

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 281. DIAGNOSTIC X-RAY SYSTEMS**

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 1. General Provisions

310:281-1-2. [AMENDED]

310:281-1-4. [AMENDED]

Subchapter 3. Registration of Diagnostic X-Ray Systems

310:281-3-3. [REVOKED]

310:281-3-5. [REVOKED]

310:281-3-6. [AMENDED]

310:281-3-7. [AMENDED]

Subchapter 5. Permits

310:281-5-1. [AMENDED]

310:281-5-2. [AMENDED]

310:281-5-3. [AMENDED]

310:281-5-4. [REVOKED]

310:281-5-5. [AMENDED]

Subchapter 9. Standards for Protection Against Radiation

310:281-9-1. [AMENDED]

310:281-9-2. [AMENDED]

310:281-9-3. [AMENDED]

310:281-9-5. [AMENDED]

310:281-9-11. [AMENDED]

310:281-9-12. [AMENDED]

310:281-9-13. [AMENDED]

310:281-9-30. [AMENDED]

310:281-9-31. [AMENDED]

310:281-9-35. [AMENDED]

310:281-9-40. [AMENDED]

Subchapter 11. Use of X-Rays in the Healing Arts and Veterinary Medicine

310:281-11-2. [AMENDED]

310:281-11-4. [AMENDED]

310:281-11-5. [AMENDED]

310:281-11-6. [AMENDED]

310:281-11-7. [AMENDED]

310:281-11-8. [AMENDED]

310:281-11-9. [AMENDED]

310:281-11-10. [AMENDED]

310:281-11-11. [AMENDED]

310:281-11-12. [AMENDED]

310:281-11-13. [AMENDED]

310:281-11-14. [AMENDED]

310:281-11-15. [AMENDED]

310:281-11-16. [AMENDED]

310:281-11-17. [AMENDED]

310:281-11-20. [AMENDED]

Appendix B. CT Operator Competency Checklist [REVOKED]

Appendix E. Equations for 310:281-1-2 Definitions [REVOKED]

AUTHORITY:

Commissioner of the Oklahoma State Department of Health; 63 O.S. § 1-104

SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:

October 20, 2020

COMMENT PERIOD:

November 16, 2020 through December 16, 2020

PUBLIC HEARING:

December 18, 2020

ADOPTION:

January 25, 2021

SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:

January 25, 2021

LEGISLATIVE APPROVAL:

Approved June 11, 2021 by HJR 1046

FINAL ADOPTION:

June 11, 2021

EFFECTIVE:

September 11, 2021

SUPERSEDED EMERGENCY ACTIONS:

n/a

INCORPORATIONS BY REFERENCE:

Incorporated standards:

21 Code of Federal Regulations Parts 900 et seq., as effective April 28, 1999

Incorporating rules:

310:281-11-9

AVAILABILITY:

8:00 a.m. to 5:00 p.m., Monday through Friday, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, 405-426-8000.

GIST/ANALYSIS:

The rule amendments modify or reduce rule language that is outdated or unnecessary, removes unnecessary restrictive language, aligns late fees with other occupational licensing programs in Consumer Health Service, and removes two appendices to be made into guidance documents. The substantive amendments are: deleted, added and amended definitions; added terms for initially bringing out-of-state diagnostic x-ray systems in-state; added conditions to issuance of permit, including requiring application within 30 days following commencement of operation of the system; removed specific named methods for reporting loss or theft of systems and reporting relocation, storage or transfer of system; added chart or manual requirements for portable systems; added requirements for contents of log maintained by processors; changed suggested exposure limits to mandatory limits; and exempted from survey requirements dental cone beam CT and CT systems not used for diagnostic purposes.

CONTACT PERSON:

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, 405-426-8563. AudreyT@health.ok.gov.

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3 (5) AND 308 (E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021:

SUBCHAPTER 1. GENERAL PROVISIONS

310:281-1-2. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special units of absorbed dose are the rad and the gray (Gy). (See definitions of "Rad" and "Gray" in this Section.)

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"ACR Technical Standard for Teleradiology" means the degree or level of requirements for the performance of teleradiology to include qualifications of personnel, equipment guidelines, licensing, credentialing, communication, quality control, and quality improvement to serve as a model for all physicians and health care workers who utilize teleradiology.

"Act" means applicable portions of the Oklahoma Public Health Code. (Title 63 O.S. Supp. 2001, Sections 1-1501.1 et seq.)

"Adult" means any individual 18 or more years of age.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"American College of Radiology" (ACR) means the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States that is a non-profit professional society whose primary purposes are to advance the science of radiology, improve service to the patient, study socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

~~**"Analog signal"** means a form information transmission in which the signal varies in a continuous manner and is not limited to discrete steps.~~

~~**"Applicator"** means a structure which determines the extent of the treatment field at a given distance from the virtual source.~~

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of a diagnostic x-ray system and/or his or her employee or an agent who assembles components into a diagnostic x-ray system that is subsequently used to provide professional or commercial services.

"Attenuate" means to reduce the exposure rate upon passage of radiation through matter.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation. (See also definition of "Phototimer" in this section.)

~~**"Average Glandular Dose"** means, in mammography, the value in millirad for a given breast or phantom thickness which estimates the average absorbed dose to the glandular tissue extrapolated from free air exposure and based on fixed filter thickness and target material.~~

~~**"Barrier"** (See definition of "Protective barrier" in this Section.)~~

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

~~**"Beam monitoring system"** means a system designed to detect and measure the radiation present in the useful beam.~~

"Beam quality" means a term that describes the penetrating power of the x-ray beam. This is identified by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

"Beam scattering foil" means a foil used in order to scatter a beam of electrons.

~~**"Board"** means the Oklahoma State Board of Health.~~

"Bone densitometer" means a system intended for medical purposes to measure bone density and mineral content by x-ray transmission measurements through the bone and adjacent tissues.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year ~~shall begin~~ begins in January and subsequent calendar quarters ~~shall be so~~ are arranged ~~such so~~ that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No permittee ~~shall~~ can change the method observed by that individual in determining calendar quarters for purposes of these regulations except at the beginning of a calendar year.

"Calendar year" means the time period running from January 1st through December 31st.

"Calibration" means the determination of:
the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or the strength of a source of radiation relative to a standard.

"Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

"Cephalometric system" means a system intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of diagnostic x-ray systems, which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968. (21 CFR Parts 1000-1030.)

"Certified system" means any diagnostic x-ray system which has one or more certified component(s).

"CFR" means Code of Federal Regulations.

"Changeable filter" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Coefficient of variation" (C) means the ratio of the standard deviation to the mean value of a population of observations. ~~It is estimated using the equation set forth in Appendix E.~~

"Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

"Computed tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" (CTDI) means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, ~~as set forth in Appendix E.~~

"Contrast scale" (CS) means the change in the linear attenuation coefficient per CTN relative to water, ~~as set forth in Appendix E.~~

"Control panel" means that part of the radiation machine control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

~~**"Cooling curve"** means the graphical relationship between heat units stored and cooling time.~~

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 310:281-11-15.

"CT gantry" means the tube housing assemblies, beam limiting devices, detectors and the supporting structures and frames, which hold these components.

"CT number" (CTN) means the number used to represent the x-ray attenuation associated with each elemental area of the CT image, ~~as set forth in Appendix E.~~

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Declared pregnant woman" means a woman who has voluntarily informed the permittee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared woman voluntarily withdraws the declaration in writing or is no longer pregnant.

"Deep dose equivalent" (DDE) (H_D) means the dose which applies to external whole-body

exposure and is the dose equivalent at a tissue depth of 1 cm (1000mg/cm²).

"Department" means the Oklahoma State Department of Health.

"Detector" (See definition of "Radiation detector" in this Section.)

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic-type tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at a distance of 1 meter from the source cannot exceed 100 mr in 1 hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization. Types of diagnostic x-ray systems are as follows:

(A) **"Mobile diagnostic x-ray system"** means a diagnostic x-ray system mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(B) **"Portable diagnostic x-ray system"** means a diagnostic x-ray system designed to be hand-carried.

(C) **"Stationary diagnostic x-ray system"** means a diagnostic x-ray system which is installed in a fixed location. A diagnostic x-ray system installed in a vehicle designed to be operated on the highway ~~shall be deemed~~ is considered to be a stationary x-ray system.

"Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See definition of "Scattered radiation" in this Section.)

"Dose" means absorbed dose or dose equivalent as appropriate.

"Dose equivalent" (DE) (H_T) means a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is ~~defined as~~ the absorbed dose in rads times certain modifying factors. The units of dose equivalent are the rem and sievert (Sv). (See definitions of "Rem" and "Sievert" in this Section.)

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with this Chapter. For the purposes of this Chapter, "limits" is an equivalent term.

"Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Dose profile" means the dose as a function of position along a line.

Σ

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also definition of "Picture element" in this section.)

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance exposure" means the exposure, ~~expressed in roentgens~~, measured in air with the specified technique, calculated or adjusted to represent the exposure at the point where the center of the useful beam enters the patient expressed in roentgens.

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See definition of "X-ray system" in this Section.)

"Exposure" means the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a unit mass volume of air are completely stopped in air. The special unit of exposure is the roentgen. (See definition of "Roentgen" in this Section.)

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the DE received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

"Facility" means the location at which one or more diagnostic x-ray systems, subject to these rules, are located and/or installed. Facilities with several such systems located and/or installed in different buildings and/or vehicles, but at the same street address and under the same administrative control will be considered to be one facility.

"Field emission systems" means systems which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

"Field size" means the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that the dose maximum is produced at the normal treatment distance when the field size is being determined.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

"Fog test" means an evaluation of increased density and reduced contrast on film, which has not been exposed to the radiation field. This is usually done by processing unexposed film and measuring the density.

"Gantry" means that part of the system supporting and allowing possible movement of the radiation head.

"General purpose radiographic x-ray system" means any diagnostic x-ray system, which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonadal shield" means a protective barrier for the testes or ovaries.

"Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads) of tissue.

"Half-value layer" (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts" means those professional disciplines authorized by the laws of this state to use x-rays in the diagnosis of human or animal disease.

