CHAPTER He-P 800 RESIDENTIAL CARE AND HEALTH FACILITY RULES

Statutory Authority: RSA 151:9

Readopt with amendment He-P 808, effective 2-2-13 (Document #10267), to read as follows:

PART He-P 808 LABORATORIES AND LABORATORY SERVICES RULES

He-P 808.01 Purpose. The purpose of this part is to set forth the licensing requirements for all laboratories, whether stationary or mobile, and laboratory services pursuant to RSA 151:2, I(c).

He-P 808.02 Scope. This part shall apply to any individual, agency, partnership, corporation, government entity, association, or other legal entity operating a laboratory, except:

(a) The facilities listed in RSA 151:2, II (a)-(i);

(b) All entities which are owned or operated by the state of New Hampshire, pursuant to RSA 151:2, II(i);

(c) All laboratories which conduct testing solely for forensic purposes, pursuant to RSA 151:2, II(i);

(d) All entities that are licensed in accordance with RSA 153-A by the department of safety as providers of transporting or non-transporting emergency medical care;

(e) All entities that perform waived testing for the sole purpose of risk assessment and which test results are not used for the diagnosis or treatment of disease;

(f) Laboratories that are duly licensed by the state of New Hampshire under this rule shall not be required to be licensed as a collection station under He-P 817, to perform the functions of a collection station; and

(g) Laboratories that are owned, operated, and located on the licensed premises of a hospital licensed in accordance with RSA 151:2, I(a) and He-P 802.

He-P 808.03 Definitions.

(a) "Administrator" means the licensee or an individual appointed by the licensee who has responsibility for all aspects of the daily operations of the laboratory.

(b) "Applicant" means an individual, agency, partnership, corporation, government entity, association, or other legal entity seeking a license for a laboratory pursuant to RSA 151:2, I(c).

(c) "Area of non-compliance" means any action, failure to act, or other set of circumstances that cause a licensee to be out of compliance with RSA 151, He-P 808, or other federal or state requirements.

(d) "Change of ownership" means the transfer in the controlling interest of an established laboratory to any individual, agency, partnership, corporation, government entity, association, or other legal entity.

(e) "Clinical laboratory improvement amendments (CLIA)" means the requirements outlined at 42 CFR Part 493 which set forth the conditions that all laboratories need to meet to be certified to perform testing on human specimens.

(f) "Patient" means any person receiving services from a laboratory licensed in accordance with RSA 151 and He-P 808.

(g) “Patient record” means a separate file maintained for each patient, which includes all documentation required by RSA 151 and He-P 808, and as required by federal and state law.

(h) “Commissioner” means the commissioner of the department of health and human services or the commissioner’s designee.

(i) “Days” means calendar days unless otherwise specified in the rule.

(j) “Department” means the New Hampshire department of health and human services.

(k) “Directed plan of correction” means a plan developed and written by the department that specifies the necessary actions the licensee must take to correct identified deficiencies.

(l) “Emergency” means an unexpected occurrence or set of circumstances, which requires immediate, remedial attention.

(m) “Emergency plan” means a document outlining the responsibilities of personnel in an emergency.

(n) “Enforcement action” means the imposition of an administrative fine, the denial of an application, or the revocation or suspension of a license in response to non-compliance with RSA 151 or He-P 808.

(o) “Facility” means ”facility” as defined in RSA 151:19, II.

(p) “Incident command system (ICS)” means a standardized on-scene emergency management system specifically designed to provide for the adoption of an integrated organizational structure that reflects the complexity and demands of single or multiple incidents, without being hindered by jurisdictional boundaries. ICS is the combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure, designed to aid in the management of resources during incidents.

(q) “Independent contractor” means an individual or business entity working under the supervision of the licensee but not employed by the licensee.

(r) “Infectious waste” means those items specified by Env-Sw 904.

(s) “Inspection” means the process followed by the department to determine an applicant or a licensee's compliance with RSA 151 and He-P 808 or to respond to allegations, pursuant to RSA 151:6, of non-compliance with RSA 151 and He-P 808.

(t) “Laboratory” means any building, place, or mobile laboratory van, for the biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease.

(u) “Laboratory director” means the person who shall provide overall management and direction for all laboratory testing procedures.

(v) “License” means the document issued to an applicant or licensee of a laboratory which authorizes operation, in accordance with RSA 151 and He-P 808, and includes the name of the licensee, the name of the business, the physical address, the license category, the effective date, and the license number.

(w) “License certificate” means the document issued by the department to an applicant or licensee that, in addition to the information contained on a license, includes the name of the administrator and the type(s) of services authorized that the laboratory is licensed for.

(x) “Licensed premises” means the building(s), other structure(s), or mobile laboratory vans, that comprises the physical location the department has approved for the licensee to conduct operations in accordance with its license. It does not include the private residence of a patient receiving services from an agency licensed under the authority of RSA 151.

(y) “Licensee” means any individual, agency, partnership, corporation, federal, state, county or local government entity, association, or other legal entity to which a license has been issued pursuant to RSA 151.

(z) “Licensing classification” means the specific category of services authorized by a license.

(aa) “Life safety code” means the adoption by reference of the life safety code, as published by the National Fire Protection Association and as amended by the state board of fire control and ratified by the general court pursuant to RSA 153:5.

(ab) “Mobile laboratory van” means a vehicle capable of traveling under its own power or being towed from site to site and fully equipped to meet all the requirements specified in section He-P 808.21.

(ac) “Modification” means the reconfiguration of any space, the addition, relocation, or elimination of any door or window, the addition or elimination of load-bearing elements, the reconfiguration or extension of any system, or the installation of any additional equipment. The term does not include “repair” or “replacement” of interior finishes.

(ad) “Owner” means any person, corporation, association, or any other legal entity, whether organized for profit or not, holding or claiming ownership of, or title to, a license.

(ae) “Patient rights” means the privileges and responsibilities possessed by each patient provided by RSA 151:21.

(af) “Personnel” means an individual who is employed by the licensee, a volunteer, or an independent contractor.

(ag) “Plan of correction (POC)” means a plan developed and written by the licensee, which specifies the actions that will be taken to correct areas of non-compliance with applicable rules or codes identified at the time of the clinical or life safety inspection conducted pursuant to RSA 151:6-a or during the course of complaint investigation conducted pursuant to RSA 151:6.

(ah) “Procedure” means a licensee's written, standardized method of performing duties and providing services.

(ai) “Qualification” means education, experience, and skill requirements specified by the federal government, state government, an accredited professional review agency, or by policy of the licensee.

(aj) “State building code” means “state building code” as defined in RSA 155-A:1, IV.

(ak) “State fire code” means “state fire code” as defined in RSA 153:1.

(al) “State monitoring” means the placement of individuals by the department at a laboratory to monitor the operation and conditions of the facility.

(am) "Specimen" means a portion of tissue, body fluid, or material from a human body.

(an) "Technical consultant" means an individual qualified as a technical consultant by 42 CFR § 493.1411.

(ao) "Volunteer" means an unpaid person who assists with the provision of laboratory services, and who does not provide direct care or services to patients.

(ap) "Waived testing" means all laboratory tests categorized as waived by 42 CFR § 493.

(aq) "Waiver" means a request for an alternative means of satisfying a rule requirement in He-P 808.

He-P 808.04 License Application Requirements.

