Ohio Administrative Code

Rule 3701:1-66-01 Definitions.

Effective: December 20, 2019

(A) As used in this chapter:

(1) "Air kerma" means the sum of the initial kinetic energy of all charged ionizing particles liberated by uncharged ionizing radiation in a given mass of air. The unit for air kerma is joules per kilogram which is given the special name of gray (Gy). To determine air kerma in Gy from exposure in units of roentgens (R) multiply exposure by the conversion factor 0.00876 Gy/R.

(2) "Air kerma rate" or "(AKR)" means the air kerma per unit time.

(3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

(4) "Automatic exposure control" or "(AEC)" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation.

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

(6) "Bone densitometry equipment" means radiation-generating equipment used for the medical purpose of quantifying bone density and mineral content by x-ray measurements through the bone and adjacent tissues.

(7) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(8) "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 radiation output of a source of radiation relative to a standard.

(9) "Coefficient of variation" means the ratio of the standard deviation to the mean value of the observations.

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

(11) "Computed radiography" means a system that utilizes a photostimulable phosphor (PSP) plate for capturing radiographic images. The components of the system include, at a minimum, the PSP plate and a computed radiography reader which laser scans the exposed plate, collects the stimulated light and ultimately creates the digital image.

(12) "Computed tomography" or "(CT)" means an imaging procedure that uses multiple x-ray transmission measurements and computer programs to generate tomographic images.

(13) "Control panel" means that part of the radiation-generating equipment used for setting the technique factors.

(14) "CT conditions of operation" means all selectable parameters governing the operation of CT radiation-generating equipment including, but not limited to, nominal image thickness, filtration, milliampere (mA), kilovoltage peak (kVp), and scan time.

(15) "CT noise" means the per cent standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.

(16) "CT number" or "(CTN)" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(17) "Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

(18) "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.

(19) "Dental equipment" means radiation-generating equipment used for dental radiography.

(20) "Digital radiography" or "(DR)" means a general radiography system that utilizes an imaging plate to capture and produce a digital image for immediate viewing without the use of a laser scanning cassette reader.

(21) "Direct scattered radiation" means scattered radiation which has been deviated once in direction only by materials irradiated by the useful beam.

(22) "Executive administration" means individuals employed in the hospital's administration and having the authority to expend capital funds, approve personnel actions, and implement changes to hospital policy and procedure.

(23) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.

(24) "Fluoroscopic irradiation time" means the cumulative duration of x-ray tube activation in any fluoroscopic mode of operation.

(25) Fluoroscopic equipment" means radiation-generating equipment used for real time imaging of internal structures for medical purposes.

(26) "Fluoroscopically-guided interventional (FGI) procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy. This statement is focused on the FGI subset of potentially high-dose procedures.

(27) "Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

(28) "Full time training in medical physics" means having been engaged in the practice of clinical medical physics for a minimum of eighteen hundred hours within twelve consecutive months, under the supervision of a board-certified medical physicist.

(29) "Full time work experience" means a minimum of eighteen hundred hours of work experience earned within twelve consecutive months.

(30) "General purpose radiographic equipment" means stationary, mobile, and portable radiation-generating equipment used for medical purpose, but does not include dental intraoral, panoral, mammography, bone densitometry, computed tomography, fluoroscopy or spot film imaging and equipment used in radiation therapy.

(31) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half of its original value.

(32) "Hand-held radiation-generating equipment" means x-ray equipment that is specifically designed to be held in the hand during operation.

(33) "Handle" means receive, possess, use, store, transfer, install, service, or dispose of radiation-generating equipment unless possession is solely for the purpose of transportation.

(34) "Hybrid imaging system" means a combination of systems that separately produce anatomic and functional images in very close temporal proximity without the need for patient repositioning and allow images to be co-registered and fused. These systems may be used for purposes including, but not limited to, attenuation correction, localization, registration, or fusion, but not used independently for diagnosis.

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

(36) "Image receptor" means any device that transforms incident x-ray photons into either a visible image or another form that can be made into a visible image by further transformation. In those cases, where means are provided to preselect a portion of the image receptor, the term "image

receptor" means the preselected portion of the device.

(37) "Individual responsible for radiation protection (IRRP)" means an individual designated by the registrant who has the knowledge and responsibility for overall radiation safety and the quality assurance program at the facility, to include daily radiation safety operations and compliance with the rules.

(38) "Interventional procedure" means an invasive procedure that utilizes radiation-generating equipment for diagnostic or therapeutic purposes.

(39) "Kilovoltage peak (kVp)" means the maximum value of the electrical potential difference between the cathode and the anode of the x-ray tube during an exposure.

(40) "Last image hold" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

(41) "Lateral fluoroscope" means the portion of a biplane system consisting of an x-ray tube housing assembly and an image receptor that are fixed in position to produce a horizontal x-ray beam.

