

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 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

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)-(g);
- (b) All entities which are owned or operated by the state of New Hampshire, pursuant to RSA 151:2, II(h);
- (c) All laboratories, which conduct testing solely for forensic purposes, pursuant to RSA 151:2, II(h); and
- (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.

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

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).
- (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 cause a licensee to be out of compliance with RSA 151 or He-P 808.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (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) "Inspection" means the process used by the department to determine a licensee's compliance with RSA 151 and He-P 808.
- (j) "Investigation" means the process used by the department to respond to allegations of non-compliance with RSA 151 and He-P 808.
- (k) "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.
- (l) "Laboratory director" means the person who shall provide overall management and direction to all laboratory operations and who meets the qualification requirements of 42 CFR § 493.1405 or 493.1443.
- (m) "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.
- (n) "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.
- (o) "Licensing classification" means the specific category of services authorized by a license.
- (p) "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.
- (q) "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.
- (r) "Personnel" means individual(s) who conduct testing or provide laboratory services.
- (s) "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.
- (t) "Procedure" means a licensee's written, standardized method of performing duties and providing services.
- (u) "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.
- (v) "Specimen" means a portion of tissue, body fluid or material from a human body.
- (w) "Technical consultant" means an individual qualified as a technical consultant by 42 CFR § 493.1411.
- (x) "Waived testing" means all laboratory tests categorized as waived by 42 CFR § 493.

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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," 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;
- b. "Certificate of Formation," if a limited liability company; or
- c. "Certificate of Trade Name," where applicable;

(4) The applicable fee of \$65.00, in accordance with RSA 151:5, I(b), for each of the following categories tested:

- a. Microbiology;
- b. Diagnostic immunology;
- c. Chemistry;
- d. Hematology;
- e. Immunohematology;
- f. Pathology;
- g. Radiobioassay; and
- h. Clinical cytogenetics;

(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:

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

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;

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) Documentation that the water supply has been tested in accordance with RSA 485 and Env-Ws 313.01 and 314.01;

(8) For renewal of a license, 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-Ws 313.01 for bacteria and Env-Ws 314.01 for nitrates;

(9) A written disclosure from the applicant, including the officers of the board of directors for a corporation or members of a limited liability corporation, licensee, if different from the applicant, and the laboratory director, containing a list of any:

- a. Convictions in this or any other state;
- b. Findings by the department or any administrative agency in this or any other state for assault, fraud, abuse, neglect or exploitation; and
- c. An explanation of the circumstances surrounding disclosure of matters described in a. and b. above; and

(10) The results of a criminal records check from the NH department of safety for the individuals identified in (9) above.

(b) The fee in (a)(4) above shall be payable in cash or, if paid by check or money order, in the exact amount of the fee, made payable to the "Treasurer of the State of New Hampshire."

(c) 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) The department shall process applications in accordance with RSA 541-A:29.
- (b) An application for an initial license shall be deemed to 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.
- (c) 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.
- (d) 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.
- (e) Licensing fees shall not be transferable to any other application(s).
- (f) 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.
- (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 for Residential or Health Care License," for license renewal prior to the expiration of the current license.
- (c) The licensee shall submit with the 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);
 - (3) A request for renewal of any existing waiver previously granted by the department, in accordance with He-P 808.10(f), if applicable; and
 - (4) A statement identifying any exemptions or waivers applied for or granted by the state fire marshal, in accordance with Saf-C 6005.03-6005.04.
- (d) 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) above prior to the expiration of the current license;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (2) Is found to be in compliance with RSA 151; and
- (3) Does not have any uncorrected deficiencies.

(e) 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.

(f) 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.

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

He-P 808.07 Laboratory Construction, Alterations or Additions.

(a) Architectural plans shall be submitted to the department at least 60 days prior to the start of construction, or initiating any structural modifications to a building for the following:

- (1) A new building;
- (2) Additions to a building;
- (3) Renovations involving more than 15% of the square footage of a licensed premise;
- (4) Renovations that involve a means of egress previously approved by the department;
- (5) Renovations and alterations that might effect compliance with the health and safety, fire or building codes; or
- (6) Alterations or additions to fire suppression and detection systems.

(b) Any licensee or applicant constructing, renovating, or modifying a building shall comply with the following:

- (1) The state fire code as adopted under RSA 153; and
- (2) The state building code as adopted under RSA 155-A:2.

