STATE OF NEW HAMPSHIRE

OFFICE OF LEGISLATIVE SERVICES
ADMINISTRATIVE RULES

STATE HOUSE ANNEX
25 CAPITOL STREET, ROOM 234
CONCORD, NH 03301

Rulemaking Notice Form

Notice Number: 2026-245

Rule Number: He-P 4046

1. **Agency:** Department of Health and Human Services

   Agency Address: Department of Health and Human Services
   Former Division of Public Health Services
   Administrative Rules
   Unit Brown Building, 2nd Floor
   129 Pleasant St. Concord, NH 03301

2. **RSA Authority:** RSA 125-F:5, V
3. **Federal Authority:** 42 USC 2021(b)
4. **Action(s):** Readopt w/Amendment
5. **Short Title:** Use of Radiation Machines: General Requirements for All Diagnostic and Veterinary X-Ray Systems
6. **(a) Summary of what the rule says and of any proposed amendments including whether the rule implements a state statute for the first time:**

   He-P 4046 describes requirements for the use of diagnostic imaging machines for dental, diagnostic, and veterinary uses.

   The Department of Health and Human Services (Department) is proposing to readopt He-P4046, with the following amendments:

   - Update language in He-P 4046.01-08 and 4046.11-12 to better align with 21 CFR 1020.30-33;
   - Remove the requirement for extremity dosimetry in He-P 4046.09 for operators of hand-held intraoral machines and provide a means to remove the requirement for lead or lead equivalent protective apparel for operators of hand-held intraoral machines;

- Establish requirements for registrants to follow the manufacturer's quality control (QC) recommendations and ensure that operators have access to QC instructions, schedules, variations and records of QC tests in He-P 4046.10;
- Establish minimum requirements for routine machine performance evaluations for fluoroscopy and computed tomography (CT) machines in He-P 4046.05 and He-P 4046.13;
- Establish the requirements for a radiation protocol committee for fluoroscopically guided interventional procedures and computed tomography imaging protocols in He-P 4046.05 and He-P 4046.13;
- Exempt veterinary CT facilities from the need to have routine machine performance evaluations, routine image quality control, and establishing a radiation protocol committee in He-P 4046.16; and
- Modify the requirements for bone density machines to operator requirements, record requirements, and machine requirements in He-P 4046.15.

These sections are part of an interim rule which is scheduled to expire on November 18, 2026, but are subject to extension pursuant to RSA 541-A:14-a, I.

Does this rule implement a state statute for the first time?

No, these rules do not implement a state statute for the first time.

6. **(b) Brief description of the groups affected:**

He-P 4046 affects any person who is an applicant for, or a holder of, a registration for all diagnostic and veterinary x-ray machines.

6. **(c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:**

Rule	State Statute or Federal Regulation Implemented
He-P 4046.01	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32
He-P 4046.02	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32
He-P 4046.03	; RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.32
He-P 4046.04	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.32
He-P 4046.05	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30, 21 CFR 1020.32

He-P 4046.06	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31
He-P 4046.07	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31
He-P 4046.08	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32
He-P 4046.09	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31
He-P 4046.10	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.30; 21 CFR 1020.31
He-P 4046.11	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.33
He-P 4046.12	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 1020.33
He-P 4046.13	RSA 125-F:5, II & V
He-P 4046.14	RSA 125-F:5, II & V; RSA 541-A:22, IV; 21 CFR 900
He-P 4046.15	RSA 125-F:5, II &V
He-P 4046.16	RSA 125-F:5, II &V
He-P 4046.17	RSA 125-F:5, II &V

7. **Contact person for copies and questions including requests to accommodate persons with disabilities:**

Name: Nicole Valanzola	**Title:** Rules Coordinator
Address: Department of Health and Human Services Administrative Rules Unit Brown Building, 2nd Floor 129 Pleasant St. Concord, NH 03301	**Phone Number:** (603) 271-9640
	FAX Number: (603) 271-5590
	Email: Nicole.Valanzola@dhhs.nh.gov

8. **Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified:**

   Thursday, December 24, 2026

   X **Fax**

   X **Email**

   _ **Other**

9. **Public hearing scheduled for:**

   Date: Thursday, December 17, 2026

   Time: 1:00 PM

   Place: Department of Health and Human Services
   129 Pleasant St.
   Brown Building, Auditorium

   Electronic Access, if applicable: N/A

10. **Fiscal Impact Statement (Prepared by Legislative Budget Assistant):**

    FIS #: 26:243, dated: Tuesday, November 3, 2026

    1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

    When compared to the existing rules, the proposed rules will have an indeterminable impact on independently owned businesses.

    2. Cite the Federal mandate. Identify the impact on state funds:

    No federal mandate, no impact on state funds.

    3. Cost and benefits of the proposed rule(s):

    A. To State general or State special funds:

    None.

    B. To state citizens and political subdivisions:

    None.

    C. To independently owned businesses:

    The Department of Health and Human Services states the rule will have the following indeterminable impacts:

    Businesses operating hand-held intraoral machines will no longer be required to provide extremity dosimetry for operators. Removing this requirement will remove the costs associated with maintaining an extremity dosimetry program

    Veterinary facilities that operate CT machines will see reductions in operating costs because they will no longer be required to have annual equipment performance evaluations and routine quality control tests. They will only be required to have a

radiation safety survey after a machine's installation, any significant change in workload, or after a major repair.

While the fluoroscopic machine and CT machine requirements state the need for the equipment performance evaluations, this is not an added cost for fluoroscopic facilities because qualified experts do performance evaluations that include the required entrance exposure rates. The rule instead establishes the minimum requirements for a machine performance evaluation.

The addition of the requirements for a radiation protocol committee will require annual meetings to evaluate the use of radiation machines. Facilities that have established a radiation safety committee due to the possession of a radioactive materials license will not need to make an adjustment for this. However, facilities that do not currently have a radiation protocol committee may experience an indeterminable cost in time, etc.

11. **Statement Relative to Part I, Article 28-a of the N.H. Constitution:**

The proposed rule does not modify an existing program or responsibility, and does not mandate any fees, duties, or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.