"Healing arts screening" means the testing of human beings using diagnostic x-ray systems for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray examinations for the purpose of diagnosis.

~~**"Heat unit"** means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.~~

"High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

"Human use" means the external administration of radiation to human beings.

"Image intensifier" means a device installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device such as a fluorescent screen or radiographic film which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means for mammographic systems that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

~~**"Inherent filtration"** means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.~~

"Inspection" means an official examination or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

"Interlock" means: a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur; or a device for precluding access to an area of high radiation by automatically reducing the exposure rate.

~~**"Interruption of radiation"** means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.~~

"Irradiation" means the exposure of matter to ionizing radiation.

~~**"Isocenter"** means the intersection of the collimator axis of rotation and the gantry axis of rotation.~~

"Kilovolts peak (kVp)" means the maximum value of the potential difference across the x-ray tube during an exposure and ~~shall be deemed to be~~ is the equivalent to kilovolts peak (kVp).

"kV" means kilovolts.

"kWs" means kilowatt second. It is equivalent to 10^3 (kV) x (mA) x (s); ~~i.e., as set forth in Appendix E.~~

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for: the useful beam, and radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic assembly, which are used in measuring leakage radiation. The technique factor(s) are defined as follows: For diagnostic source assemblies intended for capacitor energy storage equipment, it is the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, it is the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential. For all other diagnostic source assemblies, it is the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Lens dose equivalent (LDE)" means the external DE to the lens of the eye at a tissue depth of 0.3 cm ($300\text{mg}/\text{cm}^2$).

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

~~**"Line voltage regulation"** means the difference between the no load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation: Percent line voltage regulation = $100 (V_n - V_l) / V_l$ where V_n = No load line potential and V_l = Load Line potential.~~

"Linear attenuation coefficient" (u) means the quotient of dN/N by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"mA" means milliamperere.

"mAs" means milliamperere second.

~~"Maximum line current" means the root-mean-square current in the supply line of an x-ray system operating at its maximum rating.~~

"Mean" (\bar{X}) means the average value of a set of numbers as set forth in Appendix E.

"Medical physicist" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, "medical physicists" may include individuals certified in the field of diagnostic x-ray systems by the American Board of Radiology in physics, the American Board of Health Physics, the American Board of Medical Physics, individuals licensed by an appropriate state agency, or individuals otherwise deemed by the Department to have equivalent qualifications.

"MeV" means million electron volts.

"Minor" means any individual less than 18 years of age.

~~"Mobile diagnostic x-ray system" (See definition of "Diagnostic x-ray system" in this Section.)~~

"Multiple tomogram systems" means a computed tomography system, which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Multiple scan average dose (MSAD)" means the average dose at the center of a series of scans, specified at the center of the axis of rotation of a computed tomography system. MSAD is calculated as set forth in Appendix E.

"Nominal tomographic section thickness" means the full-width at half-maximum of the sensitivity profile taken at the center of the cross sectional volume over which x-ray transmission data are collected.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_w) is calculated using the expression set forth in Appendix E.

~~"Nominal section thickness" means the full width at half maximum of the sensitivity profile taken at the center of the cross sectional volume over which x-ray transmission data are collected.~~

"Occupational dose" means radiation exposure received by an individual in the course of employment in which the individual's duties involve exposure to radiation. Occupational dose ~~shall~~ does not include any radiation exposure of an individual for the purpose of diagnosis.

"Patient" means an individual subjected to healing arts examination or diagnosis.

~~"Peak tube potential" (See definition of "kilovolt peak (kVp)" in this Section.)~~

"Permittee" means any person which is issued a permit by the Department in accordance with these regulations and the Act.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

"Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated. (See definition of "Automatic exposure control" in this Section.)

"Physician" means a person who is licensed by either the Oklahoma State Board of Medical Licensure and Supervision or by the Oklahoma State Board of Osteopathic Examiners to practice medicine, radiology, and/or surgery.

~~"Picture element" means an elemental area of a tomogram.~~

~~"Portable diagnostic x-ray system"~~ (See definition of "Diagnostic x-ray system" in this Section.)

~~"Practical range of electrons"~~ corresponds to classical electron range where the only contribution to dose is from bremsstrahlung x rays. Precise definition may be found in ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Commission on Radiation Units and Measurements, September 15, 1984.

~~"Primary dose monitoring system"~~ means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

~~"Primary protective barrier"~~ (See definition of "Protective barrier" in this Section.)

~~"Primary scattered radiation"~~ means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See also definition of "scattered radiation" in this Section.)

~~"Protective apron"~~ means an apron made of radiation absorbing materials used to reduce radiation exposure.

~~"Protective barrier"~~ means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

~~"Primary protective barrier"~~ means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

~~"Secondary protective barrier"~~ means a barrier sufficient to attenuate the stray radiation to the required degree.

~~"Protective glove"~~ means a glove made of radiation absorbing materials used to reduce radiation exposure.

~~"Qualified expert"~~ (see definition of "Medical Physicist".)

~~"Rad"~~ means the special unit of absorbed dose. One rad equals 0.01 joule per kilogram (100 ergs per gram) of material; for example; if tissue is the material of interest, then 1 rad equals 0.01 joule per kilogram (0.01 gray) of tissue. (See definition of "Absorbed Dose" in this section.)

~~"Radiation"~~ means ionizing radiation delivered by x rays.

~~"Radiation area"~~ means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~"Radiation detector"~~ means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

~~"Radiation head"~~ means the structure from which the useful beam emerges.

~~"Radiation machine"~~ means any device capable of producing radiation except those which produce radiation only from radioactive material.

~~"Radiation safety officer" (RSO)~~ means one who has been delegated the responsibility to apply all of the appropriate radiation protection regulations.

~~"Radioactivity"~~ means the transformation of unstable atomic nuclei by the emission of radiation.

~~"Radiograph"~~ means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

~~"Radiographic imaging system"~~ means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

~~"Rating"~~ means the operating limits as specified by the component manufacturer.

~~"Recording"~~ means producing a permanent form of an image resulting from x-ray photons.

~~"Reference plane"~~ means a plane which is displaced from and parallel to the tomographic plane.

~~"Registration"~~ means registration with the Department in accordance with this Chapter.

~~"Rem"~~ means a special unit of the dose equivalent. One millirem (mrem) = 0.001 rem (See definition of "Dose Equivalent" in this Section.) For the purpose of these regulations, any of the following is considered to be equal to onerem:

- (A) exposure of 1 roentgen of x-ray or gamma radiation.
- (B) an absorbed dose of 1 rad due to x-ray, gamma, or beta radiation.
- (C) an absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.
- (D) an absorbed dose of 0.1 rad due to fast neutrons or high energy protons.
- (E) an absorbed dose of 0.4 rad due to thermal neutrons.
- (F) 1 rem = 0.01 sievert.

"Research and development" means:

- (A) theoretical analysis, exploration, or experimentation; or
- (B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation to human beings.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Restricted area" (controlled area) means any area, access to which is controlled by the permittee for the purpose of protecting individuals from exposure to radiation. A restricted area ~~shall~~ does not include any areas used for residential quarters, although a room or rooms in a residential building may be set apart as a restricted area.

"Roentgen" (R) means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air. (See definition of "Exposure" in this Section.)

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the periods of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See definition of "Direct scattered radiation" in this Section.)

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

~~**"Secondary protective barrier"** (See definition of "Protective barrier" in this Section.)~~

~~**"Shadow tray"** means a device attached to the radiation head to support auxiliary beam blocking material.~~

"Shallow dose equivalent (SDE)" means the DE at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 square centimeter (cm^2). (SDE applies to the external exposure of the skin or an extremity.)

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"Single tomogram system" means a CT x-ray system, which obtains x-ray transmission data during a scan to produce a single tomogram.

"Sievert" (Sv) means the SI unit of any of the qualities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

"Source" means the focal spot of the x-ray tube.

"Source-to-image receptor distance (SID)" means the distance from the source to the center

of the input surface of the image receptor.

"Source of radiation" means any instrument capable of producing or emitting radiation. (i.e., x-ray tube assembly.)

"Source-to-skin distance (SSD)" means the distance between the source and the skin of the patient.

"Special procedures" means the application of special x-ray systems and specialized techniques to obtain required diagnostic information. This usually provides enhanced detail of a given anatomical structure but with reduced visualization of other structures. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelography, and surgery.

"Special purpose x-ray system" means any diagnostic x-ray system, which is limited, by design, to radiographic examinations of specific anatomical regions. Special purpose x-ray systems include, but are not limited to, mammography systems, dedicated chest systems, cystography systems, and head and skull systems.

"Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray tube head and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Standard deviation" (s) means a measure of the dispersion or variation in distribution, equal to the square root of the mean of the squares of the deviations from the mean root of the distribution, as set forth in Appendix E.

"Stationary diagnostic x-ray system" (See definition of "Diagnostic x-ray system" in this Section.)

"Stored system" means a diagnostic x-ray system which has been disabled such that when power is supplied to the control panel (technique indicators), the x-ray tube may not be energized.

"Stray radiation" means the sum of leakage and scattered radiation.

"Supervision" means the delegating of the task of applying radiation pursuant to these regulations by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner's control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

"Survey" means an evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

~~**"Target"** means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.~~

"Technique chart" means a chart that provides all necessary generator control settings and geometry needed to make clinical radiographs when the radiography system is in manual mode.

"Technique factors" mean the conditions of operation.

Technique factor(s) are specified as follows:

(A) for capacitor energy storage systems, it is peak tube potential in kV and quantity of charge in mAs;

(B) for field emission systems rated for pulsed operation, it is peak tube potential in kV and number of x-ray pulses;

(C) for CT systems designed for pulsed operations, it is peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(D) for CT systems not designed for pulsed operation, it is peak tube potential in kV, and

either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(E) for all other systems, it is peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

~~"Telemedicine" means the use of electronic communication processes for the transmission of information and data related to the diagnosis and/or treatment of medical conditions.~~

"Teleradiology" means the electronic transmission of radiological images from one location to another for the purposes of interpretation and/or consultation.

~~"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.~~

"Test" means the process of verifying compliance with an applicable regulation.

