



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

JAN 26 2009

In Reply Refer To: 598/115HP/NLR

James L. Caldwell
Regional Administrator
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA; CAL 3-08-004

Dear Mr. Caldwell:

Per your Confirmatory Action Letter (CAL) dated October 14, 2008, I am enclosing the standard procedures for prostate brachytherapy programs. The procedures are required under action item #2.

The four procedures are for training, training for medical events, written directives, and clinical requirements. The procedures were developed and provided to prostate brachytherapy program Radiation Safety Officers on January 9, 2009. A minor adjustment to the procedure for training was made based on feedback from stakeholders when the procedures were reviewed.

The target date to implement the standard procedures is April 24, 2009. I will provide additional responses to you as actions required under the CAL are completed.

If you have any questions, please contact me at 501-257-1571.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosures

RECEIVED JAN 27 2009

VHA Standard Procedure - - Training

1. VHA facilities with prostate brachytherapy programs must complete initial and periodic training for the staff involved in, or supporting, the prostate brachytherapy program.
2. Training must be provided to physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff. Other workers who participate in the procedures (e.g., anesthesiologists or anesthesiologists, nursing staff, and resident physicians) must receive training, as needed. The Radiation Safety Committee normally tasks the Radiation Safety Officer to develop, present, and/or coordinate training. Each individual facility must determine the type and extent of training, if any, that the Radiation Safety Officer is to receive by other staff or external to the facility.
3. The training must be commensurate with duties. A separate VHA standard procedure has more details for training for medical events.
4. The training topics to consider are listed below. The facility must document training completion and evaluate effectiveness of training by various methods such as group and one-on-one discussions, written or computer-based tests, and during audits.

Training Topics

1. Basic radiation biology, including risk estimates.
2. Radiation protection to include concepts of time, distance, and shielding.
3. Concept of maintaining radiation exposure ALARA (10 CFR 20.1101).
4. Posting requirements (10 CFR 20.1902).
5. Proper use of dosimetry (if applicable).
6. Access control procedures and security (10 CFR 20.1601 and 20.1801/.1802) and two delay methods if stored.
7. Proper use of radiation shielding, if used.
8. Patient release instructions, procedures, surveys, and records (10 CFR 35.75 and 35.2075).
9. Instruction in procedures for notification of the Radiation Safety Officer and physician authorized user, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. Note: The intent of these procedures should not interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 35.310, 35.410, and 35.610).
10. Occupational dose limits (10 CFR 20.1201).
11. Worker's right to be informed of occupational radiation exposure (10 CFR 19.13).
12. Worker's obligation to report unsafe conditions to the Radiation Safety Officer (10 CFR 19.12) and have a safety focus to ensure regulatory compliance. Methods and procedures for management oversight for use of radioactive materials.

VHA Standard Procedure - - Training

13. Applicable regulations, licenses, permits, and notices (10 CFR 19.12).
14. Location and availability of applicable regulations, licenses, permits, notices, and Web sites (10 CFR 19.12).
15. Recordkeeping requirements (10 CFR 19.12), and documents and records for prostate brachytherapy procedures.
16. Radiation surveys to be completed (10 CFR 20.1501).
17. Proper calibration of survey instruments (10 CFR 20.1501).
18. Emergency procedures such as for a damaged or leaking seed, a leaking or damaged seed implanted in a patient, and a lost seed or seeds.
19. Decontamination and release of facilities and equipment (10 CFR 20.1406).
20. Dose to members of the public (10 CFR 20.1301).
21. Facility written procedures, protocols, and practices for prostate brachytherapy procedures.

Handling and security of sealed sources

- a. Radioactive material package receipt surveys and records (10 CFR 20.1906).
- b. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).
- c. Physical inventory (10 CFR 35.67(g)).
- d. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

Preparations for seed implant procedures

- e. Written procedures and checklists (10 CFR 35.40 and 35.41).
- f. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).
- g. Pre-implant imaging (volume study), modality (TRUS, CT)
- h. Pre-plan preparation.
- i. Written directive, pre-implant part preparation, including prescribed dose.
- j. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).
- k. Calibration measurements of sources (10 CFR 35.432).
- l. Acceptance testing of treatment planning system (10 CFR 35.457).

