Ohio Administrative Code

Rule 3701:1-67-04 Quality management program.

Effective: August 20, 2026

(A) Each handler of therapy equipment subject to the requirements of Chapter 3701:1-67 of the Administrative Code, shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the physician or veterinarian authorizing its use.

(B) The quality management program shall address, as a minimum, the following specific objectives regarding written directives:

(1) A written directive must be dated and signed by a physician or veterinarian authorizing its use 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 the patient's record and a revised written directive is signed by an authorized physician within forty-eight hours of the oral revision;

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions;

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized physician prior to the administration of the therapy equipment dose, or the next fractional dose; and

(4) The handler shall retain a copy of the written directive for seven years.

(C) The quality management program will address, as a minimum, the following specific objectives regarding radiation therapy services:

(1) Each radiation therapy service will evaluate the patient and assess the treatment site(s):

(a) The evaluation will be conducted by an authorized physician and will include a medical history, a physical examination, a review of the patient's diagnostic studies and reports, and, when appropriate, consultation by the authorized physician with the referring physician;

(b) The assessment of the treatment site(s) will include location, the extent, and stage of the disease;

(c) The authorized physician will establish the doses desired throughout the treatment site and set dose limits to critical structures. The authorized physician will establish the critical structures associated with the

treatment site. Treatment will meet the goals of the authorized physician; and

(d) The authorized physician will describe in detail and sign all treatment applications. The authorized physician will be notified of any changes that may be necessary in the planned schedule of treatment.

(2) Each radiation therapy service will:

(a) Provide or arrange for appropriate radiation treatment localization, simulation and verification;

(b) Provide or arrange for isodose treatment planning with complex analyses generated in appropriate cases;

(c) Provide accurate calculation of doses and dose distribution;

(d) Provide a system for independent checking of initial dose calculations. The check will be conducted before the third fraction, or before twenty per cent of the total dose when the treatment schedule provides less than ten fractions. The independent check includes utilizing another individual or method approved and documented by the medical physicist to verify dose calculations;

(e) Conduct ongoing reviews of accumulating doses;

(f) Conduct prescribed imaging prior to the second treatment and check the prescribed imaging at least every ten treatments;

(g) Conduct a chart and imaging review weekly;

(h) Accurately chart treatment doses;

(i) Maintain records of pertinent data used in planning the specific treatment for a patient in the patient's medical record; and

(j) Provide devices to aid in positioning and immobilizing the patient. Normal tissue shield, compensating filters, wedges, and other aids will be provided as medically appropriate.

(D) The quality management program will address the following specific objectives regarding stereotactic radiosurgery services: The authorized physician will establish the doses desired throughout the treatment site and set limits of doses to critical structures The authorized physician will establish the critical structures associated

with the treatment site. Treatment deliveries will meet the specifications of the authorized physician;

(E) The handler shall develop, implement, and maintain for the duration of the registration, written procedures to provide high confidence that:

(1) Prior to the administration of each radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

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

(3) The final plans of treatment and related calculations are in accordance with the respective written directives by:

(a) Checking the parameters and the results of the primary calculation with a secondary method to verify they are correct and in accordance with the written directive; and

(b) Verifying that the planned parameters are correctly transferred to the treatment charts; and

(4) Unintended treatment deviations from the written directive, approved treatment plan, or errors in the approved treatment plan or process that was identified after the administration of radiation are identified, documented, evaluated and appropriate action is taken.

(F) The handler shall retain records of unintended treatment deviations from the written directive or approved treatment plan for seven years. The record must contain the following:

(1) The identification number of the individual who is the subject of the unintended deviation;

(2) A brief description of the deviation and why it occurred; and

(3) The actions, if any, taken to prevent recurrence.