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# Department of Veterans Affairs Lessons-Learned Task Group

**FINAL REPORT**
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## Executive Summary

By memorandum dated January 21, 2010, the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission (NRC), established the Department of Veterans Affairs Lessons-Learned Task Group (VATG) in response to the activities related to prostate implant brachytherapy medical events at Department of Veterans Affairs (DVA) facilities. The VATG charter established the purpose of the VATG as follows: to assess the NRC's policies, procedures, and practices and determine whether NRC staff could have detected the issues that led to these events or mitigated subsequent events, as well as review the extent of conditions once the initial event was identified. The Director, MSSA, specifically tasked the VATG to review the adequacy of the NRC's policies, procedures, and inspection guidance, as well as NRC's training, medical consultant, and Master Materials License (MML) programs.

The VATG concluded that the NRC missed opportunities to detect the conditions that led to the medical events or detect the medical events themselves and mitigate subsequent ones. Opportunities for detection occurred both during the period when the Philadelphia Veterans Affairs Medical Center (PVAMC) was an NRC specific licensee and when PVAMC was a permittee of the DVA MML. A number of factors contributed to the missed detection, including changes in the NRC's inspection program; weaknesses in the NRC's policies, procedures, training, and guidance for inspection and event response; and deficiencies in the NRC's oversight of MML programs. Based on its review, the VATG has recommended several programmatic changes. Although most of the recommendations involve enhancements to existing NRC policies and procedures, some require the development of new NRC procedures or guidance.

Historically, the NRC has stayed well clear of areas that might be considered as "the practice of medicine." As a result, the NRC has provided licensees with little to no guidance regarding acceptable methods of achieving compliance with many of the NRC's medical regulations. Likewise, the NRC staff has little to no formal guidance for evaluating licensee performance in this area. The VATG is concerned that the NRC staff believes that it can "fix the problem" through revision of the regulations. Regardless of what regulatory revisions are made, without accompanying guidance for licensees and NRC inspectors and license reviewers, these types of situations will inevitably recur. The NRC should make every effort to provide its licensees and staff with guidance, including definitions for relevant terms, acceptable methods to comply with relevant requirements, and acceptable criteria for evaluating and responding to prostate brachytherapy medical events. This guidance should be updated concurrently with any regulatory revisions.

The VATG has identified enhancements that can be made to NRC's policies, procedures, and guidance related to NRC's response to medical events. The NRC should provide additional guidance to its staff and managers regarding the necessary level of NRC response (special inspection team, augmented inspection team, or incident investigation team) for all types of medical events (overexposures, underexposures, or unintended dose to the skin or other organs or tissues). This should include a discussion regarding conditions under which the NRC might need to reassess its response posture as it develops new information during response activities. The NRC should also provide guidance for determining the extent of conditions to ascertain whether reported medical events are isolated or programmatic.

The VATG concluded that the NRC could enhance its training program for inspectors and license reviewers to help its staff be better prepared to identify, respond to, evaluate, and disposition medical events. Additional training is needed regarding post-implant verification techniques. Medical technologies and techniques are continuously being developed and implemented; NRC inspectors and license reviewers would benefit from periodic refresher training in this area.

The VATG identified several weaknesses in NRC's medical consultant program. The VATG has made recommendations that it believes will result in a more robust process for hiring medical consultants, including developing criteria for qualification and a formal selection process. The VATG has also made recommendations regarding NRC's administration and oversight of the medical consultant program.

The VATG concluded the NRC does not have adequate procedures in place to effectively process an MML application, should it receive one in the future. As part of the NRC's efforts in knowledge management, the NRC staff that processed the existing MMLs should be called upon to develop a procedure for processing an MML application.

The VATG found that the NRC's oversight of the DVA MML was consistent with NRC policies and procedures. However, it identified several weaknesses related to the oversight of MML programs and recommended a number of revisions in this area. Recommended changes include the need to specify the roles and responsibilities of NRC MML project managers (PMs), further discuss oversight mechanisms, and provide additional guidance regarding independent NRC inspections and inspector accompaniments, turnover duties between PMs, and performance and documentation of MML program reviews.

The VATG has made additional recommendations concerning MML expiration dates, corrective action programs, and enforcement responsibilities. As it was beyond the VATG's scope to fully explore the issue of MML expiration dates, the VATG recommended that the NRC staff further review this area. Because the NRC relies on MMLs to have central control and be able to implement program changes across its permitted facilities, MML programs could be enhanced by corrective action programs. The NRC's Enforcement Manual and the letters of understanding with MMLs should clarify the responsibilities for enforcement program implementation between MMLs and the NRC. To perform enforcement activities at the level expected by the NRC, the MMLs could benefit from training and further guidance regarding the NRC's enforcement program.

Appendix A of this report contains a consolidated table of recommendations. The VATG did not identify any warranted inspection or licensing actions for other licensees of the Commission or Agreement States.

# 1. INTRODUCTION

## 1.1 Purpose

By memorandum dated January 21, 2010, the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), U.S. Nuclear Regulatory Commission (NRC), established the Department of Veterans Affairs Lessons-Learned Task Group (VATG) in response to the NRC activities related to prostate implant brachytherapy medical events at Department of Veterans Affairs (DVA) facilities. The VATG's charter established the purpose of the VATG as follows: to assess NRC policies, procedures, and practices in this area to determine if the NRC staff could have detected the issues that led to these events or mitigated subsequent events, as well as the extent of conditions, once the initial event was identified. The Director, MSSA, also tasked the VATG with determining if NRC policies, procedures, and practices related to the area of review were compatible and consistent among the agency's materials licensing and inspection organizations. Based on the VATG's assessment, the Director, MSSA, charged the VATG with recommending programmatic changes to the Deputy Director for Licensing and Inspection in FSME and identifying if inspection or licensing actions were warranted for other licensees of the Commission or Agreement States.

## 1.2 Scope and Method of Review

As directed in its charter, the scope of the VATG's assessment was to be sufficient to ensure that it clearly understood the NRC's actions taken in response to the reported prostate implant brachytherapy events at DVA facilities. Furthermore, the assessment should consider both NRC and licensee actions before, during, and after the events, but with an internal focus on how the agency's policies, procedures, and practices bore upon those actions. The NRC specifically asked the VATG to review the following areas and, as appropriate, assess the consistency and compatibility among NRC regional materials licensing and inspection programs:

- Assess the adequacy of NRC policies, procedures, and inspection guidance related to the following:
  - detecting the conditions or issues that led to the medical event(s)
  - evaluating and responding to such medical event(s)
  - mitigating subsequent events and determining the extent of conditions, once the initial event was identified
- Assess the adequacy of training programs for NRC inspectors and license reviewers (and those of the Master Materials License (or licensee) (MML)) to identify, respond to, evaluate, and disposition medical events.
- Assess whether the use of medical consultants is adequately defined in NRC policies and procedures and whether the use of a medical consultant (according to those policies and procedures) is appropriate for this type of medical event.
- Assess the adequacy of NRC policies and procedures for initial MML programs, turnover of historical licensing and inspection information, and turnover of duties between NRC MML PMs.

- Assess the adequacy of NRC policies, procedures, and the framework agreed to in the letters of understanding (LOUs) with MMLs regarding the assignment of responsibilities between the MML and the NRC for evaluating and responding to medical events; performing inspection activities, including reactive inspections; and processing and dispositioning inspection findings, including any subsequent escalated enforcement actions.

- Assess the adequacy of NRC policies, procedures, and applicable training programs for inspectors and license reviewers to properly administer and maintain oversight of MML programs.

The VATG accomplished its objectives through a review of relevant documents and interviews of NRC staff and management. It began its activities in January 2010, with initial efforts focused on identifying, gathering, and reviewing many of the relevant supporting documents. These included NRC policies and procedures, guidance documents, inspection reports (IRs), enforcement actions, training materials, licensing actions, and DVA documents and submittals. Appendix C lists these documents.

Following its preliminary review of supporting documents, the VATG identified NRC managers and staff from Headquarters (HQ) and regional offices to interview in support of its review. The VATG developed interview questions for each interviewee prior to conducting the interviews. The interviewees included managers and staff in NRC regional offices and several NRC HQ offices. Appendix D lists the personnel contacted. In addition to NRC personnel, the VATG team leader was contacted by the Director of the DVA National Health Physics Program (NHPP) and an NHPP staff member when they became aware of the ongoing VATG review and wished to share their thoughts and perspectives.

The VATG was responsible for making recommendations to correct any deficiencies in the NRC's inspection and licensing policies, practices, and procedures related to the prostate brachytherapy events at DVA facilities. The charter noted that the VATG's recommendations should focus on solutions that strengthen existing inspection and licensing policies and procedures. Appendix A summarizes the VATG's recommendations.

The Deputy Director, Licensing and Inspection Directorate, MSSA, FSME, provided the VATG with counsel and guidance. The VATG kept the Deputy Director informed of its activities and periodically provided briefings during its review.

### 1.3 Limitations of the Review

When the NRC chartered the VATG in January 2010, it had only recently conducted the Predecisional Enforcement Conference (PEC) with NHPP regarding the medical events at Philadelphia Veterans Affairs Medical Center (PVAMC) (December 2009) and had not yet issued an enforcement action. In March 2010, it issued a final enforcement action regarding the inspection at PVAMC. Furthermore, when the NRC chartered the VATG, Region III was still conducting in-office inspection activities related to its review of NHPP's oversight of licensed activities, as well as the 13 other DVA facilities that had prostate brachytherapy programs. The NRC issued an IR regarding these activities in May 2010 and held a PEC with DVA in June 2010. Final action from the NRC in this case was pending as of the date the VATG wrote this report. During the VATG review, several issues were still unresolved regarding NRC inspection activities, pending enforcement, and ongoing rulemaking activities. As a result, some issues may need further evaluation at a later date.

