PART He-P 4046 USE OF RADIATION MACHINES: GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC AND VETERINARY X-RAY SYSTEMS

Adopt He-P 4046, previously effective 7-21-15 (Document #10893), and expired 7-21-25, to be read as follows:

He-P 4046.01 General Requirements for All Diagnostic X-ray. In addition to the requirements of He-P 4040 through He-P 4045, all diagnostic x-ray systems shall meet the following requirements:

(a) The control panel containing the main power switch shall bear a warning label that shall be legible, accessible to view, and shall state:

"WARNING: THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED";

(b) For battery-powered x-ray systems, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation;

(c) Means shall be provided to permit further limitation of the x-ray field;

(d) The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed;

(e) Compliance with the requirements of (f) below shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(f) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 4046.1;

Table 4046.1 Tube Potential v. Minimum Half-Value Layer

Design Operating Range	Measured Potential	Dental Intraoral Manufactured After 12/1/1980	Dental Intraoral Manufactured on or Before 12/1/1980 (and all other x-ray systems manufactured before 6/10/2006)	All X-ray Systems except Dental Intraoral Manufactured on or after 6/10/2006.
(k Vp)	(kVp)	(Half-Value Layer mm Aluminum)	(Half-Value layer mm Aluminum)	Half-Value Layer mm Aluminum)
Below 51	30	N/A	0.3	0.3
	40	N/A	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5

Design Operating Range	Measured Potential	Dental Intraoral Manufactured After 12/1/1980	Dental Intraoral Manufactured on or Before 12/1/1980 (and all other x-ray systems manufactured before 6/10/2006)	All X-ray Systems except Dental Intraoral Manufactured on or after 6/10/2006.
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

(g) For capacitor energy storage equipment, compliance with the requirements of (f) above shall be determined with the system fully charged and a setting of 10 mAs for each exposure;

(h) The required minimum half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient;

(i) For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s);

(j) Where 2 or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated on the x-ray control panel and on or near the selected tube housing assembly prior to the exposure initiation;

(k) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system;

(l) Technique factors to be used during an exposure shall be indicated before the exposure begins;

(m) If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated;

(n) Indication of technique factors shall be visible from the operator's position except in the case of spot-films made by the fluoroscopist;

(o) Diagnostic x-ray systems and their associated components used on humans and certified pursuant to 21 CFR Part 1020 shall be maintained in compliance with applicable requirements of that standard; and

(p) All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

He-P 4046.02 Fluoroscopic X-ray Systems – General Requirements.

(a) All fluoroscopic x-ray systems used shall be image intensified or equipped with direct digital receptors.

(b) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID.

(c) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(d) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure.

(e) When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time.

(f) A means may be provided to permit completion of any single exposure of the series in progress.

(g) Beam limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall provide stepless adjustment of the x-ray field.

(h) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with:

(1) Stepless adjustment of the x-ray field; or

(2) With means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters.

(i) If provided, stepless adjustment shall permit continuous field size adjustments down to a minimum field size no greater than 5 centimeters in either length or diameter at maximum SID.

(j) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(k) Fluoroscopic spot-film devices shall meet the following requirements:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image which has been selected on the spot-film selector;

(2) The adjustment required in (l)(1) below shall be automatically accomplished except when the x-ray field size in the plane of the image receptor is smaller than that of the selected portion of the image receptor;

(3) It shall be possible to adjust the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor;

(4) The minimum field size at the maximum SID shall be no larger than 5 centimeters in either length or diameter; and

(5) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to not more than 2 percent of the SID.

(l) If means exist to override any of the automatic x-ray field size adjustments required in (g) through (k) above, that means:

(1) Shall be designed for use only in the event of system failure;

(2) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(3) Shall be clearly and durably labeled:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE".

He-P 4046.03 Fluoroscopic X-ray Systems – Exposure Rate Limits.

(a) Fluoroscopic equipment manufactured on or before May 19, 1995 provided with manual mode only, shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute, or air kerma rate in (AKR) excess of 44 mGy per minute, at the point where the center of the useful beam enters the patient except as follows:

(1) During recording of fluoroscopic images; or

(2) When an optional high level control is provided, in which case the limit shall be 10 roentgens per minute, or AKR 88 mGy per minute.

