

UNIVERSITY OF TOLEDO

SUBJECT: Medical Event Involving Radiative Material

Procedure No: HM-08-050

PROCEDURE STATEMENT

General administration requirements for a medical event involving the administration of radioactive material or radiation from radioactive material as defined in OAC 3701:1-58-101.

PURPOSE OF PROCEDURE

To define a medical event involving the administration of radioactive material or radiation from radioactive material and reporting requirements.

DEFINITION

"Medical event" means an event that meets the criteria in paragraph (A) or (B) of rule 3701:1-58-101 of the Administrative Code

PROCEDURE

- (A) The University of Toledo shall report any event as a medical event, except for an event that results from patient intervention, in which:
 - (1) The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:
 - (a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 sievert (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty rem) shallow dose equivalent to the skin; and
 - (i) The total dose delivered differs from the prescribed dose by twenty per cent or more;
 - (ii) The total dosage delivered differs from the prescribed dosage by twenty per cent or more or falls outside the prescribed dosage range; or
 - (iii) The fractionated dose delivered differs from the prescribed dose for a single fraction, by fifty per cent or more.
 - (b) A dose that exceeds 0.05 sievert (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty rem) shallow dose equivalent to the skin from any of the following:
 - (i) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;
 - (ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
 - (iii) An administration of a dose or dosage to the wrong individual or human research subject;
 - (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - (v) A leaking sealed source.
 - (c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:
 - (i) 0.5 sievert (fifty rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

- (ii) Fifty per cent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.
- (2) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:
 - (a) The total source strength administered differing by twenty per cent or more from the total source strength documented in the post-implantation portion of the written directive;
 - (b) The total source strength administered outside of the treatment site exceeding twenty per cent of the total source strength documented in the post-implantation portion of the written directive;or
 - (c) An administration that includes any of the following:
 - (i) The wrong radionuclide;
 - (ii) The wrong individual or human research subject;
 - (iii) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
 - (iv) A leaking sealed source resulting in a dose that exceeds 0.5 sievert (fifty rem) to an organ or tissue.

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

(C) The University of Toledo shall notify by telephone the Ohio department of health, bureau of environmental health and radiation protection no later than the next calendar day after discovery of the medical event.

(D) The University of Toledo shall submit a written report to the Ohio department of health, bureau of environmental health and radiation protection to the address listed in listed in rule 3701:1-40-04 of the Administrative Code within fifteen days after discovery of the medical event.

(1) The written report must include:

- (a) The licensee's 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(s) who received the administration;
- (f) What actions, if any, have been taken or are planned to prevent recurrence; and
- (g) Certification that the licensee notified the individual (or the individual's personal representative), and if not, why not.

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

(E) The University of Toledo shall provide notification of the 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 referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful to the individual. 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 University of Toledo 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 individual's personal representative. If a verbal notification is made, the licensee shall inform the individual, or appropriate personal representative, 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.

(F) 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 personal representative.

(G) The University of Toledo shall:

(1) Annotate a copy of the report provided to the Ohio department of health, bureau of environmental health and radiation protection with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

Source: Radiation Safety Officer
Joseph Agosti CNMT

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