

CHAPTER He-P 800 RESIDENTIAL CARE AND HEALTH FACILITY RULES

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).

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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)-(h);
- (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 may perform the functions of a collection station without the additional requirement of an He-P 817 collection station license; 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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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, federal, state, county or local government, entity, association, or other legal entity seeking a license for the operation of a laboratory pursuant to RSA 151:2, I(c).

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(c) “Change of ownership” means a change in the controlling interest of an established laboratory to a successor business entity.

(d) “Client record” means the documentation of all care and services, which includes all documentation required by RSA 151 and He-P 808 and any other applicable federal and state requirements.

(e) “Commissioner” means the commissioner of the department of health and human services or his or her designee.

(f) “Deficiency” means any action, failure to act or other set of circumstances that causes a licensee to be out of compliance with RSA 151 or He-P 808.

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

(h) “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.

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

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

(k) “Facility” means the building and other structures, which comprise the place or places where the licensee has applied to or is authorized to operate.

(l) “Infectious waste” means those items specified by Env-Sw 103.28.

(m) “Inspection” means the process used by the department to determine a licensee's compliance with RSA 151 and He-P 808.

(n) “Investigation” means the process used by the department to respond to allegations of non-compliance with RSA 151 and He-P 808.

(o) “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.

(p) “Laboratory/medical director” means the person who shall provide overall management and direction for all laboratory testing procedures and who meets the qualification requirements of 42 CFR § 493.1405 or 493.1443.

(q) “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 client receiving services from an agency licensed under the authority of RSA 151.

(r) “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.

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

(t) “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.

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(u) “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.

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

(w) “Personnel” means individual(s) who conduct testing or provide laboratory services.

(x) “Plan of correction (POC)” means a plan developed and written by the licensee, which specifies the actions that will be taken to correct identified deficiencies.

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

(z) “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.

(aa) “Specimen” means a portion of tissue, body fluid or material from a human body.

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

(ac) “Waived testing” means all laboratory tests categorized as waived by 42 CFR § 493.

(ad) “Waiver” means a request for an alternative means of satisfying a rule requirement in He-P 808.

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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) An application form entitled “Application for Residential or Health Care License (Laboratories and Collecting Stations),” (10/25/2011 edition) signed by the applicant or 2 of the corporate officers, 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;

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- b. "Certificate of Formation," if a limited liability company; or
  - c. "Certificate of Trade Name," where applicable;
- (4) The applicable fee in accordance with RSA 151:5, XXIII, payable in cash, check or money order in the exact amount of the fee and made payable to the "Treasurer, State of New Hampshire" if paid by check or money order;
- (5) A resume identifying the qualifications and copies of applicable licenses for the 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 applicable 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 Saf-C 6000, the state fire code, as adopted by the department of safety, and local fire ordinances applicable for an ambulatory health care facility; 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 700, or, if a public water supply is used, a copy of a water bill; and
- (8) The results of a criminal records check from the NH department of safety for the applicant, the laboratory/medical director and the administrator, as applicable.
- (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

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

(f) If a waiver is not granted, the department shall deny a licensing request after reviewing the information required by He-P 808.04(a)(8) above if it determines that the applicant, proposed 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, 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, fraud, abuse, neglect, or exploitation of any person; or

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

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

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He-P 808.06 License Expirations and Procedures for Renewal.

(a) A license shall be valid on the date of issuance and expire the following year on the last day of the month in which it was issued.

(b) Each licensee shall complete and submit to the department an application form pursuant to He-P 808.04(a)(1) at least 120 days prior to the expiration of the current license.

(c) The licensee shall submit with the renewal application:

(1) The information required by He-P 808.04(a)(1), including current license number;

(2) The licensing fee required by He-P 808.04(a)(4);

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(3) A request for renewal of any existing waiver previously granted by the department, in accordance with He-P 808.10(f), if applicable;

(4) A statement identifying any variances applied for or granted by the state fire marshal; and

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

(d) In addition to (c) above, 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 for nitrates.

(e) Following an inspection as described in He-P 808.09, an application for a license renewal shall be issued if the department determines that the licensee:

(1) Submitted an application containing all of the items required by (c) and (d) above as applicable, prior to the expiration of the current license;

(2) Has submitted a POC that has been accepted by the department and implemented by the licensee if deficiencies were cited at the last licensing inspection or investigation; and

(3) Is found to be in compliance with RSA 151 and He-P 808 at the renewal inspection.

