

four (124) electron volts produced by bombardment of a target with electrons in a vacuum. (*Indiana State Department of Health; 410 IAC 5-6.1-114; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367*)

410 IAC 5-6.1-115 "x-ray control" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 115. As used in this rule, "x-ray control" means a device which controls input power to the x-ray high voltage generator or the tube, including devices such as timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure. (*Indiana State Department of Health; 410 IAC 5-6.1-115; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367*)

410 IAC 5-6.1-116 "x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 116. As used in this rule, "x-ray equipment" means an x-ray system, subsystem, or component thereof. (*Indiana State Department of Health; 410 IAC 5-6.1-116; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367*)

410 IAC 5-6.1-117 "x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 117. As used in this rule, "x-ray system" means an assemblage of components for the controlled production of x-rays. At a minimum, an x-ray system includes the following:

- (1) An x-ray high voltage generator.
- (2) An x-ray control.
- (3) A tube housing assembly.
- (4) A beam-limiting device.
- (5) Necessary supporting structures.
- (6) Appurtenances.

Included in an x-ray system are mobile x-ray equipment, portable x-ray equipment, particle accelerators, and stationary x-ray equipment. (*Indiana State Department of Health; 410 IAC 5-6.1-117; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367*)

410 IAC 5-6.1-118 General requirements for operation of x-ray equipment

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 118. (a) All individuals associated with the operation of x-ray equipment shall comply with applicable sections of 410 IAC 5-4-2, 410 IAC 5-4-3, 410 IAC 5-4-10, and this rule.

(b) The registrant shall be responsible for directing the operation of those x-ray systems under his or her administrative control. The registrant or the registrant's agent shall comply with this section in the operation of such x-ray systems.

(c) At intervals prescribed in this rule, all new and existing facilities shall be surveyed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the x-ray system is used for diagnostic purposes, and an evaluation report, including all violations of this rule, on a form acceptable to the commissioner must be completed by the physicist or inspector and a copy forwarded to the registrant and to the commissioner within sixty (60) days of completion of the survey. The cost of this evaluation must be negotiated between the physicist or inspector and the practitioner of the healing arts or registrant and will not be borne by the department.

(d) For each x-ray system, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed on or near the x-ray control panel. This notice must indicate the date of full compliance and be signed by the physicist or inspector. For fluoroscopy systems, this notice may incorporate the entrance exposure posting requirement

of section 119(k)(6) of this rule.

(e) For each x-ray facility, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed in an area readily accessible to patients and visitors. This notice must indicate the date of full compliance and be signed by the physicist or inspector.

(f) At the intervals prescribed for facility inspections in this rule, the registrant shall be responsible for completing an x-ray machine registration application form. A diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department shall be responsible for verifying that all information on the application is correct, and the form shall be submitted to the commissioner as part of the physicist's or inspector's evaluation report.

(g) On the effective date of this rule, in order to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector in accordance with this rule, an individual must be approved by the department in accordance with subsection (h), (i), (j), or (k).

(h) In order to be approved to practice as a diagnostic imaging physicist, an individual must be certified by the ABR in diagnostic radiological physics or radiological physics or the ABMP in diagnostic imaging physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l). In determining equivalency in accordance with this section, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in diagnostic or radiological physics under the direction of a diagnostic or radiological physicist certified by the ABR or ABMP or a radiologist certified by the ABR.

(5) The individual shall provide as references the names of a radiologist certified by the ABR and a diagnostic or radiological physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of the two (2) references shall have directed the individual's work in accordance with subdivision (4).

In addition, the applicant must demonstrate to the physicist review committee that he or she is qualified to provide oversight for the establishment and conduct of a mammography quality assurance program required by section 127 of this rule. In determining qualifications in accordance with this subsection, the physicist review committee shall do the following:

(6) Determine that the individual has formal training or experience in evaluation of mammography systems, including performing, recording, and interpreting the results of required quality control checks.

(7) Determine that the individual has adequate testing equipment available to perform the quality control checks required by section 127 of this rule.

(8) Review a sample of a mammographic x-ray facility evaluation report prepared and submitted by the individual as part of their determination of his or her qualifications.

(i) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation therapy physicist is automatically approved to practice as a radiation oncology physicist. However, after the effective date of this rule, all other persons must be certified by the ABR in therapeutic radiological physics or radiological physics or the ABMP in radiation oncology physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a radiation oncology physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or a physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or a physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in radiation oncology physics, under the direction of a radiation oncology physicist or radiological physicist certified by the ABR or ABMP or a radiation oncology physician certified by the ABR.

(5) The individual shall provide as references the names of a radiation oncology physician certified by the ABR and a radiation oncology physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of these references shall be from an individual who directed the individual's work in accordance with subdivision (4).

(j) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation or health physicist is automatically approved to practice as a health physicist. However, after the effective

date of this rule, all other persons must be certified by the ABR, the ABMP, or the ABHP or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a health physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in health physics, radiological health, a physical science, engineering, or a biological science with a minor in a physical science or engineering.

(2) The individual shall have at least three (3) years of full-time active work experience in applied health physics. A master's degree in health physics or a closely related area may substitute for one (1) year of work experience required by this subsection. A doctoral degree in health physics or a closely related area may substitute for two (2) years of work experience required by this subsection.