(a) Each applicant for a license shall comply with the requirements of RSA 151:4, I-III-a, and submit the following to the department, except that subparagraphs (a)(1)-(3) and (5)-(7) shall not apply to mobile laboratory vans:

(1) A completed application form entitled "Application for Residential and or Health Care License (Laboratories and Collecting Stations)," (July 2023 edition) signed by the owner if a private facility, 2 officers if a corporation, 2 authorized individuals if an association or partnership, or the head of the government department if a government unit, affirming to the following:

"I affirm that I am familiar with the requirements of RSA 151 and the rules adopted thereunder and that the premises are in full compliance. I understand that providing false information shall be grounds for denial, suspension, or revocation of a license, or imposition of a fine.";

(2) A floor plan of the prospective laboratory;

(3) If applicable, proof of authorization from the New Hampshire secretary of state to do business in the state of New Hampshire in the form of one of the following:

a. "Certificate of Authority," if a corporation;

b. "Certificate of Formation," if a limited liability company; or

c. "Certificate of Trade Name," if a sole proprietorship;

(4) The applicable fee in accordance with RSA 151:5, XXIII, payable in cash, or if paid by check or money order, in the exact amount of the fee and made payable to the "Treasurer, State of New Hampshire";

(5) A resume identifying the qualifications, and copies of applicable licenses, for the administrator and laboratory director;

(6) Written local approvals as follows:

a. For an existing building, the following written local approvals shall be obtained no more than 90 days prior to submission of the application, from the following local officials, or if there is no such official(s), from the board of selectmen or mayor:

1. The health officer verifying that the applicant complies with all applicable local health requirements and drinking water and wastewater requirements;

2. The building official verifying that the applicant complies with all state building codes and local building ordinances;

3. The zoning officer verifying that the applicant complies with all applicable local zoning ordinances; and

4. The fire chief verifying that the applicant complies with the state fire code and any local ordinances; and

b. For a building under construction, the written approvals required by a. above shall be submitted at the time of the application based on the local official's review of the building plans and again upon completion of the construction project;

(7) If the laboratory uses a private water supply, documentation that the water supply has been tested in accordance with RSA 485 and Env-Dw 702.02, Env-Dw 704.02, or, if a public water supply is used, a copy of a water bill;

(8) The results of a criminal records check for the applicant, the licensee, if different than the applicant, the laboratory director, and the administrator, as applicable. The results must include criminal history from the state of New Hampshire; and

(9) List of all tests performed and a copy of the CLIA certificate.

(b) The applicant shall mail or hand deliver the documents to:

Department of Health and Human Services
Health Facilities Administration
129 Pleasant Street
Concord, NH 03301

He-P 808.05 Processing of Applications and Issuance of Licenses.

(a) An application for an initial license shall be complete when the department determines that all items required by He-P 808.04(a), or He-P 808.21 for mobile laboratory vans, have been received.

(b) If an application does not contain all of the items required by He-P 808.04(a) or He-P 808.21, the department shall notify the applicant in writing of the items required before the application can be processed.

(c) Any licensing fee submitted to the department in the form of a check or money order and returned to the state for any reason, shall be processed in accordance with RSA 6:11-a.

(d) Licensing fees shall not be transferable to any other application(s).

(e) Unless a waiver has been granted under He-P 808.17(f), the department shall deny a license request if it determined that the applicant, licensee, or administrator:

(1) Has been convicted of any felony in this or any other state;

(2) Has been convicted of a sexual assault, other violent crime, assault, theft, fraud, abuse, neglect, or exploitation;

(3) Has had a finding by the department or any administrative agency in this or any other state for assault, theft, fraud, abuse, neglect, or exploitation of any person; or

(4) Otherwise poses a threat to the health, safety, or well-being of patients.

(f) Following an inspection, a license shall be issued if the department determines that an applicant requesting such initial license is in full compliance with RSA 151 and He-P 808.

(g) All licenses issued in accordance with RSA 151 shall be non-transferable, including licenses issued for mobile laboratory vans.

(h) A written notification of denial, pursuant to He-P 808.13(b), shall be sent to an applicant applying for an initial license if it has been determined by the inspection in He-P 808.05(f) and a maximum of 2 follow-up inspections that the prospective premises are not in full compliance with RSA 151 and He-P 808.

(i) A written notification of denial, pursuant to He-P 808.13(b)(4), shall be sent to an applicant applying for an initial license if the department has received no communication from the applicant within 3 months of sending written notification to the applicant that their application is complete and an inspection needs to be scheduled.

He-P 808.06 License Expirations and Procedures for Renewal.

(a) A license shall be valid on the date of issuance and expire one year from the date of issuance, unless a completed application for renewal has been received.

(b) Each licensee shall complete and submit to the department an "Application for Residential and or Health Care License (Laboratories and Collection Stations)" (July 2023 edition) pursuant to He-P 808.04(a)(1) at least 120 days prior to the expiration of the current license and include with the application:

(1) The current license number;

(2) A request for renewal of any existing non-permanent waiver previously granted by the department, in accordance with He-P 808.10(f). If such a request is not received, the rule(s) for which the waiver was previously requested shall not continue to be waived beyond the expiration of the current license;

(3) A list of any current employees who have a permanent waiver granted in accordance with He-P 808.17(f):

(4) A copy of any temporary, new, or existing variances or waivers applied for or granted by the state fire marshal; and

(5) A list of all tests performed and a copy of the CLIA certificate.

(c) In addition to He-P 808.06(b), if a private water supply is used, the licensee shall provide documentation that every 3 years the water supply has been tested for bacteria and nitrates and determined to be at acceptable levels, in accordance with Env-Dw 702 for bacteria and Env-Dw 704.02 for nitrates.

(d) Following an inspection, a license shall be renewed if the department determines that the licensee:

(1) Submitted an application containing all of the items required by He-P 808.06(b) and (c), as applicable, prior to the expiration of the current license; and

(2) Is found to be in compliance with RSA 151 and He-P 808, and all the federal requirements at the renewal inspections, or has submitted a POC that has been accepted by the department and implemented by the licensee if the area of non-compliance were cited.

He-P 808.07 Laboratory Construction, Modifications, or Structural Alterations.

(a) For new construction and for rehabilitation of an existing building including, but not limited to, renovations, modifications, reconstructions, and additions, construction documents and shop drawings, including architectural, sprinkler, and fire alarm plans, shall be submitted to the department at least 60 days prior to the start of such work.

(b) The architectural, sprinkler, and fire alarm plans in (a) above shall accurately show the room designation(s) and exact measurements of each area to be licensed including, but not limited to, window and door sizes and each room's use.

(c) Architectural, sprinkler, and fire alarm plans shall be submitted to the state fire marshal's office as required by RSA 153:10-b, V.

(d) Any licensee or applicant who wants to use performance-based design to meet the fire safety requirements shall provide the department with documentation of fire marshal approval for such methods.

(e) The department shall review construction documents, drawings, and plans of a newly proposed or existing facility for compliance with all applicable sections of RSA 151 and He-P 808 and shall notify the applicant or licensee as to whether the proposal complies with these requirements.

(f) The licensee or applicant shall comply with all applicable state laws, rules, and local ordinances when undertaking any construction or rehabilitation.

(g) A licensee or applicant undertaking construction, repairs, renovations, rehabilitation, or modifications of a building shall comply with the appropriate chapters and sections of the State Fire Code and State Building Code.

(h) Department approval shall not be required prior to initiating construction, repairs, renovations, rehabilitation, or modifications of a building, however an applicant or licensee who proceeds prior to receiving approval shall do so at their own risk.

(i) All laboratories newly constructed or rehabilitated shall comply with the Facility Guidelines Institute (FGI) "Guidelines for Design and Construction of Outpatient Facilities," (2022 edition), available as noted in Appendix A.

(j) Where rehabilitation is done within an existing facility, all such work shall comply with applicable sections of the FGI "Guidelines for Design and Construction of Outpatient Facilities" (2022 edition), available as noted in Appendix A.

(k) The department shall be the authority having jurisdiction for the requirements in He-P 808.07(i)-(j) above and shall negotiate compliance with the licensee or applicant or their representatives and grant waivers in accordance with He-P 808.10 as appropriate.

(l) Penetrations, holes, or other openings in fire walls, fire partitions, smoke barriers, floors, or ceilings that allow for the transfer of fire, heat, or smoke shall be closed and sealed using a listed or approved fire system that provides an equivalent rating as provided by the original surface.

(m) Waivers granted by the department for construction or rehabilitation under the FGI guidelines above shall not require annual renewal unless the underlying reason or circumstances for the waivers change.

(n) Variances pertaining to the State Fire Code referenced in He-P 808.07(g) above shall be granted only by the state fire marshal.

(o) Variances pertaining to the state building code shall be granted by the local building official or the state fire marshal if in a state owned building.

(p) The building, including all construction and rehabilitated spaces, shall be subject to an inspection pursuant to He-P 808.09 prior to its use.

(q) He-P 808.07 shall not apply to mobile laboratory vans.

He-P 808.08 Laboratory Requirements for Organizational Changes.

(a) The licensee shall provide the department with written notice at least 30 days prior to changes in any of the following:

(1) Ownership;

(2) Physical location;

(3) Address;

(4) Name;

(5) Number of categories authorized under the current license or revisions to the current list of tests performed; or

(6) Services.