(f) A licensee who does not submit a complete application for renewal prior to the expiration of an existing license shall be required to resubmit an application for initial license pursuant to He-P 808.04.

(g) If a licensee chooses to cease the operation of the laboratory, the licensee shall submit written notification to the department at least 45 days in advance.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

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

(a) Sixty days prior to initiating construction, the laboratory shall provide to the department notice and written plans drawn to scale for construction, modifications or structural alterations for the following:

(1) A new building;

(2) Structural alterations to any client area;

(3) Modifications that require approval from local or state authorities; and

(4) Modifications that might affect compliance with the health and safety, fire or building codes, including but not limited to, fire suppression, detection systems and means of egress.

(b) A licensee or applicant constructing, modifying or structurally altering a building shall comply with the following:

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- (1) The state fire code, Saf-C 6000, including, but not limited to, NFPA 1 and NFPA 101 as adopted by the commissioner of the department of safety under RSA 153; and
- (2) The state building code as defined in RSA 155-A:1, IV, as amended by the building code review board pursuant to RSA 155-A:10, V.

(c) Department approval shall not be required prior to initiating construction, modifications or structural alterations, however an applicant or licensee who proceeds prior to receiving approval shall do so at their own risk.

(d) The department shall review the documentation for compliance with all applicable sections of RSA 151 and He-P 808 and notify the applicant or licensee as to whether the proposed plans comply with these requirements.

(e) All laboratories newly constructed on or after the 2013 effective date of He-P 808 shall comply with the Facility Guidelines Institute "Guidelines for Design and Construction of Health Care Facilities," "Laboratories" chapter, 2010 edition, as applicable (available as noted in Appendix A).

(f) The department's bureau of health facilities administration shall be the authority having jurisdiction for the requirements in (e) above and shall negotiate compliance and grant waivers in accordance with He-P 808.10 as appropriate.

(g) Waivers granted by the department for construction or renovation purposes shall not require annual renewal.

(h) Waivers pertaining to the state fire code referenced in (b)(1) above shall be granted only by the state fire marshal.

(i) The completed building shall be subject to an inspection pursuant to He-P 808.09 prior to its use.

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

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He-P 808.08 Laboratory Requirements for Organizational Changes.

(a) When there is to be a change in ownership of a laboratory:

(1) The license shall expire the day the laboratory changes ownership;

(2) The new owner shall obtain a new license, in accordance with He-P 808.04, prior to operating and submit the following to the department:

- a. A copy of any certificate of amendment of organizational filings issued by the New Hampshire secretary of state, if applicable; and
- b. A letter from the current licensee, which contains an acknowledgment of the impending change of ownership, and the date upon which the change of ownership is scheduled to take effect;

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- (3) If the current licensee is in good standing as described in (4) below, and no changes are made in the scope of services provided, at the time the completed application is received the department shall issue a new license to the new owner without first inspecting the premises;
- (4) The current licensee shall be considered to be in good standing if:
- a. Deficiencies were not cited at the last licensing inspection, investigation or federal certification survey;
  - b. Deficiencies were found at the last licensing inspection, investigation or federal certification survey, but a POC has been accepted by the department and has been implemented by the licensee; and
  - c. The licensee is not currently involved in any administrative action; and
- (5) If the current licensee is not in good standing, as described in (4) above, at the time of the change of ownership or a change in the services is requested, an initial license shall not be issued to the new owner until an inspection has been completed and the department finds the laboratory to be in full compliance with RSA 151 and He-P 808.
- (b) When there is a change in the name of the laboratory:
- (1) The licensee shall submit a written request to the department for an amended license certificate at least 30 days prior to the intended date of the name change including:
    - a. The name and license number of the laboratory as it appears on the current license;
    - b. The name of the laboratory as it will appear on the amended license certificate;
    - c. The effective date of the change; and
    - d. A copy of the certificate of any amendment of documents issued by the New Hampshire secretary of state, if applicable; and
  - (2) Upon receipt of the information required by (1) above, an amended license certificate reflecting the change in name shall be issued.
- (c) When there is to be a change in the physical location of the laboratory, except for mobile laboratory vans:
- (1) The licensee shall obtain a new license, in accordance with He-P 808.05 prior to operating at the new location; and
  - (2) The licensee shall make all past and present client and personnel records accessible at the new location.
- (d) When there is to be a change in the street address of the laboratory that results from local, state or federal action without a change in the physical location of the laboratory, the department shall issue an amended license certificate upon receipt from the licensee of a written request that includes:
- (1) The name and address of the licensee as it appears on the current license;
  - (2) The name and address of the licensee as it will appear on the amended license certificate; and
  - (3) A copy of the notification of the required change in street address.