(k) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified x-ray machine physicist is automatically approved to practice as an x-ray machine inspector. However, after the effective date of this rule, all other persons must have a minimum of a bachelor's degree in a physical or biological science, health physics, or radiological health and a minimum of two (2) years of experience working with x-ray systems under the direct supervision of a diagnostic imaging physicist, health physicist, or x-ray machine inspector, who has been approved by the department, in order to be approved to practice as an x-ray machine inspector.

(l) A physicist review committee is hereby created, which shall determine competency to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, and x-ray machine inspector in accordance with subsection (h), (i), (j), or (k). The physicist review committee shall be composed of a diagnostic imaging physicist and a radiation oncology physicist, both certified by the ABR or ABMP, and a radiologist certified by the ABR. The diagnostic imaging physicist, the radiation oncology physicist, and the radiologist shall be appointed to the physicist review committee by the commissioner. Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector shall be based upon review of a completed application which demonstrates that the individual meets applicable education, training, and experience requirements of subsection (h), (i), (j), or (k).

(m) Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector may be revoked by the commissioner for failure to perform his or her duties as required by this rule. The commissioner may audit facility evaluations performed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector. Any errors found as a result of such an audit shall be brought to the attention of the individual who performed the evaluation. If a subsequent audit indicates repetitive errors which have resulted in the issuance of unnecessary violation notices, or in violations not being reported to the commissioner, the commissioner may revoke that individual's approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector.

(n) Department employees are exempt from the credentialing requirements of this section when they are conducting inspections or surveys of x-ray facilities for the commissioner.

(o) The radiation machine registration certificate issued by the commissioner in accordance with 410 IAC 5-2-6 shall be prominently displayed in an area readily accessible to patients and visitors.

(p) An x-ray system which does not comply with this rule shall not be operated for diagnostic or therapeutic purposes, if so directed by the commissioner.

(q) Individuals who will be operating the x-ray equipment shall be adequately instructed in proper operating procedures for such equipment. Diagnostic x-ray machines shall be operated only by a person who complies with applicable provisions of 410 IAC 5-11.

(r) In the vicinity of each x-ray control panel, a technique guide shall be provided for routine examinations performed utilizing that system.

(s) Written safety procedures and rules shall be available to each individual operating x-ray equipment, including any restrictions of operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(t) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. In addition to the patient being examined, others will be protected in the following manner:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by five-tenths (0.5) mm lead equivalent.

(2) Staff and ancillary personnel shall be protected from direct scattered radiation by protective aprons or whole body protective barriers of not less than twenty-five hundredths (0.25) mm lead equivalent.

(3) Patients who cannot be removed from the room shall be protected from direct scattered radiation by whole body protective barriers of twenty-five hundredths (0.25) mm lead equivalent or shall be positioned so that portion of the body nearest to the tube head is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

(u) Gonadal shielding of not less than twenty-five hundredths (0.25) mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(v) Individuals shall not be exposed to the useful beam, except for healing arts purposes and such exposure has been authorized by a practitioner of the healing arts. This subsection specifically prohibits deliberate exposure for training, demonstration, or other nonhealing arts purposes.

(w) The following apply when a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. Written safety procedures established in accordance with subsection (s) shall list individual projections where holding devices cannot be utilized.

(2) Written safety procedures established in accordance with subsection (s) shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(3) The human holder shall be protected as required by subsection (t).

(4) No individual shall be used routinely to hold film or patients.

In those cases where the patient must hold the film, 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 five-tenths (0.5) mm lead equivalent material.

(x) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(y) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(z) Any registrant proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the commissioner. When requesting such approval, that person shall submit all department required information. If any submitted information becomes invalid or outdated, the commissioner shall be immediately notified.

(aa) The registrant shall maintain the following information for each x-ray system for inspection by the commissioner:

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all certified components.

(3) Aluminum equivalent filtration of the useful beam, including any routine variation.

(4) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray systems for the following periods:

(A) For hospitals, medical facilities, and chiropractic facilities, twenty-four (24) months.

(B) For podiatric and veterinary facilities, forty-eight (48) months.

(C) For dental facilities, seventy-two (72) months.

(5) After the effective date of this rule, a scaled drawing of the room in which a stationary x-ray system is located, which indicates the use of areas adjacent to the room, and an estimation of the extent of occupancy by an individual in such areas.

In addition, the drawing shall indicate either of the following:

(A) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions.

(B) The type and thickness of materials or the lead equivalency of each wall, window, door, ceiling, and floor in the room.

(6) A copy of all correspondence with the commissioner regarding each x-ray machine, including a copy of all facility evaluation reports issued in compliance with this section.

(bb) Floor plans and equipment arrangements for all new diagnostic x-ray installations, or modifications of such installations, shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a diagnostic imaging physicist or a health physicist approved by the department.

(cc) Floor plans and equipment arrangements for all new therapeutic x-ray installations, or modifications of such installations, shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a radiation oncology physicist or a health physicist approved by the department.