(c) Any licensee or applicant who wants to use performance based standards to meet the fire safety requirements shall provide the department with a copy of the fire marshal's written approval for such methods.

(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) The completed building shall be subject to an inspection pursuant to He-P 808.09, prior to the use of the newly constructed or modified building.

(f) 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 at the new location 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;
- (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

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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.

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

(1) Documentation of the new laboratory director's qualifications, including transcripts and a resume; and

(2) Written notification of the date the new laboratory director will begin employment.

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

(g) If the department determines that the new laboratory 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) 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) A change in the licensing classification;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (5) The renewal of a license; or
- (6) The issuance of a mobile laboratory van license.

(b) 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 the POC.

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

(d) 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.

(e) If a licensee is cited for deficiencies in the inspection report mentioned in (c) above, the licensee shall submit a written POC, in accordance with He-P 808.12(c) within 21 days of the date on the letter that transmits the inspection report.

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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;
- (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; and
- (4) The period of time for which the waiver is sought.

(b) A waiver shall not exceed 12 months or the current license expiration date.

(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) It is administrative in nature and does not 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.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(f) When a licensee wishes to renew the waiver beyond the approved period of time, the licensee shall apply for a new waiver at least 60 days prior to the expiration of the existing waiver by submitting the information required by (a) above.

(g) The request to renew a waiver shall be subject to (b) through (e) above.

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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) The complaint shall contain the following information when practicable:

- (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:

- (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 suspected violations of their statutes or rules based on the findings of the complaint investigation.

(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:

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (1) An investigation shall be completed; and
- (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, the department shall issue:

- (1) A written warning to immediately comply with RSA 151 and He-P 808; and
- (2) The information 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 name of the complainant and the information contained in the investigation file shall be kept confidential as required by RSA 151:13, but shall be released by the department on written request only:

- (1) To appropriate professional licensing boards if the information contained in the complaint file appears contrary to professional practices;
- (2) During any adjudicative proceedings that concern the suspension, denial or revocation of a license under RSA 151:8 and RSA 151:9, I(f); or
- (3) After the department suspends, denies or revokes a license under RSA 151:7, II.

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

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) POC's upon a licensee;
- (2) Directed POC's upon a licensee; and
- (3) Fines upon unlicensed individuals, applicants and licensees.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(b) When administrative remedies are imposed, the department shall provide the unlicensed individual, applicant or licensee with a written notice:

- (1) Identifying each violation;
- (2) Identifying which remedy(s) are being imposed; and
- (3) If a fine, informing the recipient of the following:
 - a. The right to a hearing in accordance with RSA 541-A prior to imposition of fines; and
 - b. The automatic reduction of a fine by 25% if the fine is paid within 10 days of the date on the written notice from 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;
- (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 notify the licensee to implement the POC with:
 - a. The issuance of a license certificate; or
 - b. Written notification of acceptance;
- (5) The department shall reject any POC, which does not meet the requirements of (3) above;
- (6) If the POC is not acceptable the department shall notify the licensee in writing of the reason for rejecting the POC;
- (7) The licensee shall develop and submit a revised POC within 21 days of the date of the written notification from the department that states the original POC was rejected;
- (8) The revised POC shall comply with (1) and (2) above and be reviewed in accordance with (3) above;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (9) If the revised POC is not acceptable to the department or is not submitted within 21 days of the written notification from the department that states the original POC was rejected, the department shall issue:
- a. A directed POC in accordance with He-P 808.12(d); and
 - b. A fine in accordance with He-P 808.12(e)(8);
- (10) 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;
- (11) The implementation verification of any POC shall only occur after the date of completion specified by the licensee in the plan; and
- (12) 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 POC's 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
- (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(e), the fine for an unlicensed individual, applicant or a licensee shall be \$2000.00;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (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) When an inspection determines that an unlicensed individual failed to comply with the conditions of a warning issued by the department, in violation of RSA 151:7-a, the fine shall be \$500.00;
 - (5) Until an unlicensed individual provides the department with documentary evidence of compliance, each day that a licensee fails to comply with the conditions of a warning beyond the initial imposition of a fine in (4) above shall be considered a separate violation subject to an additional \$100.00 fine;
 - (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 \$250.00;
 - (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 or a revised POC, within 21 days of the date on the letter that transmits the inspection report, in violation of He-P 808.12(c) the fine for a licensee shall be \$100.00;
 - (9) Until a licensee provides the department with documentary evidence of compliance, each day that a licensee fails to submit a POC beyond the initial imposition of a fine in (8) above shall be considered a separate violation subject to an additional \$100.00 fine to a maximum fine of \$2000.00;
 - (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 \$1000.00;
 - (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;
 - (12) For failure to implement any POC that has been accepted or issued by the department, in violation of He-P 808.12(c)(4), the fine for a licensee shall be \$100.00;
 - (13) Until a licensee provides the department with documentary evidence of compliance, each day beyond the initial imposition of a fine in (12) above that a licensee fails to implement a POC shall be considered a separate violation subject to an additional \$100.00 fine to a maximum fine of \$2000.00;
 - (14) 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;
 - (15) 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;
 - (16) For employing an administrator 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 \$100.00; and
 - (17) When there is a repeat violation, or failure to correct a previously cited violation, within 2 years of the date of the original violation, the fine for a licensee shall be \$2000.00.
- (f) Payment of any imposed fine to the department shall meet the following requirements:

