Documentation of the results and efficacy of corrective action taken; and

8. A process or means by which individual staff may raise any quality concerns to management to be addressed in the quality management program.

(c) The L-ESF shall annually assess the results of the quality management activities set forth at (b) above, the impact of any deviations or failures, and determine whether the scope of the quality management system is sufficient, or whether additional internal audits are needed.

8:77-4.7 Required disclosures

The L-ESF shall disseminate, in writing, to its clients, its policies regarding disposition of reproductive tissue in certain circumstances, as required pursuant to N.J.A.C. 8:77-3.1(c)5 as part of obtaining the client's informed consent.

SUBCHAPTER 5. ENFORCEMENT ACTIONS AND HEARINGS

8:77-5.1 Enforcement actions

(a) The Department may suspend or revoke an L-ESF's license, curtail an L-ESF from commencing new storage or cryopreservation activities, issue to an L-ESF a formal written warning, and/or refuse to issue a license to an ESF or renew an L-ESF's license, for violation(s) of any portion of the Act or this chapter, and/or for good cause, including:

1. Demonstrated inability to consistently provide ESF services in a manner that ensures the health and safety of staff, clients, and visitors and the integrity and viability of reproductive tissue;

2. Unauthorized disclosure of confidential client or intended recipient information;

3. Willful preparation of false or fraudulent records, or the inducement of others to do so;

4. Destruction of records that the Act and this chapter require an L-ESF to maintain;

5. Willful obstruction of any inspection or investigation by the Department; and/or

6. When the continued licensure of the L-ESF poses a threat to public health, safety, or welfare.

(b) Any actions taken pursuant to this subchapter shall be separate from any civil, criminal, or other judicial proceeding, including actions against licenses of health care professionals issued by other departments or boards, and criminal proceedings pursuant to N.J.S.A. 26:2A-31.

1. All matters of professional misconduct shall be referred to the appropriate licensing boards, and all matters of a criminal nature shall be forwarded to the appropriate authorities for disposition.

2. Action taken against an L-ESF does not preclude any action that may be taken against a licensed health care professional for the same infraction.

8:77-5.2 Hearings

(a) If the Department issues a notice in which it suspends or revokes an L-ESF's license, curtails an L-ESF from commencing new storage or cryopreservation, and/or refuses to issue a license to an ESF or renew an L-ESF's license then, if the ESF or L-ESF chooses to contest the Department's action, the ESF or L-ESF may request a hearing by submitting a written request setting forth a response to the charges included in the notice to the attention of the Office of Legal and Regulatory Compliance, NJ Department of Health, PO Box 360, Trenton, NJ 08652-0360, within 30 days of the date of the notice of suspension, revocation, curtailment, or refusal to issue or renew the license.

1. The suspension, revocation, or refusal to renew a license shall be held in abeyance until the hearing has been concluded and a final decision has been rendered.

2. Refusals to issue a license and curtailments are effective immediately.

3. Failure to submit a written request for a hearing within 30 days of the date of the notice of suspension, revocation, curtailment, or refusal to issue a license to an ESF or to renew an L-ESF's license shall result in the ESF or L-ESF forfeiting all rights to a hearing and rendering the Department's action a final agency decision.

4. A notice of curtailment may be lifted after the Department conducts an inspection and finds that the facility has achieved substantial compliance with the Act and this chapter and there is no immediate and/or serious threat to the safety of staff, clients, and visitors or to the quality, integrity, and viability of reproductive tissue and the interest therein by intended recipients.

(b) All hearings shall be conducted in accordance with the New Jersey Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the New Jersey Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(c) All enforcement actions shall be posted on the Department's website at https://www.nj.gov/health/phel/clinical-lab-imp-services/enforcement_actions.

APPENDIX

New Jersey Department of Health
Clinical Laboratory Improvement Services
Biobanking Compliance Program

INSTRUCTIONS FOR COMPLETION OF APPLICATION FOR LICENSURE OF AN EMBRYO STORAGE FACILITY

Following are instructions for completion of an application for licensure of an embryo storage facility (ESF), pursuant to N.J.S.A. 26:2A-23, et seq., and N.J.A.C. 8:77.

The application form must be completed in full and returned with requested attachment and the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the ***"Treasurer, State of NJ"*** and include the embryo storage facility code (if available). You may also make your payment using the electronic payment link on the Clinical Laboratory Improvement Services website (https://www.nj.gov/health/phel/clinical-lab-imp-services/). Please include a copy of the Department of Health Payment Confirmation with the application.

The completed application for licensure and all requested attachments should be mailed to:

Regular Mail (US Postal Service)

Biobanking Compliance Program
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
PO Box 361
Trenton, NJ 08625-0361

Overnight Delivery (FedEx, UPS)

Biobanking Compliance Program
PHEL/Clinical Laboratory Improvement Services
Public Health, Environmental and Agricultural Laboratory
New Jersey Department of Health
3 Schwarzkopf Drive
Ewing, NJ 08628-1620

LICENSURE

An applicant for initial, or renewal of, licensure to operate an ESF must complete this form, attach all requested documentation, and submit the application, and the requisite fee, to the appropriate address above.