(b) The laboratory shall complete and submit a new application form, required by He-P 808.04(a)(1), and obtain a new or revised license, license certificate, or both, as applicable, prior to operating, for:

(1) A change in ownership;

(2) A change in the physical location;

(3) An increase in the number of categories authorized under the current license; or

(4) A change in services.

(c) When there is to be a change of address without a change in location, the laboratory shall provide the department with a copy of the notification from the local, state, or federal agency that requires the address change.

(d) When there is a change in the name, the laboratory shall submit to the department a copy of the certificate of amendment from the New Hampshire secretary of state, if applicable.

(e) An inspection by the department shall be conducted prior to operation for:

(1) Ownership, unless the current licensee is in full compliance, in which case an inspection shall be conducted as soon as practicable by department;

(2) The physical location;

(3) A change in the number of categories authorized under the current license;

(4) A change in licensing classification; or

(5) A change that places the facility under a different life safe code occupancy chapter.

(f) A new license and license certificate shall be issued for a change in ownership, classification, or physical location.

(g) A revised license and license certificate shall be issued for changes in the laboratory name.

(h) A revised license certificate shall be issued for any of the following:

(1) A change of administrator;

(2) A change in categories authorized to test;

(3) A change in address without a change in physical location;

(4) A change in the scope of services provided; or

(5) When a waiver has been granted in accordance with He-P 808.10.

(i) The laboratory shall inform the department, in writing, when there is a change in administrator or laboratory director no later than 5 days prior to a change, or as soon as practicable in the event of a death or other extenuating circumstances requiring an administrator or laboratory director change, and provide the department with the following:

(1) A resume identifying the name and qualifications of the new administrator or laboratory director;

(2) Copies of applicable licenses for the new administrator or laboratory director;

(3) The results of a criminal records check to include results for the state of New Hampshire for the new administrator or laboratory director; and

(4) A copy of the signed criminal attestation, as described in He-P 808.17(j), for the new administrator or laboratory director.

(j) Upon review of the materials submitted in accordance with (i) above, the department shall make a determination as to whether the administrator or laboratory director meets the qualifications for the position as specified in He-P 808.14(e)(6) and He-P 808.14(e)(6).

(k) If the department determines that the new administrator or laboratory director does not meet the qualifications, it shall so notify the program in writing so that a waiver can be sought or the licensee can search for a qualified candidate.

(l) When there is to be a change in the testing provided, the licensee shall provide the department with:

(1) A description of the testing change(s);

(2) Identification of what additional personnel shall be hired and their qualifications, if applicable;

(3) How the new services shall be incorporated into the infection control and quality improvement programs; and

(4) A description of what changes, if any, shall be made to the physical environment.

(m) The department shall review the information submitted under (l) above and determine if the added services shall be provided under the licensee's current license.

(n) The laboratory shall inform the department, in writing via email, fax, or mail, of any change in the e-mail address no later than 10 days of the change. The department shall use email as the primary method of contacting the facility in the event of an emergency.

(o) A restructuring of an established laboratory that does not result in a transfer of the controlling interest of the facility, but which might result in a change in the name of the facility or corporation, shall not constitute a change in ownership and a new license shall not be required.

(p) If a licensee chooses to cease operation of a laboratory, the licensee shall submit written notification to the department at least 60 days in advance which shall include a written closure plan.

He-P 808.09 Inspections.

(a) For the purpose of determining compliance with RSA 151 and He-P 808, as authorized by RSA 151:6 and RSA 151:6-a, the licensee shall admit and allow any department representative at any time to inspect the following:

(1) The licensed premises;

(2) All programs and services provided by the laboratory; and

(3) Any records required by RSA 151 and He-P 808.

(b) The department shall conduct a clinical and life safety inspection, as necessary, to determine full compliance with RSA 151 and He-P 808 prior to:

(1) The issuance of an initial license;

(2) A change in ownership except as allowed by He-P 808.08(e)(1);

(3) A change in the licensee's physical location, except for mobile laboratory vans;

(4) Occupation of space after construction, renovations, or structural alterations;

(5) A change in the licensing classification;

(6) The renewal of a license; or

(7) The issuance of a mobile laboratory van license.

(c) In addition to (b) above, the department shall conduct an inspection to verify the implementation of any POC accepted or issued by the department as part of an annual inspection, or as a follow-up inspection focused on confirming the implementation of a POC.

(d) A statement of findings for clinical inspections or a notice to correct for life safety inspections shall be issued when, as a result of any inspection, the department determines that the licensee is in violation of any of the provisions of He-P 808, RSA 151, or any other federal or state requirement(s).

(e) If areas of non-compliance were cited, in either a notice to correct or a statement of findings, the licensee shall submit a POC, in accordance with He-P 808, within 21 days of the date on the letter.

He-P 808.10 Waivers.

(a) Applicants or licensees seeking waivers of specific rules in He-P 808 shall submit a written request for waiver to the commissioner that includes:

(1) The specific reference to the rule for which a waiver is being sought;

(2) A full explanation of why a waiver is necessary; and

(3) A full explanation of alternatives proposed by the applicant or license holder, which shall be equally as protective of public health and patients as the rule from which a waiver is sought, or provide a reasonable explanation why the applicable rule should be waived.

(b) Waivers granted shall be permanent unless the department specifically places a time limit on the waiver.

(c) A request for waiver shall be granted if the commissioner determines that the reasonable explanation or the alternative proposed by the applicant or licensee:

(1) Meets the objective or intent of the rule;

(2) Does not negatively impact the health, safety, or well-being of the patients; and

(3) Does not negatively affect the quality of patient services.

(d) The licensee's subsequent compliance with the alternatives approved in the waiver shall be considered equivalent to complying with the rule from which waiver was sought.

(e) Waivers shall not be transferable.

(f) When a licensee wishes to renew a non-permanent waiver beyond the approved period of time, the licensee shall apply for a new waiver when submitting a completed renewal application form pursuant to He-P 808.04(a)(1) or at least 60 days prior to the expiration of the existing waiver, as appropriate, by submitting the information required by (a) above.

He-P 808.11 Complaints.

(a) The department shall accept and investigate written complaints that meet the following conditions:

(1) The alleged violation(s) occurred not more than 6 months prior to the date the department was made aware of the allegation(s);

(2) The complaint is based upon the complainant's first-hand knowledge regarding the allegation(s) or on information reported directly to the complainant by a person who has first-hand knowledge regarding the allegation(s); or

(3) There is sufficient, specific information for the department to determine that the allegation(s), if proven to be true, would constitute a violation of any of the provisions of RSA 151, He-P 808, or any other applicable state or federal laws.

(b) When practicable, the complaint shall be in writing and contain the following information:

(1) The name and address, if known, of the laboratory or the alleged unlicensed individual or entity;

(2) The name, address, and telephone number of the complainant; and

(3) A description of the situation that supports the complaint and the alleged violation(s) of RSA 151 or He-P 808.

(c) Investigations shall include all techniques and methods for gathering information which are appropriate to the circumstances of the complaint, including, but not limited to:

(1) Requests for additional information from the complainant or the licensee;

(2) A physical inspection of the premises;

(3) Review of any relevant records; and

(4) Interviews with individuals who might have information that is relevant to the investigation.

(d) For the licensed laboratory, the department shall:

(1) Provide written notification of the results of the investigation to the licensee, along with an inspection report if areas of non-compliance were found as a result of the investigation;

(2) Notify any other federal, state, or local agencies of suspected violations of their statutes or rules based on the results of the investigation as appropriate;

(3) Require the licensee to submit a POC in accordance with He-P 808.12(c), if applicable; and

(4) Notify the licensee, in writing, and take no further action if the department determines that the complaint is unfounded or does not violate any statutes or rules.

(e) The following shall apply for the unlicensed laboratory:

(1) In accordance with RSA 151-7-a, II, the department shall provide written notification to the owner or person responsible that includes:

a. The date of investigation;

b. The reason(s) for, and the results of, the investigation; and

c. Whether or not the investigation resulted in a determination that the services being provided require licensing under RSA 151:2, I(c);

(2) In accordance with RSA 151:7-a, II, the owner or person responsible shall be allowed 7 days from the date of receipt of the notice, required by (e)(1) above, to respond if the determination is that the services require licensing;

(3) If the owner of an unlicensed laboratory does not respond in accordance with (e)(2) above, the department shall issue a written warning to immediately comply with RSA 151 and He-P 808; and

(4) Any person or entity who fails to comply after receiving a warning as described in (e)(3) above shall be subject to an action by the department for injunctive relief under RSA 151:17 and an administrative fine pursuant to He-P 808.

