Ohio Administrative Code

Rule 3701:1-67-12 Unintended treatment deviations and notifications of medical events.

Effective: September 1, 2022

(A) A handler shall report any medical event resulting from intervention of a human 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.

(B) A handler shall report, as a medical event, any treatment deviation, except for a treatment deviation that results from intervention by a human patient or human research subject, in which the administration of radiation from therapy equipment involves:

(1) The wrong patient; where wrong patient means administration of radiation to an individual using a treatment plan intended for another patient or human research subject; or

(2) The wrong treatment; where wrong treatment means administration of radiation to a human patient or human research subject that does not conform to the written directive and the approved treatment plan; and

(a) The administered dose over the entire treatment course differs from the prescribed dose as stated in the written directive by more than ten per cent for treatment courses consisting of three or fewer fractions; or

(b) The administered dose over the entire treatment course differs from the prescribed dose by more than twenty per cent for treatment courses consisting of more than three fractions; or

(c) The administered dose over any five consecutive fractions differs from the prescribed dose by more than thirty per cent; or

(d) The administered dose to any critical structure:

(i) Exceeds the critical dose limit established in the written directive or approved treatment plan by twenty per cent or more; and

(ii) Has the potential to cause serious harm according to the current published recommendations from a recognized national professional organization with expertise in radiation oncology; or

(3) An error in the approved treatment plan or process that was identified after the administration of radiation and resulted in a dose difference described in paragraph (B)(2)(a), (B)(2)(b), (B)(2)(c) or (B)(2)(d) of this rule.

(C) For purposes of paragraphs (B)(2)(a), (B)(2)(b) and (B)(2)(c) of this rule, "administered dose" means:

(1) The D_{95} (minimum dose to ninety-five per cent of the prescribed volume) for computer treatment plans; or

(2) The dose to the prescription point for treatments prescribed to a point.

(D) The handler shall notify the department by telephone no later than the next calendar day after the handler ascertains that a medical event occurred.

(E) The handler shall submit a written report to the department within fifteen days after the initial report of the medical event. The written report must include:

(1) The handler or registrant name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

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

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

(7) Certification that the handler notified the individual, or the individual's responsible relative or guardian, and if not, why not.

(F) The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

(G) The handler shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty-four hours after its discovery, unless the authorized user and/or referring physician personally informs the handler either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The handler is not required to notify the individual without first consulting the authorized user and/or referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the handler shall notify the individual as soon as possible thereafter. The handler may not delay any appropriate medical care for the individual, including any necessary remedial care as a result 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 individuals responsible relative or guardian. If a verbal notification is made, the handler shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the handler upon request. The handler shall provide such a written description if requested.

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

(I) The handler shall retain a record of each medical event report with an identification link to the individual who is the subject of the medical event for the duration of the registration.