

1 10A NCAC 15 .1902 is proposed for adoption as follows:

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3 **10A NCAC 15 .1902 DEFINITIONS**

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

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

7 (2) “Annually” means at intervals not to exceed 12 consecutive months, plus or minus 30 days.

8 (3) "Authorized Medical Physicist" means an individual authorized in accordance with Rule .1903(d).

9 (4) “Authorized user" means a physician who meets the training requirements of Rule .1903(c) and is
10 authorized by license condition to use a therapeutic radiation machine covered by this Section.

11 (5) "Barrier" see "Protective barrier".

12 (6) “Biennially” means at intervals not to exceed 24 consecutive months, plus or minus 30 days.

13 (7) “Commissioning” means an intricate and methodical process designed to:

14 (A) acquire needed machine-specific beam data;

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

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

18 (8) “Dosimetry systems” means radiation detecting equipment that may be used to characterize the
19 radiation beam and quantify the energy it may deposit within a medium.

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

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

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

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

29 (13) “Human research subject” means an individual defined pursuant to 10A NCAC 15 .0307(a)(4) and
30 shall include radiation therapy treatments covered by this Section.

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

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

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

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

- 1 (18) "Kilovolt," "kV," "kilo electron volt," and "keV" means the energy equal to that acquired by a
2 particle with one electron charge in passing through a potential difference of one thousand volts in
3 a vacuum. Current convention is to use kV for photons and keV for electrons.
- 4 (19) "Leakage radiation" means radiation emanating from the radiation therapy system except for the
5 useful beam.
- 6 (20) "Licensee" means any person who is licensed by the agency pursuant to the rules of this Section
7 .0900 of this Chapter.
- 8 (21) "Light field" means the area illuminated by light, simulating the radiation field.
- 9 (22) "Megavolt," "MV," "mega electron volt," and "MeV" means the energy equal to that acquired by a
10 particle with one electron charge in passing through a potential difference of one million volts in a
11 vacuum. Current convention is to use MV for photons and MeV for electrons.
- 12 (23) "Method of Delivery" means mode of radiation to be used during treatment, which may include
13 photons, electrons, or protons.
- 14 (24) "Patient" means an individual, for whom a written directive is intended, subjected to machine
15 produced radiation for the purposes of medical therapy.
- 16 (25) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous
17 parameter or condition continues to be valid.
- 18 (26) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. 90,
19 Article 1.
- 20 (27) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.
- 21 (28) "Primary protective barrier" (see "Protective barrier").
- 22 (29) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation
23 exposure. The types of protective barriers are as follows:
- 24 (A) "Primary protective barrier" means the material, excluding filters, placed in the useful
25 beam.
- 26 (B) "Secondary protective barrier" means the material which attenuates stray radiation.
- 27 (30) "Qualified Expert" means a person registered by the agency pursuant to Rule .0205 of this Chapter
28 for the provision of Class VII services and who meets the training and experience requirements
29 listed in Rule .0206(a)(7)(A) or (B) of this Chapter.
- 30 (30) "Quarterly" means at intervals not to exceed 13 consecutive weeks, plus or minus 7 consecutive
31 days.
- 32 (31) "Radiation oncology safety team" means, minimally, a group of individuals consisting of an
33 authorized user, authorized medical physicist, medical dosimetrist, radiation therapist and oncology
34 nurse whose purpose is to work together to deliver radiation safely and reproducibly.
- 35 (32) "Referring physician" means the physician whom referred the patient or human research subject to
36 the licensee for specialized care.

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

3 (34) "Sievert" and "Sv" mean the SI unit of dose equivalent measured as joule per kilogram.

4 (35) "Supervision" shall be defined as follows:

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

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

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

15 (36) "Therapeutic radiation machine" means equipment that is designed and used for external beam
16 radiation therapy in the healing arts. For these regulations, devices used to administer electronic
17 brachytherapy shall also be considered therapeutic radiation machines.

18 (37) "Therapeutic radiation machine medical event" means an event that meets the criteria in Rule
19 .1905(a)(4).

20 (38) "Treatment room shielding" means a location which contains fixed protective barriers to limit
21 radiation exposures to members of the public and occupationally exposed workers to within
22 regulatory limits.

23 (39) "Weekly" means at least once per calendar week.

24 (40) "Written directive" means an order in writing for the administration of radiation to a specific patient
25 or human research subject, as specified in .1905(a)(1).

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

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29 History Note: Authority G.S. 104E-7;

30 Eff. October 1, 2025.