(f) Complaint investigation files shall be confidential in accordance with RSA 151:13, and shall not be disclosed publicly, but shall be released by the department on written request only:

(1) To the department of justice when relevant to a specific investigation;

(2) To law enforcement when relevant to a specific criminal investigation;

(3) When a court of competent jurisdiction orders the department to release such information; or

(4) In connection with any adjudicative proceedings relative to the licensee.

He-P 808.12 Administrative Remedies.

(a) The department shall impose administrative remedies for violations of RSA 151, He-P 808, or other applicable licensing rules, including:

(1) Requiring a licensee to submit a POC in accordance with (c) below;

(2) Imposing a directed POC upon a licensee in accordance with (d) below;

(3) Imposing conditions upon a licensee; or

(4) Monitoring a licensee.

(b) When administrative remedies are imposed, the department shall provide a written notice, as applicable, which:

(1) Identifies each area in which the licensee is not in compliance with RSA 151 or a provision of He-P 808; and

(2) Identifies the specific remedy(s) that has been proposed.

(c) A POC shall be developed and enforced in the following manner:

(1) Upon receipt of a notice of the areas of non-compliance the licensee shall submit a POC detailing:

a. How the licensee intends to correct each area of non-compliance;

b. What measures will be put in place, or what system changes will be made to ensure that the non-compliance does not recur;

c. The date by which each area of non-compliance shall be corrected; and

d. The position of the employee responsible for the corrective action.

(2) The licensee shall submit a POC to the department within 21 days of the date on the letter that transmitted the statement of findings unless the licensee requests, either verbally or in writing, and the department agrees, to extend that deadline, based on the following criteria:

a. The licensee demonstrates that he or she has made a good faith effort, as verified by documentation or other means, to develop and submit the POC within the 21 day period but has been unable to do so; and

b. The department determines that the health, safety, or well-being of a patient will not be jeopardized as a result of granting the extension;

(3) The department shall review each POC and accept each POC that:

a. Achieves compliance with RSA 151 and He-P 808;

b. Addresses all areas of non-compliance as cited in the statement of findings;

c. Prevents a new violation of RSA 151 or He-P 808 as a result of the implementation of the POC; and

d. Specifies the date upon which the areas of non-compliance shall be corrected;

(4) If the POC is acceptable, the department shall issue a license certificate or provide written notification of acceptance of the POC, whichever is applicable;

(5) If the POC is not acceptable, the department shall notify the licensee, in writing, within 14 days of the reason for rejecting the POC;

(6) The licensee shall develop and submit a revised POC within 14 days of the date of the written notification from the department that states the original POC was rejected, unless within the 14 day period the licensee requests an extension, either via telephone or in writing, and the department grants the extension based on the following criteria:

a. The licensee demonstrates that he or she has made a good faith effort, as verified by documentation or other means, to develop and submit the POC within the 14 day period but has been unable to do so; and

b. The department determines that the health, safety, or well-being of a patient will not be jeopardized as a result of granting the extension;

(7) The revised POC shall comply with (c)(1) above and be reviewed in accordance with (c)(3) above;

(8) If the revised POC is not acceptable to the department or is not submitted within 14 days of the date of the written notification from the department that states the original POC was rejected, the licensee shall be subject to a directed POC in accordance with He-P 808.12(d) and a fine in accordance with He-P 808.13(c)(9);

(9) The department shall verify the implementation of any POC that has been submitted and accepted by:

a. Reviewing materials submitted by the licensee;

b. Conducting a follow-up inspection; or

c. Reviewing compliance during the next annual inspection;

(10) Verification of the implementation of any POC shall only occur after the date of completion specified by the licensee in the plan; and

(11) If the POC has not been implemented by the completion, at the time of the next inspection, the licensee shall be:

a. Notified by the department in accordance with He-P 808.12(b); and

b. Issued a directed POC in accordance with He-P 808.12(d).

(d) The department shall develop and impose a directed POC that specifies corrective actions for the applicant or licensee to implement when:

(1) As a result of an inspection, areas of non-compliance were identified that require immediate corrective action to protect the health, safety, and well-being of patients and personnel;

(2) A revised POC is not submitted within 14 days of the written notification from the department or such other date as applicable if an extension was granted by the department; or

(3) A revised POC submitted by the licensee or administrator has not been accepted.

(e) If at the time of the next inspection, the directed POC referenced in (d) above has not been implemented by the completion date stated in the directed POC, the department shall, as appropriate:

(1) Issue a warning that enforcement action will be taken if the POC is not implemented;

(2) Impose a fine;

(3) Deny the application of a license in accordance with He-P 808.13(b); or

(4) Revoke the license in accordance with He-P 808.13(b).

(f) The department shall offer an opportunity for informal dispute resolution to any applicant or licensee who disagrees with an area or areas of non-compliance cited by the department on a statement of findings, provided that the applicant or licensee submits a written request for an informal dispute resolution.

(g) The informal dispute resolution shall be requested in writing by the applicant, licensee, or program director no later than 14 days from the date the statement of findings was issued by the department.

(h) The department shall change the statement of findings if, based on the evidence presented, the statement of findings is determined to be incorrect. The department shall provide written notice to the applicant or licensee of the determination.

(i) The deadline to submit a POC, in accordance with (c) above, shall not apply until the notice of the determination in (h) above has been provided to the applicant or licensee.

(j) Any violations cited for the State Fire Code may be appealed to the New Hampshire state fire marshal and shall not be the subject of informal dispute resolutions as described in this section.

(k) An informal dispute resolution shall not be available for any applicant or licensee against whom the department has imposed a fine or initiated action to suspend, revoke, deny, or refuse to issue or renew a license.

(l) The department shall impose state monitoring under the following conditions:

(1) Repeated non-compliance on the part of the facility in areas that impact health, safety, or well-being of patients; or

(2) The presence of conditions in the laboratory that negatively impact the health, safety, or well-being of patients.

(3) Concern that the facility is not ending the pattern of citations for violations of licensing rules and coming into compliance with those rules; or

(4) Conditions exist for implementation of temporary management as described in (n) below but no temporary manager can be found.

(m) The department shall appoint a temporary manager to assume operation of a laboratory when, following an inspection, the department determines that:

(1) The licensee has repeatedly failed to manage and operate the laboratory in compliance with RSA 151 and He-P 808 and such laboratory practices have adversely impacted the health, safety, or well-being of patients;

(2) The licensee has failed to develop or implement policies and procedures for infection control, sanitation, or life safety codes, which results in imposing harm or the potential for harm to the patients; or

(3) The health, safety, and well-being of the patients are at risk and emergency action is required.

He-P 808.13 Enforcement Actions and Hearings.

(a) Prior to taking enforcement action against an applicant or licensee, the department shall send to the applicant or licensee a written notice that sets forth:

(1) The reasons for the proposed action;

(2) The action to be taken by the department;

(3) If a fine is imposed, the automatic reduction by 25% if the fine is paid within 10 days of the date on the written notice from the department, and the area of non-compliance has been corrected, or a POC has been accepted and approved by the department; and

(4) The right of an applicant or licensee to an administrative hearing in accordance with RSA 151:8 or RSA 541-A:30, II as applicable, before the enforcement action becomes final.