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

(43) "Leakage radiation" means all radiation coming from within the x-ray tube housing except the useful beam.

(44) "Licensed practitioner" means an individual licensed by the state of Ohio pursuant to:

(a) Chapter 4715. of the Revised Code to practice dentistry;

(b) Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery;

(c) Chapter 4731. of the Revised Code to practice podiatry;

(d) Chapter 4741. of the Revised Code to practice veterinary medicine;

(e) Chapter 4734. of the Revised Code to practice chiropractic medicine; and

(f) Chapter 4723. of the Revised Code to practice as a clinical nurse specialist within the scope of practice of his or her collaborating physician and in accordance with the standard care arrangement.

(g) Chapter 4730. of the Revised Code to practice as a physician assistant within the scope of practice of his or her supervising physician and in accordance with the utilization plan approved by the state medical board.

(45) "Light field" means that area of the intersection of the light beam from the beam-limiting device and 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 illumination is one-fourth of the maximum in the intersection.

(46) "Medical event" means one or more of the following criteria have occurred to a human patient:

(a) Unintended skin dose to the same area in a single procedure greater than 2 sievert (200 rem);

(b) Unintended dose other than skin dose in a single procedure greater than:

(i) 0.5 sievert (50 rem) to any organ; or

(ii) 0.05 sievert (5 rem) effective dose equivalent;

(c) Wrong patient or wrong site for entire procedure when the resultant dose is:

(i) Greater than 0.5 sievert (50 rem) to any organ; or

(ii) Effective dose equivalent greater than or equal to 0.05 sievert (5 rem).

(47) Medical, Medical use or Medical purpose means using radiation-generating equipment to irradiate human beings or animals for diagnostic, localization, or other healing arts purposes.

(48) "Milliampere (mA)" means the measurement of tube current which reflects the number of electrons flowing from the cathode to the anode of an x-ray tube during x-ray production.

(49) "Mobile radiation-generating equipment" means x-ray equipment permanently mounted on a base with wheels or castors for moving while completely assembled and is not used in a fixed location.

(50) "Patient" means an individual or animal subjected to radiation for the purposes of examination or therapy.

(51) "Portable radiation-generating equipment" means radiation-generating equipment designed to be hand-carried.

(52) "Primary protective barrier" means a barrier sufficient to attenuate the useful beam to the required radiation level.

(53) "Protective apron" means an apron made of radiation-attenuating materials used to reduce radiation exposure.

(54) "Protective barrier" means a barrier of radiation-attenuating materials used to reduce radiation exposure.

(55) "Protective glove" means a glove made of radiation-attenuating materials used to reduce radiation exposure.

(56) "Radiation expert" means an individual who meets the qualifications of:

(a) Applicable paragraphs of rule 3701:1-66-03 of the Administrative Code;

(b) Paragraph (D) of rule 3701-83-45 of the Administrative Code, for any facility providing radiation therapy services;

(c) Paragraph (C)(3) of rule 3701-83-52 of the Administrative Code for CT equipment, or paragraph (F)(3) of rule 3701-83-52 of the Administrative Code for fluoroscopy, at any facility providing CT or fluoroscopy services; or

(d) 21 C.F.R. 900.12(a)(3) (as effective on the effective date of this rule) for any facility providing mammography services.

(57) "Radiation worker" means an individual engaged in activities registered by the department and controlled by the registrant.

(58) "Reference plane" means a plane which is displaced from and parallel to the computed tomographic plane.

(59) "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.

(60) "Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

(61) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(62) "Secondary protective barrier" means a barrier sufficient to attenuate stray ionizing radiation to a required level.

(63) "Source" means the point of origin of the useful radiation beam.

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

of the input surface of the image receptor.

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

(66) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during the fluoroscopic procedure.

(67) "Stationary radiation-generating equipment" means equipment which is installed in a fixed location.

(68) "Stray radiation" means leakage radiation or scattered radiation.

(69) "Table 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.

(70) "Technique factors" means any combination of the following which determines the exposure rate: kVp, mA, time, x-ray pulses, or the product of tube current and exposure time in mAs.

(71) "Tomogram" means the depiction of the radiation attenuation properties of a section through a body.

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

(73) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when they are contained within the tube housing.

(74) "Unintended Dose" or "Unintended Skin Dose" means a patient radiation dose resulting from an error or equipment malfunction during a procedure.

(75) "Useful beam" means that part of the radiation which passes through the window, aperture,

cone, or other collimating device of the source housing.

(76) "Veterinary radiation-generating equipment" means radiation-generating equipment used for veterinary radiography.

(77) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

(78) "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 air kerma rate is one-fourth of the maximum in the intersection.

(B) Terms appearing in this chapter, which are not defined in this rule, may be defined in rule 3701:1-38-01 of the Administrative Code.