(b) Fluoroscopic equipment manufactured on or before May 19, 1995 provided with automatic exposure rate control with or without manual mode shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute, or AKR in excess of 88 mGy per minute, at that point where the center of the useful beam enters the patient, except during recording of fluoroscopic images.

(c) Fluoroscopic equipment manufactured after May 19, 1995 provided with manual mode only, shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute, or AKR in excess of 44 mGy per minute, at the point where the center of the useful beam enters the patient.

(d) Fluoroscopic equipment manufactured after May 19, 1995 provided with automatic exposure rate control with or without manual mode shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute, or AKR in excess of 88 mGy per minute, at that point where the center of the useful beam enters the patient, except when an optional high level control which was an option at the time of purchase is provided and activated, in which case the limit shall be 20 roentgens per minute, or AKR 176 mGy per minute.

(e) The exposure rate limits expressed in He-P 4046.04(c) and (d) shall not apply to:

(1) Fluoroscopic equipment manufactured after May 19, 1995 but before June 10, 2006 when recording images with film or video camera with the tube in pulsed mode; and

(2) Fluoroscopic equipment manufactured after June 10, 2006 when recording images from the Image Intensifier for the user after exposure termination.

(f) If a high level control is provided, it shall:

(1) Have a separate means of activation;

(2) Be operable only when continuous manual activation is provided by the operator; and

(3) Provide a continuous signal audible to the fluoroscopist when in use.

(g) Any fluoroscopic equipment manufactured after May 19, 1995 which can produce an exposure rate in excess of 5 roentgens per minute, or AKR in excess of 44 mGy per minute, shall be equipped with an automatic exposure rate control.

(h) Compliance with this section shall be determined as follows:

(1) If the source is below the x-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;

(2) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(3) For a C-arm or O-arm type of fluoroscope with fixed SID, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(4) In a C-arm type fluoroscope having an SID less than 45 centimeters, the AKR shall be measured at the minimum SSD;

(5) For a dedicated lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletopis movable, the table shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cms to the centerline of the x-ray table; and

(6) For a special procedures type C-arm fluoroscope, or angiography, interventional fluoro, with variable SID, the exposure rate shall be measured at the patient support located 30 cm from the image intensifier at minimum SID.

(i) Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;

(2) Results of these measurements shall be posted in the vicinity of the control panel to allow the fluoroscopist ready access to them while using the fluoroscope;

(3) Results of the measurements shall be posted in the record required in He-P 4045.05(c);

(4) The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results;

(5) The name of the person performing the measurements and the date the measurements were performed shall be included in the results;

(6) Conditions of periodic measurement of typical entrance exposure rate are as follows:

a. The measurement shall be made under the conditions that satisfy the requirements of (h) above;

b. The kVp, mA, or other selectable parameters shall be adjusted to those typical of clinical use on a 23 cm thick abdomen; and

c. Any x-ray system with automatic exposure rate control shall have sufficient attenuating material placed in the useful beam to produce kVp, mA, and other selectable parameters to satisfy the conditions of b. above and

(7) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

a. The measurement shall be made under the conditions that satisfy the requirements of h above;

b. The kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate; and

c. Any x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

He-P 4046.04 Fluoroscopic X-ray Systems – Barrier Transmitted Radiation Rate Limits.

(a) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor per roentgen per minute of entrance exposure rate.

(b) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters.

(c) If the source is below the tabletop, measurements shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(d) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, but no closer than 30 centimeters.

(e) Movable grids and compression devices shall be removed from the useful beam during the measurement.

He-P 4046.05 Fluoroscopic X-Ray Systems – Additional Requirements.

(a) During fluoroscopy and cine-fluorography the kV and the mA shall be continuously indicated.