(b) The department shall deny an application or revoke a license if:

(1) An applicant or a licensee has violated provisions of RSA 151 or He-P 808, which violations have the potential to harm a patient's or employee's health, safety, or well-being;

(2) An applicant or a licensee has failed to pay a fine imposed under an enforcement action;

(3) An applicant or a licensee has had a check returned to the department for insufficient funds and has not re-submitted the outstanding fee in the form of cash, money order, or certified check;

(4) After being notified of and given an opportunity to supply missing information, an applicant or licensee fails to submit an application that meets the requirements of He-P 808.04;

(5) An applicant, licensee, or any representative or employee of the applicant or licensee:

a. Provides false information to the department;

b. Prevents, interferes, or fails to cooperate with any inspection or investigation conducted by the department; or

c. Fails to provide requested files or documents to the department;

(6) The licensee failed to implement or continue to implement a POC that has been accepted or imposed by the department in accordance with He-P 808.12(c), (d), and (e);

(7) The licensee has submitted a POC that has not been accepted by the department in accordance with He-P 808.12(c)(6) and has not submitted a revised POC in accordance with He-P 808.12(c)(6)b.;

(8) The licensee is cited a third time under RSA 151 or He-P 808 for the same violation(s) within the last 5 inspections;

(9) A licensee, including corporation or its corporate officers or board members, has had a license revoked and submits an application during the 5-year prohibition period specified in (i) below;

(10) Unless a waiver has been granted, upon inspection, the applicant's premises is not in compliance with RSA 151 or He-P 808;

(11) Unless a waiver has been granted, the department makes a determination that the applicant, administrator, or licensee, has been found guilty of or pled guilty to a felony assault, fraud, theft, abuse, neglect, or exploitation adjudicated and founded by the department or any administrative agency in this or any other state;

(12) Unless a waiver has been granted, the applicant or licensee fails to employ a qualified administrator or laboratory director; or

(13) The applicant has had a license revoked by the department within 5 years prior to the application.

(c) The department shall impose fines as follows:

(1) For failure to cease providing unlicensed services after being notified by the department of the need for a license, in violation of RSA 151:2, the fine shall be $2000 for an applicant or unlicensed provider;

(2) For failure to cease operations after a denial of a license or after receipt of an order to cease and desist, in violation of RSA 151 and RSA 541-A:30 the fine for an unlicensed individual, applicant, unlicensed provider, or a licensee shall be $2000.00;

(3) For advertising services or otherwise representing themselves as having a license to provide services that the licensee is not licensed to provide, in violation of RSA 151:2, III, the fine for an applicant, licensee, or unlicensed individual or a licensee shall be $500.00;

(4) For a failure to comply with the directives of a warning issued by the department, in violation of RSA 151:7-a and He-P 808.11(e), the fine for an unlicensed provider or a licensee shall be $500.00;

(5) For a failure to submit a renewal application prior to the expiration date, in violation of He-P 808.06(b), the fine for a licensee shall be $100.00;

(6) For failure to notify the department prior to a change of ownership, in violation of He-P 808.08(a)(1), the fine for a licensee shall be $500.00;

(7) For failure to notify the department, prior to a change of location, in violation of He-P 808.08(a)(2), the fine for a licensee shall be $500.00;

(8) For a failure to allow access by the department to the laboratory's premises, programs, services, patients, or records, in violation of He-P 808.09(a)(1)-(3), the fine for an applicant, unlicensed individual, or licensee shall be $2000.00;

(9) For failure to submit a POC or revised POC within 21 or 14 days, respectively, of the date on the letter that transmits the inspection report, in violation of He-P 808.12(c)(2) and (6), the fine for a licensee shall be $100.00;

(10) For failure to implement or maintain the corrective action set forth in any POC that has been accepted or issued by the department, in violation of He-P 808.12(c)(9), the fine for a licensee shall be $1000.00;

(11) For a failure to establish, implement, or comply with licensee policies, as required by He-P 808.14(e), the fine for a licensee shall be $500.00;

(12) For a failure to provide services or programs required by the licensing classification and specified by He-P 808.14(d), the fine for a licensee shall be $500.00;

(13) For false or misleading information or misleading information or documentation, in violation of He-P 808.13(b)(5), the fine for an applicant shall be $500.00 per offense;

(14) For employing an administrator or a laboratory director who do not meet the qualifications for the position, without having a waiver granted by the department in accordance with He-P 808.10 in violation of He-P 818.18(h)-(j), the fine for a licensee shall be $500.00;

(15) For failure to submit architectural plans or drawings, when applicable, prior to undertaking construction or renovation of the licensed facility in violation of He-P 808.07(a), the fine for a licensed facility shall be $500.00;

(16) For occupying a renovated area of a licensed facility or a new construction prior to approval by local and state authorities, as required by He-P 808.09(b)(5), the fine shall be

$500.00 which shall be assessed daily if the facility fails to vacate the renovated area immediately upon receiving notice from the department;

(17) When an inspection determines that a violation of RSA 151 or He-P 808 has the potential to jeopardize the health, safety, or well-being of a patient, in addition to any other enforcement actions taken by the department, the fines assessed shall be as follows:

a. If the same deficiency is cited within 2 years of the original deficiency, the fine for a licensee shall be double the original fine, but not to exceed $2000.00; or

b. If the same deficiency is cited a third time within 2 years of being fined in a. above, the fine for a licensee shall be triple the original fine, but not to exceed $2000.00;

(18) Each day that the licensee continues to be in violation of the provisions of RSA 151 or He-P 808 shall constitute a separate violation and shall be fined in accordance with He-P 808.12; and

(19) If the licensee is making good faith efforts, as verified by documentation or other means, to obtain a license in (1) above or comply with warnings in (4) above, the department shall not issue a daily fine.

(d) Payment of any imposed fine to the department shall meet the following requirements:

(1) Payment shall be made in the form of cash, check, or money order for the exact amount due;

(2) Cash, money order, or certified check shall be required when an applicant or licensee has issued payment to the department by check, and such check was returned for insufficient funds; and

(3) When payment is made in a form other than cash, it shall be made payable to the "Treasurer - State of New Hampshire."

(e) An applicant or licensee shall have 30 days after receipt of the notice of enforcement action to request a hearing to contest the action.

(f) If a written request for a hearing is not made pursuant to (e) above, the action of the department shall become final.

(g) The department shall order the immediate suspension of a license and the cessation of operations when it finds that the health, safety, or welfare of patients is in jeopardy and requires emergency action in accordance with RSA 541-A:30, III.

(h) If an immediate suspension is upheld, the licensee shall not resume operating until the department determines through inspection that compliance with RSA 151 and He-P 808 is achieved.

(i) Hearings under this section shall be conducted in accordance with RSA 541-A and He-C 200.

(j) When a laboratory's license has been denied or revoked, the applicant, licensee, administrator, or laboratory director shall not be eligible to reapply for a license or be employed as a laboratory director for 5 years, if the enforcement action pertained to their role in the laboratory.

(k) The 5-year period referenced in (i) above shall begin on:

(1) The date of the department's decision to revoke or deny the license, if no request for an administrative hearing is requested; or

(2) The date a final decision upholding the action of the department is issued, if a request for a hearing is made and a hearing is held.

(l) Notwithstanding (k) above, the department shall consider an application submitted after the decision to revoke or deny becomes final, if the applicant demonstrates that circumstances have changed to the extent that the department now has good cause, as verified by documentation or other means, to believe that the applicant has the requisite degree of knowledge, skills, and resources necessary to maintain compliance with the provisions of RSA 151 and He-P 808.

(m) RSA 541 shall govern further appeals of department decisions under this section.

(n) No ongoing enforcement action shall preclude the imposition of any remedy available to the department under RSA 151, RSA 541-A:30, III, or He-P 808.

He-P 808.14 Duties and Responsibilities of all Licensees.

(a) The licensee shall comply with all applicable federal, state, and local laws, rules, codes, and ordinances.

(b) The licensee shall have a written policy and procedure setting forth the rights of patients in accordance with RSA 151:21.

(c) The licensee shall define, in writing, the scope and type of services to be provided at the laboratory, including mobile laboratory vans.

(d) The licensee shall not falsify or omit any information contained in:

(1) The application in He-P 808.04(a)(1) or any other documents required for the licensing of a laboratory; or

(2) The records maintained for the patients and personnel of the laboratory.

