10A NCAC 15 .2005 is proposed for adoption as follows:

10A NCAC 15 .2005 QUALITY MANAGEMENT PROGRAM

(a) Each licensee or applicant subject to Rules within this subpart shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

(b) Scope and Applicability. The quality management program shall address, as a minimum, the following specific objectives:

(1) Written Directives:

(A) A written directive must be approved by an authorized user prior to the administration of radiation. If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(B) The written directive must contain the patient's name, treatment site, method of delivery, dose per fraction, total number of fractions, and total dose.

(C) A written revision to an existing written directive may be made provided that the revision is dated and approved by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(D) The licensee shall retain a copy of the written directive for three years.

(2) Procedures for Administrations. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide that:

(A) Prior to the administration of each course of radiation treatments, the patient's identity is verified.

(B) Each administration is in accordance with the written directive.

(C) Develop a table-shift policy describing action to be taken by staff in the event shifts are used for patient setup and a table shift exceeds limitations established within the treatment plan.

(D) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by: Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive, and verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(E) Any unintended deviation from the written directive is identified, evaluated, corrective action taken, the unintended deviation documented; and

(F) The licensee retains a copy of the procedures for administrations for the duration of the license.

(c) New Procedures on Established Equipment. Established and commissioned therapeutic radiation machines shall reevaluate equipment parameters, pursuant to this Section, when new procedures are to be performed that the parameters, including dose rate, field size, imaging accuracy, maximum dose, falls outside of the original commissioned parameters.

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