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (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

He-P 808.13 Enforcement Actions and Hearings.

(a) Prior to taking 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; 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:

- (1) An applicant or a licensee is in violation of RSA 151 or He-P 808;
- (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) An applicant or a licensee has violated any of the provisions of RSA 151:7, II;
- (5) 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;
- (6) 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;
- (7) An applicant or licensee has demonstrated a history or pattern of multiple, or repeat violations of RSA 151 and He-P 808 that pose or have posed a health or safety risk to clients;
- (8) A licensee failed to fully implement or continue to comply with the POC or revised POC in accordance with He-P 808.12(c)(4) and (10) that has been accepted by the department;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (9) A licensee has failed to implement a directed POC in accordance with He-P 808.12(d);
- (10) A licensee has submitted a POC that has been rejected by the department in accordance with He-P 808.12(c)(5)-(6) and has not submitted a revised POC as required by He-P 808.12(c)(7);
- (11) A licensee is cited a third time under RSA 151 or He-P 808 for:
 - a. Repeat violations; or
 - b. Failure to correct previously cited violations within 3 years of the date of the original violation for which a POC, directed POC or fine has previously been imposed;
- (12) A licensee, including corporation officers or board members, has had a license revoked and submits an application during the 5-year prohibition period;
- (13) An inspection of the applicant's premises does not find full compliance with RSA 151 or He-P 808; or
- (14) The owner(s), licensee or laboratory director has been found guilty of or plead guilty to a felony assault, fraud, abuse, neglect, or exploitation of any person, in this or any other state, or had an investigation for abuse, neglect, or exploitation adjudicated and determined to be founded by the department.

(c) The department shall immediately suspend a license when an inspection or investigation has found the safety and welfare of clients is in jeopardy and emergency action is required.

(d) If the immediate suspension of a license is ordered:

- (1) The licensee shall immediately cease to operate; and
- (2) The department shall hold a hearing within 10 working days of the date the order was issued.

(e) If an immediate suspension is upheld at the hearing described in (d)(2) above, the licensee shall not operate until the department determines through inspection that compliance with RSA 151 and He-P 808 is achieved.

(f) If an applicant or licensee fails to submit a written request for an administrative appeal within 30 days of receipt of a notice to deny or revoke a license, as described in (a) above, the action of the department shall become final.

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

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

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

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.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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 for Residential or Health Care License,” 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 director who shall meet the qualification requirements as stated in:

a. 42 CFR § 493.1405 for laboratories performing moderate complexity testing or waived testing, as defined in He-P 808.03(x); or

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

(6) Employing a clinical consultant in accordance with 42 CFR § 493.1419;

(7) Employing a technical consultant if the laboratory is performing moderately complex tests as defined in 42 CFR § 493.1425;

(8) Employing a general supervisor and a technical supervisor if the laboratory is performing highly complex tests as defined in 42 CFR § 493.1459;

(9) Providing sufficient numbers of personnel who are present in the laboratory and are qualified 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;

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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) 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 all programs and services of any licensee that is providing laboratory services, which is the testing or examination of specimens derived from the human body, the result of which are used to diagnose or otherwise determine an individual's medical condition, at any time 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.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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.