(dd) A report of each plan review and safety survey conducted in compliance with subsection (bb) or (cc) shall be submitted to the registrant and the commissioner within twenty (20) working days of completing the plan review, and the registrant shall keep a copy of the report in its files for at least as long as the registrant uses that x-ray facility. (*Indiana State Department of Health; 410 IAC 5-6.1-118; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367*)

410 IAC 5-6.1-119 Diagnostic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 119. (a) Podiatric and veterinary x-ray facilities shall be evaluated at least once each twenty-four (24) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Dental x-ray facilities shall be evaluated at least once each thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Mammography facilities shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist approved by the department. All other diagnostic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Those x-ray facilities which have been evaluated within sixty (60) days after the end of the interval established in this section will be considered to be in compliance with this section as long as the evaluation occurs in the same calendar year as the date on which reevaluation is required. All diagnostic x-ray systems shall comply with this section.

(b) The x-ray control panel containing the main power switch shall bear the warning statement, legible and accessible to view, "WARNING: This x-ray system may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(c) For battery-powered generators, visual means shall be provided on the x-ray control panel to indicate whether the battery is charged adequately for proper operation.

(d) Leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed one hundred (100) mR in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(e) Radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) mR in one (1) hour at five (5) cm from any accessible surface of the component when it is operated in an assembled x-ray system under any condition for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(f) The half-value layer of the useful beam for a given x-ray tube voltage shall be no less than the values shown as follows:

TABLE I

Design <u>Operating Range</u>	Measured <u>Voltage</u>	Half-Value Layer <u>Aluminum Equivalent</u>
Below 50 kVp	30 kVp	0.3 mm
	40 kVp	0.4 mm
	49 kVp	0.5 mm
50 to 70 kVp	50 kVp	1.2 mm
	60 kVp	1.3 mm
	70 kVp	1.5 mm
	71 kVp	2.1 mm
	80 kVp	2.3 mm
	90 kVp	2.5 mm
	100 kVp	2.7 mm
	110 kVp	3.0 mm
	120 kVp	3.2 mm
	130 kVp	3.5 mm
	140 kVp	3.8 mm
150 kVp	4.1 mm	

For a kVp not listed in Table I, linear interpolation shall be utilized to determine the minimum acceptable half-value layer. For capacitor energy storage x-ray systems, compliance shall be determined with the maximum charge per exposure assumed to be the kVp. The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient. The requirements of this subsection will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown as follows:

TABLE II

<u>Operating Voltage</u>	<u>Total Filtration Aluminum Equivalent</u>
Below 50 kVp	0.5 mm
50 to 70 kVp	1.5 mm
Above 70 kVp	2.5 mm

In addition, there must be compliance with the following:

- (1) Beryllium window tubes shall have a minimum of five-tenths (0.5) mm aluminum equivalent filtration permanently installed in the useful beam.
- (2) For capacitor energy storage equipment, compliance with this subsection shall be determined with the maximum quantity of charge per exposure.
- (3) For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum filtration required by this subsection is in the useful beam for the kVp which has been selected.
- (g) Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.
- (h) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.
- (i) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. For equipment having fixed technique factors, the requirement in this subsection may be met by placing permanent markings on such equipment. However, the markings shall be visible from the operator's position except in the case of spot films made by the fluoroscopist. (*Indiana State Department of Health; 410 IAC 5-6.1-119; filed Oct 29, 1993, 5:00 p.m.: 17 IR 371*)

410 IAC 5-6.1-120 Fluoroscopic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 120. (a) Fluoroscopic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department and shall comply with applicable sections of this rule. Radiation therapy simulation systems are exempt from compliance with subsections (c) through (e), (g) through (l), and (p) if the following are met:

- (1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room when the system is producing x-rays.
 - (2) Systems which do not comply with subsection (p) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, procedures shall require that the timer be reset between examinations.
 - (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. An x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.
 - (c) Means shall be provided for stepless adjustment of the field size. In addition, the following requirements must be met:
 - (1) The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.
 - (2) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (d) For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID. In addition, the following requirements must be met:
 - (1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979,

and incorporated in equipment with a variable SID or a visible area of greater than three hundred (300) square cm shall be provided with means for stepless adjustment of the x-ray field.

(2) All equipment with a fixed SID and a visible area of three hundred (300) square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to one hundred twenty-five (125) square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) cm by five (5) cm or less.

(3) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(4) Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, 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.

(e) Spot film devices which are certified components shall comply with the following additional requirements:

(1) Means shall be provided between the source and the patient for adjustment of the field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(2) It shall be possible to adjust the field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.

(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID.

(4) For spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(f) X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(g) The exposure measured at the point where the center of the useful beam enters the patient and at a kVp typical of clinical use of the x-ray system shall not exceed ten (10) roentgens per minute, except during recording of fluoroscopic images or when provided with optional high-level control. Compliance shall be determined in accordance with subsection (j).

(h) When equipment is provided with a high-level control, it shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control is activated. The high-level control shall be operable only through a dead-man switch. Additionally, a continuous signal audible to the fluoroscopist shall indicate when the high-level control is being employed. Compliance shall be determined in accordance with subsection (j).

(i) Certified systems which do not incorporate an automatic exposure control shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute, at the point where the center of beam enters the patient except during recording of fluoroscopic images or when the equipment is provided with an optional high-level control. Compliance shall be determined in accordance with subsection (j).

(j) Compliance with subsections (g) through (i) shall be determined as follows:

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

(2) If the source is below the table, the exposure rate shall be measured one (1) cm above the table top or cradle.