(b) The source to skin distance (SSD) shall not be less than:

(1) Thirty-eight centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(2) Thirty-five and a half centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(3) Thirty centimeters on all mobile fluoroscopes;

(4) Twenty centimeters for all mobile fluoroscopes manufactured before June 10, 2006 when used for specific surgical applications;

(5) Nineteen centimeters for all stationary mobile C-arm fluoroscopes manufactured on or after June 10, 2006 with the SID less than 45 centimeters and labeled for extremity use only; or

(6) Ten centimeters for all stationary mobile C-arm fluoroscopes manufactured on or after June 10, 2006 with the SID less than 45 centimeters and not labeled for extremity use only.

(c) Fluoroscopic timers shall:

(1) Be provided to reset the cumulative on-time of the fluoroscopic x-ray tube;

(2) Not exceed 5 minutes without resetting for the maximum cumulative time of the timing device;

(3) Indicate the completion of any preset cumulative on-time with a signal audible to the fluoroscopist; and

(4) Continue to have such signal sound while x-rays are produced until the timing device is reset.

(d) With the exception of C-arm fluoroscopes, fluoroscopic table designs in combination with procedures shall be such that no unprotected part of any staff or ancillary person's body is exposed to unattenuated scattered radiation generated under the table.

(e) The attenuation required by (d) above shall not be less than 0.25 millimeter lead equivalent.

(f) With the exception of C-arm fluoroscopes, equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary person's body, except the extremities, is exposed to the unattenuated scattered radiation generated above the tabletop unless either:

(1) That person is at least 120 centimeters from the center of the useful beam; or

(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to drapes, bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron.

(g) Upon receipt of a written request, DHHS/RHS shall grant exemptions to (f) above where a required sterile field will not permit the use of normal protective barriers for any fluoroscopic procedures.

(h) Fluoroscopic systems equipped with spot-film mode shall meet the exposure reproducibility requirements of this part when operating in the spot-film mode.

(i) Radiation therapy simulation systems shall be exempt from:

(1) All the requirements of He-P 4046.03;

(2) The requirements of He-P 4046.02 and He-P 4046.04 provided that no person other than the patient is in the x-ray room when the system is producing x-rays; and

(3) The requirements of (c) above if such systems are capable of indicating cumulative exposure times for individual patients.

(j) Procedures for radiation therapy simulation systems shall require that the timer be reset between treatments.

(k) All fluoroscopic equipment displays manufactured on or after June 10, 2006 shall:

(1) Be equipped with means to display the last image hold (LIH) following exposure termination; and

(2) Display the air kerma rate and cumulative air kerma at the fluoroscopist's working position.

He-P 4046.06 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography X-ray Systems.

(a) The useful beam of all radiographic systems except mammographic, fluoroscopic, dental intraoral, or computed tomography systems shall be capable of being limited to the area of clinical interest.

(b) General purpose stationary and mobile x-ray systems, including veterinary systems, other than portable, shall meet the following:

(1) Only x-ray systems provided with means for independent stepless adjustment of at least 2 dimensions of the x-ray field shall be used;

(2) A method shall be provided for visually defining the perimeter of x-ray field;

(3) The total misalignment of the edges of the visually defined field compared to the respective edges of the x-ray field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when it is perpendicular to the axis of the x-ray beam;

(4) DHHS/RHS may grant non-certified x-ray systems an exemption from the requirements of(1), (2), and (3) above provided the registrant makes a written application for such exemption, and in that application:

a. Demonstrates it is impractical to comply with this paragraph; and

b. Describes how the purpose of this paragraph will be met by other methods;

(5) In addition to the requirements of (1)-(4) above, stationary general purpose x-ray systems shall meet the following requirements:

a. Methods shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field to the center of the image receptor to not more than 2 percent of the SID;

b. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted;

c. Indication of field size dimensions and SIDs shall be specified in inches and centimeters; and

d. X-ray field dimensions in the plane of the image receptor shall correspond to those indicated by the beam-limiting device to not more than 2 percent of the SID when the beam axis is perpendicular to the plane of the image receptor; and

(6) X-ray systems designed for only one image receptor size at a fixed SID shall:

a. Be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor; and

b. Align the center of the x-ray field with the center of the image receptor to not more than 2 percent of the SID.