## 2. BACKGROUND

### 2.1 Master Materials License Program

The NRC developed an MML program for a Federal organization that would consolidate different types of single entity licenses, from across the country and across multiple NRC regional office jurisdictions, under one single master license for the respective Federal organization. The MML would issue permits, similar to a broad-scope licensee, to its facilities; however, under the MML model, the licensee would implement an inspection program that was consistent with NRC's regulations, policies, and procedures and would respond to events, take enforcement action, and process allegations using programs that were equivalent to NRC's programs. The purpose of the MML program was for the NRC to have consistent oversight of the licensee programs by performing these activities under one MML instead of individual specific licenses from across different regional offices. The MML program also allowed for a reduction in full-time equivalent (FTE) staff for the NRC. In addition, an MML can institute fleet-wide changes and procedures to cover all programmatic elements rather than individual licensee facilities implementing different programs, therefore resulting in consistency in health, safety, and security programs in MML facilities across the entire United States.

The NRC approached the Department of the Air Force (Air Force) in December 1982 to consider a multisite broad-scope license, or MML, for its program. The NRC initiated these discussions because all of the Air Force activities involving radioactive materials operated under a centrally controlled organization. NRC HQ subsequently issued the first MML to the Air Force in June 1985, based on a review of the application submitted and the agreed-upon LOU. NRC HQ issued an MML to the Department of the Navy (Navy) in 1987, based on a review of the application submitted and the LOU. The NRC did not document a readiness review for the issuance of these two licenses.

DVA submitted an official application for an MML in December 1996. At that time, DVA facilities throughout the United States had individual specific licenses that were issued by the NRC Region in which the facility was physically located. In May 1997, the NRC chartered a license application review team to review DVA's application for an MML. The NRC review team identified a large number of deficiencies in the program and met with DVA in June 1998 to discuss the following fundamental weaknesses: (1) DVA had not established an adequate centrally controlled program and did not have sufficient experience and training to manage an MML program, (2) DVA lacked the proper emphasis on the "regulator" role of the MML, (3) because of its structure and organization, DVA's Master Radiation Safety Committee lacked decisionmaking responsibility, (4) the structure and organization of DVA's NHPP was not adequate to ensure protection of the health and safety of workers and the public through its permitting and inspecting program, and (5) financial support for the program was not evident. The NRC issued two deficiency letters to DVA in September 1997 and August 1998, which documented the identified fundamental weaknesses of the program.

In September 1998, DVA gave the existing NHPP and the proposed National Radiation Safety Committee (NRSC) the authority needed to establish and manage a centrally controlled program. DVA submitted a substantially revised application for an MML to the NRC on September 21, 1998, and withdrew its previous application. DVA submitted supplements in October 1998 and March 1999 in response to the NRC's request for additional information. At that time, DVA's lack of a centrally controlled program continued to be the critical deficiency in its MML application. During prelicensing visits to the NHPP program office in February and

March 1999, the NRC identified continued problems with the centrally controlled program and the fundamental chain of command, as well as structural, operational, communication, and timeliness problems with DVA's implementation of its proposed plan.

The NRC suspended its review of DVA's revised MML application in May 1999 and asked DVA to conduct a complete assessment of its centrally controlled program and develop a plan for implementing an acceptable program. DVA initiated a comprehensive radiation control program assessment and improvement action plan in October 1999. The changes included having NHPP become a separate program entity that reported directly to the NRSC, with ready access to DVA's executive management. On June 1, 2000, NRC and DVA management met to discuss DVA's efforts and accomplishments since May 1999. Subsequently, on October 26, 2000, DVA notified the NRC that it had corrected the problems identified by the NRC and that it was prepared to undergo a readiness review for an MML.

The NRC conducted the readiness review between January and June 2001, in a manner similar to its Integrated Materials Performance Evaluation Program (IMPEP) review for Agreement State programs. The NRC used six performance indicators to review the DVA program. NRC issued the readiness review report on August 20, 2001. The readiness review report documented NRC's finding that DVA's performance for all six indicators was "satisfactory"; and concluded that, based on its organizational and technical experience, DVA could effectively implement an MML. Although all six indicators were satisfactory, the readiness review team noted in its report that the NRSC lacked aggressiveness with regard to event followup.

Concurrent with the review of the DVA application, members of the application review team developed NUREG-1556, Volume 10, "Program-Specific Guidance about Master Materials Licenses," issued December 2000. The guidance in NUREG-1556, Volume 10, described the elements to be addressed as part of an MML application and the criteria to be used by NRC to evaluate it. The guidance described an MML as a broad-scope licensee with more autonomy and responsibilities as a regulator. The MML functions similarly to an NRC regional office, in that the centrally controlled program would review license (permit) requests from its organization, conduct routine and reactive inspections, and perform enforcement actions, to a limited degree. However, just as NRC HQ does not delegate all licensing, inspection, and enforcement responsibilities to the regional offices, neither does the NRC delegate all responsibilities to the MML. An LOU between the NRC and the MML establishes the extent of shared and delegated responsibilities. Therefore, the primary focus of the MML application is on the procedures, organization, and facilities required to manage a centrally controlled oversight program with a regulator component, as well as a regulated component (i.e., the individual materials use permittees (facilities)). The criteria established in the guidance specifies that an MML applicant should successfully meet the criteria in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.33, "General Requirements for Issuance of Specific Licenses," and, at a minimum, have the following attributes: (1) a centrally coordinated program for at least 5 years, (2) an acceptable regulatory performance record, (3) a radioactive materials use program requiring a variety of modalities and radionuclides, (4) an infrastructure to support the program that is adequate to protect the health and safety of workers and the public, and (5) an ability to demonstrate readiness to assume the responsibilities, as evidenced by the acceptable performance of a centrally controlled program based on an operational readiness review conducted by the NRC.

The NRC staff drafted a Commission paper (SECY-02-0160, "Department of Veterans Affairs Application for a Master Materials License," dated August 28, 2002) to document its evaluation of the DVA MML application, summarize the results of the readiness review, and make

recommendations regarding the DVA MML application. The draft Commission paper evaluated three options: (1) Option 1, deny the application or defer the licensing decision until DVA obtains 5 years of centrally coordinated program experience, (2) Option 2, issue a two-phase MML, where the first phase authorized the lower risk licenses, with the intent of considering the second-phase for higher risk licenses at a later time, and (3) Option 3, issue a full MML, consolidating all licenses. The draft Commission paper recommended Option 3.

Two members of the DVA MML application review team submitted a differing professional view (DPV) on March 5, 2002. The DPV documented the authors' position that Option 2 was the best approach to take. Option 2 would have authorized issuance of an MML to DVA for the lower risk licenses, while deferring the decision on amending the MML to include the higher risk licenses until DVA could demonstrate sustained performance with its centralized program and respond to difficult regulatory issues. The DPV noted that DVA had approximately 2 years of experience operating a centrally controlled program but did not have the recommended 5 years. The DPV authors noted that the DVA program "still has identifiable weak points…that will be more noticeable as DVA gains more experience and encounters more challenging central control and regulatory issues. Obvious sources of regulatory challenges will be broad-scope license renewals and implementation of the new 10 CFR Part 35." The DPV also discussed NRC's resource savings and noted, "However, if the DVA is unable to manage the MML, the resource savings produced by issuing the full MML prematurely will be negated by the resources needed to bring the program up to an acceptable level of performance or take back individual DVA licenses or the MML."

To address the DPV, the NRC chartered an ad hoc panel. This panel concluded that the positions in both the DPV and the draft Commission paper had some merit and recommended Option 3, with several modifications and additional actions. The additional actions included increased NRC oversight of higher priority permittees during the first year and augmented oversight for at least 2 years, and an NRC assessment of DVA after the first year. As a result of the ad hoc panel's conclusions, the NRC staff revised the draft Commission paper and submitted it to the Commissioners on August 28, 2002, requesting that the Commission approve Option 3 for the issuance of a full MML with increased NRC oversight for a period of 2 years. On October 15, 2002, the Commission approved Option 3 and requested that the staff provide a status report after 1 year.

The NRC Region III office issued an MML to DVA on March 17, 2003. The authorization of the DVA MML resulted in the transfer of 115 NRC specific licenses to DVA. The NRC terminated these licenses when they became permittees of the DVA MML. Region III developed a plan for increased oversight of the DVA MML. The oversight deviated from that contained in NRC Inspection Manual Chapter (IMC) 2810, "Master Materials License Inspection Program," dated September 15, 2003, in that the increased oversight plan included a review of: (1) the timeliness and technical quality of the permitting actions, (2) the timeliness for conducting inspections and accompaniments of each MML inspector, (3) the performance of NRC independent inspections for 10 percent of the higher risk DVA permittees, and (4) an NRC review of all NHPP IRs and enforcement actions, technical staff training, and DVA's handling and processing of allegations. The plan for increased oversight also included the performance of comprehensive team inspections of the DVA MML program.

The first year of increased oversight of the DVA MML provided an opportunity for the NRC to independently inspect 60 percent of DVA's higher priority program areas, accompany each NHPP inspector, and complete two comprehensive team inspections of NHPP's program. An Executive Director for Operations (EDO) report to the Commission (SECY-04-0076,

"Department of Veterans Affairs (DVA) Implementation of Its Master Materials License (MML)," dated May 6, 2004) contained the status report of DVA's implementation of the MML program. The report recommended that the NRC maintain increased oversight for a second year but at a reduced level.

On July 27, 2005, following the second year of increased oversight, the NRC concluded that DVA had demonstrated that it had effectively managed a centrally controlled program and that the program was functioning in a manner that was protective of the health and safety of the public and the environment. The NRC's EDO informed the Commission of the staff's intent to implement the standard MML oversight program described in IMC 2810 and terminate the program of increased oversight.

