

# **Veterans Health Administration (VHA) Update for Oversight for Uses of Radioactive Materials**

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**Remarks for Nuclear Regulatory Commission Agency Action Review Meeting**

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## **Introduction**

Good morning Chairman Jaczko and NRC Commissioners. I appreciate this opportunity to provide remarks on behalf of Dr. Petzel, VHA's Under Secretary for Health, about our ongoing efforts to ensure the safe use of radioactive materials.

Today, I want to discuss oversight initiatives implemented by VHA to ensure the safe uses of radioactive materials. I will be providing examples of changes and sustainment efforts that have resulted in immediate improvements and the establishment of a structure designed to sustain and continuously improve the effectiveness of our mission.

I would like to state that the expanded and improved interaction and communications between the VHA and the NRC at the senior leadership, regional, and staff levels has proven to be a catalyst in our efforts to accomplish the common goal of both organizations, which is the safe use of radioactive materials.

The meeting held on June 8, 2010, that included the Under Secretary for Health, the NRC Chair, and the NRC, Region, III, administrator established a clear understanding of the desire for the VHA to achieve the highest levels of compliance with NRC regulations, standards and requirements. The outcome of this meeting established a framework for follow-up meetings to pursue a collaborative effort to review, analyze, and improve our relationship including the procedural and technical processes which has formed the basis for a continuous educational, consultative, and open communication forum that has to date been highly effective. I would like to commend the Chairman and his staff for the guidance, assistance, and transparency in achieving the overarching goal to protect public health and safety in the delivery of quality care for our Nation's Veterans. This has been achieved through the improved relationship between the two agencies, while maintaining their role as a regulatory body.

As the management representative to the VHA National Radiation Safety Committee, I have had the pleasure to interact with Mr. Satorius (NRC, Region III, Administrator) frequently in the past year to address emerging issues. Milton D. Gross, M.D., who is the Chair of the National Radiation Safety Committee, has held a series of working group meetings with NRC and VHA representatives to identify opportunities for improvement which may lead to revisions to the Letter of Understanding that will enhance the task of implementing the requirements of the existing master materials license. VHA feels strongly that the results of the working group meetings will not only have a positive impact on the execution of the master materials license but the overall findings will assist the NRC in the implementation of a master materials license with other federal agencies.

Accompanying me today are Dr. Gross and Mr. Gary E. Williams, Director of the National Health Physics Program (NHPP). They are available to discuss any questions from the Commissioners related to the overall performance of our National Radiation Safety Committee, the progress made by the working group, the improved relationship between the NHPP and the NRC, and the status of actions taken to improve the VHA's overall performance or any other pertinent issues.

### **VHA initiatives for sustainable oversight**

I now want to outline briefly some key actions VHA has taken for sustainable oversight for the safe use of radioactive materials. These actions are discussed in depth at each meeting of the National Radiation Safety Committee.

I will discuss examples of our efforts and successes to date.

1. VHA identified an "executive committee" of the National Radiation Safety Committee that consists of the chair, executive secretary, management representative, and two key physicians in addition to an alternate committee chair. The "executive committee" is in a position to evaluate time-urgent issues between formal quarterly committee meetings, function as an information conduit to senior leadership, and help determine long term and sustainable strategies for regulatory compliance. The result for this effort has been more involvement by senior leadership and greater focus to programmatic oversight.

2. VHA has continued to evaluate standard procedures and other criteria for prostate seed implant programs.

- A revision to the standard procedure for medical event training was implemented effective April 1, 2011.

- A revision to the start and restart criteria for a prostate seed implant program was approved by the committee in February 2011.
  - The revision established a workload requirement for the number of patients to be treated if a program is to be started or restarted.
- From a clinical perspective, VHA is developing a plan for physician peer review and external accreditation for VHA facilities that complete prostate seed implants.
  - The result is that VHA has the most rigorous procedures for prostate seed implant treatments in the medical community.

3. VHA completed annual inspections for all prostate seed implant programs with the most recent cycle of inspections being completed in January 2011. These inspections have not identified any new medical events or significant program deficiencies. The follow-up NRC inspections at the same facilities have not identified medical events or significant program deficiencies. The results of the revised procedures and annual inspections are continued oversight for prostate seed implant programs currently approved within VHA.

4. VHA expanded the inspection scope for our routine core inspections to include new prescriptive requirements for facility level Radiation Safety Committees. These new requirements established more detailed review of key issues at routine meetings, a time period for executive management review of the meeting results, and tracking of any programmatic issues to their completion. The National Radiation Safety Committee partnered with the Office of the Deputy Under Secretary for Health for Operations and Management to improve communications to field stations resulting in positive outcomes. These outcomes are related to the implementation of new Radiation Safety Committee documentation and communication of guidance related to potential national issues including the process for ensuring continuous coverage by a Radiation Safety Officer. The communications included both written guidance, sharing of information through social media with Radiation Safety Officers and presentations on the weekly Network Director Teleconferences.

5. VHA successfully met our routine inspection schedule plan this past year and did not request any variance from NRC related to the Inspection Manual Chapter 2800 inspection priorities. The NHPP leadership and staff ensured the consistency of this process during times of resource limitations.

6. VHA successfully completed a routine biennial inspection by NRC in September 2010. The inspection evaluated VHA inspections, permitting, and investigations by VHA during the period since the last NRC routine inspection in Spring 2007.