(e) The licensees shall have responsibility and authority for:

(1) Managing, controlling, and operating the laboratory;

(2) Developing and implementing written policies and procedures governing all of the operations and services provided, and for reviewing said policies and procedures annually and revising as needed;

(3) Initiating action to maintain the laboratory in full compliance at all times with all relevant health and safety requirements contained in applicable federal, state, and local laws, rules, regulations, and ordinances;

(4) Establishing, in writing, a chain of command that sets forth the line of authority for the operational responsibilities of the laboratory;

(5) Appointing a laboratory director who shall meet the qualification requirements as stated in:

a. 42 CFR § 493.1405 for laboratories performing moderate complexity testing;

b. 42 CFR § 493.1443 for laboratories performing high complexity testing; or

c. For labs performing only waived testing the director shall meet the following qualifications:

1. A bachelor's degree in health sciences with a minimum of 3 years' experience in a laboratory; or

2. An associate's degree in health sciences with a minimum of 5 years' experience in a laboratory;

(6) Appointing an administrator who shall meet the following qualifications:

a. A bachelor's degree in health sciences with a minimum of 3 years' experience in a laboratory; or

b. An associate's degree in health sciences with a minimum of 5 years' experience in a laboratory;

(7) Employing a clinical consultant in accordance with 42 CFR § 493.1417 or 42 CFR § 493.1455 as appropriate;

(8) Employing a technical consultant if the laboratory is performing moderately complex tests as defined in 42 CFR § 493.1411;

(9) Employing a general supervisor and a technical supervisor if the laboratory is performing highly complex tests as defined in 42 CFR § 493.1449, 1461, and 1469 if the laboratory is performing cytology;

(10) Providing sufficient numbers of personnel who are present in the laboratory and are qualified as testing personnel according to 42 CFR § 493 to perform the laboratory tests stated in the laboratory's scope of services;

(11) Providing sufficient supplies, equipment, and lighting to ensure all services are provided in a safe and timely manner; and

(12) Implementing any POC that has been accepted or issued by the department.

(f) The licensee shall post the following documents in an area of the licensed premises that is conspicuous and open to patients and the general public:

(1) The current license issued in accordance with RSA 151:2;

(2) All inspection reports issued for the previous 12 months;

(3) Any notice of a pending hearing or order as required by RSA 151:29, II, pertaining to the licensee issued by the department or a court during the previous 24 months;

(4) A notice as required by RSA 151:29 stating complaints may be submitted to:

Department of Health and Human Services
Health Facilities Administration
129 Pleasant Street
Concord, NH 03301

(5) A copy of the licensee's complaint procedure as required by RSA 151:29, I; and

(6) A copy of the patients' bill of rights, in accordance with RSA 151:21.

(g) The licensee shall admit and allow any department representative to inspect the licensed premises and laboratory services for the purpose of determining compliance with RSA 151 and He-P 808 as authorized by RSA 151:6 and RSA 151:6-a.

(h) All records required for licensing shall be:

(1) Available to the department during an inspection or investigation conducted in accordance with RSA 151:6 and RSA 151:6-a; and

(2) Legible, current, and accurate.

(i) Any licensee maintaining electronic records shall develop a system with written policies and procedures to protect the privacy of patients and personnel that, at a minimum, include:

(1) Procedures for backing up files to prevent deletion;

(2) Safeguards to ensure the confidentiality of the information on patients and personnel; and

(3) Systems to prevent the tampering of information on patients and personnel.

(j) The licensee shall provide a patient or their legal representative with a copy of his or her patient record, pursuant to the provisions of RSA 151:21, X, upon request.

(k) The licensee shall develop a facility system with written policies and procedures that will ensure that only the patient and the ordering licensed practitioner are allowed to receive a copy of the laboratory tests results unless the laboratory has written consent from the patient to release the test results to others.

(l) The building or structure or mobile laboratory van that houses the laboratory shall comply with the following:

(1) All applicable local health requirements;

(2) All applicable state and local building ordinances;

(3) All applicable local zoning ordinances; and

(4) All applicable state and local fire ordinances.

(m) The licensee shall maintain a log in each mobile laboratory van to document that all on-board water is from a verifiable potable source.

(n) Licensees that perform the functions of a collection station under this rule shall also be in compliance with He-P 817 rules for collection stations.

He-P 808.15 Laboratory Standards.

(a) All laboratories shall comply with all regulations contained in 42 CFR § 493.

(b) All laboratories shall require the individual functioning as technical consultant or general supervisor to have 2 years of laboratory experience in the specialties being supervised.

(c) All laboratory equipment shall be maintained as recommended by the manufacturer to include, but not limited to, annual tachometer checks of centrifuges, annual cleaning and maintenance of microscopes, and calibration of thermometers and pipettes.

(d) All laboratories shall disinfect point of care devices used for multiple patients after each use.

(e) All laboratories shall perform quality controls on waived meter devices each day they are used, unless the device performs internal electronic controls with each test performed.

(f) Corrective measures such as repair or replacement shall be made in the event of an equipment failure and a written record of the corrective measures shall be kept at the collection station.

(g) All clinical equipment shall be:

(1) In good working order; and

(2) Serviced in accordance with manufacturers' instructions and a written record of the service performed shall be kept at the collection station.

(h) Sharps containers shall be secured so as to prevent unauthorized access and tampering.

He-P 808.16 Patient Records, Test Requisitions, and Test Reports.

(a) All patient records, test requisitions, and test reports shall be completed and maintained in accordance with 42 CFR § 493.

(b) All records, requisitions, and reports shall be safeguarded against loss, damage, tampering, and unauthorized access and retained for a minimum of 4 years.

(c) Prior to ceasing operation, the licensee shall arrange for the storage of and access to records, requisitions, and reports for a minimum period of 4 years.

He-P 808.17 Personnel.

(a) All personnel shall:

(1) Meet the educational and physical qualifications of the position and in accordance with the requirements of 42 CFR § 493;

(2) Be licensed, registered, or certified if required by state statute;

(3) Receive an orientation within the first 7 days of work that includes:

a. The duties and responsibilities of the position;

b. The laboratory's infection control program; and

c. The laboratory's fire, evacuation, and emergency plans, which outline the responsibilities of personnel in an emergency; and

(4) Prior to testing patient samples, the employee shall have an orientation in the applicable policies, procedures, of the laboratory.

(b) All personnel shall complete annual in-service education in the laboratory:

(1) Policies and procedures on patients' rights;

(2) Infection control program; and

(3) Fire and emergency procedures.

(c) All licensees using the service of independent clinical contractors shall:

(1) Provide the clinical contractors with an orientation as specified in (a)(3) above;

(2) Maintain a copy of the clinical contractors' licenses as required by (a)(2) above, if applicable;

(3) Have a written agreement with each clinical contractor that describes the services that will be provided and agrees to comply with the requirements of (a)(1) through (3) above; and

(4) Have documentation of the criminal record check or employee waiver, as applicable.

(d) For all new hires, including volunteers and independent contractors whose scope of employment will involve direct contact with a patient, patient records, or patient tissue, body fluids, or other biological material, the licensee shall:

(1) Obtain and review a criminal records check, which shall include results of criminal history from the state of New Hampshire;

(2) Review the results of the criminal records check in accordance with (e) below and verify the qualifications of all applicants prior to employment;

(3) Require the employee to submit the results of a physical examination or pre-employment health screening performed by a licensed nurse or a licensed practitioner and 2 step tuberculosis testing, Mantoux method, or other method approved by the Centers for Disease Control, conducted not more than 12 months prior to employment;

(4) Allow the employee to work while waiting for the results of the second step of the TB test when the results of the first test are negative for TB;

(5) Comply with the requirements of the United States Centers for Disease Control and Prevention, "Guidelines for Preventing the Transmission of *M. tuberculosis* in Health-Care Settings" (2005 edition), available as noted in Appendix A, if the person has either a positive TB test, or has had direct contact or potential for occupational exposure to M. tuberculosis through shared air space with persons with infectious tuberculosis; and

(6) Report all positive tuberculosis (TB) test results for personnel to the department's TB program in accordance with RSA 141-C:7, He-P 301.02, and 301.03.

(e) Unless a waiver is granted in accordance with (f) below, the licensee shall not offer employment for any position if the individual:

(1) Has been convicted for sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation;

(2) Has been found by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation of any person; or

(3) Otherwise poses a threat to the health, safety, or well-being of the patients.

(f) The department shall grant a waiver of (e) above if, after reviewing the underlying circumstances, it determines that the person does not pose a threat to the health, safety, or well-being of patients.

(g) The waiver in (f) above shall be permanent for as long as the individual remains in the same job unless additional convictions or findings under (e) above occur.

(h) If the information identified in (e) above regarding any employee is learned after the person is hired, the licensee shall immediately notify the department.

(i) An employee shall not be permitted to maintain their employment if they have been convicted of a felony, sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation of any person in this or any other state by a court of law or had a complaint investigation for abuse, neglect, or exploitation adjudicated and founded by the department unless a waiver has been granted by the department.