## 2.2 Prostate Implant Brachytherapy

Treatment options for prostate cancer include prostatectomy, external beam radiation therapy, permanent implant brachytherapy, and hormonal therapy. Prostate implant brachytherapy is an interstitial brachytherapy using small, sealed sources (i.e., seeds) of radioactive material, inserted directly within cancerous tissue (i.e., the prostate treatment volume which can include the prostate gland and a margin set by the authorized user (AU)). By placing the source of radiation close to target cells, these cells receive high radiation doses but surrounding healthy tissue receives low radiation doses. Because the seeds cannot be easily removed, prostate brachytherapy is a *permanent* implant brachytherapy procedure. Short-lived materials, such as iodine-125 (half-life = 60 days), palladium-103 (half-life = 17 days), or cesium-131 (half-life = 9.7 days) are typically used for prostate brachytherapy.

An advantage of brachytherapy is that the high-dose volume can be made to conform to the shape of the tumor volume. Another advantage of prostate brachytherapy is that, when using iodine-125 seeds, doses of approximately 145 Gray (Gy) are administered, versus 70 Gy for external beam radiation therapy. Further advantages include fewer side effects and fewer treatments (i.e., a 1-day brachytherapy implant procedure versus several visits over approximately 6 weeks for external beam). Sometimes, permanent brachytherapy is used in conjunction with external beam radiation therapy.

A typical implant involves 60 to 100 seeds at an activity of 0.3 to 0.7 millicuries (mCi) per seed. The method of implantation can be by the use of: (1) an applicator, which uses cartridges either preloaded with seeds by a vendor or loaded by the licensee, (2) preloaded needles with seeds and spaces either preloaded by a vendor or loaded by the licensee, (3) seeds fixed in absorbable suture material, or (4) seeds linked with absorbable spacers. Insertion is performed during a surgical procedure, using trans-rectal ultrasound to visualize placement of each needle/seed, with some clinicians also using fluoroscopy to further confirm organ location and proper seed placement. Following the implant procedure, localization images, such as computed tomography (CT) scans, are taken to verify the source distribution, aid in the determination of dosimetric information, and to verify the source count. The timing of the performance of localization images varies, with some facilities performing the images immediately after the implant procedure. In general, follow-up imaging is performed at 1 month for iodine-125, at 2 weeks for palladium-103, and at 1 week for cesium-131.

There are several strategies for seed loading. The loading pattern used by most clinicians until the early 2000s involved uniformly placing sources throughout the prostate (i.e. seeds placed at fixed distances from each other throughout the prostate). However, this uniform loading pattern was noted to create hot spots in the center of the prostate near the urethra and furthermore did

not treat the entire volume of the prostate or periprostatic disease. Excess dose to the urethra was shown to result in increased side effects. Peripheral loading came into use in the mid- to late-1990s and involves placing sources at the periphery of the prostate, in part to maximize the dose to the prostate volume and minimize the dose to the urethra. In peripheral loading, seeds may be intentionally placed on the exterior of the prostate gland in order to deliver the intended dose to all areas of the prostate. Clinicians may also use a modified uniform loading procedure, which involves placing approximately two thirds of the seeds at the periphery of the prostate gland.

Brachytherapy is a very flexible form of treatment that allows for individualization of the dose distribution for each patient, based on his anatomy. The conduct of prostate implant brachytherapy has evolved into a team concept with participation by a radiation oncologist (an AU), urologist, medical physicist, and sometimes, a dosimetrist. Although NRC regulations do not require a medical physicist for prostate implant brachytherapy procedures, most brachytherapy programs have adopted a process that incorporates a medical physicist's involvement in the procedures. The medical physicist can determine the number, strength, and location of the sources needed to deliver the correct therapeutic dose over several half-lives. In general, the medical physicist or dosimetrist prepares a treatment plan, which incorporates the pre-planning ultrasound prostate volumes collected for a given patient and documents the placement of needles/seeds within the prostate and outside of the prostate. Several computer-based treatment planning systems are available to help the medical physicist or dosimetrist determine the best implant parameters to achieve the dose prescribed by the AU. The AU may prescribe a dose to a certain point in the prostate, or to a region or volume in the prostate, or prescribe a minimum peripheral dose. The goal is to determine the best combination of sources, source strengths, and source locations that will deliver the prescribed dose.

Post-operative imaging provides detailed information regarding the coverage and uniformity of an implant, but the assessment of implant quality remains a debated issue. The debate centers around the appropriateness of different criteria used to assess the quality of the procedure, the discrepancies caused by the use of different imaging systems (ultrasound versus CT) for pre- and post-implant imaging, and the differences in contouring techniques used for post-implant evaluations. The American Brachytherapy Society has recently proposed that prostate brachytherapy quality be measured in terms of D90, V100, and V150, where D90 is defined as the dose to 90 percent of the prostate volume; V100 and V150 are defined as the percent of prostate volume receiving at least 100 percent or 150 percent of the prescribed dose, respectively. The NRC has not defined these terms in its regulations or guidance documents. Further, the NRC has not provided licensees with guidance on post-implant evaluation and dosimetry.

A newer technology that is being used more frequently is real-time brachytherapy with intraoperative dosimetry. Real-time brachytherapy uses ultrasound imaging, along with computerized treatment planning software. The intent is to visualize each needle/seed as it is implanted so that the AU can develop or modify the treatment plan at the same time that the needles/seeds are being implanted. With this advanced technique, if a seed is inadvertently placed incorrectly, the plan can be adapted to reposition other seeds so the radiation coverage is uniform. Because many weeks can pass between pretreatment planning and the actual implant procedure, real-time techniques also allow changes to be made to the treatment plan in response to changes in prostate shape. For example, if a patient receives hormonal treatment, the prostate size may change from the time the pre-treatment planning ultrasound is performed to the time the operating room ultrasound is performed. Effective use of this technique to

optimize the treatment plan can result in maximizing treatment to the affected tissue (e.g., prostate) while minimizing the radiation dose to other tissues (e.g., rectum, urethra).

## 2.3 DVA Prostate Implant Event Summary

### 2.3.1 February 2003 Event at PVAMC

In February 2002, PVAMC, a medical broad-scope facility specifically licensed by the NRC, established a new prostate implant brachytherapy program. From February 25, 2002, to February 2, 2003, PVAMC performed eight prostate implant brachytherapy procedures, and on February 3, 2003, it performed a ninth procedure. The written directive (WD) that the AU prepared for the ninth procedure called for the implantation of 74 iodine-125 seeds (0.38 mCi/seed) to deliver a 160 Gy dose to the treatment site. After the AU completed the implantation procedure, a cystoscopy indicated the presence of seeds in the bladder. As a result, the AU removed 40 seeds from the patient's bladder. The seeds were not re-implanted into the patient because they were no longer sterile and could have been damaged during the seed recovery process. The AU revised the WD to reflect the actual number of seeds that remained in the patient.

Following the implant procedure and over the course of the next few days there was some internal discussion between PVAMC and NHPP as to whether the procedure constituted a reportable medical event. On February 14, 2003, NHPP reported to the NRC (Event Number 39586) a "possible medical event."

On February 19, 2003, a senior health physicist from the NRC's Region I office performed a special inspection at PVAMC. On February 20, 2003, Region I initiated a discussion with the program office in NRC HQ, which, at the time, was the Office of Nuclear Material Safety and Safeguards (NMSS).[1] An email from the Region I inspector to the program office, dated February 20, 2003, indicated that the Region's initial impression "was that it was not a medical event for underdosing because the final written directive was revised prior to leaving the treatment room." Region I further indicated that "since the positioning was off in the first place, which led to the underdose of the treatment site and unintended dose to an area, we thought it would be better for discussion with the group." This group was the Part 35 Implementation Working Group, which met bi-weekly by teleconference at that time.

Following a review and discussion of the event by HQ and regional staff during the Part 35 Implementation Working Group teleconference, supporting information and documentation was given to the NRC's Office of the General Counsel (OGC). By e-mail dated June 3, 2003, OGC indicated that it had completed its review of the case and that the situation did not constitute a reportable medical event. On June 30, 2003, Region I issued IR 030-14526/2003-001, which documented the NRC's conclusion that the occurrence did not constitute a reportable medical event. No violations were identified.

### 2.3.2 October 2005 Event at PVAMC

On October 5, 2005, NHPP reported to the NRC a "possible medical event" at PVAMC involving a prostate implant brachytherapy procedure (Event Number 42038). At that time, DVA was an

[1] On October 1, 2006, following Commission approval of the proposed reorganization in SECY-06-0125, the NRC combined two technical divisions from NMSS, as well as the responsibilities of the Office of State and Tribal Programs, into a new office, FSME.

MML and PVAMC was one of its permittees. The report concerned a procedure performed on October 3, 2005, wherein the WD called for the implantation of 90 iodine-125 seeds (0.38 mCi/seed) to deliver a 160 Gy dose to the treatment area (prostate). After the AU completed the implantation procedure, a cystoscopy indicated the presence of seeds in the bladder. As a result, the AU removed 45 seeds from the patient's bladder. Because these seeds were no longer sterile and could have been damaged during the seed recovery process, in the interest of patient safety, they were not reimplanted. The AU revised the WD to reflect the actual number of seeds that remained in the patient.

On October 13, 2005, an inspector from NHPP conducted a reactive inspection at PVAMC. At the request of the DVA MML PM (Region III), a health physicist from Region I accompanied the NHPP inspector during the onsite portion of the inspection. NHPP concluded that the circumstances of the event were essentially the same as the circumstances of the February 3, 2003, event. Therefore, NHPP concluded that the October 5, 2005, event did not constitute a reportable medical event. NHPP's IR further noted that, based on a review of procedures from 2003 to the date of the inspection, the event appeared to be an isolated occurrence and not a programmatic issue. NHPP did not identify any violations.

NHPP retracted the event report on February 3, 2006, noting that, based on discussions with Region III, the circumstances for the event did not meet the definition of a medical event, as defined in 10 CFR 35.3045, "Report and Notification of a Medical Event." At the same time, NHPP also retracted the February 2003 event, citing the same reasons.