7. VHA has provided continued detailed oversight for security of radioactive materials with emphasis on sealed sources under the NRC order for increased controls. VHA has partnered with the Department of Energy to complete security assessments at specific locations with a goal to enhance security above and beyond requirements in the NRC orders. In the past year the Department of Energy has completed four assessments and disposed two "disused" sources for VHA. The VA Office of Operations, Security, and Preparedness has provided oversight for VHA security efforts. The result has been a decreased footprint for larger activity sealed sources through the disposals and ongoing security upgrades at the facilities with remaining sealed sources.

8. VHA has tracked NRC efforts for 10 CFR Part 35 rulemaking for the medical event definition for permanent brachytherapy and other issues under the proposed expanded rulemaking. VHA has offered to pilot test at a VHA facility new rulemaking proposals or the planned criteria for inspection methods under the current medical event definition. VHA has offered to participate in the NRC rulemaking workshops. The result has been a proactive approach by VHA to offer input for NRC efforts at rulemaking and to use the most current inspection methods available as VHA continues increased inspections at prostate seed implant programs.

9. VHA successfully completed all requirements under the NRC Confirmatory Action Letter that was issued in October 2008 related to prostate seed implant programs.

10. VHA responded to the NRC inspection report related to the "extent of condition" for prostate seed implant programs in a letter dated July 15, 2010. This letter outlined a list of future actions by VHA to ensure oversight for safe use of radioactive materials. The National Radiation Safety Committee agenda for subsequent meetings has considered the future actions to ensure sustained and continued oversight. These issues include the tracking of NRC rulemaking noted above, tracking issuing of the safety culture policy statement, and rulemaking for security in a possible new 10 CFR Part 37.

11. Over the 12-month period of April 2010 through March 2011, NRC inspected 24 VHA facilities and cited two minor violations. No significant violations were identified by NRC for escalated enforcement. NHPP inspected 72 facilities and cited 11 minor violations and one significant violation for escalated enforcement (related to Radiation Safety Officer coverage). NRC inspections included five of the seven active prostate seed implant programs. NHPP inspections included all seven active programs. None of the violations cited by either NHPP or NRC were related to prostate seed implant programs.

Of course, uses of ionizing radiation for medical diagnosis and treatment are not limited to radioactive materials under NRC purview. VHA extensively uses machine sources such as linear accelerators for therapy and x-ray machines for imaging in our care for Veterans. The National Radiation Safety Committee and NHPP are also providing oversight and monitoring for these modalities to exercise our responsibility for safe use of these sources of ionizing radiation.

In early 2011, VHA successfully recruited for a vacancy created by internal promotion and increased the staffing for NHPP by one health physics FTE to help with the overall VHA efforts for radiation protection.

### **NRC initiatives that impact VHA efforts**

I now want to outline briefly some key actions by NRC and results from our discussions with NRC that impact VHA efforts for sustainable oversight.

I have previously mentioned the increased interactions throughout all levels of our two agencies. I am comfortable that NRC and VHA agree that a master materials license is a unique type of license that requires continued refinement to implement successfully.

I note NRC's understanding and support that VHA has a regulatory and a concurrent consultative role in ensuring safe practices and compliance with NRC requirements.

I will mention three NRC actions that are important to VHA.

1. NRC issued a final report by an internal "Department of Veterans Affairs Lessons-Learned Task Group." This NRC self-assessment report is generally a balanced, fair, and detailed review of circumstances for medical events at VHA facilities and a useful historical record. Since the report identified deficiencies in NRC regulations, training, and procedures, the NRC corrective actions to implement the report recommendations is a future benchmark for VHA future and sustained actions.
2. VHA is tracking NRC rulemaking for 10 CFR Part 35 that includes the medical event definitions for permanent implant brachytherapy. The earliest possible resolution of the rulemaking is in the best interest of VHA and the entire medical community.
3. NRC has agreed to allow NHPP inspectors to accompany and observe NRC on-site inspections at VHA facilities. These accompaniments facilitate NHPP benchmarking to NRC inspection practices and provide for clarification for possible program deficiencies

at a facility. The accompaniments serve as a means for continuous learning and sharing of information between the two agencies and the VHA is supportive of the continuation of this opportunity and the consideration to spread this best practice to the additional two master materials licensees. The meeting scheduled by NRC with the three master material licenses on July 19<sup>th</sup>, 2011 offers the opportunity for discussions and sharing of ideas that can lead to improvements in the master materials license process, oversight and execution of expectations.

## **Summary**

In summary, the Under for Secretary for Health is firmly committed to sustainable efforts to protect the public health and safety and achieve regulatory compliance which is consistent with his mission of VA Healthcare – Defining Excellence in the 21<sup>st</sup> Century.

VHA has a goal to coordinate and interact closely with NRC at all levels of our agencies. I have outlined above some key efforts and successes by VHA and NRC in this past year.

As a result of these efforts within VHA, our prostate brachytherapy procedures are the most rigorous in the medical community. Our oversight by senior leadership and by the National Radiation Safety Committee is rigorous and ongoing.

VHA looks forward to continuing this new collaborative relationship with NRC as VHA implements a regulatory compliance program consistent with NRC expectations.

Dr. Gross, Mr. Williams, and I are available to respond to any questions or comments.