

MEDICAL EVENTS

PURPOSE

This procedure provides general instructions for developing, maintaining, and documenting Quality Management Programs for the prevention of Medical Events in diagnostic and therapeutic nuclear medicine procedures, and in brachytherapy procedures. It also provides general instructions for notifications, reports, and records of Medical Events in nuclear medicine and brachytherapy.

POLICY

Written procedures for administrations requiring a Written Directive (WD) are prepared, implemented and supervised by the Clinical Medical Physicist (CMP) in the Radiation Oncology Division of the Radiology Department and, in the Nuclear Medicine Division, by the Nuclear Medicine Technical Coordinator (NMTC) with the concurrence of the Nuclear Medicine Director (NMD). The CMP and the NMTC submit copies of all new or revised written procedures to the Radiation Safety Officer (RSO) for review and documentation. The RSO submits comments, suggestions or proposed changes to the CMP or the NMTC for action. The RSO reports on the status and acceptability of the procedures to the Radiation Safety Committee at least annually.

If a Medical Event occurs, the CMP or NMTC notifies the RSO immediately. The RSO is responsible for notification of and correspondence with the Utah Division of Radiation Control (UDRC) concerning the Medical Event. The CMP or NMTC ensures that notifications of physicians and patient are completed and that the written report concerning the Medical Event is provided to the RSO, referring physician, and patient. The CMP or NMTC and RSO are responsible for retention of records concerning the Medical Event.

DEFINITIONS

Reportable Medical Event means:

- A. An event not resulting from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:
 - 1. A dose that differs from the prescribed dose or 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; and
 - i. The total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more; or
 - ii. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
 - 2. A dose that exceeds 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 from any of the following:
 - i. An administration of a wrong radioactive drug containing radioactive material;
 - 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.
 - 3. 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 WD (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- B.** 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.
- C.** Any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved in advance by the authorized user.
- D.** Any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:
- 1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or

- 2. Has resulted in unintended permanent damage to an organ or a physiological system of the child, as determined by a physician.

WRITTEN PROCEDURES

The Nuclear Medicine and Radiation Oncology Departments of University Hospital shall develop, implement, and maintain written procedures for verifying 1) patient identity, 2) administration is in accordance with the treatment plan and written directive, 3) dose calculations, and 4) computer-generated dose calculations are correctly transferred to the consoles of therapeutic medical units. These procedures shall be in accordance with UDRC Rules in Chapter R313-32 and guidance found in NUREG 1556 Vol. 9, Appendix S.

After a Medical Event occurs, the investigation conducted by the RSO should demonstrate if an omission in the written procedures or a departure from the written procedures was the cause of the Medical Event.

NOTIFICATIONS, REPORTS, AND RECORDS OF MEDICAL EVENTS

All notifications, reports, and records concerning Medical Events shall be handled in accordance with UDRC Rules in Chapter R313-32. The CMP or NMTC shall ensure that the RSO is notified immediately after a Medical Event is discovered, that physicians and the patient are notified appropriately, and that the written report concerning the Medical Event is provided to the RSO and the referring physician and the patient. The RSO shall ensure that the UDRC is notified appropriately of the Medical Event and is provided with the written report and any other necessary information concerning the Medical Event. Records of the Medical Event shall be retained by the CMP or NMTC and the RSO.

STEPS TO FOLLOW AFTER DISCOVERY OF A MEDICAL EVENT

1. Immediately notify CMP, if the Medical Event occurs in Radiation Oncology, or immediately notify the NMTC or NMD, if the Medical Event occurs in Nuclear Medicine. *Dose calculations to confirm or deny a possible Medical Event must be performed within 24 hours of the discovery of the Medical Event.*
2. Immediately notify the RSO. The RSO notifies the UDRC Executive Secretary by phone within one calendar day of discovery of the Medical Event. The RSO initiates an investigation to determine the cause of the Medical Event.
3. Notify the referring physician and the patient (or guardian) of the Medical Event within 24 hours of its discovery or as soon as possible thereafter, in accordance with UDRC Rules Chapter R313-32. Notify the patient that a written report of the incident will be available on request within 15 days of the incident
4. The RSO with the assistance of the CMP, NMTC, or NMD submit a written report to the UDRC within 15 days after the discovery of the Medical Event (see 10 CFR 35.3045(d)(1) or 35.3047(d)(1) for contents of report). The report to the UDRC may not contain information that would identify the patient.
5. Also within 15 days of the discovery of the Medical Event, the referring physician must receive a copy of the written report annotated with the patient name and social security number (or other identification number). A copy of the report must be provided to the patient upon request.
6. The CMP or NMTC and the RSO retain records of the Medical Event for five years (see UDRC Rules Chapter R313-32 for content of records).

REFERENCES

US Nuclear Regulatory Commission, *Medical Use of Byproduct Material*. 10 CFR 35, 2005

US Nuclear Regulatory Commission, *Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Licenses*, NUREG 1556 Vol. 9, 2008

University of Utah, *Radiation Safety Manual and Procedures*, Radiation Procedures and Records

Utah Department of Environmental Quality, Division of Radiation Control:

Utah Radiation Control Rules, Standards for Protection Against Radiation, Chapter R313-15

Utah Radiation Control Rules, Medical Use of Radioactive Material, Chapter R313-32

ATTACHMENTS (1)

INITIAL EVENT REPORT

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INITIAL EVENT REPORT

Licensee Name: University of Utah

Date of Incident:

Patient Notified By (Date):

Referring Physician:

Description of Event:

Effect(s) of Event on Patient:

Corrective Actions (Planned or Taken):