### 2.3.3 May 2008 Event at PVAMC and Other Subsequently Identified Events

On May 16, 2008, NHPP reported to the NRC a "possible medical event" at PVAMC involving a prostate implant brachytherapy procedure (Event Number 44219). The report concerned a procedure performed on May 5, 2008, wherein iodine-125 seeds of a lower activity than intended were implanted into a patient. This occurrence was discovered on May 15, 2008, when a post-plan evaluation found that the calculated dose to the patient's prostate was less than 80 percent of the prescribed dose.

On May 28–29, 2008, NHPP conducted a reactive inspection at PVAMC in response to the identified medical event. It found that the WD signed by the AU specified the use of iodine-125 seeds with an activity of 0.380 mCi/seed to deliver a prescribed dose of 160 Gy to the treatment area (prostate). However, the treatment plan upon which the WD was based specified the use of iodine-125 seeds with an activity of 0.509 mCi/seed. The order to the vendor for the seeds requested 0.380 mCi seeds. The discrepancy between the treatment plan seed activity and the actual activity of seeds ordered and implanted was not identified until after the seeds were implanted. The post-plan evaluation performed on May 15, 2008, indicated that the D90 was 47 percent of the prescribed dose of 160 Gy, thus meeting the selected criteria to be considered a medical event.

NHPP asked its permittee (PVAMC) to review additional prostate implant brachytherapy cases to determine whether the discrepancy between planned seed activity and actual implanted seed activity was an isolated incident or whether there were additional occurrences. On June 6, 2008, NHPP reported to the NRC several procedures that "may be medical events because the D90 doses, determined from post-implant CT scans, were more than 20% less than the prescribed doses." However, the reason for the lower doses could not be attributed to incorrect seed activity. This prompted PVAMC to review additional prostate implant brachytherapy procedures. On June 11, 2008, the PVAMC Director voluntarily suspended its

prostate brachytherapy program and commissioned an external review of the entire program, including a review of all procedures performed since its inception in February 2002, totaling 114 patients (116 implant procedures). This review indicated numerous instances of doses to treatment areas that were sufficiently less than the prescribed doses such that they were determined to be medical events in accordance with 10 CFR 35.3045. Additionally, several procedures resulted in an unintended dose to organs or tissues other than the treatment area. This led NHPP to make many additional reports of medical events to the NRC, ultimately resulting in reports of 97 medical events. The reasons for the 97 reported medical events were attributed to several causal factors. However, only the event reported to the NRC on May 16, 2008, could be attributed to the implantation of seeds with a different activity than intended.

The NRC initiated a special inspection, with inspectors from Region III performing onsite reviews at PVAMC on July 23–25, and September 9–12, 2008. On October 16, 2008, NHPP issued its IR to its permittee PVAMC, in which it identified four violations that it categorized as a Severity Level (SL) III problem. On March 30, 2009, the NRC issued IR 030-34325/2008-029, which identified six apparent violations. The NRC postponed any enforcement action pending further inspection activities. The NRC conducted additional onsite inspections at PVAMC on June 22–26, August 27–28, and October 14–16, 2009. On December 17, 2009, the NRC held a PEC with DVA representatives. On March 17, 2010, the NRC issued an enforcement action to DVA, including escalated enforcement that was assessed a civil penalty (total $227,500), as well as nonescalated enforcement that was not assessed a civil penalty.

### 2.3.4 Extent of Conditions at Other DVA Facilities

In addition to PVAMC, NHPP authorized 13 other DVA facilities to perform prostate implant brachytherapy procedures. Because of the number of reported medical events at PVAMC, the NRC was concerned about the prostate brachytherapy programs at the other DVA facilities. On October 14, 2008, the NRC issued a confirmatory action letter to DVA wherein DVA committed to conduct inspections of all active DVA prostate brachytherapy programs. NHPP was to complete these inspections no later than January 30, 2009. As a result of these inspections and reviews, pursuant to 10 CFR 35.3045, NHPP reported to the NRC several additional medical events involving prostate implant brachytherapy. Several different causal factors contributed to the events, and there was no singular root cause.

The NRC initiated an extent-of-condition inspection, to include onsite inspection activities at all 13 identified facilities, as well as at the NHPP program office. The NRC conducted an inspection at the NHPP program office on December 8–12, 2008, and inspections at the 13 facilities between October 8, 2008 and April 24, 2009. On May 24, 2010, the NRC issued IR 030-34325/2008-030, identifying three apparent violations that involved 11 DVA facilities. The IR also identified several concerns regarding programmatic issues and oversight by the NRSC and NHPP. The NRC held a PEC with DVA representatives on June 30, 2010. NRC's final enforcement action regarding the extent-of-condition inspection was issued to DVA on August 23, 2010.

## 2.4 Applicable Regulatory Requirements

A number of regulatory requirements apply to the medical events that NHPP reported. These include 10 CFR 35.40, "Written Directives"; 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive"; and 10 CFR 35.3045, "Report and Notification of a Medical Event."

### 2.4.1 10 CFR 35.40, "Written Directives"

The NRC added 10 CFR 35.40 to the regulations in April 2002 (67 *Federal Register* (FR) 20250; April 24, 2002[2]). Although the NRC removed the quality management program from the regulations in the April 2002 revision to 10 CFR Part 35, the requirement for WDs was one of the three elements of the quality management rule that was retained. The NRC made changes to the information that the WDs must include.

In the new regulation, 10 CFR 35.40(a) describes the types of procedures for which a WD is required; 10 CFR 35.40(b) specifies the content to be included in WDs for the various modalities; 10 CFR 35.40(c) describes when and how WDs may be revised; and 10 CFR 35.40(d) refers to the records retention requirements in 10 CFR 35.2040, "Records of Written Directives."

The main purpose for requiring a WD for certain procedures is to clearly communicate details regarding the intended procedure. Because a number of individuals are involved in these types of procedures, it is important that the details regarding the prescribed dose be documented and clearly communicated to all individuals involved with preparing or administering it.

In the April 2002 rulemaking, the NRC assigned 10 CFR 35.40(a) and (b) Compatibility Category Health and Safety (H&S), because it provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The Compatibility Category H&S identifies requirements that are not required for compatibility but have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements to maintain an adequate program. The NRC assigned 10 CFR 35.40(c) and (d) to Compatibility Category D, which is not required for purposes of compatibility.

### 2.4.2 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive"

The NRC added 10 CFR 35.41 to the regulations in April 2002 (67 FR 20250; April 24, 2002). The requirement for procedures for administrations requiring a WD was one of the three elements of the quality management rule that the NRC retained in the April 2002 rulemaking. As a result of this rulemaking, the NRC no longer required licensees to submit their procedures to NRC for review and approval, as the quality management rule previously mandated.

The regulations in 10 CFR 35.41(a) require, in part, that, for any administration requiring a WD, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration will be in accordance with the WD. The NRC's intent in requiring procedures to provide "high confidence" that the administration will be as directed by an AU is to avoid burdening licensees with an absolute requirement that this objective be met. The intent is not to imply that all medical events can be prevented. It provides licensees with flexibility to develop procedures that are appropriate for their programs.

The NRC included in 10 CFR 35.41(b) the minimum items that procedures must address to provide high confidence, as applicable to the licensee's use(s) of byproduct material. The level

[2] The regulation became effective on October 24, 2002, 6 months after publication on the final rule. When the final 10 CFR Part 35, "Medical Use of Byproduct Material," became effective, the Agreement States had up to 3 years to adopt compatible regulations.

of detail of this list is sufficiently broad to allow licensees flexibility in determining how these items can be met.

In 10 CFR 35.41(c), the NRC refers to the records retention requirements in 10 CFR 35.2041, "Records for Procedures for Administrations Requiring a Written Directive."

In the April 2002 rulemaking, the NRC assigned 10 CFR 35.41(a) Compatibility Category H&S. As noted above, Agreement States should adopt the essential objectives of such requirements to maintain an adequate program. The NRC assigned 10 CFR 35.41(b) and (c) Compatibility Category D, which is not required for purposes of compatibility.

### 2.4.3 10 CFR 35.3045, "Report and Notification of a Medical Event"

When the NRC revised 10 CFR 35.3045 in the April 2002 revision of 10 CFR Part 35 (67 FR 20250; April 24, 2002), it replaced the term "misadministration" with "medical event" because some believed "misadministration" had a negative connotation that implied negligence on the part of the physician or other medical staff. The NRC staff believed that "medical event" more simply conveyed that the byproduct material was not administered as directed by the AU. The NRC also made changes to have the reporting threshold based on dose, where possible.

Regulations in 10 CFR 35.3045 require, in part, that licensees report to the NRC events, other than those attributable to patient intervention, that are based on the differences between the information in the WDs and the actual administrations. As applicable to permanent implant prostate brachytherapy, the NRC's regulations detailed in 10 CFR 35.3045 require licensee reporting of any event resulting in a dose that differs from the prescribed dose by more than 0.05 sievert (Sv) effective dose equivalent, 0.5 Sv to an organ or tissue, or 0.5 Sv shallow dose equivalent to the skin; and the total dose delivered differs from the prescribed dose by 20 percent or more. For manual brachytherapy, 10 CFR 35.2 defines *prescribed dose* as either the total source strength and exposure time, or the total dose, as documented in the WD. Licensees must also report a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the WD (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

When a licensee identifies an event that meets the medical event criteria, in accordance with 10 CFR 35.3045(c), it shall notify the NRC Operations Center no later than the next calendar day after discovery of the medical event. According to 10 CFR 35.3045(d), the licensee shall submit a written report to the appropriate NRC regional office within 15 days of the discovery of the medical event. This section further specifies the content of the written report.

The NRC assigned 10 CFR 35.3045 Compatibility Category C, which means Agreement States should adopt the essential objectives of the requirement to avoid conflicts, duplications, or gaps. The manner in which the Agreement State addresses the essential objectives does not need to be the same as that of the NRC, provided the essential objectives are met.

If an Agreement State is notified of the occurrence of a medical event at one of its licensed facilities, the Agreement State must, in turn, report the occurrence to the NRC. As a general rule, Agreement States must report events to the NRC in the same timeframe that licensees must report to the Agreement State. The Agreement State should also provide updates regarding the occurrence to the NRC Operations Center in order for those updates to be included in the Nuclear Materials Events Database.