(j) All personnel shall sign a statement at the time the initial offer of employment is made and then annually thereafter stating that they:

(1) Do not have a felony conviction in this or any other state;

(2) Have not been convicted of a sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation or pose a threat to the health, safety, or well-being of a patient; and

(3) Have not had a finding by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation of any person.

(k) For individuals with the waiver described in (f) above, the statement required by (j) above shall cover the period of time since the waiver was granted.

(l) An individual shall not be required to re-disclose any of the matters in (f) above if the documentation is available and the department has previously reviewed the material and determined that the individual can continue employment.

(m) Current and complete personnel files shall be maintained at the licensed premises, except as allowed by (p) below.

(n) Personnel files shall include:

(1) Identification data;

(2) Qualifications and work experience;

(3) Record of satisfactory completion of the orientation program required by (a)(3) above;

(4) A copy of each current New Hampshire license, registration, or certification in health care field, if applicable;

(5) Documentation of annual in-service education as required by (b) above; and

(6) The statement required by (j) above.

(o) Personnel files shall be:

(1) Maintained on an individual basis, separate and distinct from other employees, and contain only information relating to the specific personnel member;

(2) Stored in locked containers or cabinets or in a locked room on the premises; and

(3) Maintained for at least 5 years following termination of employment.

(p) Personnel files may be stored in a central location provided that:

(1) The personnel file is available to the department at the licensed premises within 30 minutes of being requested; and

(2) The files are in accordance with (n) and (o) above.

(q) All testing personnel shall have a competency review for each test procedure performed prior to testing patient samples, as well as twice in the first year and annually thereafter.

(r) The competency review shall include:

(1) Monitoring the pre-analytic, analytic, and post analytic phases of the testing procedure;

(2) Direct observation of the testing personnel in the performance of the test procedure; and

(3) Documentation of test results and awareness of test parameters and limitations as described in the package insert.

He-P 808.18 Quality Assessment. Licensed laboratories, including mobile laboratory vans, shall develop and implement a quality assessment program that reviews policies and services and maximizes quality by preventing or correcting identified problems.

He-P 808.19 Infection Control.

(a) All laboratories shall develop and implement an infection control program.

(b) The laboratory's infection control program shall:

(1) Comply with all regulations contained in 29 CFR § 1910.1030;

(2) Include education and instruction on:

a. Proper hand washing techniques; and

b. The utilization of universal precautions;

(3) Include written procedures for the handling, storage, transportation, or disposal of those items identified as infectious waste in Env-Sw 904;

(4) Include written procedures for the management of patients or staff with infectious or contagious diseases or illnesses; and

(5) Include the reporting of infectious and communicable diseases as required by He-P 301.

(c) The infection control program shall address at a minimum the:

(1) Causes of infections;

(2) Effects of infections;

(3) Transmission of infections; and

(4) Prevention and containment of infections.

(d) Personnel infected with a disease or illness transmissible through contact, fomites, or droplets shall not have any contact with patients until they are no longer contagious.

(e) Only sterile equipment and containers such as needles, syringes, test tubes, and urine containers used for cultures shall be used when collecting specimens.

(f) The handling, storing, transporting, or disposing of items specified as infectious waste in Env-Sw 904.01 shall be done in accordance with Env-Sw 904.

(g) There shall be no use of tobacco products, smoking, eating, drinking, or applying of cosmetics in the areas where specimen collection takes place or where specimens are processed in accordance with 29 CFR § 1910.1030.

He-P 808.20 Physical Environment.

(a) The licensee shall comply with all federal, state, and local laws, rules, codes, and ordinances for:

(1) Buildings or mobile laboratory vans, as applicable;

(2) Health;

(3) Fire; and

(4) Waste disposal.

(b) The laboratory shall have all entrances and exits to the licensed premises accessible at all times.

(c) The laboratory shall be clean and maintained in a safe manner and good repair and kept free of hazards.

(d) All supplies shall be stored in enclosed storage spaces.

(e) All corridors shall be free from obstruction.

(f) The licensee shall ensure that the laboratory has:

(1) Working space for the analysis and reporting of tests performed by the laboratory;

(2) Refrigeration and freezers, as required, to preserve specimens and reagents at optimal temperatures as recommended by a given procedure or manufacturer;

(3) Cooling, heating, and ventilation systems that are maintained in accordance with manufacturers' specification;

(4) Temperature and humidity control in the laboratory work area that is maintained and monitored in accordance with manufacturer's instructions for the testing being performed to ensure quality results; and

(5) Access to bathrooms that contain at least one toilet and one hand-washing sink with:

a. A supply of hot and cold running water;

b. Soap dispensers;

c. Paper towels or a hand drying device providing heated air; and

d. Non-porous floors.

(g) If equipment or supplies need to be sterilized in order to prevent contamination, a system for sterilization shall be provided.

(h) The sterilization system required in (g) above shall be checked for effective sterilization in accordance with the manufacturer's recommendation, and the results of these quality control tests shall be documented.

(i) Sterile supplies and equipment shall not be mixed with unsterile supplies and shall be stored in dust-proof, moisture-free storage areas.

(j) Cleaning solutions, compounds, and substances, which might be considered hazardous waste as defined in RSA 147-A:2, VII, also known as hazardous and toxic materials in these rules, shall be:

(1) Distinctly labeled and legibly marked so as to identify the contents;

(2) Stored in a place separate from food and supplies; and

(3) Kept in an enclosed section separated from other cleaning materials.

(k) Toxic materials shall not be used in a way that contaminates equipment or in any way that constitutes a hazard to personnel or other persons, or in any way other than in full compliance with the manufacturer's labeling.

(l) Equipment, work surfaces, and flooring within areas used for collection and processing patient specimens shall include only non-porous material suitable for disinfection and shall be free of tape and adhesives.

He-P 808.21 Mobile Laboratory Vans.

(a) Mobile laboratory vans shall be eligible for licensure only if they are:

(1) Operated by a laboratory that is located in a building or other permanent structure; and

(2) The laboratory in (1) above has a valid license issued by the department in accordance with He-P 808.

(b) Each applicant shall comply with He-P 808, except that:

(1) He-P 808.07 shall not apply to mobile laboratory vans;

(2) In lieu of He-P 808.04(a)(1)-(3) and (5)-(7), each applicant shall submit:

a. A copy of the applicant's current laboratory and laboratory services license;

b. A valid New Hampshire motor vehicle registration for the mobile laboratory van;

c. The VIN of the mobile laboratory van; and

d. A space utilization diagram for the mobile laboratory van; and

(3) Patient and facility records that are stored off site shall be available for inspection upon request of licensing personnel within 30 minutes of being requested.

(c) The laboratory portions of the mobile laboratory van used to collect, process, store, or transport specimens, reagents, or supplies shall have a non-porous floors and work surfaces.

(d) Only such tests that are identified as waived in 42 CFR § 493 shall be performed in a mobile laboratory van.

(e) Detailed written documentation of travel dates, times, and locations, including periods of non-use, shall be maintained for the mobile laboratory van.

(f) Mobile laboratory vans shall record temperatures each day of laboratory use and whenever testing reagents are stored in the van to ensure compliance with manufacturers' instructions for the test system used by the laboratory.

He-P 808.22 Emergency and Fire Safety.

(a) Laboratories shall meet the requirement in the applicable chapters and sections of the state fire code and state building code.

(b) An emergency and fire safety program shall be developed and implemented based upon the hazards present in the lab.

(c) Smoke detectors shall be hardwired, powered by the electrical service, and located on every level of the facility.

(d) At least one fire extinguisher shall be located on every level of the facility or every 75 feet of corridor, type based on the hazards present in the lab, and be:

(1) Manually inspected when initially placed in service; and

(2) Inspected either manually or by means of an electronic monitoring device or system at intervals not exceeding 31 days.

(e) A carbon monoxide monitor shall be located on every level.

(f) Immediately following any fire or emergency situation, excluding a false alarm, licensees shall notify the department by phone and follow up with written notification within 72 hours.

(g) The written notification under (f) above shall include:

(1) The date and time of the incident;

(2) A description of the location and extent of the incident, including any damage;

(3) A description of events preceding and following the incident;

(4) The name of any personnel or patients who required medical treatment as a result of the incident, if applicable; and

(5) The name of the individual the licensee authorizes the department to contact if additional information is required.