VHA Standard Procedure - - Training

- m. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer).
- n. Possible problems, precautions to prevent, and follow-up actions for the following:
 - (1) Lost seeds.
 - (2) Seeds damaged during procedure.
 - (3) Leaking seeds, including leaking seeds implanted in patient.
- 22. Medical event definitions and roles and responsibilities to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event. Procedures for after-hours recall or notifications (10 CFR 35.3045).
- 23. Methods and procedures to verify seed placement is correct and determine proper needle placements during prostate brachytherapy procedures, including appropriate imaging modality verifications.
- 24. Preparation and completion of written directives (pre- and post-implant parts).
- 25. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

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. A specific training topic is medical events to include specific details for 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 this training 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,

VHA Standard Procedure - - Training Medical Events

- 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.

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.

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 prostate. Note: Some physicians deliberately implant seeds just outside the prostate to treat a margin around 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.

VHA Standard Procedure - - Training Medical Events

How to identify a medical event including the criteria for a medical event?

A medical event is identified by comparing the results of the treatment, particularly the post-treatment images and dose indices such as the D90; the authorized user's intent, as defined in the written directive and approved pre-plan; and the NRC definition of a medical event. Deviations or discrepancies are determined to help identify if a medical event occurred.

The post-implant dose analysis produces the D90. The D90 is a figure of merit for determining whether the prescribed dose was achieved. The D90 must exceed 80% of the prescribed dose in the written directive or a medical event has occurred.

Identification of a medical event resulting from seed(s) outside of the prostate is determined on a case-by-case basis in consultation with NHPP. Circumstances to consider include: a seed or seeds distant from the prostate, unless the seed(s) migrated; a seed or seeds in the rectum or very close to the rectum; and a volume of the rectum exceeding 160 gray that is more than about 1.5 cc.

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.

January 9, 2009

VHA Standard Procedure - - Training Medical Events

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.

**VHA Standard Procedure - - Preparation and Completion of Written Directives
for Permanent Implant Prostate Brachytherapy**

1. VHA facilities that perform permanent implant prostate brachytherapy must prepare and complete a written directive for each patient treatment. The Nuclear Regulatory Commission (NRC) has regulatory requirements for written directives. This standard procedure provides specific guidelines to be followed by VHA facilities.

2. Current regulatory information is available on the NRC Web site at the following address.

<http://www.nrc.gov/materials/miau/med-use-toolkit.html>

3. NRC defines a written directive, in 10 CFR 35.2, as:

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

4. For permanent implant prostate brachytherapy, the NRC requirements for a written directive in 10 CFR 35.40 are:

a. A written directive must be dated and signed by an authorized user before the administration any therapeutic dose of radiation from byproduct material.

b. The written directive must contain the patient or human research subject's name and the following information:

(1) Before implantation: treatment site, the radionuclide, and dose; and

(2) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

c. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

d. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

5. NRC requirements to retain a copy of the written directive are in 10 CFR 35.2040 as follows:

A licensee shall retain a copy of each written directive as required by 10 CFR 35.40 for 3 years.

6. VHA facilities must comply with NRC requirements. In addition, VHA facilities must follow these additional guidelines for prostate brachytherapy procedures.

a. Ensure initial and periodic training for prostate brachytherapy programs includes the requirements in this standard procedure and is provided to, as a minimum, physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff.

**VHA Standard Procedure - - Preparation and Completion of Written Directives
for Permanent Implant Prostate Brachytherapy**

- b. Complete and document quarterly audits of written directives to ensure NRC and VHA requirements have been met.
- c. Use the standard procedure for training for medical events as criteria to evaluate written directives and to determine if a medical event has occurred.
- d. For the pre-implant portion of the written directive, provide the following information per 10 CFR 35.40: treatment site, the radionuclide, and dose.
- e. For the post-implant part of the written directive, provide the following information per 10 CFR 35.40: radionuclide, treatment site, number of sources, total source strength, and the word "permanent."
- f. At the bottom of the written directive, after the post-implant part, or on a separate review worksheet for written directives provide the following information.
 - (1) Name, date, and signature for medical physicist review to determine if a medical event occurred. (If possible, the reviewing medical physicist should be a reviewer other than the medical physicist who prepared the treatment plan.)
 - (2) Name, date, and signature for Radiation Safety Officer review to determine if a medical event occurred.