(3) If the source is above the table, the exposure rate shall be measured at thirty (30) cm above the table top with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(4) For C-arm type fluoroscopes, the exposure rate shall be measured thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

(k) Periodic measurement of entrance exposure rate shall be performed in accordance with the following:

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

(2) Such measurements shall be made under conditions that satisfy the requirements of subsection (j).

- (3) The kVp shall be the kVp typical of clinical use of the x-ray system.
- (4) An x-ray system that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system.
- (5) An x-ray system that does not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.
- (6) Results of such measurements shall be posted where any fluoroscopist has ready access to such results, and in the record required by section 118(aa)(5) of this rule. Such measurements shall be stated in roentgens per minute, and shall include the technique factors used in determining such results. The name of the person who performed the measurements and the date the measurements were performed shall be included with the results.
- (l) 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 two (2) mR per hour at ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. The exposure rate shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm. During such measurements, movable grids and compression devices shall be removed from the useful beam, and the attenuation block shall be positioned in the useful beam between the input surface of the fluoroscopic imaging assembly and a point ten (10) cm from the point of measurement of the entrance exposure rate. Exceptions to the measurement shall be as follows:
- (1) If the source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the table top.
- (2) If the source is above the table top and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the table top as possible, but no closer than thirty (30) cm.
- (m) During fluoroscopy and cinefluorography, kV and mA shall be continuously indicated.
- (n) The SSD shall be no less than:
- (1) thirty-eight (38) cm on stationary fluoroscopes installed after June 25, 1978;
- (2) thirty-five and five-tenths (35.5) cm on stationary fluoroscopes which were in operation prior to June 25, 1978;
- (3) thirty (30) cm on all mobile fluoroscopes; or
- (4) twenty (20) cm for image intensified fluoroscopes used in specific surgical applications.
- (o) For image intensified fluoroscopes used in specific surgical applications, written safety procedures must be provided which state precautionary measures to be adhered to during use of such equipment.
- (p) Means shall be provided to preset the cumulative ontime of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative ontime. Such signal shall continue to sound while x-rays are produced until the timing device is reset.
- (q) Mobile fluoroscopes shall provide intensified imaging.
- (r) Scattered radiation shall be controlled in accordance with the following:
- (1) Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be no less than twenty-five hundredths (0.25) mm lead equivalent.
- (2) Equipment configuration, when combined with procedures, shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the table top, unless that individual:
- (A) is at least one hundred twenty (120) cm from the center of the useful beam; or
- (B) the radiation has passed through not less than twenty-five hundredths (0.25) mm 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 referred to in section 118(t)(2) of this rule.
- (3) The commissioner may grant an exemption to subdivision (2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for protective barriers is practical, the commissioner shall not permit such exemption.

(Indiana State Department of Health; 410 IAC 5-6.1-120; filed Oct 29, 1993, 5:00 p.m.: 17 IR 372)

410 IAC 5-6.1-121 General purpose radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29

Sec. 121. (a) All general purpose radiographic systems, except extraoral dental x-ray systems, shall be evaluated at least each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Extraoral dental x-ray systems must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. General purpose radiographic systems shall comply with all applicable portions of this section.

(b) The useful beam shall be limited to the area of clinical interest.

(c) General purpose stationary x-ray systems and mobile x-ray systems shall comply with the following requirements:

(1) There shall be a means for stepless adjustment of the field size.

(2) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(3) The commissioner may grant an exemption to subdivisions (1) and (2) for noncertified x-ray systems, provided the registrant applies for such an exemption in writing. An application for such exemption shall demonstrate that it is impractical to comply with subdivisions (1) and (2) and that the protection afforded through compliance with subdivisions (1) and (2) will be assured through alternate methods.

(4) Any light localizer used to define the x-ray field shall provide an average illumination of not less than ten (10) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less.

(d) Stationary general purpose x-ray systems shall also comply with the following requirements:

(1) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor:

(A) to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID;

(B) to indicate the SID to within two percent (2%).

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

(3) The field size dimension and SID shall be indicated, in inches or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(e) Radiographic equipment having only one (1) image receptor size at a fixed SID shall 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. Additionally, such equipment shall be provided with a means to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(f) A timer shall be provided to terminate the exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position, if either is provided.

(g) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half (1/2) second duration or less, or during serial radiography when means are provided or permit completion of any single exposure of a series in process. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or a suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same

location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient. (4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(h) The following apply when an automatic exposure control is provided:

(1) Indication shall be made on the x-ray control panel when the mode of operation is selected.

(2) If the x-ray tube voltage is fifty (50) kVp or greater, the exposure time for field emission equipment rated for pulsed operation shall be no greater than the time interval equal to two (2) pulses.

(3) The exposure time for all equipment other than that specified in subdivision (2) shall be no greater than one-sixtieth (1/60) second or the time interval required to deliver five (5) mAs, whichever is greater.

(4) Either the product of peak x-ray tube voltage, current, and exposure time shall be no more than sixty (60) kW per exposure or the product of x-ray tube current and exposure time shall be no more than six hundred (600) mAs per exposure, except when the x-ray tube voltage is less than fifty (50) kVp, in which case the product of x-ray tube current and exposure time shall be no more than two thousand (2,000) mAs per exposure.

(5) A visible signal shall indicate when an exposure has been terminated as required by subdivision (4). Manual resetting shall be required before further automatically timed exposures can be made.

