

## **VHA Standard Procedure - - Training for Medical Events**

1. VHA facilities performing permanent implant prostate brachytherapy must provide initial and periodic training to the staff involved in, or supporting, the prostate brachytherapy program. The training must be provided to physician authorized users, medical physicists, urologists participating in these procedures, dosimetrists, and the Radiation Safety Officer (RSO) and staff.
2. Specific training topics will include the following: NRC definition of a medical event, how to recognize a medical event, and actions to be taken if a medical event is discovered. The training should be provided by the RSO or by a qualified person, such as a therapeutic medical physicist, designated by the facility Radiation Safety Committee or RSO.
3. The guidelines for training for medical events are listed below and consist of questions and answers to be addressed at the facility level. Training must be commensurate with duties. Also, facilities must incorporate these guidelines into other facility procedures, as needed, to ensure requirements for medical events are made known to the staff.

### **Training for Medical Events**

#### **What is the regulatory definition of a medical event?**

NRC defines a medical event in 10 CFR 35.3045. A link to the NRC Web site with the definition is:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>

The definition of a medical event is listed below.

“A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct 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
  - a. The total dose delivered differs from the prescribed dose by 20% or more,
  - b. The total dosage delivered differs from the prescribed dosage by 20% 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% 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.
  - a. An administration of a wrong radioactive drug containing byproduct material,
  - b. An administration of a radioactive drug containing byproduct material by the wrong route of administration,

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- c. An administration of a dose or dosage to the wrong individual or human research subject,
  - d. An administration of a dose or dosage delivered by the wrong mode of treatment, or
  - e. 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% 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).

A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.”

#### **What are roles and responsibilities related to medical events?**

The Radiation Safety Committee provides oversight of the safe use of radioactive materials and requires initial and periodic training for staff commensurate with their duties.

The RSO or a designee normally provides or coordinates staff training, including the training for medical events, and maintains training records. The RSO has primary responsibility for identifying and reporting medical events. If a medical event is discovered, the RSO makes required notifications to NHPP (to be reported to the NRC Operations Center by the next calendar day after discovery) and prepares the 15-day written report to send to NHPP.

The physician authorized users, medical physicists, dosimetrists, and other staff involved in prostate brachytherapy procedures must be aware of patient circumstances that might be a medical event and the requirement to report those circumstances to the RSO promptly upon identification.

Staff must be aware of the significance of the written directive, both the pre-implant part, which documents the prescribed dose, and the post-implant part, which documents the administered activity.

#### **What is a medical event?**

A medical event is patient circumstances that are within the NRC definition in 10 CFR 35.3045.

For prostate brachytherapy procedures, the figure of merit to identify a medical event during the post-treatment dose analysis is D90. The D90 must be 80% or greater of the prescribed dose in the written directive. If the post-implant D90 value is determined using CT imaging, the D90 should either (a)\* be greater than 72% of the prescription dose, or (b) should be determined after correcting for the change in volume from the volume preplanned.

\* Due to intermodality differences in the apparent prostate volume, the CT-estimated target volume should receive 90% of that dose prescribed on the basis of ultrasound planning.

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A medical event may also result from an overly large dose to tissue outside the prostate. A cause would be a seed or seeds outside the treatment site. Note: The implant team might deliberately implant seeds outside of the prostate. For this determination, a medical event will be reported if the dose to 1cc of either the rectum or uninvolved bladder or 2cc of other non-specified tissue equals or exceeds 150% of the dose prescribed to the prostate.

An implanted leaking seed is a medical event if the seed will cause a dose exceeding 0.5 gray (50 rad) to an organ or tissue. For I-125 seeds, the primary organ of concern is the thyroid. NHPP will be notified immediately notified when the possibility of a leaking seed has been determined.

Identification of a medical event will be determined on a case-by-case basis in consultation with Director, National Radiation Oncology Program, and NHPP. NHPP will be notified immediately upon the possible determination that a medical event has occurred per the criteria established above. This notification does not alter those reporting requirements established by 10CFR 35.3045, discussed below.

#### **What are the notification and reporting requirements for a medical event?**

10 CFR 35.3045 requires:

- Notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.
- Submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event.
- Notify the referring physician and the patient.

Under the master materials license issued to VHA, NHPP makes notifications to the NRC Operations Center. The facility must contact NHPP as soon as possible about any patient circumstances that might be a medical event. The telephone information is noted below.

- Normal business hours for Central Time Zone at 501-257-1571.
- After normal business hours for Central Time Zone at 800-815-1016.
- Intranet Web page for information to contact individual NHPP staff at the following URL.

<http://nhpp.med.va.gov/emergency.asp>

For notification of, or contact with, NHPP, voice mail or e-mail must NOT be substituted for a direct discussion with NHPP staff, preferably a technical staff member. This is particularly important if an immediate or next day notification is required to NRC.

The RSO must have a recall list with contact information for the physician authorized users, referring physicians if possible, and NHPP. The list should have the office and cellular telephone numbers so key staff can be contacted and consulted in a medical event situation, both during and outside normal working hours.

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The after-hours recall information is especially important for a weekend recall when a patient therapy procedure or post-implant dose analysis might have been completed late in the week, such as on a Friday, and notification is required within a specific time period.

This recall list should also include vendor telephone numbers if sealed sources are used in the patient therapy procedure.