August 22, 2008

MEMORANDUM TO: Cassandra F. Frazier, Senior Health Physicist
Division of Nuclear Materials Safety

FROM: Steven A. Reynolds, Director***/RA by Mark S. Delligatti acting for/***
Division of Nuclear Materials Safety

SUBJECT: SPECIAL INSPECTION OF THE DEPARTMENT OF VETERANS AFFAIRS (DVA), MASTER MATERIALS LICENSE FOR ISSUES ASSOCIATED WITH MULTIPLE MEDICAL EVENTS INVOLVING PERMANENT PROSTATE BRACHYTHERAPY TREATMENTS AT THE VA MEDICAL CENTER, PHILADELPHIA PENNSYLVANIA

Background

On May 18, 2008, the DVA National Health Physics Program (NHPP) notified the NRC of a possible medical event at the VA Medical Center, Philadelphia, Pennsylvania that occurred on May 5, 2008, involving a prostate brachytherapy treatment in which the total dose delivered differed from the prescribed dose by more than 20 percent. The procedure was performed using iodine-125 seeds of a lower source strength than intended. Specifically, the permittee inadvertently ordered and implanted iodine-125 seeds with the wrong source strength. As a result, the patient received a dose less than 80 percent of the prescribed dose.

The NHPP initiated an onsite reactive inspection on May 28-29, 2008, at the VA Philadelphia Medical Center in response to the medical event. Based on the preliminary inspection findings, the NHPP expanded the scope of the inspection and requested that the VA Medical Center perform a review of approximately 20 additional prostate brachytherapy treatments. Based on the Medical Center's review, four additional possible medical events were identified. The Medical Center discovered that the circumstances for the additional medical events were unrelated to the initial medical event that involved lower seed source strength. Therefore, the VA Medical Center expanded the review of prostate brachytherapy treatments to include all 112 procedures performed since the inception of the brachytherapy program in February 2002. As a result of the expanded review, the VA Medical Center suspended its prostate brachytherapy program on June 11, 2008. The NHPP conducted a follow up onsite inspection on June 23-24, 2008 and continues to review the circumstances surrounding the medical events. To date, the VA Medical Center has identified 47 medical events (doses delivered less than 80 percent of the prescribed dose).

In response to the multiple medical events, NRC Region III dispatched inspectors to conduct a reactive inspection at the VA Philadelphia Medical Center on July 23-25, 2008. The inspectors noted that the permittee's initial medical event reported on June 9, 2008 was the only one that involved a permanent implant prostate brachytherapy treatment with iodine-125 seeds of a lower source strength than intended. The inspectors also noted that the root cause(s) for the remaining 46 medical events was unrelated to the initial medical event and is currently undetermined.

Management Directive 8.3

The circumstances surrounding the medical events were reviewed against the criteria in Management Directive 8.3 "NRC Incident Investigation Program", and Management Directive 8.10 "NRC Medical Event Assessment Program." Based on the preliminary findings of an NRC reactive inspection conducted on July 23 - 25, 2008 and the high number of medical events involving iodine-125 prostate brachytherapy treatments, the NRC considers this a significant event. A Special Inspection is necessary to evaluate the conditions and circumstances surrounding the medical events at the VA Medical Center in Philadelphia, Pennsylvania, sufficient to determine the probable causes and the contributing factors of the events.

Special Inspection Activities

The Special Inspection will commence the week of September 8, 2008, utilizing Inspection Procedure 93812 and will be led by Cassandra F. Frazier, Senior Health Physicist, Division of Nuclear Materials Safety (DNMS). Darrel Wiedeman, Senior Health Physicist, DNMS, and Kenneth Lambert, Senior Health Physicist, DNMS, will be the other inspectors.

The Special Inspection will include evaluation of the facts, circumstances, and the licensee actions surrounding the events. A Charter, prescribing the areas to be reviewed, was developed and is enclosed. An entrance meeting will be conducted with the licensee on September 9, 2008.

Docket No. 030-34325

Enclosure:
As stated

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DEPARTMENT OF VETERANS AFFAIRS SPECIAL INSPECTION CHARTER

The Special Inspection will be conducted to examine the conditions and circumstances surrounding the multiple medical events involving prostate brachytherapy treatments conducted at the VA Medical Center in Philadelphia, Pennsylvania from February 2002 to June 2008. In addition, the Special Inspection will be conducted to determine the probable causes and the contributing factors of the prostate brachytherapy treatments. The Special Inspection should include, but is not limited to, the following:

1. Develop a chronology of events leading to the discovery of prostate brachytherapy medical events and subsequent licensee actions taken in response.

2. Evaluate the scope and methodology used by the licensee to determine that the events identified by the licensee are medical events as defined in 10 CFR Part 35.3045.

3. Review the licensee's procedures for prostate brachytherapy treatments, and evaluate their adequacy to ensure high confidence that each administration is in accordance with the written directive.

4. Evaluate the training and qualifications of the individuals (i.e., authorized users, physicists, etc.) involved with the iodine-125 prostate brachytherapy treatments and the licensee's training program.

5. Conduct an independent assessment of a representative sample of the medical events (obtain assistance from headquarters staff and an NRC medical consultant, as appropriate).

6. Review the licensee's overall investigation, including root and contributing causes and extent-of-condition.

7. Evaluate the licensee's immediate and long term corrective actions to prevent recurrence.

8. Identify any potential generic issues associated with the event.

9. Assess the adequacy of the licensee's 15-day reports (required by 35.3045(d)).

10. Evaluate the response to the medical events by the National Health Physics Program (NHPP).

Charter Approval

/RA by Mark S. Delligatti acting for/ Patricia Pelke, Chief, Materials Licensing Branch
Division of Nuclear Materials Safety

/RA by Mark S. Delligatti acting for/ Steven A. Reynolds, Director
Division of Nuclear Materials Safety