Upon approving an application, the Department will issue a License.
A License is not transferable.

New Jersey Department of Health
Clinical Laboratory Improvement Services
Biobanking Compliance Program

APPLICATION FOR LICENSURE OF AN EMBRYO STORAGE FACILITY

FOR NJDOH USE ONLY			
Date Mailed	Date Received	Approved Denied Other: _____	
Received By	Check Number	Amount	Check Date

I. APPLICATION

Type of Application

Initial Licensure
Renewal of Licensure | Provide existing ESF Code: _____
Provisional Licensure

II. ESF AND OPERATOR INFORMATION

Name of ESF	Name of Applicant ESF Owner ESF Operator
Mailing Address of ESF	Mailing Address of Applicant
Physical Address of ESF	Name and Address of Registered Agent for Service of Process or other entity authorized to receive official notices on behalf of the ESF
Telephone Number of ESF	Telephone Number of Applicant
ESF Email Address	Email Address of Applicant
Website	

Is the applicant/ESF the office of a licensed health care provider that stores fresh human eggs or embryos on a temporary basis for use in assisted reproduction on the same premises?

Yes No

Has applicant been convicted of a crime? If yes, please state the jurisdiction and approximate date of conviction:

III. OWNERSHIP AND ORGANIZATIONAL STRUCTURE

Check all that apply

Reproductive Laboratory IVF Facility Hospital Medical Practice

Individual or Sole Proprietorship

If doing business or trading under another name, state the name: _____

Partnership: Attached sheet listing names, addresses, and telephone numbers of each partner, and respective ownership share of each.

LLC: Attach a sheet listing names, addresses, and telephone numbers of each member, and respective ownership share of each.

Corporation: State of Incorporation (Attach copy of Articles of Incorporation): _____

Other: _____

Name and title of Administrator at ESF who is responsible for operations and is on site full time	
Telephone Number	Email Address
Name and title of another individual at ESF who is a designated contact to communicate with NJDOH	
List name, address, telephone number of any other ESF that is owned or operated by the applicant or a parent or subsidiary of the applicant in any jurisdiction:	
ESF Name	Telephone Number
Address	Email Address
Website	
ESF Name	Telephone Number
Address	Email Address
Website	

IV. ESF MEDICAL DIRECTOR, LABORATORY DIRECTOR, OR PHYSICIAN (IF MEDICAL PRACTICE)	
Name and title of ESF Medical Director, Laboratory Director, or Physician	
Telephone Number	Email Address
Medical License Number	Date Issued
Bioanalytical Laboratory Director License	Date Issued
Please provide photocopy of each of the above licenses, as applicable, and submit with application.	
CLIA Number (if applicable)	NJDOH Clinical Laboratory License (if applicable)
Description of activities performed at facility with respect to human eggs and/ or embryos	

V. ACCREDITING ORGANIZATION

Is the applicant or L-ESF accredited by CAP or Joint Commission

Yes, please attach a copy of the certificate of accreditation with current seal.

No

I, the undersigned, certify that the statements made herein are true and accurate. I am aware that if any of the statements made herein are willfully false, I am subject to punishment.

Signature of Applicant/ ESF Owner or Operator	Date

VI. REQUIRED DOCUMENT CHECKLIST

(please attach copies of requested documents; original documents will not be returned):

ALL APPLICATIONS (Initial and Renewal):

Requisite Fee: Check or money order payable to "Treasurer, State of NJ," or electronic payment at https://www.nj.gov/health/phel/clinical-lab-imp-services (if electronic payment, please attach copy of the Department of Health Payment Confirmation with this application)

INITIAL LICENSURE:

ALL APPLICANTS:

- Copy of applicant's current Certification of Accreditation issued by the accrediting body (unless a licensed health care provider that stores fresh reproductive tissue temporarily for use in ART on site)
- Copy of the Certificate of Occupancy issued by the municipality for premises, if applicable
- Copy of the applicant's lease or deed to the premises
- Evidence of current registration with the FDA as a human cell and tissue establishment, if applicable
- Copy of the Form #483 and Establishment Inspection Report, if any, issued by FDA following its most recent inspection of the applicant as well as documentation of any actions taken or proposed by the applicant in response to Form #483.
- Report of any inspection performed by the jurisdiction in which the ESF is located for each ESF that the applicant and/or a subsidiary or parent of the applicant owns or operates in New Jersey or another jurisdiction during the 10 years preceding this application for initial licensure.

RENEWAL OF LICENSURE

- Copy of applicant's current Certification of Accreditation issued by the accrediting body (unless a licensed health care provider that stores fresh / wet reproductive tissue temporarily for use in ART on site)
- Evidence of current registration with the FDA as a human cell and tissue establishment, if applicable
- Copy of the Form #483 and Establishment Inspection Report, if any, issued by FDA following its most recent inspection of the applicant, if inspected by FDA in the period since current license was issued, as well as documentation of any actions taken or proposed by the applicant in response to Form #483.

Number of additional pages attached: _____