## 3. NRC INSPECTION PROGRAM

The NRC asked the VATG to assess the adequacy of NRC policies, procedures, and inspection guidance related to: (1) detecting the conditions or issues that led to the medical events, (2) evaluating and responding to this type of medical event, and (3) mitigating subsequent events and determining the extent of conditions, once the initial event is identified.

The VATG determined that NRC policies, procedures, and inspection guidance varied somewhat over the time period. Accordingly, the NRC's ability to detect the conditions or issues that led to the medical events varied over time. Likewise, the NRC's ability to evaluate and respond to these types of medical events, mitigate them, and determine the extent of conditions also varied over the time period. The sections below discuss the various time periods and the NRC policies, procedures, and inspection guidance in effect during those periods.

### 3.1 Before the February 2003 Event at PVAMC

#### 3.1.1 Discussion

An inspector from Region I conducted a routine inspection of licensed activities at PVAMC on July 31, August 1, and August 3, 2001. On August 7, 2001, the NRC issued IR 030-14526/2001-001. No violations were identified. The inspection record indicated that PVAMC planned to begin iodine-125 prostate implant brachytherapy procedures in January 2002.

At the time of the NRC's 2001 inspection, the December 30, 1999, version of NRC IMC 2800, "Materials Inspection Program," was in effect. IMC 2800 noted that inspectors should evaluate whether licensed activities had significantly expanded since the last inspection. At the time of the NRC's 2001 inspection, licensed activities at PVAMC had not significantly expanded, but the licensee anticipated beginning a prostate implant brachytherapy program in the near future. Beginning such a program would increase the types, quantities, and uses of licensed materials and possibly increase the number of AUs. IMC 2800 further noted that the inspector should document the changes and notify his or her immediate supervisor. The inspector followed the inspection guidance by documenting the anticipated change in the inspection record, which the inspector's immediate supervisor reviewed and approved.

The annotation in the inspection record would have provided the supervisor with an opportunity to determine whether additional inspection activities were warranted when the brachytherapy program began. However, it is unlikely that additional inspection activities were deemed necessary because, at the time of the 2001 inspection, PVAMC was an NRC "medical institution broad" licensee (Program Code 02110) and the version of IMC 2800 in effect at that time indicated that the inspection was Priority 1, meaning a 1-year inspection frequency, with a 25 percent window around the inspection due date. As a result, the next inspection due date for PVAMC was set for July 2002. An inspection performed around July 2002 would likely have provided an opportunity to inspect the prostate implant brachytherapy program while it was still in its beginning stages, review applicable procedures, and interview AUs and other relevant staff.

However, the NRC did not conduct the next routine inspection of PVAMC in July 2002, because in April 2002, it issued Temporary Instruction (TI) 2800/033, "Revised Materials Inspection Program," to test proposed revisions to IMC 2800. One of the revisions was to change the

"medical institution broad" licensee (Program Code 02110) from Priority 1 to Priority 2. As a result, the next inspection due date for PVAMC was changed from July 2002 to July 2003. As described in Section 2.3.1 above, in February 2003, PVAMC reported to the NRC a prostate implant brachytherapy event. Therefore, the NRC did not inspect PVAMC between the initiation of the prostate implant brachytherapy program and the February 2003 event.

It is indeterminate as to when PVAMC began developing protocols and procedures related to the prostate implant brachytherapy program. A medical institution broad licensee is, by the nature of its license type, granted significant decisionmaking authority. As such, its Radiation Safety Committee (RSC), and not the NRC, would have had the responsibility of reviewing and approving new AUs, procedures, and protocols. For this type of licensee, an NRC inspector would have reasonably been expected to review the RSC's oversight and its effectiveness, rather than review individual procedures and protocols. NRC inspectors typically review individual procedures and protocols when there is a suspected violation, problem, or deficiency.

The VATG concluded that it was unlikely that the NRC's 2001 inspection could have detected the conditions or issues that led to the medical events because: (1) licensees of broad scope are granted significant decisionmaking authority regarding the development and implementation of their programs, and (2) the prostate implant brachytherapy program had not yet been initiated at the time of the NRC inspection. However, this does not imply that NRC procedures and inspection guidance were inadequate to detect the conditions or issues that led to the medical event(s). The fact that the inspector identified that the brachytherapy program would begin in January 2002 and documented it in the inspection record, which the immediate supervisor reviewed, demonstrates the effectiveness of the inspection procedures (IPs) and guidance at that time.

On the other hand, a change in NRC policy for inspection frequencies pushed the next routine inspection due date out an additional year. Of the eight prostate implant brachytherapy procedures performed before the February 3, 2003, procedure (which PVAMC reported as a possible medical event), NHPP eventually reported all eight as medical events. The dates of these procedures were February 2002 (one procedure), July 2002 (one procedure), September 2002 (two procedures), October 2002 (two procedures), and November 2002 (two procedures). This data is based on PVAMC's spreadsheet entitled "Revised Prostate Brachytherapy Information for PVAMC," dated October 19, 2009. Had the next inspection due date been left at July 2002, and considering that there is a 25-percent window before and after the inspection due date, there may have been several or at least a few procedures to review during the originally scheduled inspection. An NRC inspector would likely have spent additional time reviewing the prostate brachytherapy program, considering that it was a newly authorized activity. Had the NRC reviewed the brachytherapy program during an inspection through a review of procedures, protocols, WDs, and post-treatment dose verification plans, it is possible that the medical events themselves or the conditions or issues that led to their occurrence could have been detected.

### 3.1.2 Recommendations

The VATG made the following recommendation:

- Future revisions to inspection priority codes in IMC 2800 should be carefully implemented, especially when inspection priorities are being extended (e.g., Priority 1 changing to Priority 2). Instead of making changes across the board for a program code, the regional offices should review each potentially affected licensee on a case-by-case

basis to determine the appropriateness of implementing the change immediately. There may be some cases that warrant delaying implementation, such as the case of significantly expanded licensee programs.

## 3.2 During the February 2003 Event

### 3.2.1 Discussion

As noted earlier, on February 14, 2003, NHPP reported to the NRC (Event Number 39586) a "possible medical event" involving a prostate implant brachytherapy procedure. Because PVAMC identified the possible medical event, there was no opportunity for the NRC to detect it. Accordingly, this section addresses the adequacy of NRC policies, procedures, and inspection guidance related to evaluating and responding to this type of medical event, as well as mitigating subsequent events and determining the extent of conditions.

On February 19, 2003, a senior health physicist from the NRC's Region I office conducted a special inspection at PVAMC. At that time, the NRC specifically licensed PVAMC, and TI 2800/033, Revision 2, issued December 31, 2002, was in effect. This revision of TI 2800/033 included 12 new NRC IPs for various types of materials licensees. TI 2800/033, Revision 2, Section 04.02, "Reactive Inspections," noted that inspections involving medical events should be conducted using the guidance in Management Directive (MD) 8.10, "NRC Medical Event Assessment Program," dated July 6, 1994. The NRC last revised MD 8.10 in 1994, and therefore the MD uses terminology such as "misadministration." At the time of the February 2003 event, the NRC had replaced the term "misadministration" with the term "medical event," concurrent with the revision of 10 CFR Part 35. The PVAMC event report indicated that the report was made pursuant to 10 CFR 35.3045(a)(3) regarding a dose to the skin or an organ or tissue other than the treatment site. The guidance in MD 8.10 for activating an inspection gives the response time for "overexposure" and "underexposure" of the patient as 5 and 10 working days, respectively. It does not address a timeframe for response to an unintended dose to other than the treatment site. Region I responded within 3 working days of the licensee report.

PVAMC identified a "possible" medical event, which indicated some degree of uncertainty as to whether or not a medical event occurred. There is no specific NRC IP for the performance of special inspections related to medical events. As described above, IMC 2800 notes that the NRC will conduct inspections involving medical events using the guidance in MD 8.10. MD 8.10 states that the NRC will assess all medical "misadministrations" in accordance with the MD. The stated objective of the Medical Event Assessment Program described in MD 8.10 is to conduct a timely, thorough, systematic, and formal assessment of medical events. MD 8.10 is written to evaluate actual medical events, not "possible" medical events, and therefore does not provide inspection guidance to determine whether or not a medical event occurred.

On February 20, 2003, the day after the NRC's onsite inspection, Region I initiated a discussion with NMSS regarding the situation and its reportability as a medical event. To try to determine exactly what question Region I presented to NMSS and ultimately forwarded to OGC, the VATG reviewed the minutes for the Medical Projects Working Group/Part 35 Teleconferences; interviewed NRC managers and staff who participated in the discussion; and reviewed other associated documentation, including e-mails provided by interviewees or available in the NRC's Agencywide Document Access and Management System (ADAMS). The OGC attorney informed the VATG that the question concerned the revision of the WD and whether it constituted a medical event.

The possibility of a medical event resulting from an unintended dose to the bladder was dismissed by the NRC staff based on the conclusion that the seeds were not in the bladder long enough to deliver a dose that exceeded the medical event criteria. This left the possibility of a medical event resulting from either an underdose to the prostate or unintended dose to other tissues from remaining implanted seeds. The AU had revised the WD in the operating room to reflect the actual number of seeds implanted and not removed. The NRC staff appears to have focused on whether there was a medical event resulting from an underdose to the prostate, based on whether the regulations would allow the AU to revise the written directive. Some staff believed that the AU had rewritten the WD "to avoid having to report an error." There was also discussion as to when the procedure was considered to be completed. The NRC staff failed to consider whether a medical event may have resulted from a dose to unintended tissue from the remaining misplaced seeds. In the end, this was the reason that this administration was considered a medical event.