"These regulations" means all subchapters of the Diagnostic X-ray Systems Regulations. (Chapter 281 of this Title.)

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Total Effective Dose Equivalent (TEDE)" means, for external exposure only to x-ray radiation from diagnostic x-ray systems, the TEDE is equal to the DDE. If an individual receives an occupational dose from both diagnostic x-ray systems and radioactive materials, the TEDE is the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

"Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

"Transfer" means:

(A) To change the possession or legal title of a diagnostic x-ray system; or

(B) To relocate from one physical address to another.

~~"Tube" means an x ray tube, unless otherwise specified.~~

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

~~"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.~~

"Unrestricted area" (uncontrolled area) means any area access which is not controlled by the permittee for purposes of protection of individuals from exposure to radiation and any area used for residential quarters.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"User" means any person who causes any radiation producing machine, subject to these regulations, to be energized.

~~"Variable aperture beam limiting device" means a beam limiting device which has capacity for stepless adjustment of the x ray field size at a given SID.~~

"Virtual source" means a point from which radiation appears to originate.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"Whole Body" means for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

"Worker" means an individual engaged in work in a facility issued a permit by the Department and controlled by a permittee, but does not include the permittee.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

~~**"X-ray subsystem"** means any combination of two or more components of an x-ray system.~~

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

310:281-1-4. General regulatory requirements

(a) **Records.** Each permittee shall maintain records showing the receipt, transfer, and disposal of all diagnostic x-ray systems. ~~Additional record requirements are specified elsewhere in these regulations.~~

(b) **Inspections.**

(1) Each permittee shall afford the Department at all reasonable times opportunity to inspect diagnostic x-ray systems and the premises and facilities wherein such diagnostic x-ray systems are used or stored.

(2) Each permittee shall make available to the Department for inspection, upon reasonable notice, records maintained pursuant to these regulations.

(c) **Tests.** Each permittee shall perform upon instructions from the Department, or ~~shall permit~~ allow the Department to perform, such reasonable tests as the Department deems appropriate or necessary to ensure safety including, but not limited to, tests of:

(1) facilities wherein diagnostic x-ray systems are used or stored;

(2) radiation detection and monitoring instruments; and

(3) other equipment and devices used in connection with utilization or storage of permitted diagnostic x-ray systems.

(d) **[RESERVED]**

(e) **[RESERVED]**

(f) **[RESERVED]**

(g) **Prohibited uses.**

(1) Fluoroscopic screens used in conjunction with a source of radiation shall not be held by an individual.

(2) The intentional exposure of persons to ionizing radiation by persons other than licensed practitioners of the healing arts or persons acting under their direction is prohibited.

(h) **Communications.** All communications and reports concerning these regulations, and permit applications or registration filed thereunder, should be addressed to the Oklahoma State Department of Health, Consumer Health Service Protection Division, 1000 N.E. 10th Street 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma, 73117-1299 73102.

(i) **Severability.** ~~Should any of these regulations be declared unconstitutional or invalid for any reason, the remainder of the regulations shall not be affected thereby. If any regulation is~~

determined to be unconstitutional or invalid, it does not impact the enforceability or validity of any other regulation in this Chapter.

SUBCHAPTER 3. REGISTRATION OF DIAGNOSTIC X-RAY SYSTEMS

310:281-3-3. Registration [REVOKED]

~~The owner or lessee shall register each non-exempt diagnostic x-ray system in use in Oklahoma with the Oklahoma State Health Department within thirty (30) days following the commencement of operation of a diagnostic x-ray system. Application for registration shall be completed on forms prescribed by the Department and shall contain all information required by the form and accompanying instructions.~~

310:281-3-5. Approval not implied [REVOKED]

~~No person shall state or imply that any activity under such registration pursuant to the provisions of 310:281-3-4 has been approved by the Department.~~

310:281-3-6. Assembler and/or transferor obligation

(a) Except as provided under 310:281-3-2(b), any person who sells, leases, transfers, lends, disposes, assembles, or installs diagnostic x-ray systems in this state shall record the following information and submit it to the Department within 15 days:

- (1) the name and address of persons who have received these systems;
- (2) the manufacturer, model, and serial number of each diagnostic x-ray system transferred; and
- (3) the date of transfer of each diagnostic x-ray system.

(b) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with ~~requirements of~~ the Federal diagnostic x-ray standard (21 CFR 1020.30 (d)) shall be submitted to the Department within 15 days following completion of the assembly. Such report ~~shall~~ will suffice in lieu of any other report by the assembler.

(c) No person shall make, sell, lease, transfer, lend, assemble, or install diagnostic x-ray systems or the supplies used in connection with such systems unless such supplies and systems when properly placed in operation ~~shall~~ meet the requirements of these regulations.

310:281-3-7. Out-of-state diagnostic x-ray systems

(a) Whenever any diagnostic x-ray system is initially ~~to be~~ brought into the State, for diagnostic use other than in a permanent facility, ~~the person proposing to bring such systems into the State, shall give written~~ notice to the Department will be provided at least three (3) working days before such systems are to be used in the State, and ~~shall register~~ such systems will be registered with the Department. The notice shall include:

- (1) the number(s) and type(s) of diagnostic x-ray systems;
- (2) the nature, start date, duration, and scope of use;
- (3) the exact location(s) where the diagnostic x-ray systems are to be used;
- (4) the name(s) and address (es) where the equipment user(s) can be reached while in the state;
- (5) if other than an individually owned machine, the designated service agent shall also be listed;
- (6) comply with all applicable regulations of the Department; and
- (7) supply the Department with such other information as the Department may reasonably request.

(b) If, for a specific case, the three working-day period would impose an undue hardship on the person, approval to proceed sooner may be granted upon request to the Department.

SUBCHAPTER 5. PERMITS

310:281-5-1. General

No person shall use, operate or cause to be operated a diagnostic x-ray system which does not have a valid facility permit issued to the owner or lessee of that system by the Oklahoma State Department of Health pursuant to Title 63 O.S. ~~2004~~, Sections 1-1501.1 through 1-1505, as amended. Only a person who is in substantial compliance with the requirements of these rules and regulations ~~shall be~~ is entitled to receive or retain such a permit. Permits are not transferable. A valid permit shall be posted in each facility where the diagnostic x-ray system is located.

310:281-5-2. Issuance of permit

(a) Any person(s) wishing to operate or cause to be operated a diagnostic x-ray system shall ~~make written application for a permit on forms provided by the Oklahoma State Department of Health. The applicant(s) shall be the owner or lessee of the system(s). Such application shall include the name and address of each applicant, the location and type of diagnostic x-ray facility, name of service agent, where applicable, and the signature of each applicant or his authorized agent.:~~

(1) be the owner or lessee of the system; and

(2) make application for a permit on forms provided by the Oklahoma State Department of Health; and

(3) Submit an application within 30 days following the commencement of operation of a diagnostic x-ray system.

(b) No permit will be issued except upon successful registration of the diagnostic x-ray system with the Department, compliance with applicable rules, and payment of the appropriate permit fee.

310:281-5-3. Expiration of permit

A permit ~~shall expire~~ expires one year from the date of issuance unless canceled or revoked prior to its expiration. For purposes of determining the expiration date of all permits, the date of issuance ~~shall be deemed to be~~ is the date that a permit is first issued by a duly authorized representative of the Department. An expired permit shall follow the regulations listed in 310:250-3-4. Late Renewal.

310:281-5-4. Renewal of permit [REVOKED]

~~A permit not renewed within ninety (90) days after the date of its expiration shall require payment of an amount equivalent to the initial permit fee.~~

310:281-5-5. Revocation or suspension of permit

A permit may be revoked or suspended for noncompliance with 63 O.S. ~~2004~~, sections 1-1501.1 through 1-1505, as amended, or any rules or regulations promulgated thereunder.

SUBCHAPTER 9. STANDARDS FOR PROTECTION AGAINST RADIATION

310:281-9-1. Purpose

(a) This subchapter establishes standards for protection against radiation hazards. Except as otherwise specifically provided, this subchapter applies to all permittees. It is the purpose of the regulations in this subchapter to control the use and transfer of diagnostic x-ray systems by any permittee in such a manner that the total dose to an individual does not exceed the standards of radiation protection prescribed in this subchapter. ~~Nothing in this~~ This subchapter shall should not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis.

(b) In addition to complying with the requirements set forth in this subchapter, every reasonable effort shall be made to maintain radiation exposures to unrestricted areas to as low as is reasonably achievable.

310:281-9-2. Radiation dose standards for individuals in restricted areas

(a) For determining the doses specified in this section, a dose from x-rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate. In accordance with the provisions of 310:281-9-3(a), and except as provided in 310:281-9-2(b) and 310:281-9-3 (c), no permittee shall use or transfer diagnostic x-ray systems in such a manner as to cause any individual in a restricted area to receive in any period of one calendar year from all diagnostic x-ray systems a total occupational dose in excess of the standards specified in 310:281-9-2(b).

(b) Rems per Calendar Year

- (1) Total effective dose equivalent (TEDE) is 5 Rems;
- (2) Deep dose equivalent (DDE) and committed dose equivalent (CDE) to any individual organ or tissue (other than the lens of the eye) are 50 Rems;
- (3) Lens dose equivalent (LDE) is 15 Rems; and
- (4) Shallow dose equivalent (SDE) to the skin or any extremity is 50 Rems.

(c) A permittee may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under 310:281-9-2(a), provided:

- (1) during any calendar quarter, the total occupational dose to the whole body ~~shall not~~ cannot exceed 3 rem; and
- (2) the permittee has determined the individual's accumulated occupational dose to the whole body on a form provided by the Department or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of 310:281-9-3. As used in ~~310:281-9-2(b)~~ this subsection, "dose to the whole body" ~~shall be deemed to include~~ includes any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye.

310:281-9-3. Determination of accumulated occupational dose

(a) Excess of quarterly occupational dose.

(1) Each permittee shall require any individual, prior to first entry of the individual into the permittee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 310:281-9-2(a) and 310:281-9-5, to disclose in a written, signed statement, either;

- (A) that the individual had no prior occupational dose during the current calendar quarter, or
- (B) the nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter from sources of radiation used or controlled by other persons.