(c) X-ray systems other than those described in this section, and all veterinary x-ray systems shall meet the following when the axis of the x-ray beam is perpendicular to the plane of the image receptor:

(1) Means shall be provided to limit the x-ray field within, and perpendicular to, the plane of the image receptor such that the field does not exceed each dimension of the image receptor by more than 2 percent of the SID; and

(2) Means shall be provided to align the center of the x-ray field with the center of the image receptor to not more than 2 percent of the SID.

(d) Means shall be provided to initiate the radiation exposure only by a deliberate action on the part of the operator.

(e) An exposure shall not be possible when the timer is set to a "zero" or "off" position.

(f) Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced.

(g) A signal audible to the operator shall indicate that the exposure has terminated.

(h) Means shall be provided to terminate the exposure at:

(1) A preset time interval or number of pulses;

(2) A preset product of current and time; or

(3) A preset radiation exposure to the image receptor.

(i) Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(j) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated manually, by the operator, at any time except for:

(1) Exposures of one-half second or less; or

(2) Serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(k) When an automatic exposure control is provided:

(1) The control panel shall indicate when this mode of operation is selected;

(2) If the x-ray tube potential is equal to or greater than 51 kVp, the minimum exposure time for pulsed operation shall be equal to 2 pulses;

(3) The minimum exposure time for all equipment other than specified in He-P 4047.06(k)(2) shall be no greater than one-sixtieth (1/60) second, or a time interval required to deliver 5 mAs, whichever is greater; and

(4) Manual exposure resetting shall be required before further timed exposures can be made.

(l) For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of milliroentgens per second (mR/s), obtained at any 2 clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$\left|X_1 - X_2\right| \leq 0.10\left(X_1 + X_2\right)$$

where X_1 and X_2 are the average mR/s values.

(m) The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

(n) Stationary x-ray systems, except veterinary systems, shall be required to have the x-ray control permanently mounted in a protected area that by virtue of shielding or distance or both shall protect the operator during the entire exposure from radiation scatter and is sufficient to comply with the occupational dose limits required by He-P 4020.05.

(o) Mobile and portable x-ray systems, except veterinary systems shall meet the requirements of (n) above if used continuously for greater than one week in the same location, and shall be provided with means to limit the source to skin distance equal to, or greater than 30 centimeters.

(p) All stationary, mobile or portable x-ray systems used for veterinary work shall be provided:

(1) With a 2 meter, or6.5 feet, high protective barrier for operator protection during exposures or

(2) With means to allow the operator to be at least 2.7 meters, or 9 feet, from the tube housing assembly during the exposure.

(q) All mobile or portable radiographic systems, except veterinary systems, shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

(r) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05.

(s) Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour (mR/hr) at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(t) Deviation of measured technique factors shall:

(1) Not exceed 10 percent of the indicated kVP value unless allowed by the manufacturer's written specification; and

(2) Not exceed 20 percent of the exposure time, which is either indicated or which can be inferred from known mA or mAs values, unless allowed by the manufacturer's written specification.

(u) When equipment having independent selection of x-ray tube current (mA), or a combined x-ray tube current exposure time product (mAs), is operated between 40 percent and 100 percent of the maximum rated kVp, the absolute value of the difference in the ratios (X_i) of exposure to the indicated milliampere-seconds product mR/mAs obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left|X_1 - X_2\right| \leq 0.10\left(X_1 + X_2\right)$$

where the values of X_1 and X_2 are the average values which are obtained at each of 2 consecutive tube current settings, or are obtained at 2 settings differing by no more than a factor of 2 where the tube current selection is continuous.

He-P 4046.07 Certified Diagnostic Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following:

(a) For beam limitation for stationary and mobile general purpose x-ray systems, the following shall be provided:

(1) A means of stepless adjustment of the size of the x-ray field;

(2) A minimum field size at an SID of 100 centimeters equal to or less than 5 centimeters by 5 centimeters;

(3) A light localizer, if used to define the x-ray field, shall provide an average illumination, based upon measurements made in the approximate center of each quadrant of the light field, of not less than 160 lux or 15 foot-candles at 100 centimeters or the maximum SID, whichever is less; and

(4) Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from the requirement of(3) above;

(b) For beam limitation on stationary general purpose x-ray systems equipped with positive beam limitation (PBL), the following requirements shall be met:

(1) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size;

(2) The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters; and

(3) The PBL system shall function such that any change of image receptor size or SID shall cause the automatic return to PBL;

(c) Beam limitation for portable x-ray systems shall meet the beam limitation requirements of He-P (a) or (b) above as applicable;

(d) A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures; and

(e) Hand-held dental intraoral x-ray systems shall not be subject to the requirements of (d) above.

