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PART He-P 4045 USE OF RADIATION MACHINES: ADMINISTRATIVE REQUIREMENTS

Adopt He-P 4045.02 and He-P 4045.04 – 4045.09, previously effective 7-21-15 (Document #10893), and expired 7-21-25, to be read as follows:

He-P 4045.02 General Requirements.

(a) The registrant shall assure that the requirements of He-P 4040 are met prior to the use of any radiation or MRI machine.

(b) The registrant shall be responsible for directing the operation of the radiation or MRI machine(s) under the registrant's administrative control.

(c) The registrant or the registrant's agent shall assure that the requirements of He-P 4045, in addition to all other applicable parts, are met in the operation of the radiation or MRI machine(s).

He-P 4045.04 Healing Arts Screening.

(a) Any person proposing to conduct a healing arts screening program shall submit the following information for preapproval:

(1) Name, address, and telephone number of the applicant and, where applicable, the names, addresses, and telephone number(s) of agents within this state;

(2) A detailed description of the x-ray examinations proposed in the screening program, including;

a. Diseases or conditions subject to x-ray examinations;

b. A description of the population to be examined in the screening program;

c. Technique factors to be used;

d. A description of the diagnostic x-ray quality control program;

e. A description of procedures to advise persons screened and their practitioners of the results of the screenings;

f. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations; and

g. An indication of the frequency of screening and the anticipated duration of the entire screening program;

(3) An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and reasons why these methods are not used instead of the x-ray examinations;

(4) An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program which shall:

a. Show that such system(s) do satisfy all requirements of this part; and

b. Include a measurement of patient exposures from the x-ray examinations to be performed;

(5) The qualifications of each person who will be operating the x-ray system(s), of those who will be supervising the operators of the x-ray system(s), the extent of supervision, and the method of work performance evaluation; and

(6) The name and address of the person who will interpret the radiograph(s).

(b) If any information submitted to DHHS/RHS becomes invalid or outdated, DHHS/RHS shall be notified within 15 days.

He-P 4045.05 Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system or MRI machine for inspection by DHHS/RHS until the registration requiring records is terminated:

(a) Model and serial numbers of all major components, and user's manuals for those components;

(b) Records of shielding reviews and surveys, where applicable;

(c) Records of calibrations, maintenance, and modifications performed on the x-ray system(s); and

(d) A copy of all correspondence with DHHS/RHS regarding that x-ray system.

He-P 4045.06 X-Ray System Utilization Log.

(a) Each facility shall maintain or be able to generate electronically a record containing:

(1) The patient's name;

(2) The type of examinations; and

(3) The dates the examinations were performed.

(b) When the patient or image receptor must be provided with human auxiliary support, the name of the human holder shall be recorded in the patient record for whom the support was provided, or cross-referenced to the patient record.

He-P 4045.07 X-Ray Film Processing Facilities and Practices.

(a) Each registrant using analog image receptors, such as film, shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) For manually developed film:

a. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material;

b. Developer solutions in the developing tanks shall be maintained at temperatures within the range of 60°F to 80°F (16°C to 27°C);

c. Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the recommendations set forth in Table 4045.1;

d. Devices shall be utilized which will indicate the actual temperature of the developer solution; and

e. Devices shall be used to signal the passage of a preset time appropriate to the developing time required;

Table 4045.1 Manual Time-Temperature Chart

Developer Solution Temperature (Degrees) (C)	(F)	Minimum Developing Time (Minutes)
26.7	80	2.0
26.1	79	2.0
25.6	78	2.5
25.0	77	2.5
24.4	76	3.0
23.9	75	3.0
23.3	74	3.5
22.8	73	3.5
22.2	72	4.0
21.7	71	4.0
21.1	70	4.5
20.6	69	4.5
20.0	68	5.0
19.4	67	5.5
18.9	66	5.5
18.3	65	6.0
17.8	64	6.5
17.2	63	7.0
16.7	62	8.0
16.1	61	8.5
15.6	60	9.5

(2) For automatic processors and other closed processing systems:

a. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; or, in the absence of such recommendations, the film shall be developed using Table 4045.2; and

b. The specified developer solution temperature and immersion time shall be posted in the darkroom or on the automatic processor; and

Table 4045.2 Automatic Time-Temperature Chart

Developer Solution Temperature (C)	(F)	Minimum Immersion Time[1] (Seconds)
35.5	96	19
35.0	95	20
34.5	94	21
34.0	93	22
33.5	92	23
33.0	91	24
32.0	90	25
31.5	89	26
31.0	88	27
30.5	87	28
30.0	86	29
29.5	85	30

[1] Immersion time only, no crossover time included.

(3) Processing deviations from the requirements of this paragraph shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded.

(b) Each installation using an x-ray system and analog image receptor shall be subject to the following additional requirements:

(1) Pass boxes shall be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes;

(2) Pass boxes shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

(3) The darkroom shall be light tight;

(4) The darkroom shall use proper safe lighting such that any film type in use exposed in a cassette to x-rays sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1, 0.05 for mammography, when exposed in the darkroom for 2 minutes with all safelights on;

(5) If used, daylight film handling boxes shall preclude fogging of the film;

(6) Darkrooms typically used by more than one person shall be provided with a method to prevent accidental entry while undeveloped films are being handled or processed;

(7) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation;

(8) Film in open packages shall be stored in a light tight container;

(9) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary, but at least annually;

(10) Outdated x-ray film shall not be used for diagnostic radiographs, unless:

a. The film has been stored in accordance with the manufacturer's recommendations; and

b. A sample of the film passes a sensitometric test for normal ranges of base plus fog and speed;

(11) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer; and

(12) Film developing solutions shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

He-P 4045.08 Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR). Unless other recommendations are made in writing by a qualified expert, each registrant using computed radiography (CR) or direct digital radiography (DDR) modes shall comply with the manufacturer's or vendor's recommendations with regard to:

(a) Exposure indicator values;

(b) CR cassette erasure frequency; and

(c) Image evaluation for artifacts, spatial resolution, contrast or noise, and exposure indicator constancy unless otherwise advised in writing by a qualified expert.

He-P 4045.09 Veterinarian Facilities – Administrative Requirements.

(a) All veterinarian facilities using radiation or MRI machines shall:

(1) Complete registration procedures as set forth in He-P 4040.04 or He-P 4040.07 for machines in storage;

(2) Complete a renewal of registration as set forth in He-P 4040.09; and

(3) Complete shielding evaluations as set forth in He-P 4040.03; and

(b) All veterinarian facilities shall comply with all other radiation or MRI machine administrative requirements as specified in He-P 4045, except for He-P 4045.04.

APPENDIX

Rule	State Statute or Federal Regulation Implemented
He-P 4045.02	RSA 125-F:1, F:2, F:5 II & V
He-P 4045.04	RSA 125-F:1, F:2, F:5, II & V
He-P 4045.05	RSA 125-F:1, F:2, F:5, II & V; RSA 125-F:13; 21 CFR 1002.10, 1002.11, 1002.12, 1002.13, 1002.30, 1020.31, 1020.32, 1020.40
He-P 4045.06	RSA 125-F:1, F:2, F:5, II & V
He-P 4045.07	RSA 125-F:1, F:2, F:5, II & V
He-P 4045.08	RSA 125-F:1, F: 2, F:5, II & V
He-P 4045.09	RSA 125-F:1, F:2, F:5, II & V