10A NCAC 15 .1910 is proposed for adoption as follows:

10A NCAC 15 .1910 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not regulated under any existing category of therapeutic radiation machine, until:

(1) The applicant or licensee has, at a minimum, provided the Agency with:

(2) Documentation that equipment to be licensed conforms to the relevant International Electrotechnical Commission standard, documentation of US Food and Drug Administration clearance, or documentation of participation in a research study approved by the licensee's Institutional Review Board;

(3) A detailed description of the device and its intended application(s);

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

(5) Documentation of appropriate training for authorized user physician(s), authorized medical physicist(s), and other personnel who will be involved in performing quality assurance tasks and/or setting up patients or human research subjects for treatment or delivering treatment;

(6) Methodology for measurement of dosages to be administered to patients or human research subjects;

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

(8) Radiation safety precautions and instructions; and

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

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

History Note: *Authority G.S. 104E-7;*
Eff. October 1, 2025.