He-P 4046.08 Dental Intraoral Radiographic Systems. In addition to the provisions of He-P 4045 and He-P 4046.01, the requirements of this section shall apply to x-ray systems used for dental radiography:

(a) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:

(1) 18 centimeters if operable above 50 kVp; or

(2) 10 centimeters if operable at 50 kVp only;

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters;

(c) The radiation exposure control shall meet the following requirements:

(1) No radiation exposure shall occur unless initiated by the operator;

(2) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position;

(3) A visual indication of x-ray production shall be observable by the operator;

(4) An audible signal to the operator shall indicate that the exposure has terminated;

(5) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor;

(6) Exposures can be terminated by the operator at any time, except for exposures of 0.5 second or less;

(7) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero";

(8) Stationary intraoral systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure;

(9) Mobile intraoral systems which are:

a. Used for greater than one week in the same location, for example a room or suite, shall meet the requirements of (8) above; or

b. Used for less than one week in the same location shall be provided with either a protective barrier at least 2 meters, or 6.5 feet, high for operator protection, or means to allow the operator to be at least 2.7 meters, or9 feet, from the tube housing assembly while making exposures; and

(10) Hand-held dental intraoral x-ray machines shall not be subject to the requirements of (8) and (9) above;

(d) When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors;

(e) Deviation of technique factors from indicated values for kVp and exposure time shall not exceed the limits specified for that system by its manufacturer or in the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time;

(f) Dental x-ray systems with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans; and

(g) The following administrative controls shall be in place:

(1) Patient and image receptor holding devices shall be used when the techniques permit;

(2) Neither the tube housing nor any position indicating device (PID) such as a Rinn kit shall be hand-held during an exposure; and

(3) Dental fluoroscopy without image intensification shall not be used.

He-P 4046.09 Hand-held Dental Intraoral Machines. The following requirements shall apply to the use of hand-held dental intraoral machines:

(a) For all uses:

(1) The registrant shall follow all applicable requirements set forth in this section, as well as all manufacturers's requirements;

(2) The machine shall be used only for dental diagnostic imaging;

(3) The protective shielding shall not be removed or modified;

(4) The registrant shall provide a copy of their operating, safety, and security procedures to operators to prevent unauthorized or improper use;

(5) The registrant shall prepare a quality assurance plan, with an emphasis on ensuring limited retaking of radiographs;

(6) Operators of hand-held dental intraoral machines shall be specifically trained to operate such equipment, and the registrant shall provide proof of training for all operators;

(7) When operating a hand-held dental intraoral machine, operators shall wear a lead apron as well as an extremity dosimeter on the hand closest to the protective shielding;

(8) A hand-held dental intraoral machine shall be held without any motion during a patient examination. A tube stand or Rinn kit may be utilized to immobilize a hand-held dental intraoral radiographic unit during patient examination;

(9) Operators of hand-held dental intraoral machines shall provide a secondary protective barrier for patients; and

(10) The operator shall ensure that there are no bystanders within a radius of at least 6 feet, or2 meters, from the patient being examined with a hand-held intraoral machine and

(b) Additional requirements for operatories in permanent facilities:

(1) Hand-held dental intraoral machines shall be used for patient examinations only in dental operatories that meet the structural shielding requirements specified by DHHS/RHS or by a qualified expert;

(2) Hand-held dental intraoral machines shall not be used for patient examinations in hallways and waiting rooms; and

(3) For battery-powered units, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

He-P 4046.10 Dental Cone-Beam CT (CBCT). Dental systems shall be:

(a) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C-Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act;

(b) Registered in accordance with He-P 4040;

(c) Maintained and operated in accordance with the manufacturer's specification; and

(d) Operated by persons who have been specifically trained by the manufacturer.