(2) Each permittee shall maintain records of such statements until the Department authorizes disposition.

(b) Previously accumulated occupational doses.

(1) In the preparation of a form provided by the Department or a clear and legible record containing all the information required in that form, the permittee shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the permittee obtains such reports, he shall use the dose shown in the report in preparing the form. In any case where a permittee is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it ~~shall be~~ is assumed that the individual has received the occupational dose specified in 310:281-9-3(b)(2) and (3).

(2) Assumed dose in Rems for calendar quarters prior January 1, 1961 for wholebody gonads is $3\frac{3}{4}$ for active blood forming organs, head, trunk and lens of eye.

(3) Assumed dose in Rems for calendar quarters beginning on or after January 1, 1961 is $1\frac{1}{4}$ for active blood forming organs, head, trunk and lens of eye.

(4) The permittee shall retain and preserve records used in preparing forms required by the Department until the Department authorizes their disposition.

(c) Determination of occupational effective dose for individuals wearing protective lead clothing during diagnostic x-ray procedures. When a protective apron is worn while working with radiographic and fluoroscopic x-ray systems used for clinical diagnostic or research purposes, the effective dose equivalent (EDE) for external radiation ~~shall be~~ is determined as follows:

- (1) When only one personal monitoring device (310:281-9-12) is used and it is located at the neck (collar) outside the protective apron, the deep dose equivalent (DDE) ~~shall be~~ is the EDE for external radiation; or
- (2) When only one personal monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported DDE value will be multiplied by 0.3 ~~shall be and is~~ the EDE for external radiation; or
- (3) When personal monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck (collar), the EDE for external radiation ~~shall be~~ is assigned the value of the sum of the DDE reported for the personal monitoring device located at the waist under the protective apron multiplied by 1.5 and the DDE reported for the personal monitoring device located at the neck (collar) outside the protective apron multiplied by 0.04.

310:281-9-5. Exposure of minors

No permittee shall use or transfer any diagnostic x-ray system in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to receive in any period of one calendar year from all diagnostic x-ray systems in the permittee's possession a dose in excess of 10 percent of the standards specified ~~in the table~~ in 310:281-9-2(a).

310:281-9-11. Surveys

- (a) Each permittee shall make or cause to be made such surveys as may be necessary to establish compliance with these rules.
- (b) Any survey instruments used to make physical radiation surveys ~~as required by~~ in accordance with 310:281-9-11(a) shall be calibrated and operable.
- (c) Each radiation survey instrument shall be calibrated:
 - (1) by a person recognized by the Department as competent to perform such service;
 - (2) at intervals not to exceed 12 months unless a more restrictive time interval is specified in another subchapter of these rules;
 - (3) after each survey instrument repair;
 - (4) for the types of radiation used and at energies appropriate for use; andat an accuracy within 20 percent of the true radiation level.
- (d) Records of survey instrument calibrations shall be maintained for inspection by the Department.

310:281-9-12. Personnel monitoring

- (a) Each permittee shall supply and require the use of appropriate personnel monitoring equipment to, ~~and shall require the use of such equipment by:~~
 - (1) each individual who enters a controlled radiation area;
 - (2) each individual who enters a high radiation area; and
 - (3) each individual who uses or operates any source of radiation.
- (b) The Department may, upon written request from a permittee grant an exemption to 310:281-9-12(a) provided, in the opinion of the Department upon consideration of information submitted in support of such a request, that no individual is likely to receive a dose in any calendar year in excess of 25 percent of the applicable value specified in 310:281-9-2 and that no individual under 18 years of age is likely to receive a dose in any calendar year in excess of 5 percent of the applicable value specified in 310:281-9-2.
- (c) After the effective date of these rules, all personnel monitoring equipment (except extremity dosimeters and pocket ionization chambers) that require processing to yield a dose value and that are provided to comply with 310:281-9-2 and 310:281-9-12(a), or the applicable terms and conditions of any license or certificate of registration issued by the Department shall:

- (1) be processed by a processor accredited by the National Voluntary Laboratory Accreditation Program for Personnel Dosimetry Processors of the National Bureau of Standards in accordance with accreditation criteria established in 15 CFR Part 7b; and
- (2) be approved in this accreditation process for the type of radiation or radiations and the time period for which the individual wearing the dosimeter is monitored.
- (d) Location and use of individual monitoring equipment.
 - (1) Each permittee shall ensure that individuals who are required to monitor occupational doses in accordance with 310:281-9-12(a) wear and use individual monitoring equipment as follows:
 - (A) Individual monitoring equipment ~~shall be~~ is assigned to and worn by only one individual.
 - (B) Individual monitoring equipment used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring equipment is typically at the neck (collar).
 - (C) If additional individual monitoring equipment is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, in accordance with 310:281-9- 40, it shall be located at the waist under any protective apron being worn by the woman.
 - (D) Individual monitoring equipment used for monitoring LDE, to demonstrate compliance with 310:281-9-2(a), shall be located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.
 - (E) Individual monitoring equipment used for monitoring the dose to the extremities, to demonstrate compliance with 310:281-9-2(a), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring equipment, to the extent practicable, shall be oriented to measure the highest dose to the extremity being monitored.
 - (F) Individual monitoring equipment shall be worn for the period of time authorized by the dosimetry processor's certificate of registration or for no longer than three months, whichever is more restrictive.

310:281-9-13. Caution signs, labels and signals

(a) General.

(1) Except as otherwise authorized by the Department, symbols prescribed by 310:281-9-14 shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this section is the conventional three-blade design, as set forth in Appendix A of this Chapter.

(2) In addition to the contents of signs and labels prescribed in this section, a permittee may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

(b) **Radiation Areas.** Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

- (1) CAUTION or DANGER
- (2) RADIATION AREA

(c) High Radiation Areas.

(1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

- (A) "CAUTION" Or "DANGER"
- (B) HIGH RADIATION AREA

(2) Each entrance or access point to high radiation area shall be:

- (A) equipped with a control device ~~which shall cause~~ that causes the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area; or
- (B) equipped with a control device ~~which shall energize~~ that energizes a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the permittee, a supervisor of the activity are made aware of the entry; or

- (C) maintained locked except during periods when access to the area is required, with positive control over each individual entry.
- (3) The controls required by 310:281-9-13(c)(2) shall be established in such a way that no individual will be prevented from leaving a high radiation area.
- (4) The controls required by 310:281-9-13(c)(2)(A) shall be constructed in such a manner that the primary radiation cannot be reactivated until all entrances have been secured, and the radiation on-off control is reset at the control panel.
- (5) The controls required by 310:281-9-13(c)(2)(B) shall be constructed in such a manner that when the warning device is activated, it shall be necessary to shut off or secure the source of radiation and secure all tripped entrances prior to being able to de-activate the alarm system.
- (6) Control devices required by either 310:281-9-13(c)(2)(A) or 310:281-9-13(c)(2)(B) shall be tested for proper operation at intervals not to exceed six months. If such testing indicates failure of the device, corrective action shall be taken immediately to restore the control device to proper working order.
- (7) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by 310:281-9-13(c)(2).
- (8) Any permittee may apply to the Department for approval of methods not included in 310:281-9-13(c)(2) and (7) for controlling access to high radiation areas. The Department may approve the proposed alternatives if the permittee demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of 310:281-9-7(c)(3) is met.

310:281-9-30. Reports of theft or loss of diagnostic x-ray systems

- (a) Each permittee shall report to the Department ~~by telephone and telegraph, mailgram, e-mail, or facsimile~~ the theft or loss of any permitted diagnostic x-ray system immediately after such occurrence becomes known.
- (b) Each permittee who is required to make a report pursuant to 310:281-9-30(a) shall, within 30 days after the permittee learns of the loss or theft, make a report in writing to the Department, setting forth the following information:
- (1) a description of the diagnostic x-ray system involved, including the kind, quantity, chemical, physical form, and/or model and serial numbers;
 - (2) a description of the circumstances under which the loss or theft occurred;
 - (3) a statement of disposition or probable disposition of the diagnostic x-ray system involved;
 - (4) radiation exposures to individuals, circumstances under which the exposures occurred, and the extent of possible hazard to persons in unrestricted areas;
 - (5) actions which have been taken, or will be taken, to recover the diagnostic x-ray system; and procedures or measures which have been or will be adopted to prevent a recurrence of the loss or theft of diagnostic x-ray system.
- (c) Subsequent to filling the written report, the permittee shall also report any substantive information on the loss or theft which becomes available to the permittee within 30 days after learning of such information.

310:281-9-31. Notification of incidents

- (a) **Immediate notification.** Each permittee shall immediately notify the Department by telephone, email, or facsimile of any incident involving any diagnostic x-ray system used ~~by him~~ and which may have caused or threatens to cause:
- (1) a dose to the whole body of any individual of 25 rems or more of radiation; a dose to the skin of the whole body of any individual of 150 rems or more of radiation;
 - (2) or a dose to the feet, ankles, hands, or forearms of any individual of 375 rems or more of radiation; or
 - (3) a loss of 1 working week or more of the operation of any facilities affected; or

damage to property in excess of \$200,000.

(b) **Twenty-four hour notification.** Each permittee shall within 24 hours notify the Department by telephone, email, or facsimile, of any incident involving any diagnostic x-ray system used ~~by him~~ and which may have caused or threatens cause:

- (1) a dose to the whole body of any individual of 5 rems or more of radiation; a dose to the skin of the whole body of any individual of 30 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of 75 rems or more of radiation;
- (2) a loss of 1 day or more of the operation of any facilities affected; or
- (3) damage to property in excess of \$2,000.

310:281-9-35. Vacating premises

Each permittee shall notify the Department, ~~in writing~~, of their intent to relocate, store or transfer the diagnostic x-ray system 30 days before they relocate, transfer or store.

310:281-9-40. Exposure to pregnant employees

If an employee of any permittee declares her pregnancy by written notification, the permittee shall ensure that the DE to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv).

