10A NCAC 15 .2011 EMERGING TECHNOLOGIES

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

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

(1) Must include an explicit strategy to ensure quality of processes and patient safety.

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

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

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

(1) Education and training about new technologies and features;

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

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

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

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

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

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

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

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

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