10A NCAC 15 .0103 DEFINITIONS

(a) As used in the rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, and persons licensed under the rules in Sections .0300, .0900, .1200, and .1300 of this Chapter, the following definitions apply:

(1) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.
(2) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.
(3) "Authorized representative of the agency" means an employee of the agency.
(4) "Annually" means either:
    (A) at intervals not to exceed 12 consecutive months; or
    (B) once per year at the same time each year (completed during the same month each year over a period of multiple years).
(5) "Calendar month" means January, February, March, April, May, June, July, August, September, October, November, or December.
(6) "Calendar year" means the period of time between 12:00:00 am January 1 to 11:59:59 pm December 31.
(7) "Calibration" means the determination of the reading or response of an instrument to known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.
(8) "CFR" means Code of Federal Regulations.
(9) "Commission" has the meaning as defined in G.S. 104E-5(5), except as stated in Paragraph (c) of this Rule.
(10) "Department" has the meaning as defined in G.S. 104E-5(6) except as stated in Paragraph (c) of this Rule.
(11) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.
(12) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.
(13) "Inspection" means an examination or observation by an authorized representative of the agency to determine compliance with rules, orders, requirements, and conditions of the agency or the Commission.
(14) "Monthly" means once every calendar month.
(15) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
(16) "Person" has the same meaning as defined in G.S. 104E-5(11).
(17) "Quarterly" means four times per calendar year, and:
    (A) at intervals not to exceed 13 weeks; or
    (B) once per month during the months of January, April, July, and October; or
    (C) once per month during the months of February, May, August, and November; or
    (D) once per month during the months of March, June, September, and December.
(18) "Radiation" except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).
(19) "Semiannually" means twice per calendar year at six month intervals.
(20) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.
(21) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
(22) "State" means the State of North Carolina.
(23) "These Rules" means Chapter 10 of this Title.

(b) As used in the rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following definitions shall apply:

(1) "Clinical study" means human use of a radiation machine for research and development. The terms "clinical investigation", "clinical research", "research", and "study" also mean "clinical study".
(2) "Consulting" means providing professional technical advice on radiological matters by an expert registered with the agency in accordance with Rule .0205 of this Chapter.
(3) "Facility" means the location at which one or more radiation machines or sources of radiation are installed or located within one building, at one address or vehicle, and are under the same administrative control.

(4) "Healing arts" means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.

(5) "Individual responsible for radiation protection" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.

(6) "Install or installation" means the assembly, placement, initial calibration, operational testing, or other actions that allow a radiation machine to be used in a new location or after being moved from one location to another.

(7) "Licensed practitioner" means a person authorized to order diagnostic exams that use radiation machines for diagnosing or treatment of human or animal diseases. The person shall be:

(A) a physician in accordance with Subparagraph (8) of this Paragraph; or

(B) licensed by the appropriate licensing board in North Carolina pursuant to G.S. Chapter 90 to provide professional services in chiropractic, dentistry, podiatry, and veterinary medicine.

(8) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.

(9) "Radiation machine" has the same meaning as defined in G.S. 104E-5(13).

(10) "Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 of this Chapter.

(11) "Registration" means the process of registration, with the agency, by completing and submitting agency forms in accordance with Rules .0203 and .0205 of this Chapter.

(12) "Registered" means a facility or service provider that has completed the registration process in accordance with Rules .0203 and .0205 of this Chapter and has been issued a Notice of Registration in accordance with Rule .0207 of this Chapter.

(13) "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.

(14) "Service" means calibration, conversion, repair, routine maintenance, or other testing performed on a radiation machine, x-ray system or subsystem, or source of radiation, other than those actions taken during installation.

(15) "Service Provider" means any person engaged in equipment services included in Rule .0205(d) of this Chapter.

(c) Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1000, .1200, .1300, .1400, .1600, and .1700 of this Chapter.

(d) To reconcile differences between the rules of this Chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) With the exception of 10 CFR 30.4 and in the definition of Special Nuclear Material, a reference to "NRC" or "Commission" means the "Agency".

(2) A reference to "NRC or agreement state" means the "Agency or agreement state".

(3) In 10 CFR 40.4 and 70.4, in the definition of "Special Nuclear Material", the sentence "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material", remains preserved as implemented by G.S. 104E-5.(16).

(4) In 10 CFR 30.18(d), 30.32(g), 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 1.10(b)(1), 31.12(c)(4), 32.13, 32.51(a), 32.51(c), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(c)(10), 40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(c), (c)(1), (d)(1)(ii), (d)(2) and (d)(3), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC".

(5) In 10 CFR 31.6, where the words "any non-agreement state" or "offshore waters" are used, substitute the words "State of North Carolina,".

(6) In 10 CFR 70.19(a)(1) and 70.19(c)(3), the term "Commission or the Atomic Energy Commission" remains and does not mean the Agency or have the same definition shown in G.S. 104E-5(5). In 10 CFR 70.42(b)(1), the word "Department" means the "U.S. Department of Energy".

(7) "Written directive," except as defined in Rule .0307 of this Chapter, means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of radiation therapy through the use of a licensed accelerator that contains the patient or human research subject's name and the following information:

(A) total dose;
(B) dose per fraction;
(C) treatment site, and
(D) number of fractions.

History Note: *Authority G.S. 104E-7(a); 10 CFR 20.1003;*
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