- (1) If a woman chooses not to declare pregnancy the occupational dose limits specified in 310:281-9-2 (a).
- (2) The permittee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 310:281-9-40 (a). The National Council on Radiation Protection and Measurement in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) states that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month will be adopted.
- (3) If by the time the woman declares pregnancy the permittee the DE to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the permittee ~~shall be deemed to be~~ is in compliance with 310:281-9-40 (a), if the additional DE to the Embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.
- (4) The DE to an embryo/fetus shall be taken as the DE that is most representative of the DE to the embryo/fetus from external radiation. The DE from the mother's lower torso region will be used.
- (5) If multiple measurements have been made, assignment of the DDE for the declared pregnant woman for the personal monitoring device that is most representative of the DE to the embryo/fetus shall be the DE to the embryo/fetus. Assignment of the highest DDE for the declared woman to the embryo/fetus is not required unless that dose is also the most representative DDE for the region of the embryo/fetus.
- (6) If multiple measurements have not been made, assignment of the highest DDE for the declared pregnant woman shall be the embryo/fetus.

SUBCHAPTER 11. USE OF X-RAYS IN THE HEALING ARTS AND VETERINARY MEDICINE

310:281-11-2. Accountability

- (a) The permittee ~~shall be~~ is responsible for directing the operation of the diagnostic x-ray systems under the administrative control of the permittee. The permittee ~~shall assure~~ is responsible for assuring that the requirements of this subchapter are met in the operation of such diagnostic x-ray systems.
- (b) The provisions of this subchapter are in addition to, and not in substitution for, other applicable provisions of these regulations.

310:281-11-4. Diagnostic operational requirements for practitioners

(a) **Technique chart.** A chart or manual shall be provided in the vicinity of the control panel of each non-APR diagnostic x-ray system, CR portable, or DR portable system which specifies, for all diagnostic examinations usually performed with that diagnostic x-ray system, the following information:

- (1) technique factors to be utilized versus patient's anatomical size (except for diagnostic x-ray systems which have only automatic exposure controls);
- (2) type of the film or film-screen combination to be used, if any;
- (3) type of the grid to be used, if any; and
- (4) source-to-image receptor distance to be used.

(b) **Safety procedures.** Written operating and safety procedures shall be made available to each individual who operates diagnostic x-ray systems. These procedures shall include restrictions required for the safe operation of each diagnostic x-ray system.

(c) **Radiation dose limitation and personnel monitoring.** Except as otherwise exempted, all individuals who are associated with the operation of a diagnostic x-ray system are subject to the radiation dose requirements of 310:281-9-2, 310:281-9-3, 310:281-9-5 regarding dose limits to individuals, 310:281-9-40 and the personnel monitoring requirements of 310:281-9-12.

(d) **Protective clothing and devices.** ~~The use of protective clothing and devices is encouraged.~~ Such protective clothing and devices shall be utilized when required, as in 310:281-11-6(c)- (e), 310:281-11-7(c), and 310:281-11-11(d).

(1) When protective clothing or devices are worn on portions of the body (such as trunk apron) and personnel monitoring is required, the whole body badge shall be worn in accordance with 310:281-9-12 (d). The dose measured by this device shall be recorded as the whole body dose on the personnel radiation exposure records, as required by 310:281-9-29.

(2) Protective equipment including aprons, gloves, and shields shall be checked annually for defects, such as holes, cracks, and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Department. If such defect is found, equipment shall be replaced or removed from service until repaired.

(e) **Information and records.** The permittee shall maintain the following information for each diagnostic x-ray system for inspection by the Department:

- (1) records of receipt, transfer, and disposal;
- (2) a copy of all correspondence to and from the Department regarding each diagnostic x-ray system; and
- (3) records of surveys, calibrations, spot checks, maintenance, and modifications performed on the diagnostic x-ray system. The signature of the individual performing the service and the date it was performed shall be on the record.

(f) **Operator training.** Individuals who operate diagnostic x-ray systems shall be instructed in and be able to demonstrate competence with the permittee's operating and safety procedures.

(g) **Healing arts screening.** Any person proposing to conduct a healing arts screening program for humans shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in 310:281-11-21. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days.

(h) **Processor control.**

(1) In conjunction with all human diagnostic x-ray systems, all processors shall be maintained on a predetermined schedule for quality assurance.

~~(A) The types of tests shall be included in a log containing acceptability limits, results of tests, date, initials of technician or testing individual, and corrective action taken if needed.~~

A log shall be kept that states the following:

- (i) type of test;
- (ii) acceptability limits for that particular test;

- (iii) results of the test;
- (iv) the date the test was performed;
- (v) initials of technician or testing individual;
- (vi) if needed, corrective action taken.

(B) Tests shall include, but not be limited to, fog test, chemical replacement, and darkroom light leak.

(C) All processing shall be by the time/temperature method. The predetermined method shall be documented and ~~shall indicate~~ state the manufacturer, development time, and type of all chemicals used in the film processing method (including hand processing methods).

(D) Deviations from the recommended use (as detailed by the manufacturer) or changes in the method or manufacturer shall be documented (date, initials of technician) in the processor log.

(E) Lighting in the film processing/loading area shall be with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion. When 2 or more types of film are used, the more sensitive type will be accommodated.

(2) For dental and veterinary diagnostic x-ray systems, the film manufacturer's recommendations, including maintenance of the equipment and maintenance of the developing solutions of a constant temperature, shall be used for processing film.

(i) **Diagnostic x-ray system requirements.** Each permittee ~~shall assure that the following is responsible for satisfying the following diagnostic x-ray equipment requirements are met on each diagnostic x-ray system:~~ shall assure that the following is responsible for satisfying the following diagnostic x-ray equipment requirements are met on each diagnostic x-ray system:

(1) **Warning label.** The control panel containing the main power switch shall bear the radiation symbol and a statement, legible and plainly visible to view, containing the following or similar wording:

"WARNING" or "Caution": "This machine produces radiation when energized."

(2) **Mechanical support of tube head.** The tube housing assembly shall be adjusted such that it will remain stable during an exposure. If tube housing movement is a designed function of the diagnostic x-ray system the tube housing assembly shall be adjusted such that it will remain stable except during such a designed function.

(A) The tube housing assembly supports shall not be hand-held.

(B) Veterinary portable units designed to be hand-held are exempted if they provide a diagnostic-type tube housing.

(j) **Film and image retention.** Human radiographic images shall be retained for a minimum of five years with the exception of mammographic images. ~~pursuant to section 310:281-11-9 shall be~~ In accordance with 310:281-11-9 mammographic images are to be maintained for ten years.

310:281-11-5. Radiographic entrance exposure limits

The in-air exposure determined for the technique used for the specified average human adult patient thickness for routine medical radiography ~~shall not~~ cannot exceed the entrance exposure or dose limits shown below ~~in 310:281-11-5.~~

(1) Entrance exposure and dose limits for the following radiographic technique are:

(A) for a 23 cm P/A chest has the ~~suggested~~ exposure of 22 mR and the exposure/dose limit of 30mR;

(B) for a 23 cm P/A grid chest has the ~~suggested~~ exposure of 25 mR and the exposure/dose limit of 35mR;

(C) for a 23 cm abdomen(KUB) has the ~~suggested~~ exposure of 500 mR and the exposure/dose limit of 600mR;

(D) for a 23 cm lumbar spine (A/P) has the ~~suggested~~ exposure of 500 mR and the exposure/dose limit of 800 mR;

(E) for a 13 cm cervical spine (AP) has the ~~suggested~~ exposure of 125 mR and the exposure/dose limit of 200 mR;

(F) for a 15 cm skull (lateral) has the ~~suggested~~ exposure of 150 mR and the exposure/dose

limit of 250 mR;

(G) dental intraoral exams have a ~~suggested~~ exposure of 400 mR and the exposure/dose limit of 600 mR; and

(H) for computed tomography ~~suggested~~ exposures for the following techniques are:

(i) for a 16 cm adult head the ~~suggested~~ exposure is 6000 mR;

(ii) for a 32 cm adult abdomen the ~~suggested~~ exposure is 3500 mR; and

(iii) for a 16 cm pediatric abdomen the ~~suggested~~ exposure is 2500 mR.

(iv) These are CTDI_w dose measurements as recommended by the American College of Radiology in their voluntary certification of CT system.

~~(v) These are suggested exposures only and are meant to be general guidelines.~~

310:281-11-6. Additional requirements for use of diagnostic x-ray systems in the healing arts of medicine, podiatry, and chiropractic

(a) **Viewing system.** Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit operator to continuously observe the patient during irradiation.

(b) **Control panel.** Each x-ray control shall be located in such a way as to meet the following requirements:

(1) Stationary diagnostic x-ray systems ~~shall be~~ are required to have the x-ray control permanently mounted in a permanent control booth or station so that the operator is required to remain in that area during the entire exposure and not be exposed to greater than 2 millirems in any 1 hour. See section 310:281-11-20 for measurement protocol to determine compliance.

(2) Mobile and portable diagnostic x-ray systems shall meet the requirements of a stationary diagnostic x-ray system when used for greater than 7 consecutive working days in the same location.

(3) For mobile and portable diagnostic x-ray systems, single event exposures and configuration, the x-ray control shall be positioned so that the operator is at least 6 feet away from the tube housing and the patient during an exposure and is not exposed to greater than 2 millirems in any 1 hour.

(4) The operator shall be able to maintain visual and aural contact with the patient.

(c) **Exposure of individuals other than the patient.** Except for other patients who cannot be moved out of the area where the diagnostic x-ray system is to be used (e.g., ICU or trauma units) or individuals specified in 310:281-11-6(e), only the staff and ancillary personnel required for the medical procedure or training shall be in the area where the diagnostic x-ray system is to be used during the radiation exposure.

(1) All individuals, other than the patient being examined, shall be positioned such that no part of the body will be struck by the useful (direct) beam unless protected by an apron, gloves, or other shielding having 0.5 millimeter lead equivalent material.

(2) Staff and ancillary personnel shall be protected from primary scatter (once-scattered) radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

(3) Notwithstanding the provisions of 310:281-11-6(c)(1), other patients who are in line with the primary beam and who cannot be removed from the room, shall be protected by whole body protective barriers of 0.25 millimeter lead equivalent material or so positioned that the nearest portion of their body is at least 6 feet from both the tube head and the nearest edge of the image receptor.