(i) With a timer setting of five-tenths (0.5) second or less, the average exposure time (T_{avg}) shall be no less than five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}). A minimum of four (4) timer tests must be performed to determine T_{avg} , T_{max} , and T_{min} . This requirement is expressed mathematically as:

$$T_{avg} \geq 5 (T_{max} - T_{min})$$

(j) All mobile or portable radiographic systems shall be provided with means to limit the SSD to no less than thirty (30) cm.

(k) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5 (E_{max} - E_{min})$$

(l) For capacitor energy storage equipment in standby status, radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed two (2) mR per hour at five (5) cm from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(m) General purpose x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the estimated coefficient of variation shall be no greater than five-hundredths (0.05) for any specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10 |X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed ten percent (10%) or the limits specified for that system by its manufacturer, whichever is greater.

(4) The following apply for general purpose stationary and mobile x-ray systems:

(A) There shall be means for stepless adjustment of the field size. The minimum field size at an SID of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm.

(B) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than one hundred sixty (160) lux or fifteen (15) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light

field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from compliance with this clause.

(C) The edge of the light field at one hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of at least four (4) for beam-limiting devices used on stationary equipment and a contrast ratio of at least three (3) for beam-limiting devices used on mobile x-ray equipment. Compliance shall be determined utilizing a measuring instrument aperture of one (1) mm diameter.

(5) Beam limitation for portable x-ray systems shall comply with subsection (d) and subdivision (4).

(6) Stationary general purpose x-ray systems equipped with a tube housing assembly, an x-ray control, and, if so equipped, a table, all of which are certified in accordance with 21 CFR 1020.30(C), shall comply with the following:

(A) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(B) The field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent (3%) of the SID. The sum of the absolute values for the field size length and width differences shall be no more than four percent (4%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(C) The radiographic system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm. Return to positive beam limitation as specified in clauses (A) and (B) shall occur upon a change in image receptor.

(D) Positive beam limitation may be bypassed:

- (i) when radiography is conducted without use of the cassette tray or permanently mounted vertical cassette holder;
- (ii) or when either the beam axis or table angulation is not within ten (10) degrees of horizontal or vertical during any part of the exposure; or
- (iii) during stereoscopic radiography.

If a bypass mode is provided, return to positive beam limitation shall be automatic.

(E) Capability may be provided to override positive beam limitation in the event of system failure or when it is necessary to perform special procedures which cannot be performed in the positive mode. However, if such capability is provided, it shall be necessary to use a key to override the positive mode and it shall be impossible to remove the key while the positive mode is overridden.

(n) Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position. (*Indiana State Department of Health; 410 IAC 5-6.1-121; filed Oct 29, 1993, 5:00 p.m.: 17 IR 374*)

410 IAC 5-6.1-122 Special purpose x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 122. (a) In addition to compliance with sections 118, 119, and 121 of this rule, special purpose x-ray systems and associated facilities shall comply with this section. Special purpose x-ray facilities must be evaluated at intervals not to exceed twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(c) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. This subsection may be met if the system complies with section 121(c) of this rule. This subsection may also be met if means for alignment are provided, with either of the following:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed, with each such device having clear and permanent markings

to indicate the image receptor size and SID for which it is designed.

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(Indiana State Department of Health; 410 IAC 5-6.1-122; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377)

410 IAC 5-6.1-123 Intraoral dental radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 123. (a) In addition to compliance with sections 118 and 119 of this rule, intraoral dental x-ray equipment and associated facilities shall comply with this section. Extraoral dental radiographic systems are exempt from this section, but must comply with section 121 of this rule. Intraoral dental x-ray facilities must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the SSD to no less than eighteen (18) cm if the system is capable of operation above fifty (50) kVp or no less than ten (10) cm, if the system is not capable of operation above fifty (50) kVp.

(c) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(1) if the minimum SSD is eighteen (18) cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter seven (7) cm or less; or

(2) if the minimum SSD is less than eighteen (18) cm, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter six (6) cm or less.

(d) Means shall be provided to terminate exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position if either is provided. With a timer setting of five-tenths (0.5) seconds or less, the average exposure period (T_{avg}) shall be no less than five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed. This requirement is expressed mathematically as:

$$T_{avg} \geq 5 (T_{max} - T_{min})$$

(e) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems installed after June 25, 1978, shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient.

(4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(f) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5 (E_{max} - E_{min})$$

- (g) Patient and film holding devices shall be used when the techniques permit.
- (h) The tube housing and the position indicating device shall not be hand held during an exposure.
- (i) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin complies with subsection (c).

(j) Dental fluoroscopy shall be conducted only with image intensification.

(k) Diagnostic x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the coefficient of variation of exposure shall be no greater than five-hundredths (0.05) for any specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$\frac{|X_1 - X_2|}{X_1 + X_2} \leq 0.10$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position.

(5) All dental x-ray systems manufactured on or after December 1, 1980, shall have a half-value layer of not less than one and five-tenths (1.5) mm aluminum equivalent. Systems operating above seventy (70) kVp are subject to the filtration requirements of section 119(f) of this rule.

(Indiana State Department of Health; 410 IAC 5-6.1-123; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377)

410 IAC 5-6.1-124 Therapeutic x-ray systems operating at less than one MeV

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 124. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray systems capable of operating at less than one (1) MeV.

