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 G F Williams

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

January 22, 2009

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.

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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.

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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.

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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).