VHA Standard Procedure - - Clinical Requirements

1. This VHA standard procedure has requirements for technical quality assurance (QA), pre-implant or intraoperative treatment planning, post-implant treatment planning, post-treatment dose analysis, and seed placement and verification.
2. VHA facilities performing permanent implant prostate brachytherapy must develop, maintain, and implement written procedures for the clinical requirements listed above. The facilities must also develop, maintain, and implement written procedures for written directives per 10 CFR 35.41. A facility has the option to combine written procedures into a single document. The items below are specific guidelines to be followed by VHA facilities performing permanent implant prostate brachytherapy.
3. The guidelines are based on the American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer* and publications by the American Association of Physicists in Medicine (AAPM).
4. The facility must have a QA program for each device used for planning, performing, and assessing the implant procedures; these devices include the stepper/stabilizer, transrectal ultrasound system (TRUS), treatment planning system, and CT or MRI system. A therapeutic medical physicist experienced in prostate brachytherapy procedures must approve the QA program and periodically review the program. QA for the TRUS should substantially conform to the AAPM TG 128 report. Medical physicists and physicians should pay attention to spatial resolution, grey scale contrast, geometric accuracy, and distance measurement. The correspondence between the electronic grid pattern on the ultrasound image and the template grid pattern should be verified. For the CT system used for imaging for post-implant dose assessment, the QA program must address image quality, accuracy of the transfer of geometric parameters to the treatment planning system, and dose to the patient.
5. Computerized treatment planning system requirements are as follows.
 - a. Complete acceptance testing of the treatment planning system per 10 CFR 35.457 before the first patient treatment use and after software revisions or upgrades and commissioning other models of seeds. The acceptance testing methods and results should be reviewed and approved by a therapeutic medical physicist experienced in prostate brachytherapy procedures. The acceptance testing and seed commissioning must be documented in a written report describing references, methods, and results. The testing must assess:
 - (1) Geometric accuracy of image information transferred from imaging modalities used for pre- and post-plans,
 - (2) Source specific input parameters required by the dose calculation algorithm, and
 - (3) Accuracy of calculated doses and displays of dose distributions, such as dose plots and graphical displays, at representative points.
 - b. Compare dose rate values from the planning system for applicable seed models to current values listed in the appropriate AAPM report: Report No. 51 (TG-43), Report No. 84, Report No. 84s, or its successor.
 - c. Ensure medical physics staff is aware of and uses technical guidelines in AAPM Report No. 68 (TG-64).
6. Seed strength calibration requirements are as follows.

VHA Standard Procedure - - Clinical Requirements

a. The source output or activity of each seed must be determined before implantation as required by 10 CFR 35.432. A record of each calibration must be maintained.

b. The output or activity of the seeds may be determined by a commercial vendor such as the seed manufacturer or a vendor that loads the seeds into needles or cartridges or places them in suture material. If the facility does not measure every seed, the facility must maintain written documentation that the seed manufacturer or vendor assays every seed and the measurements conform to 10 CFR 35.432.

c. In addition to the above, the facility may choose to assay seeds from each shipment on site. AAPM Report No. 98 provides guidance on such assays and should be followed.

7. Pre-implant or intraoperative treatment planning requirements are as follows.

a. Complete treatment planning for each patient before or during seed implantation.

b. Use appropriate imaging modalities such as TRUS, CT scanning, or MRI to assist in the treatment planning process.

c. Checking of the treatment plan must be performed as required by 10 CFR 35.41(b)(3). The written procedures should specify how this check is to be performed.

d. Before implantation of the first seed, complete the pre-implantation portion of the written directive, which must include the NRC required information in 10 CFR 35.40 (treatment site, radionuclide, and dose).

e. Before implantation of the first seed, verify the ultrasound images of the prostate are of adequate quality to perform the implant. Verify the prostate dimensions match those of the pre-plan. If they differ excessively, another pre-plan should be created.