OGC expended considerable time and effort to review the situation and come to a decision regarding the question it believed was asked, with many individuals offering different perspectives. The staff provided OGC with extensive documentation regarding other historical cases involving similar circumstances. An e-mail dated June 3, 2003, sent from OGC to an NMSS staff member, stated, "We have completed the review of the cases you provided to me. We believe that the current situation (described as Pending Item 35 in the Part 35 Biweekly Teleconference Meeting Minutes) did not constitute a reportable medical event." On June 11, 2003, the NMSS staff met with OGC to discuss OGC's position on the matter. Following the meeting, on June 13, 2003, NMSS communicated OGC's position to Region I. On June 30, 2003, the NRC issued its IR to PVAMC, wherein it informed the licensee that the occurrence did not constitute a reportable medical event. By this time, PVAMC was no longer specifically licensed by the NRC but rather was a permittee of the DVA MML.

The VATG determined that the information Region I provided to NMSS, which was then forwarded to OGC, was not fully developed. Specifically, Region I sent the case to NMSS for evaluation before PVAMC's evaluation of the actual dose to the prostate and other tissues. The final dose evaluation would be paramount to determining whether or not a medical event occurred. Pursuant to 10 CFR 35.3045(d), on February 25, 2003, PVAMC gave NHPP its 15-day report. NHPP sent this report to Region I by a letter dated February 27, 2003. As noted on the Region I form, "NMSS Licensee Event Report," Region I sent the NHPP report to OGC on February 28, 2003. Region I recalled that they also provided the NHPP report to NMSS although this was not documented on the Region I form. The NMSS staff would have been in a better position than OGC to evaluate the technical content of the report. The report indicates that the actual dose from the 34 iodine-125 seeds implanted into the patient and not removed from the bladder was 75 Gy to 10 percent of the prostate (D10 = 75 Gy). Region I should have reviewed this report and questioned this data and the location of the implanted seeds. Likewise, although it is indeterminate as to whether NMSS actually received the 15-day report, it does not appear that NMSS ever asked where the implanted seeds were located. Based on the inspection, the Region believed that "the positioning was off" but did not pursue this issue to determine the location of the implanted seeds and the resultant dose to the prostate and other organs or tissues.

The background information given to OGC stated "the AU documented the number of seeds and activity actually implanted into the prostate." However, this is not accurate. The AU documented the number of seeds implanted (into the patient) and not removed. The number of seeds actually implanted into the prostate (or the treatment area) was likely a different number

than the number of seeds implanted into the patient given that "the positioning was off." The number of seeds implanted into the prostate would have been determined by imaging technology and not just by manual insertion by the AU according to a set of coordinates. As described earlier in this report, this type of determination is usually made several days after implantation, when edema has subsided. Therefore, revision of the WD for number of seeds implanted and ascertaining the dose expected to be delivered to the treatment area by the lower number of implanted seeds was not the issue since NRC's regulations allowed the AU to revise the WD. But rather, the underlying issue was in determining the dose to unintended tissue from the remaining implanted seeds. Given that so many seeds were known to have been implanted in an unintended site (i.e., the bladder), NRC staff should have inferred that some of the remaining seeds may have been incorrectly implanted in other tissue outside of the prostate besides the bladder. The regional and NMSS staffs' focus on the AU's revision of the WD and possible resultant underdose to the prostate appears to have distracted them from the underlying issue of dose to unintended tissue from the remaining implanted seeds. The NRC staff failed to ask further questions of the licensee regarding this procedure, including questions about post-treatment verification to determine the placement of the remaining seeds and potential dose to unintended organs or tissues.

On June 30, 2003, Region I issued IR 030-14526/2003-001, which documented the NRC's conclusion that the occurrence did not constitute a reportable medical event and that no violations were identified. The IR further documented that the licensee's implementation of their written directive procedures specific to prostate implant brachytherapy was adequate and met the requirements of 10 CFR 35.41. The IR also documented that "a root cause analysis was initiated" by PVAMC. Yet PVAMC had already performed this root cause analysis and completed it on June 5, 2003. In fact, because of the low quality of the implant procedure, the AU elected to re-implant the patient. The patient was re-treated on March 31, 2003, and additional seeds were implanted. This was done before the NRC made a final decision in the case or issued an IR. It would have been valuable for the NRC to have followed up on the re-implantation. This would have taken no additional time, given that OGC was still reviewing the original issue. It would also have been an opportunity to review the licensee's corrective actions and assess whether they were effective in preventing a recurrence.

All eight of the prostate brachytherapy procedures performed prior to the February 2003 event have since been reported by NHPP as medical events. The VATG asked if the NRC inspector who conducted the inspection reviewed any of these eight prior cases or just the one subject case. The inspector recollected that the previous eight cases were reviewed during the inspection although this is not documented in the IR. The DVA Office of the Inspector General's report, "Healthcare Inspection Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania and Other VA Medical Centers," dated May 3, 2010, stated that, of the eight prior procedures, seeds were removed from the bladder in three cases. Given that there were previous potentially similar cases, a review of these prior cases could have revealed a pattern of problems, leading to additional questioning of the licensee.

As indicated above, IMC 2800 notes that the NRC will conduct inspections involving medical events using the guidance in MD 8.10. In defense of the inspection staff, MD 8.10 does not specifically provide guidance on conducting a review of prior procedures. It treats medical events as isolated occurrences. Therefore, the MD does not provide any guidance regarding determining the extent of conditions or reviewing potential programmatic issues. The VATG interviewed several NRC inspectors and asked how they conduct reactive inspections at medical facilities. Several inspectors noted that, despite no explicit guidance to do so, they always review prior cases to determine if the event is isolated or programmatic. Through these

actions, they can determine the extent of conditions. During interviews, several inspectors noted that their management expected them to ascertain whether reported events were isolated or programmatic, which therefore requires a review of prior procedures. NRC inspectors offered that, if the number of prior procedures was large, they would look at a sample; but if there were only a few procedures, they would review all of them.

### 3.2.2 Recommendations

The VATG made the following recommendations:

- The NRC should revise the guidance in MD 8.10 as follows:
  - The language in the MD should closely mirror the current definitions and regulations in 10 CFR Part 35, addressing both over- and under-exposures, as well as unintended doses to the skin or other organs or tissues. When the NRC revises the 10 CFR Part 35 regulations, especially those that relate to the reporting criteria for medical events, it should review MD 8.10 to determine if any changes are necessary.
  - The NRC should revise the MD to discuss the determination of the extent of conditions and whether reported medical events are isolated or programmatic. The MD should also provide further guidance regarding the assessment of multiple medical events and how to evaluate potential medical events.

## 3.3 <u>During the August 2003 NRC Inspection</u>

### 3.3.1 Discussion

The NRC issued the DVA MML on March 17, 2003. In a letter dated May 9, 2003, Region III requested that the other regional offices assist in inspections of the MML permittees. PVAMC was one of the DVA permittees that Region III asked Region I to inspect independently, no later than August 15, 2003, to coincide with the first period of the NRC's increased oversight of DVA. A Region I inspector conducted a routine, unannounced inspection of PVAMC on August 6, 2003. The inspection therefore occurred only a few weeks after the NRC had issued its June 30, 2003, IR for the February 2003 reactive inspection.

At the time of the August 6, 2003, NRC inspection, the method to document inspection findings had changed with the revision of IMC 2800. Before this revision, inspectors would document their inspection observations, findings, and general information about the licensee's program scope and activities in an "inspection record." The inspection records allowed inspectors to capture and document detailed information about program activities. The inspection record for the August 2001 routine inspection of PVAMC was approximately 14 pages. In contrast, after the revision of IMC 2800, inspectors were to document their inspection observations on a one-page form that, at the time, was called "NRC Form 591X Part 3." The top part of the form contained information about the licensee, such as address, docket number, and program code. This left about half a page for inspectors to document inspections. If an NRC "Form 591" is not used, inspection results are documented on a different form or in a narrative report. The August 6, 2003, inspection at PVAMC did not result in any violations and therefore was documented on a Form 591, resulting in limited information. With regard to the brachytherapy program, the inspector documented in the Form 591 that, "The current brachytherapy program consists of iodine-125 prostate seed implants. They performed less than one procedure per

month last year. Unused seeds are either decayed in storage or returned to the manufacturer." This level of documentation would be consistent with NRC management expectations at that time.

Another consideration is that, concurrent with the revision of IMC 2800 and the materials IPs, the NRC was moving away from compliance-based inspections and was implementing performance-based inspections. These changes meant that inspectors were to observe or inquire about licensed activities, and if no deficiencies were noted, further review of licensee documentation or procedures was not necessary.

When interviewed, the NRC inspector could not recollect many details of the inspection. The inspector noted that it was doubtful that the prostate brachytherapy issues were explored beyond what was written in the 591X Part 3, given that the February 2003 inspection resulted in no violations. Therefore, the inspector felt that there would have been no specific issues for followup in this area.

Considering the changes that had been made to the NRC's inspection program and the lack of followup items from the previous inspection, the VATG concluded that it is unlikely that the inspection could have detected the issues that led to the additional medical events or mitigated the subsequent events.

### 3.3.2 Recommendations

None.

## 3.4 During the October 2005 Event

### 3.4.1 Discussion

As described in Section 2.3.2 above, on October 5, 2005, NHPP reported to the NRC a "possible medical event" at PVAMC involving a prostate implant brachytherapy procedure (Event Number 42038). On October 13, 2005, an inspector from NHPP conducted a reactive inspection at PVAMC. At the request of the DVA MML PM (Region III), an NRC Region I inspector accompanied the NHPP inspector during the onsite portion of the inspection. Although the NRC did not conduct the inspection, this discussion is included in this section for continuity with the timeline.