He-P 4046.11 Computed Tomography X-ray System Requirements.

(a) Automatic termination of x-ray exposures in the event of equipment failure shall occur either by de-energizing the x-ray source or shuttering the x-ray beam.

(b) Termination as required in (a) above shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value.

(c) Premature termination of the x-ray exposure by the operator shall require resetting of the CT conditions of operation prior to initiation of another scan.

(d) A visible signal shall indicate when the x-ray exposure has been terminated.

(e) The operator shall be able to terminate the x-ray exposure at any time during a scan of greater than one-half second duration.

(f) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(g) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane.

(h) If a device using a light source is used to satisfy the requirements of (f) or (g) above, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(i) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(j) Each emergency button or switch shall be clearly labeled as to its function.

(k) The CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence.

(l) Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(m) The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(n) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985 shall be as follows:

(1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters;

(2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second;

(3) Indicators at or near the gantry shall be discernible from any point external to the patient opening;

(4) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device; and

(5) The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along the incremented distance.

He-P 4046.12 Computed Tomography X-ray Systems – Facility Design Requirements.

(a) Provision shall be made for 2-way aural communication between the patient and the operator at the control panel.

(b) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(c) When the primary viewing system is by electronic means, an alternate viewing system shall be available for use in the event of failure of the primary viewing system.

He-P 4046.13 Computed Tomography X-ray Systems – Surveys, Calibrations, Spot Checks, and Operating Procedures.

(a) All CT x-ray systems shall have a survey made by or under the direction of a qualified expert.

(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to DHHS/RHS upon request.

(c) The calibration of the radiation output of the CT x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

(d) The calibration of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

(e) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system which is traceable to a national standard and has been calibrated within the preceding 2 years.

(f) CT dosimetry phantom(s) shall meet the following specifications and conditions of use shall be used in determining the radiation output of a CT X-ray system:

(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter;

(2) The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0

centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(3) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom; and

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(g) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(h) Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable;

(2) Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(3) The CTDI along 2 axes) shall be measured;

(4) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified; and

(5) The CT conditions of operation shall correspond to typical values used by the registrant for body parts represented by that phantom type.

(i) Calibration procedures shall be in writing.

(j) Records of calibrations performed shall be maintained for inspection by DHHS/RHS.

(k) The spot check procedures shall be in writing and shall have been developed by a qualified expert.

(l) The spot check procedures shall incorporate the use of a CT dosimetry phantom capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(m) All spot checks shall be included in the CT calibration and at time intervals and under system conditions specified by a qualified expert.

(n) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations.

(o) The spot check images shall be retained, until a new calibration is performed, as images stored in digital form on a backed-up storage medium compatible with the CT x-ray system.

(p) Written records of the spot checks performed shall be maintained for inspection by DHHS/RHS.

(q) The CT x-ray system shall not be operated except by a person who has been specifically trained in its operation.

(r) Information shall be available at the control panel regarding the operation and calibration of the system to include the following:

(1) Dates of the latest calibration and spot-checks and the location within the facility where the results of those tests might be obtained;

(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot-checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot-checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized;

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination; and

(5) If the calibration or spot- check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

He-P 4046.14 Mammography X-ray System Requirements.

(a) In addition to other rules pertaining to radiation safety, registration and use of radiation machines, only radiation machines pursuant to the "Mammography Quality Standards Reauthorization Act of 1998," Public Law 105-248, and 21 CFR Part 900, shall be used for screening and diagnostic mammography.

(b) A facility performing screening and diagnostic mammography shall have a valid certificate issued by the US Department of Health and Human Services, pursuant to the "Mammography Quality Standards Reauthorization Act of 1998," Public Law 105-248, and 21 CFR Part 900.

He-P 4046.15 Bone Densitometry.