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(e) When there is to be a change in the laboratory/medical director, the licensee shall submit the following to the department prior to the change of laboratory/medical director:

- (1) Documentation of the new laboratory/medical director's qualifications, including transcripts and a resume; and
- (2) Written notification of the date the new laboratory/medical director will begin employment.

(f) Upon receipt of the information required in (e) above, an amended license certificate reflecting the change in laboratory/medical director shall be issued.

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

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

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

(b) The department shall conduct an inspection 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(a)(3);
- (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 verify the implementation of any POC accepted or issued by the department.

(d) Following the inspection described in (b) and (c) above, the department shall provide the licensee with a written inspection report.

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(e) A written notification of denial shall be sent to an applicant applying for an initial license if it has been determined by the inspection mentioned in (a) above, that the premises is not in full compliance with RSA 151 and He-P 808.

(f) A notice of deficiencies shall be issued when, as a result of any clinical inspection, the department determines that the laboratory is in violation of any of the provisions of He-P 808 or RSA 151.

(g) A notice to correct shall be issued when, as a result of any life safety inspection, the department determines that the laboratory is in violation of any of the provisions of He-P 808 or RSA 151.

(h) If deficiencies were cited and a notice of deficiencies or a notice to correct is issued, the licensee shall submit a POC, in accordance with He-P 808.12(c) within 21 days of the date on the letter that transmits the inspection report.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

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He-P 808.10 Waivers.

(a) With the exception of He-P 808.07(h), 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 clients as the rule from which a waiver is sought.

(b) Waivers granted shall be permanent.

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

- (1) Meets the objective or intent of the rule;
- (2) Does not negatively impact the health or safety of the clients; and
- (3) Does not negatively affect the quality of client 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.

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New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

He-P 808.11 Complaints and Investigations.

(a) The department shall accept and investigate written complaints that allege:

- (1) A violation of RSA 151 or He-P 808;
- (2) That an individual or entity is operating a laboratory without being licensed; or
- (3) That an individual or entity is advertising or otherwise representing the laboratory as having or performing services for which they are not licensed to provide, in violation of RSA 151:2, III.

(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) The department shall not investigate a complaint if the commissioner determines that the complaint is without a factual basis.

(d) For the licensed laboratory with a valid complaint:

- (1) An investigation shall be completed; and
- (2) The department shall:
  - a. Provide written notification of the results of the investigation to the licensee along with an inspection report if deficiencies were found as a result of the investigation; and
  - b. Notify any other federal, state or local agencies of alleged violations of their statutes or rules based on the findings of the complaint investigation, as appropriate.

(e) If the department determines that the complaint is unfounded or does not violate any statutes or rules, the department shall take no further action.

(f) If the investigation results in deficiencies being cited, the licensee shall be required to submit a POC in accordance with He-P 808.12(c).

(g) For the unlicensed individual or entity:

- (1) An investigation shall be completed; and

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(2) The department shall provide to the owner or person responsible written notification including:

- a. The date of investigation;
- b. The reasons for the investigation; and
- c. Whether or not the investigation determined that the services being provided require licensing under RSA 151:2, II(c).

(h) In accordance with RSA 151:7-a, II, the owner or person responsible shall be allowed 7 days from the date of the notice required by (g)(2) above to respond to any findings cited by the department.

(i) The department shall accept the response in (h) above if it includes a plan to achieve compliance with RSA 151 and He-P 808 within 60 days.

(j) If the owner of a laboratory where services are being provided without a license does not provide a response as described in (h) above, or if the department does not agree with the owner's response, the department shall:

- (1) Issue a written warning to immediately comply with RSA 151 and He-P 808; and
- (2) Provide notice stating that the individual has the right to appeal the warning in accordance with RSA 151:7-a, III.

(k) Any person or entity who fails to comply after receiving a warning as described in (j) above shall be subject to an action by the department for injunctive relief under RSA 151:17.

(l) The fact that the department takes action for injunctive relief under RSA 151:17 shall not preclude the department from taking other action under RSA 151, He-P 808, or other applicable laws.

(m) 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.