(b) When the tube is operated at its leakage technique factors, leakage radiation shall not exceed the following:

(1) For contact therapy systems, one hundred (100) mR per hour at five (5) cm from the surface of the tube housing assembly.

(2) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which are manufactured prior to June 25, 1978, one (1) roentgen per hour at one (1) meter from the source.

(3) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which were manufactured on or after June 25, 1978, one hundred (100) mR per hour at one (1) meter from the source.

(4) For systems capable of operating from greater than one hundred fifty (150) to five hundred (500) kVp, one (1) roentgen per hour at one (1) meter from the source.

(5) For systems capable of operating in excess of five hundred (500) kVp, no more than one-tenth of one percent (0.1%) of the useful beam at one (1) meter from the source.

(c) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(d) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent (1%) of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the patient.

(e) Adjustable beam-limiting devices installed after June 25, 1978, shall comply with subsection (d). Adjustable beam-limiting devices installed before June 25, 1978, shall, for the portion of the x-ray beam to be blocked by such devices, transmit no more than five percent (5%) of the useful beam at the maximum kilovoltage and maximum treatment filter.

(f) The filter system shall be such that filters cannot be accidentally displaced from the useful beam at any possible tube orientation. Each filter shall be marked to identify its thickness and material of which it is constructed. For wedge filters, the

wedge angle shall appear on the wedge or wedge tray. The radiation at five (5) cm from the filter insertion slot opening shall not exceed thirty (30) roentgens per hour at any operating condition.

(g) The tube housing assembly shall be capable of immobilization for stationary treatment. It shall be marked so that it is possible to determine the location of the focal spot to within five (5) mm. The marking shall be readily accessible for use during calibration procedures.

(h) Contact therapy system tube housing assemblies shall have a removable shield of at least five-tenths (0.5) mm lead equivalency at one hundred (100) kVp which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(i) Therapeutic x-ray systems capable of operating at greater than one hundred fifty (150) kVp, which were manufactured after June 25, 1978, shall be provided with a beam monitor system having the following capabilities:

- (1) The system shall have the radiation detector of the monitoring system interlocked to prevent incorrect positioning.
- (2) The system shall not allow irradiation until a value for exposure has been selected at the x-ray control panel.
- (3) The system shall independently terminate irradiation when the selected exposure has been reached.
- (4) The system shall be so designed that the dose administered to a patient prior to any system malfunction or power failure can be accurately determined.
- (5) The system shall have a display at the x-ray control panel from which the dose at a reference point in the soft tissue can be calculated. This display must be intentionally reset to the zero (0) position.
- (6) The system shall have a display at the x-ray control panel which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

(j) A timer shall be provided with a display at the x-ray control panel. The timer shall have a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer which activates with the production of radiation and retains its readings after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to the zero (0) position. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation. The timer shall permit accurate presetting and determination of exposure times as short as one (1) second. The timer shall not permit an exposure if set at the zero (0) position. When irradiation is controlled by a shutter mechanism, the timer shall not activate until the shutter is opened.

(k) The x-ray control panel shall be fitted with a device to terminate exposure at any time. In addition to displays required by other provisions of this section, the x-ray control panel shall indicate the following:

- (1) When electrical power is available at the x-ray control panel.
- (2) If activation of the x-ray tube is possible.
- (3) When x-rays are being produced.
- (4) kV and x-ray tube current.

For x-ray equipment manufactured after June 25, 1978, the x-ray control panel shall display specific filters in the beam.

(l) When an x-ray control panel may energize more than one (1) x-ray tube, it shall be possible to activate only one (1) x-ray tube at a time. The x-ray control panel shall identify which x-ray tube is energized, and the tube housing assembly shall also indicate when that tube is energized.

(m) There shall be means of determining the SSD to within one (1) cm.

(n) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. After the system is at operating parameters, the shutter shall be controlled electrically by the operator from the x-ray control panel. The x-ray control panel shall indicate the shutter position.

(o) Each x-ray system equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube housing assembly and at the x-ray control panel.

(p) Facilities which will house therapeutic x-ray systems capable of operating at fifty (50) kVp or more shall comply with the following:

- (1) Provision shall be made for verbal communication between the patient and the operator at the x-ray control panel. However, where treatment requirements or excessive noise levels make verbal communication impractical, other effective methods of communication shall be utilized.
- (2) Windows, mirrors, closed circuit television, or an equivalent system 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 x-ray control panel.
- (3) When the primary viewing system is electronic, an alternate viewing system shall be available for use in the event of

failure of the primary viewing system. The alternate viewing system may also be electronic. In the event of failure of both viewing systems, the therapeutic x-ray system shall not be used to irradiate patients until one (1) of the viewing systems is again fully operational.

(q) Facilities which will house therapeutic x-ray systems capable of operating at one hundred fifty (150) kVp or more shall comply with subsection (o) and the following:

- (1) All protective barriers shall be fixed, except for entrance doors or beam interceptors.
- (2) The x-ray control panel shall be located outside the treatment room.
- (3) Interlocks shall be provided such that all treatment room entrances must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to continue irradiation without closing all entrance doors and manually reinitiating irradiation at the x-ray control panel.
- (4) When any door referred to in subdivision (3) is opened while the x-ray tube is activated, the exposure one (1) meter from the source shall be reduced to less than one hundred (100) mR per hour.

