APPENDIX II-G

COVER SHEET FOR FINAL PROPOSAL

Notice Number **2022-31** Rule Number **He-P 4045.03**

1. Agency Name & Address:

Dept. of Health and Human Services
Division of Public Health Services
Radiological Health Section
29 Hazen Drive
Concord, NH 03301

2. RSA Authority: **RSA 125-F:5, V**
3. Federal Authority: **42 U.S. Code § 2021(b)**
4. Type of Action:
   - ☐ Adopt
   - ☐ Amendment (only if Initial Proposal was filed before 9/27/20.)
   - ☐ Repeal
   - ☐ Readoption
   - ☒ Readoption w/amendment

5. Short Title: **Administrative Controls**

6. Contact person for copies and questions:

Name:	**Nicole Burke**	Title:	**Administrative Rules Coordinator-Administrative Rules Unit**
Address:	**Dept. of Health & Human Services** **Administrative Rules Unit** **129 Pleasant Street, Brown Bldg.** **Concord, NH 03301**	Phone #:	**(603) 271-9640**

7. The rulemaking notice appeared in the Rulemaking Register on March 10, 2022

SEE THE INSTRUCTIONS--PLEASE SUBMIT ONE COPY OF THIS COVER SHEET AND ONE COPY OF THE FOLLOWING:
(optional to number correspondingly)

8. The "Final Proposal-Fixed Text," including the cross-reference table required by RSA 541-A:3-a, II as an appendix.

9. Yes ☐ N/A ☒ Incorporation by Reference Statement(s) because this rule incorporates a document or Internet content by reference for which an Incorporation by Reference Statement is required pursuant to RSA 541-A:12, III.

10. Yes ☒ N/A ☐ The "Final Proposal-Annotated Text," indicating how the proposed rule was changed because the text of the rule changed from the Initial Proposal pursuant to RSA 541-A:12, II(d).

11. Yes ☐ N/A ☒ The amended fiscal impact statement because the change to the text of the Initial Proposal affects the original fiscal impact statement (FIS) pursuant to RSA 541-A:5, VI.

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2. RSA Authority: **RSA 125-F:5, V**

3. Federal Authority: **42 U.S.C. § 2021(b)**

4. Type of Action:

Adoption ____
Repeal ____
Readoption ____
Readoption w/amendment **X**

5. Short Title: **Administrative Controls for Use of Radiation or MRI Machines**

6. (a) Summary of what the rule says and of any proposed amendments:

The Department of Health and Human Services proposes to readopt with amendment He-P 4045.03 on administrative controls by the Department's Radiological Health Section (DHHS/RHS) for use of radiation or MRI machines.

The proposed amendment is to He-P 4045.03(k) on gonad shielding to clarify the role of the radiologist as the medical expert in determining the necessity of the use of a gonad shield in certain diagnostic imaging procedures.

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

The group who may likely be impacted by the proposed rule revision includes radiologists, radiographers, and their patients. Radiologists are the most qualified medical professionals who can determine the necessity of the use of gonad shield for certain imaging procedures. The radiographer who prepares the patient and acquires the x-ray image is responsible for applying the shield, if necessary, in accordance with the radiologist's x-ray image prescription. The patient's concerns about radiation dose from that imaging procedure with or without the use the gonad shield will need to be fully addressed.

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

Rule	Specific State or Federal Statute or Regulation the Rule Implements
He-P 4045.03	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32, 21 CFR 1020.40

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

Name: **Nicole Burke**

Title: **Rules Coordinator – Administrative Rules Unit**

Address: **Dept. of Health and Human Services**
Administrative Rules Unit
129 Pleasant Street, 2nd Floor
Concord, NH 03301

Phone #: **(603) 271-9640**

Fax#: **(603) 271-5590**

E-mail: **Nicole.V.Burke@dhhs.nh.gov**

TTY/TDD Access: Relay NH 1-800-735-2964
or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:
http://www.dhhs.nh.gov/oos/aru/comment.htm

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Thursday, April 14, 2022**

☒ Fax ☒ E-mail ☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, April 7, 2022 at 1:00 pm**

Place: **DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**

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

FIS # **22:018** , dated **2/22/2022**

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

There is no difference in cost when comparing the proposed rule to the existing rule.

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:
None.

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

The proposed rule modifies an existing program or responsibility, but 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.

CONSENT/EDIT

Readopt with amendment He-P 4045.03, effective 7/21/15 (Document #10893), as amended in paragraph (c) effective 10/28/16 (Document #12024, Interim) and expired 4/26/17, and as amended in paragraph (c) effective 6/20/17 (Document #12215), to read as follows:

He-P 4045.03 Administrative Controls.

(a) A radiation or MRI machine which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes.

(b) Persons who operate radiation or MRI machines shall be instructed in the manufacturer's safe operating procedures and be competent in the safe use of the equipment.

(c) All MRI machine operators shall be able to demonstrate competence in the operation of the machine as required by (b) above, including, at a minimum, competence in the following areas:

(1) Familiarity with equipment to include:

a. Identification of controls; and

b. Function of each control; and

(2) Emergency procedures including procedure termination.

