10A NCAC 15 .1905 is proposed for adoption as follows:

10A NCAC 15 .1905 QUALITY MANAGEMENT PROGRAM

(a) Each licensee or applicant subject to Rules within this Section shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user. 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, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient or human research subject'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 or human research subject'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 or human research subject'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 (3) 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 treatment, the patient or human research subject's identity is verified by more than one method as the individual named in the written directive;

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

(E) Develop a table-shift policy describing action to be taken by staff in the event shifts are used for patient or human research subject 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 and action is taken; and

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

(3) New Procedures on Established Equipment: Licensees possessing 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, fall outside of the original commissioned parameters.

(4) Documentation, Reports, and Notifications of Medical Events:

(A) Any unintended treatment deviation from the written directive or approved treatment plan shall be identified, evaluated, and documented. Licensees shall document the corrective action taken by the licensee as a result of any unintended deviation from the written directive or approved treatment plan.

(B) A licensee shall report any medical event resulting from intervention of a patient or human research subject in which the administration of radiation from therapy equipment results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

(C) Except as required by Part (B) of this Subparagraph, licensees shall report any treatment deviation as a medical event, except for a treatment deviation that results from intervention by a patient or human research subject, when the treatment deviation is caused by any of the conditions listed in Parts (D), (E), or (F) of this Subparagraph.

(D) Treatment deviations in which the administration of radiation from therapy equipment involves the administration of radiation to an individual using a treatment plan intended for another patient or human research subject;

(E) Treatment deviations in which the administration of radiation to a patient or human research subject does not conform to the written directive and the approved treatment plan, and the administered dose over the entire treatment course differs from the prescribed dose as stated in the written directive by twenty percent or more; or,

(F) Treatment deviations in which the administered dose delivered differs from the prescribed dose, for a single fraction, by an overdose of 50 percent or more.

(G) The licensee shall notify the Agency by telephone no later than the next calendar day after the licensee determines that a medical event occurred.

(5) The licensee shall submit a written report to the Agency within fifteen days after the initial report of the medical event. The written report must include:

(A) The licensee name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual who received the medical event;

(F) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(G) Certification that the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and

(H) The report shall not contain the patient's name or any other information that could lead to the identification of the patient;

(6) The licensee shall provide notification of the medical event to the referring physician no later than twenty-four hours after its discovery. The licensee shall also notify the individual who is the subject of the medical event no later than twenty-four hours after the initial notification, unless the authorized user or referring physician determines that, based on their medical judgment, informing the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care because of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(7) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(8) The licensee shall retain a record of each unintended deviation in accordance with Part (4)(A) of this Paragraph. If the unintended deviation is a medical event, a copy of the record shall be provided to the referring physician if other than the licensee within fifteen days after its discovery.

(9) The licensee shall retain a record of each unintended deviation for three years. The record must contain the following:

(A) The licensee name and the names of the individuals involved;

(B) A unique identification number, if one has been assigned, of the individual who is the subject of the unintended deviation;

(C) A brief description of the event; why it occurred; the effect, if any, on the individual;

(D) The actions, if any, taken or planned to prevent recurrence; and

(E) Whether the licensee notified the individual, or the individual's responsible relative or guardian; and, if not, whether such failure to notify was based on guidance from the referring physician.

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