The accompanying NRC inspector's role was to observe the NHPP inspector's performance during the conduct of the reactive inspection and provide feedback to the DVA MML PM. The NRC inspector informed the VATG that there were no major deficiencies associated with the NHPP inspector's performance and that the NHPP inspector appeared to meet the minimum standards expected of qualified inspectors. The NRC inspector did note, however, that the NHPP inspector did not appear to be very familiar with prostate brachytherapy procedures and that the accompanying NRC inspector provided the NHPP inspector with some pertinent technical information. For example, according to the NRC inspector, the NHPP inspector did not understand the ramification of using stranded seeds (multiple iodine-125 seeds in one ribbon or "strand") and that, when using certain types of stranded seeds, if a seed was seen protruding into the bladder during cystoscopy, removing the one seed would result in removing the entire strand of seeds.

The VATG reviewed NHPP's site visit report for the October 13, 2005, reactive inspection. The report noted that the circumstances of the event were "essentially the same as the circumstances of the previous event of February 3, 2003." NHPP's report further noted that, because the NRC had concluded that the February 2003 event did not constitute a reportable medical event, the October 2005 occurrence was not a reportable medical event. The documents reviewed by the NHPP inspector during the inspection included PVAMC RSC minutes, records of seed inventories, the WD, procedures pursuant to 10 CFR 35.41, records of patient releases, and records of post-implantation surveys of the operating room. It does not appear that the NHPP inspector reviewed the permittee's 15-day report, which was submitted in accordance with 10 CFR 35.3045(d), although the permittee sent this report, dated October 18, 2005, to the NHPP inspector. NHPP also forwarded this report to the DVA MML PM. This report provided the post-implant dose determination information and noted that the "event may meet the regulatory criteria of a medical event."

The 15-day report stated that 45 seeds were recovered from the bladder in the operating room and that the WD was revised before the procedure was completed to accurately reflect the actual number of seeds implanted into the patient. Before the revision, the prescribed dose to the prostate was 160 Gy, to be delivered by 90 seeds. As documented in the 15-day report, the dosimetry revealed that the D90 to the prostate was 47.14 Gy. The report further stated, "The dose reduction to the prostate was more than 20% lower than expected from the 50% reduction in the number of seeds implanted." It does not appear that the NHPP inspector questioned this information. As in the February 2003 event, even though the WD was revised, the remainder of the seeds implanted into the patient was not sufficiently located in the treatment area, leading to unintended doses to other organs or tissues. The DVA MML PM, who was copied on the 15-day report, did not question NHPP's conclusions.

In the February 2003 event, the NRC did not fully develop the inspection information and the NMSS program office did not sufficiently question the data obtained or solicit additional information. The same thing essentially happened during the October 2005 event, but in this case, the NHPP did not fully develop the inspection information and the NHPP program office did not sufficiently question the data obtained or solicit additional information.

Section 04.01 of IMC 2810 indicates that the lead region is responsible for the review of MML incident or event notification reports. The DVA MML PM had NHPP's event report, NHPP's IR, and the NHPP's 15-day report but did not determine that NHPP's conclusions in the case were not well founded. A second opportunity for the NRC to review NHPP's conclusions occurred during the biennial inspection, conducted on April 16–20, 2007. Section 6.3.3 below discusses the biennial inspection.

### 3.4.2 Recommendations

None.

## 3.5 After the October 2005 Event

### 3.5.1 Discussion

NHPP reported the event at PVAMC involving the use of seeds with the wrong activity to the NRC on May 16, 2008, as described in Section 2.3.3. The NRC had not independently inspected the PVAMC facility since August 2003. The most recent previous NHPP inspections of PVAMC occurred on January 26, 2006, and January 23–24, 2008. PVAMC identified the

May 2008 event involving the wrong seed activity and reported it to NHPP, which conducted a reactive inspection. NHPP's inspection determined that the medical event involving the wrong seed activity was an isolated occurrence. Although NHPP's inspection found no additional cases of wrong activity seeds, it found numerous other medical events related to misplaced seeds causing underdoses to the prostate or unintended doses to other tissues. It was the singular wrong seed activity event that caused NHPP to initiate a more thorough review to determine the extent of conditions, leading to the NHPP's identification of the other unrelated medical events. The VATG believes that had it not been for the singular event involving the wrong seed activity, the remaining unrelated medical events might not have been otherwise detected by NHPP or NRC during a routine inspection.

NHPP's reactive inspection at PVAMC occurred on May 28–29 and June 24–25, 2008. On June 11, 2008, the PVAMC director voluntarily suspended the prostate brachytherapy program. On July 17, 2008, PVAMC established an Administrative Board of Inquiry to review the facts and circumstances of the medical events. During the time from the initial event notification in May 2008 through July 2008, NHPP's review of the PVAMC prostate brachytherapy cases revealed numerous additional medical events. NHPP reported these events to the NRC. Region III inspectors conducted a reactive inspection on July 23–25, 2008. By that time, NHPP had reported 39 medical events at PVAMC.

On August 22, 2008, the Director, Division of Nuclear Materials Safety (DNMS), Region III, chartered a team to conduct a special inspection. By that time, NHPP had reported to the NRC 55 medical events at PVAMC. The special inspection team (SIT) consisted of the DVA MML PM and two senior health physicists. The charter described the areas to be reviewed and indicated that the special inspection would begin the week of September 8, 2008. Members of the SIT conducted inspection activities at PVAMC on September 9–12, 2008. On October 14, 2008, the NRC issued a confirmatory action letter to DVA wherein NHPP agreed to take certain actions, including, but not limited to: (1) conducting inspections of DVA's active prostate brachytherapy programs, (2) developing and implementing standardized procedures for conducting prostate brachytherapy procedures, (3) identifying the root causes and corrective actions that had been implemented or were planned for implementation, and (4) taking certain actions to determine whether prostate brachytherapy programs would be suspended and, if so, how they would be restarted. Additionally, the NRC retained the services of a medical consultant to evaluate some of the reported medical events.

On October 16, 2008, NHPP issued an IR to its permittee, PVAMC, which identified four violations which NHPP characterized as a SL III problem. The violations involved the failure to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the WD, (2) have adequate written procedures to address the verification of the administration, (3) document the required information on the WD, and (4) make reports of the medical events, as appropriate.

The SIT's IR 030-34325/2008-029, dated March 30, 2009, identified six apparent violations, involving the failure to: (1) develop adequate written procedures to provide high confidence that the administrations were in accordance with the WD, (2) develop procedures that address methods for verifying that administrations are in accordance with the WD and treatment plan, (3) train supervised individuals regarding medical events, (4) train nonsupervised individuals regarding medical events, (5) record information on the WD, and (6) provide the required information in 15-day reports. In addition to the apparent violations, the NRC identified several concerns regarding adequate management oversight by the PVAMC Radiation Safety Officer

and RSC and an overall lack of safety culture. The NRC scheduled a PEC with NHPP for April 29, 2009, to discuss the apparent violations.

By letter dated April 20, 2009, the NRC postponed the PEC to review additional information and conduct additional inspection activities, which occurred at PVAMC on June 22–26, 2009, August 27–28, 2009, and October 14–16, 2009. The August inspection also included NRC's medical consultant and a staff member from the NRC HQ FSME medical team.

On November 17, 2009, the SIT issued its supplemental IR 030-34325/2009-001. The IR reiterated the six apparent violations identified in the March 30, 2009, IR. One of the previously identified apparent violations was recharacterized as two separate apparent violations. The IR also identified one additional apparent violation involving notification requirements. The report reiterated the NRC's concerns regarding adequate management oversight and overall lack of safety culture. The NRC held a PEC with DVA representatives on December 17, 2009.

By letter dated January 28, 2010, DVA proposed to retract 80 of the 97 reported medical events. Both the February 2003 and October 2005 events were among the 17 medical events that DVA did not ask to retract and therefore continued to assert were medical events. DVA proposed to retract the 80 events based on the results and recommendations of a blue ribbon panel of external experts commissioned by DVA. The reasons for retraction largely related to a difference in interpretation of the regulations and the use of medical event criteria that used total source strength implanted in the treatment site instead of absorbed dose. The NRC reviewed this information before it issued any enforcement action. The NRC concluded that the medical event criteria proposed by DVA did not conform to the NRC's regulatory criteria and rejected DVA's proposal to retract the medical events. The NRC issued a Notice of Violation to DVA on March 17, 2010, which included SL II and SL III violations assessed a civil penalty of $227,500.

Concurrent with the above inspection activities, which focused on activities at PVAMC, the NRC also conducted inspection activities at the NHPP program office and at 13 DVA permittee facilities that had prostate brachytherapy programs. Inspections at the 13 facilities occurred between October 8, 2008, and April 24, 2009, and the inspection of the NHPP program office took place on December 8–12, 2008. On May 24, 2010, the NRC issued IR 030-34325/2008-030, identifying three apparent violations that involved 11 DVA facilities. The IR also identified several concerns regarding programmatic issues and oversight by the NRSC and NHPP. The NRC held a PEC with DVA representatives on June 30, 2010. NRC's final enforcement action for this extent-of-condition inspection was issued to DVA on August 23, 2010.

Like PVAMC, the NRC and NHPP had previously inspected each of these 13 DVA facilities. However, those previous inspections did not identify problems with the brachytherapy programs. It was beyond the scope of the VATG's charter to review NRC's activities at each of these facilities and consider the adequacy of NRC policies, procedures, and inspection guidance in each of those cases.

### 3.5.2 Recommendations

None.

## 3.6 Guidance Regarding Written Directives and Medical Events

### 3.6.1 Discussion

With any regulation, especially those that are more complex, there is a need for guidance. Many groups of individuals need this guidance, including applicants for licenses, licensees, and NRC license reviewers and inspectors.

Guidance for license applicants appears in the NUREG-1556 series of guidance documents, "Consolidated Guidance About Materials Licenses." NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses," Revision 2, dated January 31, 2008, contains information that is intended to assist those preparing applications for licenses for the medical use of byproduct material. The NUREG-1556 series of documents, including Volume 9, reflect the risk-informed, performance-based approach by reducing the amount of information an applicant is required to submit. In general, the regulations do not require license applicants to submit detailed procedures to the NRC but instead to confirm that they have developed and will implement and maintain the required procedures. This approach is intended to be less prescriptive and to allow implementation by licensees that will be specific to their needs while meeting the regulatory requirements. NUREG-1556, Volume 9, Revision 2, also includes appendices that provide additional general guidance and examples of model procedures for applicants and licensees. The model procedures provide acceptable means to demonstrate compliance with the requirements. The NRC does not intend for these to be the only acceptable methods to comply but rather examples of acceptable methods.

