

1 10A NCAC 15 .1911 is proposed for adoption as follows:

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3 **10A NCAC 15 .1911 EMERGING TECHNOLOGIES**

4 (a) Each registrant shall develop, implement, and maintain a dedicated quality management program to control the
5 processes used to administer therapeutic radiation with US Food and Drug Administration cleared emerging
6 technologies or previously unused features of a future or existing technology system.

7 (b) Implementation and on-going clinical use of the technology dated before the technology arrives at the facility or
8 the new features are used:

9 (1) Must include an explicit strategy to ensure quality of processes and patient or human research
10 subject safety.

11 (2) Must include approval from facility management and the radiation oncology safety team before the
12 technology arrives or new features are used.

13 (c) The quality management program shall be developed by the radiation oncology safety team.

14 (d) The quality management program shall address, at a minimum:

15 (1) Education and training about the new technology or features;

16 (2) A system and timeline for on-going competency assessment;

17 (3) A system for real-time recording of on-going issues related to the technology and clinical use of the
18 new technology or features;

19 (4) A strategy for timely investigation and adjudication of accidents and process deviations that may be
20 captured in the system developed in Subparagraph (b)(1) of this Rule;

21 (5) A strategy for routine review at intervals not to exceed thirteen (13) months of the clinical use of
22 the new technology or features which includes an assessment of the current use compared to
23 Subparagraph (b) of this Rule and plan to either update the clinical use plan or steps to bring the
24 clinical use back into alignment with Subparagraph (b) of this Rule;

25 (6) A strategy to ensure quality of equipment functions;

26 (7) A strategy for ensuring quality after hardware and software updates and after equipment repair.

27 (e) The quality management program shall be developed in accordance with current published recommendations from
28 a recognized national professional association with expertise in the use of therapeutic radiation technologies, that
29 includes the American Association of Physicists in Medicine, the American College of Radiology and the American
30 Society for Radiation Oncology. In the absence of a protocol published by a national professional association, the
31 manufacturer's protocol or equivalent quality, safety, and security protocol shall be followed.

32 (e) New technology issues should be reported through the vendor or manufacturer, applicable regulatory agency
33 alerts, or customer service bulletins and be reviewed and addressed via a documented reporting system.

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

36 *Eff. October 1, 2025.*