(d) **Gonadal shielding.** For patients who have not passed the reproductive age, gonadal shielding shall be used when the gonads are in or within 5 centimeters of the useful beam. This requirement does not apply if the shielding will interfere with the diagnostic procedure. Gonadal shielding shall be of at least 0.5 millimeter lead equivalent material.

(e) **Holding of patient or film.** 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. In accordance with

310:281-11-4(b) ~~The~~ the written safety procedures ~~required by 310:281-11-4(b)~~ shall list circumstances in which mechanical holding devices cannot be routinely utilized.

(2) The requirements for selecting an individual who holds or supports the patient, and the procedure which the holder ~~shall follow~~ follows, shall be included in the written safety procedures, as required by 310:281-11-4(b).

(3) In accordance with 310:281-11-6(c), ~~The~~ the human holder shall be protected, ~~as required by 310:281-11-6(e)~~.

(4) ~~No~~ An individual ~~shall~~ cannot be used routinely to hold film or patients.

310:281-11-7. Additional operational controls for fluoroscopic x- ray systems and spot-film devices

(a) Fluoroscopic configuration, including fluoroscopic table designs when combined with operating and safety procedures, shall not permit any portion of any individual's body, except the head, neck, and extremities, to be exposed to scattered radiation emanating from above or below the tabletop unless the radiation has passed through not less than a total of 0.25 millimeter lead equivalent material. The material may be, but is not limited to, drapes, self-supporting curtains, or viewing shields, in addition to any lead equivalency provided by a protective apron.

(b) Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, 310:281-11-7(a) ~~shall~~ does not apply, if all of the following conditions are met:

(1) All persons, except the patient, in the room where fluoroscopy is performed, shall wear protective aprons which provide a shielding equivalent of 0.5 millimeter of lead.

(2) The fluoroscopist and all other personnel in the room, except the patient, shall have appropriate personnel monitoring devices.

(3) The fluoroscopic field size shall be reduced to the absolute minimum required for the procedure being performed (area of clinical interest).

(4) Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or nonuse of the protective drapes.

(c) For image-intensified fluoroscopic systems with only a manual mode of collimation, the x-ray field produced shall be limited to the area of the spot-film cassette at 16 inches above tabletop. Additionally, during fluoroscopy, the beam shall be restricted to the area of the input phosphor.

310:281-11-8. Additional operational controls for CT x-ray systems

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

(b) ~~Information shall be available at the control panel regarding the operation and evaluation of the system. That information shall contain:~~ The control panel must include the following information for the system's operation and evaluation:

(1) dates of the latest evaluation and spot checks, and the location within the facility where the results of those tests may be obtained;

(2) the results of at least the most recent spot checks conducted on the system; and

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

310:281-11-9. Additional operational controls for mammography systems

(a) Incorporation by reference: ~~(1)~~ Adopted reference. Except as otherwise specifically provided, the performance of mammography shall conform to standards as described in "Quality Mammography Standards" Code of Federal Regulations (CFR) 21 CFR Parts 900, et. seq. effective April 28, 1999, as amended, promulgated pursuant to be the federal "Mammography Quality Standards Act." Final Rule as published in Federal Register of October 28, 1997 and corrected in Federal register of November 10, 1997.

(b) ~~Exceptions. None.~~

310:281-11-10. Additional operational controls for dental radiographic systems

- (a) Film holding devices shall be used except in individual cases in which the practitioner has determined that such holding devices are contraindicated. Written safety procedures required by 310:281-11-4(b) shall state the criteria under which the exception may apply.
- (b) The tube housing support shall be constructed and adjusted so that the tube housing ~~shall not~~ cannot drift from its set position during an exposure. Neither the tube housing nor support housing shall be hand-held during an exposure.
- (c) The operator shall stand at least 6 feet from the useful beam or behind a protective barrier. Where a protective barrier is utilized, a viewing system shall be provided.
- (d) Individuals who operate only dental radiographic systems are exempted from the personnel monitoring requirements of 310:281-9-12.

310:281-11-11. Additional operational controls for veterinary x-ray systems

- (a) In no case shall an individual hold the x-ray tube during any radiographic exposure.
- (b) Unless required to restrain an animal, the operator shall stand at least 6 feet away from the useful beam and the animal during radiographic exposures.
- (c) No individual, other than the operator, shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.
- (d) When an animal must be held in position during radiography, mechanical supporting or restraining devices ~~shall~~ may be used when technique permits.
 - (1) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and the person shall be so positioned that no part of his/her body except hands and arms will be struck by the useful beam.
 - (2) The exposure of any individual who holds animals shall be monitored by film badge, TLD, or other appropriate device.

310:281-11-12. General requirements for all human diagnostic x-ray systems

- (a) **Battery charge indicator.** On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- (b) **Leakage radiation from the diagnostic x-ray tube assembly.** The leakage radiation from the diagnostic x-ray tube assembly measured at a distance of 1 meter in any direction from the x-ray tube assembly shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (c) **Radiation from components other than the diagnostic x-ray tube assembly.** The radiation emitted by a component other than the diagnostic x-ray tube assembly ~~shall not~~ cannot exceed 2 milliroentgens in 1 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. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (d) **Beam quality.**
 - (1) **Half-value layer (HVL).**
 - (A) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown below. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in the following table, linear interpolation may be made. Half-value layer measurements shall be made at no less than 90 percent maximum rated potential or 80 kVp, whichever is lower for the unit.
 - (i) the half-value layer for the selected tube potential of 30 kVp is 0.3 mm of aluminum; (terminology and units listed below are the same listed here);
 - (ii) ~~the half-value layer for the selected tube potential of 40 kVp is 0.4 mm of aluminum;~~
 - (iii) ~~the half-value layer for the selected tube potential of 50 kVp is 0.5 mm of~~

aluminum;

(iv) ~~the half value layer for the selected tube potential of 51 kVp is 1.2 mm of aluminum;~~

(v) ~~the half value layer for the selected tube potential of 60 kVp is 1.3 mm of aluminum;~~

(vi) ~~the half value layer for the selected tube potential of 70 kVp is 1.5 mm of aluminum;~~

(vii) ~~the half value layer for the selected tube potential of 71 kVp is 2.1 mm of aluminum;~~

(viii) ~~the half value layer for the selected tube potential of 80 kVp is 2.3 mm of aluminum;~~

(ix) ~~the half value layer for the selected tube potential of 90 kVp is 2.5 mm of aluminum;~~

(x) ~~the half value layer for the selected tube potential of 100 kVp is 2.7 mm of aluminum;~~

(xi) ~~the half value layer for the selected tube potential of 110 kVp is 3.0 mm of aluminum;~~

(xii) ~~the half value layer for the selected tube potential of 120 kVp is 3.2 mm of aluminum;~~

(xiii) ~~the half value layer for the selected tube potential of 130 kVp is 3.5 mm of aluminum;~~

(xiv) ~~the half value layer for the selected tube potential of 140 kVp is 3.8 mm of aluminum;~~and

(xv) ~~the half value layer for the selected tube potential of 150 kVp is 4.1 mm of aluminum.~~

(B) In addition to the requirements of 310:281-11-12(d)(1)(A)(i), all intraoral dental radiographic systems manufactured on or after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

(C) For capacitor energy storage equipment, compliance with the requirements of 310:281-11-12(d) ~~shall be~~ is determined with the maximum quantity of charge per exposure.

(D) The required minimal aluminum equivalent filtration ~~shall include~~ includes the filtration contributed by all materials which are always present between the source and the patient.

(2) **Filtration controls.** For diagnostic 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 amount of filtration ~~required by~~ as stated in 310:281-11-12(d)(1) is in the useful beam for the given kVp which has been selected.

(e) **Multiple tubes.** Where two or more diagnostic x-ray tubes are controlled by one 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 panel and at or near the tube housing assembly which has been selected.

(f) **Technique and exposure indicators.**

(1) The system shall display the selected exposure factors before the exposure begins.

(2) The requirement of 310:281-11-12(f)(1) may be met by permanent markings on equipment having fixed technique factors.

(3) The x-ray control shall provide visual indication of the production of x-rays.

(g) **Certified diagnostic x-ray systems.** In addition to the requirements of these rules, the permittee shall not make, nor cause to be made, any modification of components or installations of components certified pursuant to U.S. Food and Drug Administration Regulation 21 CFR 1020, "Performance Standards for Ionizing Radiation Emitting Products," in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, Food and Drug Administration.

310:281-11-13. Fluoroscopic x-ray systems and spot-film devices except radiation therapy simulators

(a) Limitation of useful beam.

(1) Primary barrier.

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

(B) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(2) X-Ray field.

(A) Means shall be provided for stepless (continuous) adjustment of the field size.

(B) The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

(C) 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 3 percent of the SID.

The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(D) Spot-film devices shall meet the following additional requirements:

(i) Means shall be provided between the source and the patient for adjustment of the x-ray 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.

(ii) Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(iii) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor.

(iv) The sum, without regard to sign of the misalignment along any 2 orthogonal dimensions, shall not exceed 4 percent of the SID.

(v) 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 2 percent of the SID.

(E) Compliance with 310:281-11-13(a)(2) shall be ~~is~~ determined with the beam axis perpendicular to the plane of the image receptor.

(b) Activation of the fluoroscopic tube. 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 the exposure (dead-man switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

(c) Exposure rate limits:

(1) Entrance Exposure Rate Allowable Limits.

(A) Fluoroscopic equipment provided with automatic exposure rate control mode (no manual mode) shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images; or

(ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by

the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(B) Fluoroscopic equipment (manual mode only) not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images; or

(ii) When an optional high level control is activated. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(C) Fluoroscopic equipment, provided with both automatic exposure rate control and manual modes, shall not be operable at any combination of tube potential and current that shall result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images; or

(ii) When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current ~~which shall that result results~~ in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist ~~shall~~ will indicate that the high level control is being employed.

(D) Any fluoroscopic equipment manufactured after May 19, 1995 which can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure ~~rate rates limits shall be~~ are limited to 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when the high level control is activated.

