Ohio Administrative Code

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

Effective: September 1, 2022

(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 user within forty-eight hours of the oral revision;

(2) The written directive must contain the patient or human research subjects 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 user 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 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 patients 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.

(D) 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.