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To: Radiopharmaceutical Diagnostic and Therapy Licensees
Interested Parties

From: David M. Howe, Program Director
Radiation Protection Services

Subject: Amended Oregon Administrative Rules (OAR) pertaining to the definition of medical event, reporting, notification and the removal of OARs pertaining to misadministration.

The Center for Health Protection, Radiation Protection Services (RPS) is releasing this informational bulletin to notify licensees using radioactive materials for medical purposes that OARs pertaining to the definition of a medical event and related reporting requirements have been amended. In addition, the definition of misadministration and its reporting requirements have been repealed from OAR.

On June 5, 2016, RPS filed proposed medical event rules with the Oregon Secretary of State office effective September 1, 2016. The previous definitions relating to "misadministration" and "medical event" were conflicting and difficult to interpret. As a result, RPS subsequently developed a specific set of regulations that address medical errors when administrating radiopharmaceuticals during therapy and imaging procedures. Oregon's medical event regulations are more restrictive than the Nuclear Regulatory Commission's federal regulations relating to the definition of medical events.

Please see the amended OARs below regarding a medical event (OAR 333-116-0020) and report and notification of a medical event (OAR 333-116-1000) for your review. If you need further clarification, please feel free to contact Todd S. Carpenter, Radiation Protection Services, (971) 673-0500; or email: Todd.s.carpenter@state.or.us.

333-116-0020
Definitions
(19) "Medical Event "means an event where a patient or human research subject:
(a) Receives a dose that differs from the prescribed dose by:
(A) The total dose delivered differs from the prescribed dose by 20 percent or more; or
(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or
(D) A dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; or
(E) An administration of a wrong radiopharmaceutical drug containing radioactive material; or
(F) An administration of a radiopharmaceutical drug containing radioactive material by the wrong route of administration; or

(G) An administration of a dose or dosage to the wrong individual or human research subject; or
(H) An administration of a dose or dosage delivered by the wrong mode of treatment; or
(I) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
(c) An 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 shall be considered as a medical event.
(d) A leaking sealed source shall be considered as a medical event.

333-116-1000
Report and Notification of a Medical Event
(1) A licensee must report any medical event as defined in OAR 333-116-0020(19), except for an event that results from patient intervention..
(2) The licensee must notify by telephone the Authority no later than the next calendar day after discovery of the medical event.
(3) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.
(a) 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 responsible relative or guardian), and if not, why not.
(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.
(4) The licensee must 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 24 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. 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 24 hours, the licensee must 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 as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, 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 must 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 must provide such a written description if requested.
(5) 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.