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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;

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- (2) Imposing a directed POC upon a licensee;
  - (3) Imposing fines upon an unlicensed individual, applicant, or licensee;
  - (4) Suspension of a license; or
  - (5) Revocation of a license.
- (b) When fines are imposed, the department shall provide a written notice, as applicable, which:
- (1) Identifies each deficiency;
  - (2) Identifies the specific remedy(s) that has been proposed; and
  - (3) Provides the licensee with the following information:
    - a. The right to a hearing in accordance with RSA 541-A and He-C 200 prior to the fine becoming final; and
    - b. The automatic reduction of a fine by 25% if the licensee waives the right to a hearing, the fine is paid within 10 days of the date on the written notice from the department and the deficiency has been corrected, or a POC has been accepted and approved by the department.
- (c) A POC shall be developed and enforced in the following manner:
- (1) Upon receipt of a notice of deficiencies the licensee shall develop a written POC describing:
    - a. How the licensee intends to correct each deficiency;
    - b. What measures will be put in place, or what system changes will be made to ensure that the deficiency does not recur; and
    - c. The date by which each deficiency shall be corrected;
  - (2) The licensee shall submit a written POC to the department within 21 days of the date on the letter that transmitted the inspection report 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 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 client will not be jeopardized as a result of granting the extension;
  - (3) The department shall review and accept each POC that:
    - a. Achieves compliance with RSA 151 and He-P 808;
    - b. Addresses all deficiencies and deficient practices as cited in the inspection report;
    - c. Prevents a new violation of RSA 151 or He-P 808 as a result of this implementation; and
    - d. Specifies the date upon which the deficiencies will 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) The department shall reject any POC, which does not meet the requirements of (3) above;
- (6) If the POC is not acceptable:
  - a. The department shall notify the licensee in writing of the reason for rejecting the POC;
  - b. 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:
    - 1. The licensee demonstrates that he or she has made a good faith effort to develop and submit the POC within the 14 day period but has been unable to do so; and
    - 2. The department determines that the health, safety or well being of a client will not be jeopardized as a result of granting the waiver;
  - c. The revised POC shall comply with (1) above and be reviewed in accordance with (3) above; and
  - d. 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 (d) below and a fine in accordance with (f)(11) below;
- (7) 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;
- (8) The implementation verification of any POC shall only occur after the date of completion specified by the licensee in the plan; and
- (9) If the POC or revised POC has not been implemented by the completion date stated in the POC or revised POC at the time of the next inspection, the department shall:
  - a. Notify the licensee in accordance with He-P 808.11(d)(2); and
  - b. Issue a directed POC in accordance with He-P 808.12(d) and a fine in accordance with He-P 808.12(e)(12).
- (d) The department shall develop and impose directed POCs as follows:
  - (1) A written plan specifying the corrective actions for the licensee to implement to correct identified deficiencies shall be developed when:
    - a. An inspection or investigation has found and reported deficiencies that require immediate corrective action to protect the health and safety of the clients and personnel; or
    - b. A revised POC submitted by the licensee or administrator has not been accepted; and

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- (2) If the directed POC has not been implemented by the completion date stated in the directed POC, at the time of the next inspection the department shall:
- a. Impose a fine in accordance with He-P 808.12(e)(12); and
  - b. Deny an application or revoke the license, as applicable.
- (e) 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 for an unlicensed individual or a licensee shall be \$2000.00;
  - (2) For failure to cease operations of an unlicensed laboratory or after a denial of a license or after receipt of a court order to cease and desist, in violation of RSA 151 and He-P 808.13(b), the fine for an unlicensed individual, applicant 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 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(k), the fine for an unlicensed provider or a licensee shall be \$500.00;
  - (5) For a failure to submit a renewal application for a license at least 120 days 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), 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(c), the fine for a licensee shall be \$500.00;
  - (8) For failure to submit a POC, within 21 days of the date on the letter that transmits the inspection report, or a revised POC within 14 days of the date of written notification that the POC was rejected, in violation of He-P 808.12(c)(2) and (6), the fine for a licensee shall be \$100.00;
  - (9) For failure to implement 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;
  - (10) For falsification of information contained on the application, in violation of He-P 808.13(b)(4), the fine for an applicant shall be \$500.00 per offense;
  - (11) For falsification of any records required to be maintained for licensing, in violation of He-P 808.14(g), the fine for a licensee shall be \$500.00 per offense;
  - (12) For a failure to establish, implement or comply with licensee policies, as required by He-P 808.14(d)(1), the fine for a licensee shall be \$500.00;
  - (13) For failure to allow access to a laboratory, in violation of He-P 808.14(f), the fine for an unlicensed individual, applicant or licensee shall be \$2000.00;
  - (14) For failure to provide to the department any records maintained by the licensee and required by He-P 808.14(g)(1), the fine for a licensee shall be \$2000.00;