(E) Compliance with the requirements of OAC 310:281- 11-13 ~~shall be~~ is determined as follows:

(i) If the source is below the x-ray table, then the exposure rate ~~shall be~~ is measured 1 centimeter above the tabletop or cradle:

(ii) 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;

(iii) For a c-arm type of fluoroscope, then the exposure rate ~~shall be~~ is measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, 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;

(iv) For a lateral type fluoroscope, the exposure rate ~~shall be~~ is measured at a point 15 centimeters for 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 to the point of measurement. If the tabletop is movable, it 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 centimeters to the centerline of the x-ray table.

(2) **Periodic Measurements.** Periodic measurements of the entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows (Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.):

(A) Such measurements shall be made annually or after any maintenance of the system

which might affect the exposure rate;

(B) ~~Results of these measurements~~ Measurement results shall must be kept where any fluoroscopist may have ready access to such results while using the fluoroscope, and include the following information: ~~The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in results;~~

(i) stated in coulombs per kilogram (roentgens) per minute;

(ii) include the technique factors used in determining such results;

(iii) The name of the individual performing the measurements; and

(iv) the date the measurements were performed.

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

(i) The measurements shall be made under the conditions that satisfy the conditions of OAC 310:281-11-13(c)(1)(E);

(ii) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

(iii) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of OAC 310:281-11-13(c)(2)(C)(ii);

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

(i) The measurement shall be made under the conditions that satisfy 310:281-11-13(c)(1)(E);

(ii) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

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

(d) Barrier transmitted radiation rate limits.

(1) **Primary barrier transmission.** 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 shall not exceed 2 milliroentgens per hour for each roentgen per minute exposure rate. Measurements shall be made at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(2) Measuring compliance of barrier transmission.

(A) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier ~~shall be~~ is determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

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

(C) If the source is above the tabletop and the SID is variable, then the measurement ~~shall be~~ is made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

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

(E) The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(F) The collimator shall be fully open when the measurement is made.

(e) Indication of potential and current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated at the control panel and/or the fluoroscopist's position.

(f) Source-to-Skin distance. The SSD shall not be less than:

(1) 38 centimeters on all stationary fluoroscopes,

- (2) 30 centimeters on all mobile fluoroscopes, and
- (3) 20 centimeters for image intensified fluoroscopes used for specific surgical application.

(g) Fluoroscopic timer.

- (1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
- (2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal ~~shall~~ will continue to sound while x-rays are produced until the timing device is reset.

(h) Radiation therapy simulation systems. ~~If a Radiation radiation~~ radiation therapy simulation system complies with (1) and (2) of this subsection, then it ~~shall be~~ is exempt from all the requirements of 310:281-11-13(a), (c), (d), and (g) provided that:

- (1) such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
- (2) systems which do not meet the requirements of 310:281- 11-13(g) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

310:281-11-14. Radiographic diagnostic x-ray systems

(a) Beam limitation. This Subsection applies to radiographic systems used in the healing arts of medicine, chiropractic, and podiatry. It does not apply to fluoroscopic, dental, veterinary, or computed tomography systems.

(1) General purpose stationary, mobile and portable diagnostic x-ray systems.

- (A) The tube housing shall be of diagnostic type.
- (B) Adjustable collimators, with the same degree of protection as is required of the housing, shall be provided to restrict the useful beam to the area of clinical interest. They shall provide for independent, stepless adjustment of at least two dimensions of the x- ray field.
- (C) 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 2 percent 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.

(2) Additional requirements for stationary general purpose diagnostic x-ray systems. In addition to the requirements of 310:281-11-14(a)(1), all stationary general purpose diagnostic x-ray systems shall meet the following requirements:

- (A) A method shall be provided to align the center of the x-ray field with respect to the center of the image receptor to within 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 SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which deviate from those indicated by the beam-limiting device by no more than 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) General purpose diagnostic x-ray systems designed for one image receptor size.

Radiographic systems designed for only one 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, and to align the center of the x-ray field with the center of the image receptor to within 2 percent 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.

(4) Special purpose diagnostic x-ray systems.

- (A) A 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 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(B) A means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent 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.

(C) The above 310:281-11-14(a)(4)(A) and (B) may be met with a system that meets the requirements for general purpose x-ray system as specified in 310:281-11-14(a)(1) or, when alignment means are also provided, may be met with either:

(i) 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 unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) 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 unit 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.

(b) Radiation exposure control devices.

(1) X-Ray control.

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

(i) for exposure of 0.5 second or less; or

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

(B) The exposure switch shall be of the dead-man type.

(2) **Timers.** A 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. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position.

(3) **Automatic exposure controls.** When an automatic exposure control is provided:

(A) Indication shall be made on the control panel when this mode of operation is selected.

(B) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses.

(C) The minimum exposure time for all systems other than that specified in 310:281-11-14(b)(3)(B) shall be equal to or less than 0.0167 second or a time interval required to deliver 5 mAs, whichever is greater.

(D) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure.

(E) A visible signal shall will indicate when an exposure has been terminated at the limits required by 310:281-11-14(b)(3)(iv), and manual resetting shall be required before further automatically timed exposures can be made.

(4) **Reproducibility.** With a timer setting of 0.5 second or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when 4 timer tests are performed: $T \geq 5(T_{\max} - T_{\min})$

(5) **Accuracy.** Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the

absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and for times greater than 0.05 (1/20) seconds.

(c) **Source-to-Skin Distance (SSD).** All mobile or portable diagnostic x-ray systems shall be provided with means to limit the SSD to 30 centimeters or greater.

(d) **Exposure reproducibility.** The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, and the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{\max}) minus the minimum exposure (E_{\min}): $E \geq 5(E_{\max} - E_{\min})$

(e) **Linearity.** The average ratios of exposure (mR) to the indicated milliamperere-seconds (mAs) product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum: $[X_1 - X_2] \leq 0.10(X_1 + X_2)$ where X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

(f) **Radiation from capacitor energy storage systems in standby status.** Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

310:281-11-15. Computed tomography x-ray systems

(a) System requirements.

(1) Tomographic plane indication and alignment.

(A) 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.

(B) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

(C) If a device using a light source is used to satisfy 310:281-11-15(a)(1)(A) or (B), 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.

(2) **Indication of CT conditions of operation.** The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On a system having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(3) Initiation of operation.

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

(B) Means shall be provided to require operator initiation of each individual scan or series of scans.

(C) All emergency buttons/switches shall be clearly labeled as to their functions.

(4) Termination of exposure.

(A) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of the equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(B) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 310:281-11-15(a)(4)(A).

(C) The operator shall be able to terminate the x-ray exposure at any time during a scan, or

series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

(5) **Extraneous radiation.** The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by 310:281-11-12(c).

(6) **Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.**

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

(B) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be activated for at least 0.5 second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(C) The deviation of indicated scan increment versus actual increment shall not exceed to within 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. 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 can be taken anywhere along this travel.

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

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

(b) **Facility design requirements.**

(1) **Aural communication.** Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) **Viewing systems.**

(A) 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~~ positioned that the operator can observe the patient from the control panel.

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

(c) **Surveys, dose measurements, spot checks, operating procedures, and preventative maintenance services.**

(1) **Surveys.**

(A) All CT systems shall have a survey made by or under the direct supervision of a medical physicist.

(i) All dental cone beam CTs under 120 kVp are exempt from this requirement; and

(ii) CT systems not used for diagnostic purposes are exempt from this requirement.

(B) Performance surveys by a medical physicist shall be made:

(i) at intervals not to exceed 1 year;

(ii) when major maintenance, except x-ray tube replacement, that could affect radiation output is performed; and

(iii) when a major change in the systems operation is accomplished; for example, introduction of a new software package.

(C) The permittee shall obtain a written report of the survey from the medical physicist and a copy of the report shall be made available to the Department upon request.

(2) **Dose measurements.**

(A) The dose measurements of the radiation output of the CT system will be done by a

medical physicist. Dose limits for adult head, adult abdomen, and pediatric abdomen are listed in 310:281-11-5.

(B) Any calibration or recalibration on a CT system required by the medical physicist's survey shall be done by a qualified service representative. Any work deemed necessary by the permittee, other than that permitted by the manufactures' operators manual, shall be performed by a qualified service representative.

(C) Calibration of the dose measurements of a CT system is required for each type of head, body, or whole-body scan performed at the facility.

(D) Dose measurements shall meet the following requirements:

(i) The dose profile along the center axis of the CT phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the permittee shall be measurable. Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(ii) The CTDI along the two axes specified in 310:281-11-15(c)(3)(A)(ii) shall be measured. 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. The CT conditions of operation shall correspond to typical values used by the permittee.

(E) Calibration of the dose measurements of a CT equipment shall be performed with a calibrated dosimetry system.

(i) Calibration of such a system shall be traceable to the national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(ii) Calibration procedures of the dosimetry system shall be in writing. Records of calibration performed shall be available for inspection by the Department.

(3) **CT dosimetry phantom(s).** CT dosimetry phantom(s) shall be used in determining the radiation output of CT systems. Such phantom(s) shall meet the following specifications and conditions of use:

(A) CT dosimetry phantom(s) shall be made of a material analogous to human tissue.

(Water and acrylic are acceptable). If they are made of acrylic, they should have a density of 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have a diameter of 32.0 centimeters for testing CT systems designed to image any section of the body and 16.0 centimeters for equipment designed to image the head or for whole body equipment operated in the head scanning mode.

(B) CT dosimetry phantoms shall provide a means for the placement of a dosimeter(s) along the axis of rotation and a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeter or alignment devices at other locations should be provided.

(C) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

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

(E) If contrast studies are done, the materials used should be made of water, acrylic, polyethylene, and air. They will be used to simulate bone and different types of tissue.

(4) **Spot checks.**

(A) Spot check procedures shall be developed by a medical physicist.

(B) All spot checks shall be included in the medical physicist survey required by 310:281-11-15(c)(2), and otherwise at time intervals and under equipment conditions specified by a medical physicist.

(C) 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 dose measurements required by 310:281-11-15(c)(2). The images shall be retained, until a new dose measurement is performed, in two forms as follows:

- (i) photographic copies of the images obtained from the image display device; and
- (ii) images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

(D) Written records of the spot checks performed shall be maintained for inspection by the Department.