(h) Storage of flammable gases or liquids shall be within an enclosed interior space constructed of noncombustible or limited-combustible construction. If stored outdoors, storage shall be in an enclosure with doors or gates, that can be secured against unauthorized entry.

(i) Oxidizing gases, such as oxygen and nitrous oxide, shall:

(1) Not be stored with any flammable gas, liquid, or vapor;

(2) Be separated from combustibles or incompatible materials by:

a. A minimum distance of 20 ft or 6.1 meters;

b. A minimum distance of 5 ft or 1.5 meters if the entire storage location is protected by an automatic sprinkler system designed in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems; or

c. An approved, enclosed flammable liquid storage cabinet of noncombustible construction having a minimum fire protection rating of one-half hour for cylinder storage; and

(3) Be secured in an upright position, such as with racks or chains.

(j) All freestanding tanks of compressed gases shall be firmly secured to the adjacent wall, or secured in a stand or rack, except for in mobile laboratory vans, where they shall be secured during transport as required by the state fire code.

(k) Flammable gases and liquids shall be stored in metal fire retardant cabinets, except when located in a mobile laboratory van, where they shall be secured during transport as required by the state fire code.

(l) Quantities of flammable gases and liquids under 500 milliliters may be retained at the bench work area when directly in use.

(m) A precautionary sign, readable from a distance of 5 ft or 1.5 meters, shall be conspicuously displayed on each door or gate of the storage room or enclosure, and shall include, at a minimum, the following: “CAUTION, OXIDIZING GAS(ES) STORED WITHIN - NO SMOKING”.

(n) Precautionary signs, readable from a distance of 5 ft or 1.5 meters, and with language such as “OXYGEN IN USE, NO SMOKING”, shall be conspicuously displayed wherever supplemental oxygen is in use and in aisles and walkways leading to the area of use, and shall be attached to adjacent doorways or to building walls or be supported by other appropriate means.

(o) The laboratory shall develop a fire safety plan, which includes the following:

(1) Use of alarms;

(2) Transmission of alarms to fire department;

(3) Emergency phone call to fire department;

(4) Response to alarms;

(5) Isolation of fire;

(6) Evacuation of immediate area;

(7) Evacuation of smoke compartment;

(8) Preparation of floors and building(s) for evacuation;

(9) Extinguishment of fire; and

(10) List of written emergency telephone numbers for key personnel, fire and police departments, poison control center, 911, and ambulance service(s).

(p) Fire drills shall be conducted quarterly on each shift to familiarize facility personnel including, but not limited to, medical personnel, maintenance engineers, and administrative personnel, with the signals and emergency action required under varied conditions.

(q) Fire drills shall include the transmission of a fire alarm signal and simulation of emergency fire conditions.

(r) Facilities shall complete written records of fire drills and include the following:

(1) The date and time, including AM or PM, the fire drill was conducted and if the actual fire alarm system was used;

(2) The location of exits used;

(3) The number of people participating at the time of the fire drill;

(4) The amount of time taken to completely evacuate the facility or to an approved area of refuge or through a horizontal exit;

(5) The name and title of the person conducting the fire drill;

(6) A list of all problems and issues encountered during the fire drill;

(7) A list of improvements and resolutions to the issues encountered during the fire drill; and

(8) The names of all personnel participating in the fire drill.

(s) Written records of the fire drills shall be maintained on site and available to the department during an inspection or investigation conducted in accordance with RSA 151:6 and RSA 151:6-a.

(t) At no time shall a personnel member who has not participated in a fire drill be the only personnel member on duty within the facility.

(u) The facility shall conduct a fire drill in the presence of a representative of the department, state fire marshal's office, or the local fire department upon request.

(v) A written plan for fire safety, evacuation, and emergencies shall be adopted and posted in multiple locations throughout the laboratory.

He-P 808.23 Emergency Preparedness.

(a) Each facility shall have an emergency management committee, with the authority for developing, implementing, exercising, and evaluating the emergency management program.

(b) The committee shall include:

(1) The facility administrator;

(2) Others who have knowledge of the facility and the capability to identify resources from key functional areas within the facility; and

(3)An applicable external representation, if the licensee is a high complexity lab, including but not limited to:

a. Elected state and local officials;

b. Police, fire, civil defense, and public health professionals;

c. Environment, transportation, and hospital officials;

d. Facility representatives; and

e. Representatives from community groups and the media.

(c) The emergency management committee shall develop and institute a written emergency preparedness plan (plan) to respond to a disaster or an emergency.

(d) The plan in (c) above shall:

(1) Include site-specific plans for the protection of all persons on-site in the event of a fire, natural disaster, severe weather, chemical emergency, or human-caused emergency;

(2) Be reviewed and approved by the local emergency management director;

(3) Be available to all personnel;

(4) Be based on realistic conceptual events;

(5) Be modeled on the Federal Emergency Management Agency's Incident Command System (ICS) in coordination with local emergency response agencies;

(6) Provide that all personnel designated or involved in the facility's plan shall be supplied with a means of identification, such as vests, baseball caps, or hard hats, which shall be worn at all times in a visible location during the emergency;

(7) Include the facility's response to both short-term and long-term interruptions in the availability of utility services in the disaster or emergency, including establishing contingency plans for continuity of essential building systems or evacuation to include the following, as applicable:

a. Electricity;

b. Water;

c. Ventilation;

d. Fire protection systems;

e. Fuel sources;

f. Medical gas and vacuum systems; and

g. Communications systems;

(8) Include a process for alerting and managing personnel in a disaster, and accessing Critical Incident Stress Management (CISM), if necessary;

(9) Identify a designated media spokesperson to issue news releases and an area where the media can be assembled, where they won't interfere with the operations of the facility;

(10) Reflect measures needed to restore operational capability with consideration of fiscal aspects because of restoration costs and possible cash flow losses associated with the disruption;

(11) Include an educational, competency-based program for the personnel, to provide an overview of the components of the emergency management program and concepts of the ICS and the personnel's specific duties and responsibilities; and

(12) If the facility is located within 10 miles of a nuclear power plant and is part of the New Hampshire plan for radiological emergency preparedness, include this process in the plan in the event of a radiological disaster or emergency.

(e) The facility shall conduct and document with a detailed log, including personnel signatures, 2 drills a year at least one of which shall rehearse mass casualty response for the facility with emergency services, disaster receiving stations, or both.

APPENDIX A: Incorporation by Reference Information

Rule	Title	Publisher; How to Obtain; and Cost
He-P 808.07(i) and (j)	Facility Guidelines Institute (FGI) "Guidelines for Design and Construction of Outpatient Facilities" (2022 Edition)	Publisher: Facility Guidelines Institute Cost: Digital: $90 per year/ Print: $235 per copy The incorporated document is available at: https://fgiguidelines.org/guidelines/editions/
He-P 808.17(d)(5)	United States Centers for Disease Control and Prevention's "Guidelines for Preventing the Transmission of *M. tuberculosis* in Health-Care Settings" (2005 Edition)	Publisher: United States Centers for Disease Control and Prevention Cost: Free of Charge The incorporated document is available at: https://www.cdc.gov/tb/publications/slidesets/infectionguidelines/default.htm

Appendix B

Rule	Specific State or Federal Statutes the Rule Implements
He-P 808.01 – He-P 808.03	RSA 151:2,I(c); RSA 151:2,II; RSA 151:9,I(a)&(b), 42 CFR Part 493, 42 CFR § 493.1411, 42 CFR § 493
He-P 808.04 – He-P 808.06	RSA 151:9,I
He-P 808.07 – He-P 808.08	RSA 151:9,I(a)
He-P 808.09	RSA 151:9,I(e)
He-P 808.10	RSA 151:9,I(a)
He-P 808.11	RSA 151:9,I(e)
He-P 808.12	RSA 151:9,I(f),(g),(i),(l)
He-P 808.13	RSA 151:9,I(f),(h),(l),(m)
He-P 808.14 – He-P 808.23	RSA 151:9,I(a), 42 CFR § 493.1405, 42 CFR § 493.1443, 42 CFR § 493.1417, 42 CFR § 493.1455, 42 CFR § 493.1411, 42 CFR § 493.1449, 1461and 1469, 42 CFR § 493, 29 CFR § 1910.1030