

1 10A NCAC 15 .2010 is adopted as published in 39:19 NCR 1225-1262 as follows:

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3 **10A NCAC 15 .2010 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER**
4 **THERAPEUTIC RADIATION DOSAGE**

5 (a) A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to
6 deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation
7 machine, until the applicant or licensee has, at a minimum, provided the Agency with:

8 (1) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical
9 Commission standard, documentation of US Food and Drug Administration clearance, or
10 documentation of participation in a clinical research study approved by the licensee's Institutional
11 Animal Care and Use Committee.

12 (2) A detailed description of the device and its intended applications;

13 (3) Facility design requirements, including shielding and access control;

14 (4) Documentation of appropriate training for authorized users, authorized medical physicists, and other
15 personnel who will be involved in performing quality assurance tasks and setting up patients for
16 treatment or delivering treatment;

17 (5) Methodology for measurement of dosages to be administered to patients;

18 (6) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments
19 and equipment necessary for quality assurance and radiation safety

20 (7) Radiation safety precautions and instructions; and

21 (8) Other information requested by the Agency in its review of the application; and

22 (b) The applicant or licensee has received written approval from the Agency to utilize the device in accordance with
23 the regulations and specific conditions the Agency considers necessary for the medical use of the device.

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

26 *Eff. October 1, 2025.*