(r) Registrants shall have all new therapeutic x-ray facilities, and existing facilities not previously surveyed, surveyed by a radiation oncology physicist approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the therapeutic x-ray system is used for therapeutic purposes, and an evaluation report, including all violations of this rule on a form acceptable to the commissioner, must be completed by the radiation oncology physicist and a copy forwarded to the registrant and to the commissioner within thirty (30) days of receipt of the completion of the survey. The survey and report shall indicate all locations where the dose equivalent rate exceeds the limits specified in this rule.

(s) The registrant shall establish procedures to check all timer calculations by an independent method or by a second individual before administering thirty percent (30%) of the prescribed total dose, to assure that the given dose agrees with the manual or computer generated dose calculation, and with the written order of a practitioner of the healing arts. Additionally, the registrant shall verify that the correct beam filtration and cone factors are used and documented.

(t) Calibration of therapeutic x-ray systems subject to this section shall be performed before the system is first used for irradiation of an individual and thereafter at time intervals not to exceed twelve (12) months. Calibrations shall be also be performed after any change which might significantly alter the beam energy, spatial distribution, or other output characteristics of the therapy beam. Calibration shall be performed by a radiation oncology physicist approved by the department, who is physically present at the facility. Radiation measurements conducted during calibrations required by this subsection shall be performed using a dosimetry system which complies with the following:

- (1) The dosimetry system shall have an air-kerma or exposure calibration factor traceable to the National Institute for Standards and Technology.
- (2) The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected its calibration. The system shall have been calibrated in such a fashion that an uncertainty can be stated for the radiation output measured by the system. The dosimetry system shall have had constancy checks performed on the system as specified by a radiation oncology physicist. Calibration shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated with a maximum uncertainty of five percent (5%).
- (3) Calibration of each therapy beam shall include, but not be limited to, the output, half-value layer, and cone factors. Records of calibration measurements and dosimetry system calibrations conducted in accordance with this subsection shall be maintained by the registrant for at least five (5) years after completion of such calibration.

(u) An independent check of the output of a therapeutic x-ray system shall be performed annually. The check shall be performed by either of the following:

- (1) A radiation oncology physicist approved by the department, other than the one who performed the annual output calibration, using a dosimetry system other than the one that was used during said annual calibration. The dosimetry system must also comply with subsection (t).
- (2) A thermoluminescence dosimetry service capable of measuring doses with an accuracy of five percent (5%) or less.

(v) Output spot checks shall be performed on therapeutic x-ray systems during spot checks conducted in accordance with subsection (t), and thereafter at intervals not to exceed one (1) month, by a radiation oncology physicist approved by the department. Output spot check procedures shall be in writing and shall have been developed by a radiation oncology physicist approved by the department. Output spot check procedures shall specify:

- (1) which tests or measurements are to be performed;
- (2) the frequency the tests or measurements are to be performed;
- (3) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last

calibration conducted in accordance with subsection (t); and

(4) the action to be taken if a tolerance has been exceeded for any test or measurement required by the written output spot check procedures.

If an output spot check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last spot check conducted under this subsection, the radiation oncology physicist shall calibrate the therapeutic x-ray system. Records of each output spot check measurement conducted in accordance with this subsection shall be maintained by the registrant for a minimum of five (5) years from the date the output calibration was performed.

(w) The registrant shall perform weekly output constancy checks on each of their therapeutic x-ray systems in accordance with written output constancy check procedures developed by a radiation oncology physicist approved by the department. The output constancy check procedures shall specify:

(1) the tests or measurements to be performed;

(2) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (t); and

(3) the action to be taken if a tolerance has been exceeded for a test or measurement required by the written output constancy check procedures.

At least monthly, a radiation oncology physicist approved by the department shall review the results of all required output constancy checks performed since his or her last such review. If an output constancy check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last calibration conducted in accordance with subsection (t), the registrant shall repair the therapeutic x-ray system or undertake other corrective action before the equipment is again used to irradiate patients. The registrant shall also perform an output constancy check to determine whether or not the therapeutic x-ray system is again in compliance with this subsection prior to utilizing the equipment to irradiate patients. A record of each output constancy check performed in accordance with this subsection, and any repairs or corrective action undertaken in compliance with this subsection, shall be maintained by the registrant for a minimum of two (2) years from the date the output constancy check, repair, or corrective action was performed.

(x) The registrant shall perform checks on treatment planning computers and dose calculation algorithms in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require that the registrant do the following:

(1) Ensure that any computer software changes, including beam data files, have been correctly implemented without corrupting beam data.

(2) Verify that all users of treatment planning computers have been trained in the use of the computers.

(y) The registrant shall establish and maintain a written quality management plan to assure that radiation from an x-ray therapy system is administered as ordered by a practitioner of the healing arts. At a minimum, a quality management plan must assure all of the following:

(1) Prior to administration, a written order for therapeutic radiation must be prepared by a practitioner of the healing arts.

The order shall specify, at a minimum, the following:

(A) The patient's name.

(B) The anatomical treatment site or sites.

(C) For each treatment site, the following:

(i) Beam energy.

(ii) HVL.

(iii) The dose per fraction.

(iv) The number of fractions.

(v) The total dose.

If, in the opinion of a practitioner of the healing arts, any delay could jeopardize the health of a patient, the practitioner may verbally order therapeutic radiation, as long as the practitioner prepares a written order in accordance with this subdivision, to confirm his or her verbal orders, within seventy-two (72) hours of issuing the verbal order.