(5) Operating procedures.

(A) The CT system shall not be operated except by an individual who has been specifically trained in its operation (~~See Appendix B for CT operator competency checklist~~).

Documentation of this training must be available upon request of the Department inspector.

(B) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following.

- (i) Dates of the latest survey, preventative maintenance service, spot checks, and location within the facility of where to find the results of those tests;
- (ii) 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;
- (iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
- (iv) A current technique chart available at the control panel which specifies, each routine examination, the CT conditions of operation, and the number of scans per examination.

(C) If the medical physicist survey or spot checks of the CT system identifies that a systems operating parameter(s) has exceeded a tolerance established by the medical physicist, use of the CT equipment on patients shall be limited to those uses permitted by established written instructions of the medical physicist.

(6) Preventative maintenance services. Each permittee shall establish a preventative maintenance schedule where their CT system is serviced at least once every 3 months by a qualified service representative.

310:281-11-16. Dental radiographic systems

General requirements.

(1) **Timers.** 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. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) **Reproducibility.** With a timer setting of 0.3 second or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when 4 timer tests are performed: $T \geq 5(T_{\max} - T_{\min})$

(3) X-Ray control.

(A) An x-ray control shall be incorporated into each dental x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(B) The exposure switch shall be of the dead-man type.

(C) Each x-ray control shall be located in such a way as to permit the operator to remain in an area of less than 2 millirems in any 1 hour during the entire exposure.

(4) **Exposure reproducibility.** The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement ~~shall be deemed to have been~~ is met if, when 4 exposures are made at identical technique factors, the value of the average exposure (E) is

greater than or equal to 5 times the maximum exposure (E_{\max}) minus the minimum exposure (E_{\min}): $E \geq 5(E_{\max} - E_{\min})$

(b) **Additional requirements for dental intraoral systems.**

(1) **Source-to-Skin distance (SSD).** Dental x-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than:

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

(B) 10 centimeters if not operable above 50 kVp.

(2) **Field limitation.**

(A) Dental 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 x-ray field, at the minimum SSD, ~~shall be~~ is containable in a circle having a diameter of no more than 7 centimeters or a rectangle with a longer side of no more than 5 cm.

(B) An open-ended, shielded, beam-indicating device shall be used.

(c) **Additional requirements for dental extraoral system field limitation.**

(1) Dental rotational panoramic systems shall be provided with means to limit the x-ray beam to the imaging slit in the transverse axis and shall not exceed a total of 0.5 inch larger than the imaging slit in the vertical axis.

(2) All other dental extraoral x-ray systems (e.g., cephalometric) shall be provided with means to both size and align the x-ray field so that it does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

310:281-11-17. Veterinary x-ray systems

(a) **Systems.**

(1) The system shall display the selected exposure factors before the exposure begins.

(A) The requirement of 310:281-11-17(a)(1)(A) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(B) The x-ray control shall provide visual indication of the production of x-rays observable at or from the operator's protected position whenever x-rays are produced.

(2) The leakage radiation from the diagnostic tube head assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(3) The useful beam shall be restricted to the area of clinical interest and no larger than the size of the image receptor.

(4) Collimating devices shall be provided and shall limit the beam to the area of the image receptor to within 2 percent of the SID, and shall provide the same degree of protection as is required of the housing.

(5) The half-value layer of the useful beam shall not be less than 0.5 millimeter aluminum equivalent for systems operating up to 50 kVp, 1.5 millimeters aluminum equivalent for systems operating between 50 and 70 kVp, and 2 millimeters aluminum equivalent for systems operating above

70 kVp.

(6) A device shall be provided to terminate the exposure after a preset time or exposure.

(7) A dead-man type of exposure switch shall be provided, together with an exposure control cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet from the animal during all x-ray exposures.

(8) The coefficient of variation for exposure shall not exceed 0.10 when all technique factors are held constant. This requirement ~~shall be deemed to have been~~ is met if, when 4 exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{\max}) minus the minimum exposure (E_{\min}): $E \geq 5(E_{\max} - E_{\min})$

(9) The primary beam shall be aligned with the film by using specified technique in the facility's operating procedures.

(10) Fluoroscopic and CT systems used in veterinary facilities shall meet the requirements of 310:281-11-13 and 310:281-11-15 respectively, except the aural communications requirements of 310:281-11-15(b)(1).

(11) Portable systems shall be used in a manner which complies with these rules.

(b) **X-ray control location.** Each x-ray control shall be located in such a way as to permit the operator to remain in an area of less than 2 millirems in any 1 hour during the entire exposure.

310:281-11-20. Determining skin entrance exposures

The following is the method for measuring and calculating patient entrance skin exposures in diagnostic x-ray examinations.

(a) (1) Have the operator set the x-ray tube at the source to image receptor distance (SID) routinely used, and adjust the collimation as though a patient was in the beam. Measure the distance from the x-ray source to the surface against which the patient rests. Subtract the thickness of the patient part to obtain the source to skin distance (SSD).

(b) (2) Place the ionization chamber in the center of the x-ray field and measure the source to chamber distance (SCD). Use of a test stand (such as the CDRH stand) to position the chamber at a reasonable distance from the table will reduce backscatter contribution. Placing the chamber at the actual SSD will accomplish this and allow direct reading of the ESE.

(c) (3) Record the routine technical factors used by the facility for the standard patient thickness (Table 1) and make exposures utilizing these techniques.

(d) (4) For phototimed procedures a phantom must be utilized to control the exposure time and achieve an accurate exposure estimate. When utilizing a phantom, the measuring chamber should be positioned in the beam between the phantom and the x-ray tube (but not placed over an active photocell), and should be located approximately nine inches from the phantom to reduce backscatter contribution.

(e) (5) Calculate the entrance skin exposure as follows if a direct result was not obtained: $ESE = (Raw\ mR) \times (SCD)^2 / (SSD)^2$

(f) (6) Compare the results of these measurements for the speed of the imaging system used by the facility with the ESE guides published by the ~~Conference~~ Conference of Radiation Control Program Directors, Publication 88-5 "Average Patient Exposure Guides - 1988", or a similarly derived group of values, (allowing for the speed of the imaging system used by the facility).

(g) (7) There are many different techniques for measuring ESE, which may result in significant differences in measured values. Factors that can cause variations include instrument calibration, backscatter, collimation, estimation of focal spot location, choice of phantom, and location of chamber in the primary beam.

APPENDIX B. CT OPERATOR COMPETENCY CHECKLIST [REVOKED]

The checklist with the minimum requirements for CT operator competency follows:

OPERATOR COMPETENCY

CT (model): _____ Rm #: _____

The following CT functions have been monitored for the individual listed below. The individual has been evaluated as proficient to operate the equipment independently of supervision as indicated.

- 1. Basic machine setup for making an exposure
 - A. Positioning of patient _____
 - B. Reference plane and tomographic plane _____
 - C. Tomographic plane light source _____
 - D. Indications of CT scan conditions _____
 - E. X-ray production, shutter indicators _____
 - F. Emergency buttons, switches _____
 - G. Aural communication with patient _____
 - H. Viewing of patient _____
 - I. Dose measurements of the beam _____
 - J. Phantom images quarterly _____

- 2. The proper operation and orientation of gantry _____
- 3. The proper operation and orientation of couch _____
- 4. The proper initiation of scans _____
- 5. Knowledge of emergency buttons, switches _____
- 6. Knowledge of film loading, exposing and unloading _____
- 7. Knowledge of occupancy requirement during exposure _____
- 8. Knowledge of basic radiation safety rules _____
- 9. Aware of special concerns for infant and pediatric _____
- 10. Aware of special concerns for pregnant patient _____

Employee (name) _____

Employee signature _____ Date _____

Supervisor signature _____ Date _____

APPENDIX E. EQUATIONS FOR 310:281-1-2 DEFINITIONS [REVOKED]

"Coefficient of variation" (C) is estimated using the following equation:

$$c = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \sqrt{\left[\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]}$$

where:

s = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = ith observation in sample.

n = Number of observations in sample.

"Computed tomography dose index" (CTDI):

$$\overline{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

"Contrast scale" (CS):

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = linear attenuation coefficient of the material of interest.

μ_w = linear attenuation coefficient of water.

\overline{CTN}_x = CTN of the material of interest.

\overline{CTN}_w = CTN of water.

"CT number" (CTN):

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = constant (a normal value of 1000 when the Hounsfield scale of \overline{CTN} is used.)

μ_x = linear attenuation coefficient of the material of interest.

μ_w = linear attenuation coefficient of water.

"kWs":

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{10^3 kV \times mA \times s} = \frac{XYZkWs}{10^3}$$

"Mean" (\bar{X}):

$$\bar{X} = \frac{\sum(x_1 + x_2 + \dots x_n)}{n - 1}$$

n = Number of observations in sample.

x = A number in the sample of observations.

"Multiple scan average dose (MSAD)":

1.

$$MSAD = \frac{(E \times f \times K \times L)}{T}$$

where:

E=average exposure reading in coulombs per kilogram or in milliroentgens.

f=factor to convert exposure in air to absorbed dose in tissue or other attenuating matter, in grays per coulomb per kilogram or in rad per milliroentgen for acrylic, at an effective energy of 70 KeV; f is equal to 30.2 Gy per C/Kg(0.78x10⁻³ rad/mR).

K=calibration factor to account for the radiation measuring device's response and volume.

L=effective length of the radiation measuring device in millimeters.

T=thickness in millimeters of the tomographic section selected.

NOTE: this calculation assumes tomographic sections are contiguous, without overlap of sections or gaps between sections.

2. If the tomographic sections overlap, the MSAD must be multiplied by a fraction, which is the thickness of the tomographic section divided by the scan increment.

Corrected MSAD= MSAD X (T/scan increment.)

"Noise":

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

\overline{CS} = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation of water.

s = Standard deviation of the CTN of picture element in a specified area of the CT image.

"Standard deviation" (s):

$$s = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n - 1}}$$

s = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = ith observation in sample.

n = Number of observations in sample.