(a) When an application for registration of a new or additional bone densitometry machines is received by DHHS/RHS in accordance with He-P 4040, registration shall be denied unless the application is accompanied by the following information:

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

(2) A description of the diagnostic x-ray quality control program;

(3) The qualifications of each person who will be operating the x-ray system(s);

(4) The qualifications of the person who will be supervising the operators of the x-ray systems(s), the extent of supervision, and the method of work performance evaluation; and

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

(b) Bone densitometry systems shall be:

(1) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C- Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act;

(2) Licensed in accordance with He-P 4040; and

(3) Maintained and operated in accordance with the manufacturer's specifications.

(c) Bone densitometry systems with a stepless beam limitation device shall be provided with means to both size and align the x-ray field such that at a plane of the image receptor the x-ray field does not extend beyond 2 percent of the SID.

(d) Operators of bone densitometry systems shall be:

(1) Licensed as a practitioner of the healing arts; or

(2) Complete a training course on bone densitometry which is provided by the densitometer manufacturer or vendor, and which shall include:

a. Basic radiation protection;

b. Operating procedures for bone densitometry systems, to include use of various system functions, safety, and maintenance; and

c. Patient positioning for the types of examinations performed.

(e) During the operation of any bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination; and

(2) The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

(f) The registrant shall keep maintenance records for bone densitometry records as prescribed by He-P 4045.05. These records shall be maintained for inspection DHHS/RHS for a minimum period of 5 years.

(g) Bone densitometry on human patients shall be conducted only under the prescription of a licensed practitioner of the healing arts.

He-P 4046.16 Veterinarian Facilities – Radiation or MRI Machine General Requirements.

(a) All veterinarian facilities shall be subject to the following requirements:

(1) Radiation machine general requirements set forth in He-P 4046.01; and

(2) Tube potential versus minimum half-value layer set forth in Table 4046.1.

(b) Veterinarians using fluoroscopic systems shall be subject to requirements for:

(1) General requirements and activation of the fluoro tube set forth in He-P 4046.02;

(2) Barrier transmitted exposure rate limits set forth in He-P 4046.04;

(3) Additional requirements set forth in He-P 4046.05; and

(4) Certified diagnostic systems set forth in He-P 4046.07.

(c) Veterinarians using dental intraoral systems shall be subject to the requirements for:

(1) Dental intraoral radiographic systems, other than hand-held systems set forth in He-P 4046.08; and

(2) Hand-held dental intraoral systems set forth in He-P 4046.09.

(d) Veterinarians using computed tomography systems shall be subject to requirements for:

(1) Equipment requirements set forth in He-P 4046.11;

(2) Facility design requirements set forth in He-P 4046.12; and

(3) Surveys, calibrations, spot checks, and operating conditions set forth in He-P 4046.13.

He-P 4046.17 Magnetic Resonance Imaging (MRI) Systems. MRI systems shall be:

(a) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C-Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act;

(b) Registered in accordance with He-P 4040; and

(c) Maintained and operated in accordance with the manufacturer's specifications.

APPENDIX

Rule	State Statute or Federal Regulation Implemented
He-P 4046.01	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
He-P 4046.02	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.32
He-P 4046.03	RSA 125-F:1, F:2, F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.32, 21 CFR 1020.32(d)(3)(iv)
He-P 4046.04	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.32
He-P 4046.05	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.32
He-P 4046.06	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.32
He-P 4046.07	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.30, 21 CFR 1020.31
He-P 4046.08	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, 21 CFR 1002.13, 21 CFR 1002.30, 21 CFR 1002.40, 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32
He-P 4046.09	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, 21 CFR 1002.13, 21 CFR 1002.30, 21 CFR 1002.40, 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32

He-P 4046.10	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, 21 CFR 1002.13, 21 CFR 1002.30, 21 CFR 1002.40, 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32
He-P 4046.11	RSA 125-F:1, F:2, F:5, II & V, 21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, 21 CFR 1002.13, 21 CFR 1002.30, 21 CFR 1002.40, 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32, 21 CFR 1020.33
He-P 4046.12	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.33
He-P 4046.13	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 1020.33
He-P 4046.14	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5, II & V; 21 CFR 900
He-P 4046.15	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5
He-P 4046.16	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5
He-P 4046.17	RSA 125-F:1, RSA 125-F:2, RSA 125-F:5