- (15) For employing a laboratory/medical director or other personnel who do not meet the qualifications for the position, in violation of He-P 808.17(a)(1), the fine for a licensee shall be \$500.00;
- (16) For failure to notify the department of construction or alterations prior to initiating construction as required by He-P 808.07(a), the fine shall be \$500.00;
- (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 client, 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 to obtain a license in (1) above or comply with warnings in (4) above, the department shall not issue a daily fine.
- (f) 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."

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

He-P 808.13 Enforcement Actions and Hearings.

- (a) At the time of imposing a fine, or denying, revoking or suspending a license, 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; and
  - (3) The right of an applicant or licensee to a hearing in accordance with RSA 541-A.
- (b) The department shall deny an application or revoke a license if:



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- (1) An applicant or a licensee has violated provisions of RSA 151 or He-P 808, which violations have the potential to harm a client's or employee's health, safety or well-being;
  - (2) An applicant or a licensee has failed to pay a fine imposed under administrative remedies;
  - (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 or He-P 808.06;
  - (5) An applicant, licensee or any representative or employee of the applicant or licensee:
    - a. Provides false information to the department;
    - b. Prevents or interferes 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);
  - (7) The licensee is cited a third time under RSA 151 or He-P 808 for the same violations within the last 5 inspections;
  - (8) A licensee, including corporation officers or board members, has had a license revoked and submits an application during the 5-year prohibition period specified in (h) below;
  - (9) Upon inspection, the applicant's premise is not in compliance with RSA 151 or He-P 808;
  - (10) The department makes a determination that one or more of the factors in He-P 808.05(f) is true; or
  - (11) The applicant or licensee fails to employ a qualified laboratory/medical director or received a waiver allowing the employment of a laboratory/medical director who does not meet all of the qualifications listed in He-P 808.17(a).
- (c) An applicant or licensee shall have 30 days after receipt of the notice of enforcement action to request a hearing to contest the action.
- (d) If a written request for a hearing is not made pursuant to (c) above, the action of the department shall become final.
- (e) 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 clients is in jeopardy and requires emergency action in accordance with RSA 541-A:30, III.
- (f) 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.
- (g) Hearings under this section shall be conducted in accordance with RSA 541-A and He-C 200.

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

(i) The 5-year period referenced in (h) 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.

(j) Notwithstanding (i) 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 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.

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

(l) 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.

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

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

(o) The department shall review the evidence presented and provide a written notice to the applicant or licensee of its decision.

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

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

He-P 808.14 Duties and Responsibilities of all Licensees.

(a) The licensee shall have a written policy and procedure setting forth the rights and responsibilities of clients admitted to the laboratory in accordance with RSA 151:20.

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

(c) 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 clients and personnel of the laboratory.
- (d) 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/medical director who shall meet the qualification requirements as stated in:
    - a. 42 CFR § 493.1405 for laboratories performing moderate complexity testing or waived testing; or
    - b. 42 CFR § 493.1443 for laboratories performing high complexity testing;
  - (6) Employing a clinical consultant in accordance with 42 CFR § 493.1417 or 42 CFR § 493.1455 as appropriate;
  - (7) Employing a technical consultant if the laboratory is performing moderately complex tests as defined in 42 CFR § 493.1411;
  - (8) Employing a general supervisor and a technical supervisor if the laboratory is performing highly complex tests as defined in 42 CFR § 493.1461, 1449 and 1468 if the laboratory is performing cytology;
  - (9) 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;
  - (10) Providing sufficient supplies, equipment and lighting to ensure all services are provided in a safe and timely manner; and
  - (11) Implementing any POC that has been accepted or issued by the department.
- (e) The licensee shall post the following documents in an area of the licensed premises that is conspicuous and open to clients and the general public:
- (1) The current license issued in accordance with RSA 151:2;
  - (2) All inspection and investigation reports issued in accordance with He-P 808.09(c) and He-P 808.11(d)(2)a. 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;

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(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) The licensee's evacuation floor plan identifying the location of, and access to all fire exits, except that mobile laboratory vans shall be exempt from this requirement.

(f) 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.

(g) 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.

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

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

(2) Safeguards to ensure the confidentiality of the information on clients and staff; and

(3) Systems to prevent the tampering of information on clients and staff.