8. At the end of each procedure, obtain a radiographic or fluorographic image depicting seed positions in the patient. Fluoroscopic imaging should be immediately available during the procedure, to serve as a check that seeds are not being inadvertently placed away from the intended region.

9. After completion of the implant procedure, complete the post-implant portion of the written directive to record the information required in 10 CFR 35.40 (treatment site, radionuclide, number of sources implanted, total source strength implanted, and the word "permanent").

10. Immediately after the completion of each implant, perform a survey of the room using a portable radiation survey meter to locate any misplaced sources, as required by 10 CFR 35.404. The survey should include the floor, linens, waste material, applicators, and empty needles and cartridges. A record of the survey must be made as required by 10 CFR 35.2404. The survey should include the feet of people leaving the room.

11. Before releasing the patient, perform a release survey as required by 10 CFR 35.75 and document the survey as required by 10 CFR 35.2075(a). The survey should include measurement of the exposure rate, air kerma rate, dose rate, or dose equivalent rate at a distance of 1 meter from the patient. The survey must be made with a radiation survey meter calibrated for the energy of the radiation emitted from the seeds, or the measurement must be corrected for energy using the energy response curve of the meter and any attached detector. The patient must also be given instructions, both in writing and verbally, on

VHA Standard Procedure - - Clinical Requirements

actions recommended to keep doses to others as low as reasonably achievable. The instructions must include actions to take if a seed is passed in the urine.

12. Post-treatment planning requirements are as follows.

a. Post-implant imaging and dosimetric analysis is mandatory and must be completed for each implant procedure, unless the patient refuses post-implant imaging.

b. Complete post-treatment planning of each patient using post-implant CT or MRI imaging.

c. Determine the actual dose distribution delivered and identify any variances or deviations from the original treatment plan.

d. The post-treatment planning must evaluate the relationship of the implanted seeds to the prostate, rectum, and other extra prostatic tissues.

e. Establishment of a consistent post-implant image acquisition time frame. Examples:

(1) Obtain CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, or

(2) Obtain post-implant CT images on the day of the procedure or during the next 2 days. If the post-implant dose distribution is unacceptably low, obtain repeat CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, and create another post-plan.

f. Report the following parameters in a reviewable document, such as a quarterly report:

(1) Date of implant procedure and date of post-implant CT imaging.

(2) Prescribed dose.

(3) D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT. According to AAPM Report No. 68 (TG-64), "An implant with good coverage is characterized by D90 equal to or greater than the prescribed dose."

(4) V100, defined as the percentage of the target volume delineated on the post-implant CT receiving 100% of the prescribed dose. A V100 equal to 90% (of the prostate volume) is equivalent to a D90 equal to the prescription dose.

(5) Rectal dose index, such as the R100 (volume of the rectum in cm^3 that receives 100% or more of the prescribed dose).

(6) Evaluation of seeds outside the intended treatment volume.

13. Post-treatment dose analysis requirements are as follows.

a. Review dose indices including D90, V100, and rectal dose index, and evaluate seeds significantly outside the intended treatment volume. Note: Seeds may be deliberately implanted at the boundary of or just outside the prostate to provide adequate treatment margins.

VHA Standard Procedure - - Clinical Requirements

b. Compare the results to the prescribed dose to determine if a medical event occurred, including whether the D90 is less than 80% of the prescription dose (10 CFR 35.3045(a)(1)(i)).

c. Notify the patient and determine whether corrective action, such as implantation of additional seeds, is warranted, if the dose distribution for a specific patient is inadequate.

14. Perform physician peer review to reduce intra-observer variability in the contouring of prostate volumes from post-implant CT scans and definition of rectal volumes and to assess quality of care. This should include ongoing within-department peer review. In addition, five cases each year should receive external peer review as specified by the Director, National Radiation Oncology Program, or as required by a VHA Handbook or Directive.