(2) Treatment plans and related calculations for radiation are in accordance with the written order of a practitioner of the healing arts.

(3) Each administration of therapeutic radiation is in accordance with a written order of a practitioner of the healing arts.

(4) Any deviation from the written order of a practitioner of the healing arts in excess of ten percent (10%) of the daily prescribed dose is identified, evaluated, and the findings communicated to the practitioner of the healing arts.

(z) The registrant shall review the radiation oncology chart of patients subjected to irradiation from a therapeutic x-ray system in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require the following:

- (1) The documented timer settings used for each field is *[sic., are]* in conformance with the calculations.
- (2) The therapeutic x-ray system operator initials the treatment documentation for each patient he or she treats, each day.
- (3) The daily radiation dose and the cumulative radiation dose are recorded.
- (4) Each written order for therapy treatment is being followed.
- (5) The total prescribed dose for each treatment site is appropriately indicated.

(aa) The registrant shall submit a written report to the commissioner of any misadministration within fifteen (15) days of discovery of the misadministration. The report shall:

- (1) state the name and address of the registrant;
- (2) state the name of the practitioner of the healing arts who prescribed the x-ray therapy at issue;
- (3) state the name of the individual who was improperly irradiated or the name of that individual's parent or guardian, if applicable;
- (4) briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated;
- (5) describe the actions taken by the registrant to prevent a recurrence of similar misadministrations; and
- (6) state what information has been presented to the individual who was improperly irradiated, or to that individual's parent or guardian, if applicable.

A copy of the report shall be maintained by the registrant for at least five (5) years after the date of the misadministration.

(bb) If possible, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the individual who has been improperly irradiated, or that individual's parent or guardian, if applicable, about the misadministration, unless, in the opinion of a practitioner of the healing arts, such notification would be harmful to that individual. Also, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the referring practitioner of the healing arts about the misadministration. At a minimum, the notification shall briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(cc) Therapeutic x-ray systems shall not be left unattended unless the system or the treatment room door is secured against unauthorized use.

(dd) When a patient must be held in position for radiation therapy, mechanical supports or restraining devices shall be used.

(ee) The tube housing assembly shall not be held by hand during operation unless the system is designed to require holding and the kVp of the system does not exceed fifty (50) kVp. In such cases, the holder shall wear protective gloves and an apron of not less than five-tenths (0.5) mm lead equivalency at one hundred (100) kVp.

(ff) No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems unless such individual is shielded by protective barriers sufficient to reduce their exposure to no more than that allowed by 410 IAC 5-4-2. No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems operating above one hundred fifty (150) kVp.

(gg) A therapeutic x-ray system shall not be used to administer radiation therapy unless it complies with subsections (t), (v), and (w). (*Indiana State Department of Health; 410 IAC 5-6.1-124; filed Oct 29, 1993, 5:00 p.m.: 17 IR 379*)

410 IAC 5-6.1-125 Therapeutic x-ray or electron systems operating at one MeV or more

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 125. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray or electron systems capable of operating at one (1) MeV or more.

(b) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall comply with the following:

- (1) The absorbed dose due to leakage radiation, when measured at any point in the patient plane, shall not exceed one-tenth of one percent (0.1%) for x-ray leakage or five-hundredths percent (0.05%) for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance.
- (2) For each therapeutic x-ray or electron system, the registrant shall determine or obtain from the manufacturer the leakage

radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements excluding neutrons shall be averaged over an area of one hundred (100) square cm or less. Neutron measurements shall be averaged over an area of two hundred (200) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(c) Therapeutic x-ray or electron systems manufactured on or before January 1, 1985, shall comply with the following:

(1) The absorbed dose due to leakage radiation at any point in the patient plane shall not exceed one-tenth of one percent (0.1%) of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance for x-ray leakage.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements shall be averaged over an area of one hundred (100) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(d) Adjustable or interchangeable beam-limiting devices shall be provided. Such devices shall transmit no more than two percent (2%) of the useful beam, excluding its neutron component, at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device.

(e) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation shall be available at the control panel describing each filter. For wedge filters, the wedge angle shall be indicated on the wedge or wedge tray. If the absorbed dose rate data required by subsection (t) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall not be removable by hand.

(f) Those therapeutic x-ray or electron systems manufactured after January 1, 1985, which utilize a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering filters shall comply with the following:

(1) Irradiation shall not be possible until a selection of a filter or filter code has been made at the x-ray control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the x-ray control panel.

(g) The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following requirements are met:

(1) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten (10) cm greater than the practical range of the electrons shall not exceed the values stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE III

<u>Maximum Energy of Electron Beam</u>	<u>X-Ray Absorbed Dose as a Fraction of Maximum Dose</u>
1 MeV	0.03
15 MeV	0.05
35 MeV	0.10
50 MeV	0.20

Compliance shall be determined using the following:

(A) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam.

(B) A phantom having cross sectional dimensions which exceed the measurement radiation field by at least five (5) cm and of depth sufficient to perform the required measurement.

(2) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE IV

<u>Maximum Photon Energy</u>	<u>Absorbed Dose at the Surface as a Fraction of the Maximum Dose</u>
1 MeV	0.80
2 MeV	0.70