(d) All diagnostic radiation machine operators shall be able to demonstrate competence in the operation of the machine as required by (b) above, including, at a minimum competence in the following areas:

(1) Familiarity with equipment to include:

a. Identification of controls;

b. Function of each control; and

c. Use of a technique chart;

(2) Radiation protection measures to include:

a. Collimation;

b. Filtration;

c. Lead equivalent material patient protection devices, if used;

d. Restriction of x-ray tube radiation to the image receptor;

e. Personnel protection; and

f. Grids;

(3) Film and film processing to include:

a. Film speed as related to patient exposure;

b. Film processing parameters; and

c. Quality assurance techniques;

(4) Emergency procedures to include termination of exposure in the event of automatic timing device failure;

(5) Proper use of personnel dosimetry;

(6) An understanding of the units of radiation and dose; and

(7) An understanding of these rules.

(e) Specific technique factors and protocols for any diagnostic radiation machine which cannot be programmed to select body part, projection, or patient size, shall be created to include protocols to identify the following:

(1) Patient's body part and anatomical size, or body part thickness, or age for pediatric, versus technique factors to be utilized;

(2) Type and size of the image receptor;

(3) Type of grid, if any;

(4) Source to image receptor distance to be used, except in dental intraoral radiography;

(5) Type and location of placement of patient shielding used; and

(6) Technique factors kVp, mA, time.

Edit: "and"

(f) The registrant of a facility shall:

(1) Establish written safety procedures for the safe operation of radiation or MRI machines;

(2) Make written safety procedures available to all operators of radiation or MRI machines;

(3) Write safety procedures for use of machines at the facility which shall include, but not be limited to:

a. Patient holding; and

b. Any restrictions in the operating techniques required for the safe operation of a particular system.

(g) The radiation or MRI machine operator shall be able to demonstrate familiarity with the written safety procedures required in (f) above.

(h) Only staff, other persons required to be in attendance, and patients who cannot be evacuated shall be in the room during the radiographic exposure.

(i) All persons in the room other than the patient being examined shall be positioned so that no part of the body will be struck by the useful beam and shall be protected from scatter radiation by either protective aprons or whole body protective barriers, of not less than 0.5 millimeter lead equivalent material.

(j) Patients who cannot be removed from the room shall be positioned so that the nearest portion of the body is at least 2 meters from the tube head or the image receptor, whichever is closer.

(k) Radiologists shall assess the need for gonad shielding for diagnostic imaging acquisition including requiring that gonad shielding of no less than 0.5 millimeter lead equivalent material be used:

(1) For patients who have not passed the reproductive age; and

(2) During radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(l) Persons shall not be exposed to the useful beam, except for healing arts purposes when such exposure has been authorized by a licensed practitioner of the healing arts.

(m) Deliberate exposure of a person shall be prohibited for the following purposes:

(1) Exposure of a person for training, demonstration, or other non-healing-arts purposes; and

(2) Exposure of a person for the purpose of healing arts screening except as authorized by He-P 4045.04.

(n) If a patient or image receptor must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used whenever possible;

(2) The written safety procedures, required by He-P 4045.03(f), shall indicate the requirements for selecting a human holder and the procedure the human holder shall follow;

(3) The human holder shall be instructed in personal radiation safety and protected as required by He-P 4045.03(f);

(4) No person shall be used routinely to hold image receptors or patients;

(5) In cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;

(6) Each facility shall have lead equivalent garments or barriers available in sufficient numbers to provide protection to all personnel who shall be involved with radiation machine operations and not otherwise shielded; and

(7) All protective apparel or barriers shall be clearly labeled with its lead equivalence.

(o) Procedures and auxiliary equipment designed to minimize patient and personnel exposure shall be utilized as follows:

(1) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations;

(2) Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography;

(3) The radiation exposure to the patient shall be the minimum exposure required to produce images of high diagnostic quality;

(4) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray system;

(5) X-ray systems other than fluoroscopic, dental, computed tomography, or veterinary systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters; and

(6) If grids are used between the patient and the image receptor, the grid shall:

a. Be positioned properly;

b. Centered to the central ray; and

c. If of the focused type, be of the proper focal distance for the SIDs being used.

(p) All persons who are associated with the operation of an x-ray system shall be subject to the requirements of He-P 4020 through He-P 4022 of these rules.

Appendix

Rule	**Specific State or Federal Statutes or Regulations the Rule Implements**
He-P 4045.03	RSA 125-F:1, F:2, 125-F:5, II & V; 21 CFR 1020.30, 1020.31, 1020.32, 1020.40

Edit: Update to read as follows (bold is new text):
"RSA 125-F:1, **RSA 125-**F:2, **RSA** 125-F:5, II &V; 21 CFR 1020.30, **21 CFR** 1020.31, **21 CFR** 1020.32, **21 CFR** 1020.40"