References

American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer*

AAPM Report No. 68 (TG-64), *Permanent Prostate Seed Implant Brachytherapy*, October 1999

AAPM Report No. 51 (TG-43), *Dosimetry of Interstitial Brachytherapy Sources*, March 1995

AAPM Report No. 84, *Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations*, February 2004

AAPM Report No. 84s, *Supplement to the 2004 update of the AAPM Task Group No. 43 Report*, June 2007

AAPM Report No. 89, *Recommendations of the American Association of Physicists in Medicine regarding the Impact of Implementing the 2004 Task Group 43 Report on Dose Specification for 103Pd and 125I Interstitial Brachytherapy*, April 2005

AAPM Report No. 98, *Third-party Brachytherapy Source Calibrations and Physicist Responsibilities*

AAPM TG 128, *Quality Assurance Tests for Prostate Brachytherapy Ultrasound Systems*

NRC Regulations – 10 CFR 35, *Medical Use of Byproduct Material*



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

JAN 23 2009

In Reply Refer To: 598/115HP/NLR

James L. Caldwell
Regional Administrator
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA; CAL 3-08-004

Dear Mr. Caldwell:

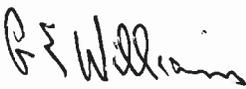
Per your Confirmatory Action Letter (CAL) dated October 14, 2008, I am enclosing a root or basic cause analysis for medical events for prostate brachytherapy programs. The analysis is required under action item #4.

The analysis represents the initial findings for root causes and planned corrective actions. The analysis will be revised in the future as ongoing inspections are completed and medical events are investigated.

I will provide additional responses to you as actions required under the CAL are completed and any substantive updates to the root cause analysis.

If you have any questions, please contact me at (501) 257-1571.

Sincerely,

for 

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

Background

In follow-up to a telephone conference call between Veterans Health Administration (VHA) and Nuclear Regulatory Commission (NRC), the National Health Physics Program (NHPP) sent a letter to NRC dated October 12, 2008, with specific commitments related to recent medical events that had been reported for VHA facilities. The medical events were for patients undergoing prostate brachytherapy procedures.

One of the specific commitments in the NHPP letter was to complete identification and corrective action to prevent recurrence for root or basic causes that resulted in medical events at VHA facilities. In a letter dated October 14, 2008, NRC sent to NHPP a Confirmatory Action Letter with similar requirements about root cause identification and corrective actions to prevent recurrence of the medical events.

This root or basic cause analysis uses the methods and procedures under the “TapRoot©” system for root cause analysis (RCA) to complete the NHPP commitment. The specific root causes are selected from the “TapRoot© Root Cause Tree©” chart with minor adjustments in wording for specific circumstances in a healthcare environment.

In the “TapRoot©” system, root cause is defined as “the most basic cause or (causes) that can reasonably be identified that management has control to fix, and when fixed, will prevent (or significantly reduce the likelihood of) the problem’s recurrence.” RCA is a method for problem solving aimed at identifying the root causes of problems or events. The use of RCA is based on the concept that problems are best solved by attempting to correct or eliminate the underlying root causes, as opposed to merely or only addressing immediately obvious symptoms.

By directing corrective measures at root causes, the goal is to minimize likelihood of a problem or event recurring. RCA methods recognize that complete prevention of recurrence by a single intervention is not always possible. Thus, RCA is often considered to be an iterative process, and is frequently viewed as a tool of continuous improvement.

The “TapRoot© Root Cause Tree©” chart helps reviewers find root causes based on analysis of specific circumstances related to an event. The chart has a fairly comprehensive set of defined root causes to lead to identification of corrective actions to prevent recurrence of an event.

The set of non-overlapping causes that are listed in the chart allows for an overall trending of root causes from circumstances at multiple locations into a system-wide delineation of root causes and the associated corrective actions to prevent recurrence of events.

“TapRoot©” does not list human error as a root cause category; rather, human performance difficulty is addressed by identification of underlying root causes.