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

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 area of testing responsibility.

(c) The licensee shall write an incident report for each occurrence of an error, negative outcome or accident that requires treatment by a licensed practitioner.

(d) The incident report shall include:

(1) The date of the incident;

(2) A description of the incident;

(3) The actions taken by personnel; and

(4) The signature of the person reporting the incident.

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

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

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; and
 - (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 policies, procedures and guidelines;
 - c. The laboratory's infection control program; and
 - d. The laboratory's fire, evacuation and emergency plans, which outline the responsibilities of personnel in an emergency.
- (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) Regardless of the complexity of the laboratory testing, all testing personnel shall, at a minimum;
 - (1) Have an associate degree in a laboratory science or in medical laboratory technology from an accredited institution;
 - (2) Be federally certified as a medical laboratory technician by the US department of health, education and welfare (HEW);
 - (3) Have attained the level of medical laboratory technician or its equivalent in military service; or
 - (4) Have at least 2 years post high school education in a life science leading to certification in a health care field.
- (d) 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; and
 - (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.
- (e) Current and complete personnel files shall be maintained at the licensed premises, except as allowed by (h) below.
- (f) Personnel files shall include:

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

- (1) Identification data;
 - (2) Qualifications and work experience;
 - (3) A signed statement acknowledging compliance with (b)(2) above;
 - (4) Record of satisfactory completion of the orientation program required by (b)(3) above;
 - (5) A copy of each current New Hampshire license, registration or certification in health care field, if applicable; and
 - (6) Documentation of annual in-service education as required by (b) above.
- (g) 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; and
 - (2) Stored in locked containers or cabinets or in a locked room on the premises.
- (h) 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 (f) and (g) above.

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

He-P 808.18 Quality Assessment. Independent laboratories and hospital 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

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 or applying of cosmetics in the laboratory work area; and

(4) The handling, storage, transportation or disposal of those items specified as infectious waste in Env-Wm 2604.01 shall be done in accordance with Env-Wm 2604.

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

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 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 the laboratory's procedure manual, for preservation of specimens, reagents and supplies; 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.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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.

(n) All freestanding tanks of compressed gases shall be firmly secured to the adjacent wall, except for mobile laboratory vans, which 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, 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.

NEW HAMPSHIRE CODE OF ADMINISTRATIVE RULES

(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

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 has a valid license issued by the department.

(b) Each applicant shall comply with He-P 808, except for He-P 808.07(a)-(e) and:

(1) 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

(2) 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.

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

Source. #8852, eff 3-24-07

APPENDIX

Rule	Specific State or Federal Statutes the Rule Implements
He-P 808.01	RSA 151:9, I
He-P 808.02	RSA 151:9, I
He-P 808.03	RSA 151:9; RSA 151:9, I(b)
He-P 808.04	RSA 151:9, I(c)
He-P 808.05	RSA 151:9, I(c)
He-P 808.06	RSA 151:9, I(d)
He-P 808.07	RSA 151:3-a; RSA 151:9, I(a)
He-P 808.08	RSA 151:9, I(a)
He-P 808.09	RSA 151:6-a; RSA 151:9, I(e) and (f)
He-P 808.10	RSA 151:9, I(a)
He-P 808.11	RSA 151:9, I(a)
He-P 808.12	RSA 541-A:30; RSA 151:7-a; RSA 151:9, I(f), (g) and (l); RSA 151:16-a
He-P 808.13	RSA 541-A:30; RSA 541-A:30-a; RSA 151:9, I(f) and (l); RSA 151:7
He-P 808.14	RSA 151:9, I(a); RSA 151:20; RSA 151:29
He-P 808.15	RSA 151:9, I(a); 42 CFR 493
He-P 808.16	RSA 151:9, I(a); 42 CFR 493
He-P 808.17	RSA 151:9, I(a); 42 CFR 493
He-P 808.18	RSA 151:9, I(a); 42 CFR 493
He-P 808.19	RSA 151:9, I(a); 29 CFR 1910.1030
He-P 808.20	RSA 151:9, I(a)
He-P 808.21	RSA 151:9, I(a),(c) and (d); 42 CFR 493