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

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

(k) 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.

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

(m) 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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss 8852, eff 3-24-07; ss by #10267, eff 2-2-13

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 4 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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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

(a) All client 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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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;

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- (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; and
    - 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 client 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 employees and volunteers whose scope of employment will involve direct contact with a client, client records or client tissue, body fluids or other biological material, the licensee shall:
- (1) Obtain and review a criminal records check from the New Hampshire department of safety in accordance with RSA 151:3-c;
  - (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) Verify that the potential employee is not listed on the state registry maintained by the department's bureau of elderly and adult services;
  - (4) 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;
  - (5) 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; and
  - (6) Comply with the requirements of the Centers for Disease Control "Guidelines for Preventing the Transmission of Tuberculosis in Health Facilities Settings," 2005 edition (available as noted

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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.

(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, abuse, neglect or exploitation;
- (2) Has been found by the department or any administrative agency in this or any other state for assault, fraud, abuse, neglect or exploitation of any person; or
- (3) Otherwise poses a threat to the health, safety or well-being of the clients.

(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 clients.

(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, 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, abuse, neglect or exploitation or pose a threat to the health, safety or well-being of a client; and
- (3) Have not had a finding by the department or any administrative agency in this or any other state for assault, fraud, 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;

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- (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 client 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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13



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. Universal precautions;
  - (3) Prohibit the use of tobacco products, smoking, eating, drinking, chewing gum or applying of cosmetics in the laboratory work area; and
  - (4) Include written procedures for the handling, storage, transportation or disposal of those items identified as infectious waste in Env-Sw 103.28.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

He-P 808.20 Physical Environment, Emergency and Fire Safety.

- (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 manufacturers 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 or toxic materials, as defined in RSA 147-A:2, VII, 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) The licensee shall immediately notify the department by phone, fax or e-mail within 24 hours and in writing within 72 hours, of any fire or situation, excluding a false alarm, that requires the evacuation of the licensed premises.

(m) The written notification under (l) 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 person evacuated as a result of the incident, if applicable;
- (5) The name of any personnel who required medical treatment as a result of the incident, if applicable; and
- (6) The name of the individual the licensee wishes the department to contact if additional information is required.

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(n) All freestanding tanks of compressed gases shall be firmly secured to the adjacent wall, except for in mobile laboratory vans, where they shall be secured during transport as required by the department of safety in Saf-C 6000.

(o) 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 department of safety in Saf-C 6000.

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

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

(r) If a licensee is located in a building where fire evacuation drills are required under Saf-C 6000 or any other state or local ordinance, then the licensee shall participate in those drills.

Source. #2192, eff 11-25-82; ss by #3193, eff 1-28-86; ss by #5317, EMERGENCY, eff 1-29-92, EXPIRED: 5-28-92

New. #5758, eff 12-20-93, EXPIRED: 12-20-99

New. #8409, eff 8-19-05; ss by #8852, eff 3-24-07; ss by #10267, eff 2-2-13

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

(c) The laboratory portions of the mobile laboratory van shall have a non-porous floor.

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

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(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.

Source. #8852, eff 3-24-07; ss by #10267, eff 2-2-13

**Appendix A: Incorporation by Reference Information**

<b>Rule</b>	<b>Title</b>	<b>Obtain at:</b>
He-P 808.07(e)	Facility Guidelines Institute “Guidelines for Design and Construction of Health Care Facilities,” “Laboratories” chapter, 2010 edition	This publication is published and may be obtained by contacting the Facilities Guidelines Institute (formerly the American Institute of Architects) either by phone: 1-800-242-2626; or in writing via <a href="http://www.ashestore.com">www.ashestore.com</a> . This publication is available in three formats: Bound Book Catalog #055373, Secure PDF on CD Catalog # 055374, and Three-Hole Punched Loose Leaf Catalog #055375. The cost of this publication is \$168.00 each.
He-P 808.17(d)	Centers for Disease Control “Guidelines for Preventing the Transmission of Tuberculosis in Health Facilities Settings,” 2005 edition	Available free of charge from the CDC website at <a href="http://www.cdc.gov">www.cdc.gov</a> .

**APPENDIX B**

<b>Rule</b>	<b>Specific State or Federal Statutes the Rule Implements</b>
He-P 808.01 – He-P 808.03	RSA 151:2,I(c); RSA 151:2,II; RSA 151:9,I(a)&(b)
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 808.21	RSA 151:9,I(a)