The VHA facilities under evaluation for root causes related to medical events are VA Medical Center, Philadelphia; G.V. (Sonny) Montgomery VA Medical Center, Jackson; VA Medical Center, Washington, DC; VA Medical Center, Cincinnati; VA New York Harbor Healthcare System, Brooklyn; and VA Medical Center, Durham. A brief description of circumstances at each facility is provided with a listing of possible root causes for medical events. Finally, a summary for VHA is provided.

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

VA Medical Center, Philadelphia

For this facility, medical events resulted from two different circumstances. In the first circumstance, the single medical event involved ordering and using incorrect brachytherapy seed activities. The root causes were identified in the inspection report as follows.

“Quality control - inspection not required,” in that the written procedures did not require verification steps to compare seed activities ordered to seed activities in the treatment plan and needle loading diagrams and received seeds.

“Human engineering - complex system - knowledge based decision required,” in that an adequate evaluation of seed brachytherapy procedures was not completed to identify the tasks in which a single human error might result in a significant treatment error.

“Work direction - preparation,” in that the authorized user physician and medical physicist with primary involvement in preparing the treatment plan and written directive had limited recent experience in seed brachytherapy procedures, but were not provided any retraining or briefing before the patient procedure.

“Procedures - followed incorrectly,” in that the current written procedures were not followed explicitly.

In the second circumstance, numerous medical events resulted from inadequate seed distributions. The root causes were discussed in the inspection report from the perspective of causal factors. These causal factors included the following.

“Work direction,” in that team or individual preparation, supervision, clinical peer reviews, and other quality control reviews were less than adequate.

“Training,” in that lack of training in regulatory requirements or understanding of regulatory requirements was less than adequate for the staff to identify and report circumstances that were medical events. The roles and responsibilities for various staff were unclear.

For specific regulatory violations, the inspection report noted the following root causes. These are similar to the casual factors noted above that resulted in inadequate seed distributions and medical events.

“Procedures - inadequate,” in that written procedures lacked specificity about roles and responsibilities to evaluate possible medical events and did not require training about medical events.

“Work direction - preparation and supervision during work,” in that authorized user physicians had less than adequate preparation and ongoing clinical supervision to ensure appropriate seed distributions. A causal factor was lack of quality control for changes to the radiation oncology computer network.

The medical center completed a separate Administrative Board of Investigation (ABI). The ABI report noted root causes related to lack of training, lack of peer reviews, lack of procedures to ensure reporting of medical events, lack of Radiation Safety Committee oversight, and lack of a safety culture.

NHPP evaluated three overall root causes related to lack of effective oversight such as by management, Radiation Safety Committee, or Radiation Safety Officer, lack of a focus to a safety culture, and undue reliance on affiliates or outside consultants.

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

G.V. (Sonny) Montgomery VA Medical Center, Jackson

Based on external clinical reviews for 10 patient treatments, 7 medical events were identified and reported to NRC. The medical events, if confirmed, likely resulted from inadequate seed distributions. NHPP initiated a reactive inspection at the medical center during October 8-11, 2008. The inspection remains open. The initial inspection findings noted deficiencies for failure to complete a post-plan dose analysis for each patient treatment, inability to transfer CT images to a treatment planning system for the post-plan dose analysis, and inadequate medical physics staffing. During this inspection, one additional medical event was discovered and reported. The basis for this event was related to seed distribution.

The root causes for the inadequate seed distributions that resulted in medical events were similar to those noted above for Philadelphia and include procedures, training, work direction, and quality control (such as peer review and program audits).

The circumstances for the medical events are under review since the inadequate seed distributions might represent a difference in clinical judgment about prostate contouring and not be determined as a medical event as defined by NRC regulations.

Subsequently, two other medical events have been discovered and reported. The causes for these other medical events are likely similar to those noted above for this facility.

VA Medical Center, Washington, DC

Based on external clinical reviews for 10 patient treatments, 3 medical events were identified and reported to NRC. NHPP initiated a reactive inspection at the medical center during September 30 and October 1, 2008. Based on discussions with the medical center staff and further evaluation of patients circumstances for the events that had been reported, NHPP retracted the medical events on December 2, 2008. The inspection was closed the same date and an inspection report was issued December 18, 2008.

