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Ohio Administrative Code

Rule 3701:1-67-01 Definitions.

Effective: September 1, 2022

(A) Terms defined in rule 3701:1-38-01 of the Administrative Code shall have the same meaning when used in Chapter 3701:1-67 of the Administrative Code except for:

(1) Terms redefined within this rule which shall be used within Chapter 3701:1-67 of the Administrative Code; and

(2) Terms redefined in specific rules in Chapter 3701:1-67 of the Administrative Code, are for use within that specific rule only.

(B) As used in this chapter:

(1) "Absorbed dose " means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(2) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) "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.

(4) "Authorized user" means an individual qualified in accordance with paragraph (C) of rule 3701:1-67-02 of the Administrative Code.

(5) "Beam axis" means the axis of rotation of the beam limiting device.

(6) "Beam-limiting device" means a field defining collimator, integral to the therapy equipment, which provides a means to restrict the dimensions of the useful beam.

(7) "Beam monitoring system" means a system installed in the radiation head to detect and measure the radiation present in the useful beam.

(8) "Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(9) "Computed tomography" or " (CT)" means an imaging procedure that uses multiple x-ray transmission measurements and a computer program to generate tomographic images of a patient or material.

(10) "Contact therapy system" means a therapeutic radiation machine that is a type of electronic brachytherapy device.

(11) "Control panel" means that part of the radiation-generating equipment control system used to initiate and terminate the beam.

(12) "Control system" means the collective hardware and software components used for determining and selecting the treatment parameters and monitor the course of treatment.

(13) "Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

(14) "Daily" means each treatment day before the evaluated equipment component is used clinically.

(15) "Direct supervision" means to be physically present at the same address and available to respond to the needs of something or someone.

(16) "Dose monitoring system" means

(a) "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 delivered.

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

(17) "Dose rate" means absorbed dose per unit time, for machines with timers, or monitor unit per unit time for linear accelerators.

(18) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(19) "Electronic brachytherapy device" means the system used to deliver electronic brachytherapy including the x-ray tube, the control mechanism, the cooling system, and the power source.

(20) "Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

(21) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(22) "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

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

(24) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(25) "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.

(26) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

(27) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(28) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions via the control system.

(29) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(30) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(31) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(32) "Light field" means the area illuminated by light, simulating the radiation field.

(33) "Medical Event" means an event that meets the criteria in paragraph (B) or (C) of rule 3701:1-67-12 of the Administrative Code.

(34) "Megavolt" or " (MV)" or "mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

(35) "Mobile Electronic Brachytherapy Service" means transportation of an electronic brachytherapy

device to provide electronic brachytherapy at an address that is not the address of record.

(36) "Monitor unit" or " (MU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(37) "Monthly" means at least once each calendar month, not to exceed forty-five days from previous event.

(38) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

(39) "Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(40) "Patient" means an individual or animal subjected to radiation from therapy equipment for the purposes of medical therapy.

(41) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(42) "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(43) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is a estimation from measured data from a piece of therapy equipment using assumptions that are clinically acceptable for that treatment technique and historically

consistent with the clinical calculations previously used for patients treated with the same clinical technique.

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

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

(45) "Qualified Medical Physicist" means an individual qualified in accordance with paragraph (D) of rule 3701:1-67-02 of the Administrative Code.

(46) "Radiation detector or detector" means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(47) "Radiation head" means the structure from which the useful beam emerges.

(48) "Redundant beam monitoring system" means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

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

(50) "Signature" or "sign" means an identifier that authenticates the person who made it.

(51) "Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field.

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

(53) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(54) "Stray radiation" means the sum of leakage and scattered radiation.

(55) "Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(56) "Target-skin distance" or " (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

(57) "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.

(58) "Tenth-value layer" or " (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(59) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions via the control system.

(60) "Therapy equipment" means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these regulations, devices used to administer electronic brachytherapy or contact therapy shall also be considered therapy equipment.

(61) "Treatment site" means the description of the specific tissue volume intended to receive a radiation dose, as described in the written directive and treatment plan.

(62) "Tube" means an x-ray tube, unless otherwise specified.

(63) "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.

(64) "Useful beam" or "radiation field" 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 therapy equipment to produce radiation.

(65) "Virtual Simulator" means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

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

(67) "Wedge" means a device which effects continuous change in transmission over all or a part of the useful beam.

(68) "Weekly" means once per calendar week in which the evaluated equipment component has or will be used clinically, unless the equipment component was not evaluated during the prior week. If the equipment component was not evaluated during the prior week, "weekly" means once per calendar week before the evaluated equipment component is used clinically.

(69) "Written directive" means a documented order for the administration of radiation to a specific patient or human research subject, as specified in paragraph (B) of rule 3701:1-67-04 of the Administrative Code.

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