10A NCAC 15 .2002 is proposed for adoption as follows:

10A NCAC 15 .2002 DEFINITIONS

(a) As used in this Section the following definitions apply:

(1) "Acceptance testing" means an evaluation of equipment and systems to confirm they meet the specifications stated by the manufacturer.

(2) "Animal" means any mammal other than human, and includes birds, fish, and reptiles, wild or domestic, living or dead.

(3) "Annually" means at intervals not to exceed 12 consecutive months, plus or minus 30 days.

(4) "Authorized Medical Physicist" means an individual authorized in accordance with Rule .2003(c) of this Section.

(5) "Authorized user" means a veterinarian who meets the training requirements of Rule .2003(b) of this Section and is authorized by license condition to use a therapeutic radiation machine covered by this Section.

(6) "Barrier" see "Protective barrier".

(7) "Biennially" means at intervals not to exceed 24 consecutive months, plus or minus 30 days.

(8) "Commissioning" means an intricate and methodical process designed to:

(A) acquire needed machine-specific beam data;

(B) validate the safe, accurate, and effective operation of a therapeutic radiation machine, treatment planning systems, ancillary systems, and associated procedural protocols; and,

(C) set baseline for future measurements for performance constancy.

(9) "Dosimetry systems" means radiation detecting equipment that may be used to characterize the radiation beam and quantify the energy it may deposit within a medium.

(10) "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.

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

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

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

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

(15) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

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

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

(18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons

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

(20) "Licensee" means any person who is licensed by the agency pursuant to the Rules of Section .0900 of this Chapter.

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

(22) "Megavolt," "MV," "mega electron volt," and "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.

(23) "Method of Delivery" means mode of radiation to be used during treatment, which may include photons, electrons, or protons.

(24) "Patient" means an animal, for whom a written directive is intended, subjected to machine produced radiation for the purposes of medical therapy.

(25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

(26) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

(27) "Primary protective barrier" see "Protective barrier".

(28) "Protective barrier" means a barrier of radiation absorbing materials 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.

(29) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter for the provision of either Class VII or IX services.

(30) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 days.

(31) "Radiation oncology safety team" means, minimally, a group of individuals consisting of an authorized user, authorized medical physicist, and veterinary therapeutic radiation machine operator whose purpose is to work together to deliver radiation safely and reproducibly.

(32) "Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(33) "Semiannually" means at intervals not to exceed 6 consecutive months, plus or minus 15 days.

(34) "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram.

(35) “Supervision” shall be defined as follows:

(A) "General supervision" means the activity is performed under the overall direction and control of a supervising individual. The supervising individual’s physical presence shall not be required during the performance of the procedure but must be available by phone to provide assistance and direction if needed.

(B) “Direct supervision” means an individual exercise General Supervision and be present within the facility and immediately available to furnish assistance and direction throughout the performance of the activity. Direct Supervision does not require that the supervising individual must be present in the room when the procedure is being performed.

(C) "Personal supervision" means an individual exercises General Supervision and be present in the room during the performance of the procedure.

(36) “Treatment room shielding” means a location which contains fixed protective barriers to limit radiation exposures to members of the public and occupationally exposed workers to within regulatory limits.

(37) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

(38) "Veterinarian" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 11.

(39) "Veterinary therapeutic radiation machine," also known as a “Therapeutic radiation machine,” means equipment that is designed and used for external beam radiation therapy in the healing arts. For these regulations, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

(40) “Weekly” means at least once per calendar week.

(41) "Written directive" means an order in writing for the administration of radiation to a specific patient, as specified in Rule .2005(b)(1) of this Section.

(b) Definitions of certain other words and phrases used in the Rules in this Section are set forth in Rules .0103, .1001 and .1601 of this Chapter.

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