The discussion below is for the regulatory violations cited by NHPP and not for medical events. NHPP cited three violations. The first violation was that the facility did not develop, implement, and maintain written procedures for prostate brachytherapy to provide high confidence each administration requiring a written directive is per the written directive and treatment plan.

The second violation was that the facility did not provide training to the Radiation Oncology Service staff for current NRC regulations on medical events or on medical center procedures for procedures requiring a written directive. The third violation was that the release surveys did not determine that the total effective dose equivalent to any other individual from exposure to the released patient was not likely to exceed 0.5 rem.

The root or basic causes for the first and second violations were the following:

“Management system - procedures - need improvement,” in that an adequate written procedure for the prostate brachytherapy procedures was not available.

“Work direction - preparation - needs improvement,” in that the authorized user physicians and medical physicists with primary involvement in preparing treatment plans, written directives, and dose analysis were not provided any training or briefing to ensure compliance with current NRC regulations.

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

The root or basic causes for the third violation was “procedures - need improvement.” The procedures for release surveys did not specify use of an appropriate survey meter.

While the initial reports of medical events were retracted, the facility had difficulty in achieving adequate seed distributions for patient treatments. The root causes for inadequate seed distributions were similar to those noted above for Philadelphia and include procedures, training, work direction, and quality control (such as peer review and program audits).

VA Medical Center, Cincinnati

Based on external clinical reviews for 10 patient treatments, 6 medical events were identified and reported to NRC. The medical events, if confirmed, likely resulted from inadequate seed distributions.

NHPP initiated a reactive inspection at the medical center during October 16-17, 2008. The inspection remains open. The initial inspection findings noted deficiencies for seed inventories and use of incorrect model numbers for seeds.

The root causes for the inadequate seed distributions that resulted in medical events were similar to those noted above for Philadelphia and include procedures, training, work direction, and quality control (such as peer review and program audits).

The circumstances for the medical events are under review since the inadequate seed distributions might represent a difference in clinical judgment about prostate contouring and not be determined as medical events as defined by NRC regulations.

VA New York Harbor Healthcare System, Brooklyn

Brooklyn discovered one medical event on November 17, 2008. The basis for this medical event was the D90 dose to the treatment site was slightly less than 80% of the prescribed dose. A supplemental implant procedure was performed to achieve an acceptable D90.

NHPP inspected the facility on November 20 and December 8-9, 2008, to evaluate the possible medical event and concluded that, even though a medical event occurred, the inspection findings did not identify any regulatory violations.

For the patient treatment involving a medical event, the physician authorized user had omitted a step in the motor skills necessary for proper seed placement (before withdrawing two needles, the physician did not advance the plungers sufficiently causing the seeds to follow the needles as they were withdrawn).

The inspectors evaluate possible root or basic causes with the following conclusions.

A root cause was “human engineering, non-fault tolerant system, errors not recoverable,” in that, if an error is made in seed or seed strand placement and the error is promptly identified, the seeds cannot be recovered. A second root cause was “work direction, preparation, needs improvement,” in that the physician omitted a step in the motor skills necessary for proper seed placement.

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

The corrective actions to have proper preparation to ensure all steps are completed in proper sequence for placement of seeds addresses both of the root causes. The error in seed placement was an isolated and infrequent event.

VA Medical Center, Durham

Durham discovered a medical event on January 15, 2009. The basis for the medical event was the D90 dose to the treatment site being less than 80% of the prescribed dose and resulted after seeds migrated from the treatment site.

NHPP will initiate a reactive inspection on January 26, 2009, to investigate the circumstances related to the medical event.

The evaluation of root or basic causes is pending.

VHA Summary for Root Causes and Corrective Actions

The discussion above for the six facilities noted medical events, likely medical events, radiation safety program deficiencies, and apparent (and cited) violations. The root causes common to the facilities, that, if corrected, should result in adequate, and sufficient corrective actions to prevent recurrence include the following.

- “Procedures” as a general category with subcategories “not used/not followed,” “wrong,” “followed incorrectly,” and “need improvement” applicable to medical events and other program deficiencies.
- “Training” as a general category with subcategories “no training” and “understanding less than adequate” applicable to medical events and other program deficiencies.
- “Quality control” as a general category with subcategories “no inspection” and “quality control less than adequate” applicable to medical events and other program deficiencies.
- “Work direction” as a general category with subcategories “preparation” and “supervision” applicable to medical events.
- “Human engineering, non-fault tolerant system, errors not recoverable,” in that, if an error is made in seed or seed strand placement and even if the error is promptly identified, seeds cannot be recovered.

Finally, three overall root causes are related to lack of oversight such as by management, Radiation Safety Committee, or Radiation Safety Officer, lack of a focus to a safety culture with a willingness to stop work if regulatory compliance is not achieved, and undue reliance on affiliates or outside consultants.

The prostate brachytherapy programs reviewed above are suspended, with the exception of Brooklyn and Durham which remain active. This is an initial corrective action for the medical events at the facilities that are suspended. In addition, Brooklyn and Durham will be tasked to implement standard procedures discussed below. The suspended facilities must undergo a restart process, if patient treatments are to resume.

Root Cause Analysis for Medical Events Related to Prostate Brachytherapy Procedures

The longer term corrective actions to prevent recurrence are outlined below and are applicable to both current prostate brachytherapy programs and new or restarted programs.

These corrective actions are from the NHPP commitment letter to NRC and other initiatives by VHA for regulatory and clinical actions for prostate brachytherapy programs.

NHPP commitment letter dated October 12, 2008

The NHPP commitment letter to NRC included specific corrective actions. One action was to develop and implement standard procedures to include, but not be limited to, the following:

- Initial and periodic training for physician authorized users, medical physicists, dosimetrists, and Radiation Safety Officers and staff.
- Training in medical events to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event.
- Preparation and completion of written directives.
- Methods and procedures to verify seed placement is correct for determination of proper needle placements during prostate brachytherapy procedures, including appropriate imaging modality verifications.
- Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

NHPP developed four standard procedures for implementation at the facilities. A standard procedure for clinical requirements has the overall requirements for the last two bullets above.

VHA regulatory initiatives (under National Radiation Safety Committee purview)

Require periodic self-audits using NHPP audit checklist at facility level.

Complete annual inspections for prostate brachytherapy programs.

Complete tasks under the NRC Confirmatory Action Letter to include implementation of the standard procedures.

VHA clinical initiatives (not under National Radiation Safety Committee purview)

Establish and implement peer review process for patient treatments.

Require facilities to participate successfully in external accreditation for prostate brachytherapy programs.

Develop and implement standardized clinical protocols for prostate brachytherapy programs.
Review, evaluate, and resolve data transmission problems for prostate brachytherapy programs.

Schedule and hold radiation oncology conference (completed January 8-9, 2009).

From: Origin ID: LITA (501) 257-1571
Kelly Mayo
VHA National Health Physics Pr
2200 FORT ROOTS DR
B101 R208D
NORTH LITTLE ROCK, AR 72114



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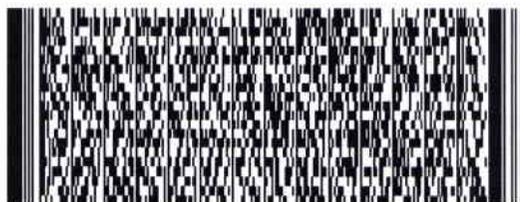
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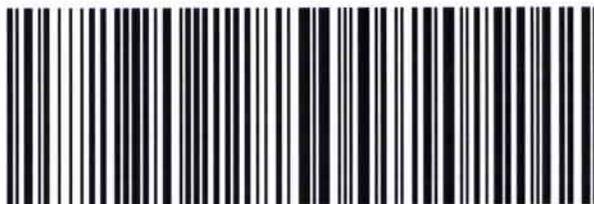
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