Appendix S to NUREG-1556, Volume 9, contains model procedures for developing, maintaining, and implementing WDs. The model procedure notes that it does not restrict the use of other guidance by licensees in developing, maintaining, and implementing WDs. One example provided in Appendix S is that, after insertion of the brachytherapy sources, an AU should "promptly record the actual number of sources implanted and the total source strength." Regarding licensee reviews of administrations requiring a WD, Appendix S guidance recommends conducting them periodically, looking at a sample of patient cases, and if possible, ensuring that the persons conducting them do not review their own work. Regarding medical events, Appendix S merely reiterates the regulatory requirement with no additional guidance. The guidance and model procedures do not provide any acceptable methods or examples of how to evaluate or determine whether a medical event has occurred or what criteria are acceptable to the NRC in making such a determination.

When OGC rendered its opinion on the February 2003 event, the staff accepted OGC's position but many believed that the rule itself was "flawed." In a June 13, 2003, e-mail from the program office to Region I, a member of the FSME medical team noted that, based on the current rule, the associated statements of consideration, and precedent decisions, the act of the AU revising the WD is consistent with the rule but that the "rule is flawed to permit such a maneuver" and that the NRC should consider revising the rule. Region I agreed with this assessment and stated that they did not challenge OGC's position because Region I agreed that rulemaking was necessary to address the "flaw" in the regulation. The staff discussed the cost-effectiveness of seeking corrective rulemaking, based on the "current probable frequency of such occurrences," and noted that there was an opportunity for possible input by the NRC Advisory Committee on the Medical Use of Isotopes (ACMUI) to the draft rule language.

On December 27, 2005, the NRC staff sent SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public," to the Commission with recommendations for revising the criteria for medical events. This document identifies the 2003 and 2005 prostate brachytherapy events at PVAMC and the 21 prostate brachytherapy medical events at Guthrie Healthcare System as reasons to revise the regulation.

The Commission directed the staff to develop a proposed rule to modify the WD requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy. The NRC published the proposed rule on August 6, 2008 (73 FR 45635). When NRC staff reviewed the medical events at PVAMC and compared them to the proposed rule, the staff believed that, if the proposed changes to the regulations were allowed to proceed, many of the 97 reported medical events would not be reportable under the proposed criteria. At the staff's request, the Commission granted it more time to complete the rulemaking, and the staff later provided a revised proposed rule to the Commission. Following a July 8, 2010, briefing of the Commission on the new proposed rule, the Commission voted to disapprove its publication. As a result, until the staff develops another proposed rulemaking, the current regulations remain in effect.

The VATG acknowledges that parts of the existing regulations could benefit from clarification or revision. The VATG believes that, with additional guidance to licensees and the staff (including inspectors and license reviewers), the existing rule could be implemented effectively. There has been a great reluctance to provide guidance to the NRC staff and licensees, because many believe that such guidance would infringe on or impede the practice of medicine. In addition, several interviewees expressed the opinion that the NRC staff does not possess the technical expertise to develop such guidance.

Due to of the lack of guidance, the Regions have submitted several technical assistance requests (TARs) to FSME seeking resolution of a specific situation related to a specific licensee. FSME responds to these TARs; however, it intends the results to be applied to the specific case that was the subject of the TAR and not used as generic inspection guidance. The VATG observed that some regional staff members have used TAR responses (i.e. Guthrie Healthcare System, described below) as generic inspection guidance related to prostate brachytherapy. One regional manager acknowledged to the VATG that the regional office was using a recently submitted TAR regarding prostate brachytherapy to "establish precedent" in the absence of inspection guidance.

The VATG noted that having multiple medical events involving prostate brachytherapy was not unique to DVA. For example, in the June 2003 case at Guthrie Healthcare System, the licensee reported 21 medical events involving prostate brachytherapy. The case involved the licensee making one report of a medical event in June 2003. The licensee identified this medical event nearly 2 years after it performed the procedure. The NRC conducted a reactive inspection that subsequently led to the licensee's identification of 20 additional medical events. The NRC chartered two medical consultants to review the cases. One consultant reviewed only one case and the other reviewed the remainder. The NRC asked the second consultant to expand the standard charter to "assess whether these events may signify a generic issue that affects other licensees." The VATG reviewed the consultant's report but found no evidence that it addressed this matter.

Because of the lack of NRC guidance in this area, Region I submitted a TAR in November 2003 to determine whether the use of V100 at Guthrie Healthcare System was appropriate to determine whether a medical event occurred. The TAR further inquired about the appropriate definition of a medical event for prostate brachytherapy, which involves a volumetric target and an array of implanted sources. The TAR response, dated January 24, 2004, indicated that an ACMUI member had noted, without dissent from other members, that the appropriate measure for determining whether a prostate brachytherapy medical event occurred was D90. The TAR response also noted that D90 was a more appropriate criterion than V100. Furthermore, the TAR response stated that, while D90 was a satisfactory criterion for "underdosing" (D90 less

than 80 percent of the prescribed dose), it might not be appropriate for "overdosing" (D90 greater than 120 percent of the prescribed dose). The TAR response also stated that the NRC staff would determine the appropriate criterion for "overdosing" in cooperation with ACMUI. It appears that this issue was never resolved. As a result, 6 years later, a TAR from Region III dated February 26, 2010, refers to the Guthrie Healthcare System TAR and again requests that the staff provide an appropriate criterion for "overdosing." The Region III TAR also requests a response for what constitutes completion of the brachytherapy procedure. FSME is still reviewing this TAR. An interesting aside is that the NRC inadvertently placed the original Guthrie Healthcare System TAR and HQ response into ADAMS as publicly available. The NHPP staff found these documents in ADAMS and used the information contained in them to establish the dose criteria (D90) that PVAMC used to evaluate the PVAMC prostate implant procedures. The documents are no longer publicly available in ADAMS.

The regulations in 10 CFR 35.40(b)(6) describe the required contents of a WD for all forms of brachytherapy, including permanent brachytherapy. The regulation requires that WDs for these types of brachytherapy include two sets of information, one for before implantation and one for after implantation. Before implantation, the WD must include the treatment site, the radionuclide, and the dose. The "before implantation" WD often identifies the treatment site as "prostate" but, in many cases, the AU actually intends to treat the prostate plus some margin around the prostate. If the WD says "prostate" and there are seeds observed just along the margin but outside the prostate on the post-treatment images, some might interpret this as being outside the treatment site and unintended, although this is actually what the AU intended. Therefore, the term "treatment site" is perhaps not as straightforward as one would expect.

After implantation but before completion of the procedure, the WD must include the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose). This "after implantation" WD is sometimes used as an opportunity to revise the WD. There may be circumstances where it is medically necessary for an AU to revise the WD. Many in the regulated community have stated that they need this flexibility to revise WDs, for example, to adjust for changes in prostate anatomy from the pre-treatment plan. However, in the 2003 and 2005 PVAMC cases, it appears that the AU revised the WD because seeds were inadvertently placed into the bladder and then removed. The AU revised the WDs after implantation but "before completion of the procedure," as allowed by the regulations. What constitutes "completion of the procedure"? Is the procedure completed in the operating room after the AU has implanted all of the seeds? Is it complete before cystoscopy or after cystoscopy? Is it complete only when the patient leaves the operating room? Is it complete when the patient is discharged from the facility? Is the procedure complete only after the final dosimetry calculations are performed, which is sometimes 30 days after the implantation procedure? Is the procedure complete only after all of the seeds decay to a negligible amount? What if only half of the seeds were implanted and the physician decides to reschedule the patient for another day to implant the other half? In this case, is the procedure complete after the second procedure is performed and all of the intended seeds are implanted? There currently is no formal guidance to licensees or the NRC staff as to what constitutes completion of the procedure, leaving this subject to varying interpretations.

The "after implantation" WD must document the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose). Total number of sources can be vague: does this mean the total number of sources implanted, or the total number implanted minus any that were removed? Likewise, is it the total number of sources implanted into the patient or the total number of sources implanted into the treatment site? In the 2003 and 2005 PVAMC cases, the AU documented the number of sources that remained in the patient after the

removal of sources from the bladder. This was the number implanted into the patient, as opposed to the number implanted into the treatment site, which would have been fewer. Regarding exposure time, in the case of permanent implant brachytherapy, the exposure time is implied, because it is permanent and therefore is, for all intents and purposes, infinity or until all of the implanted sources decay to a negligible activity level.

Some additional confusion occurs when revised "after implantation" WDs are used to determine whether a medical event occurred. Using the 2005 PVAMC event as an example, the "before implantation" WD called for the prostate to be treated with iodine-125 to yield a dose of 160 Gy. The pre-treatment plan determined that 90 seeds would be necessary to deliver the prescribed dose. After implantation but "before completion of the procedure," a cystoscopy was performed, revealing seeds in the bladder. The number of seeds removed was 45, leaving another 45 seeds "inside the patient" but not necessarily within the treatment site. What does the licensee then use to determine whether a medical event occurred? The WD was revised to reflect 45 seeds. Assuming that they are all in the treatment site, what dose would those seeds be expected to deliver? Obviously the dose would not be the prescribed 160 Gy, considering that only half of the seeds were implanted. Using conventional brachytherapy techniques, there is no reasonable method to determine what dose these seeds would be expected to deliver. Because the medical event criteria are based on dose and the licensee does not know the expected dose from the reduced number of seeds, it is nearly impossible to render a decision as to whether a medical event has occurred.

Many licensees interpret the medical event criteria to be a percentage difference in the number of seeds rather than a percentage difference in dose. In this case, the "after implantation" WD has the number of seeds implanted, and the licensee then compares this to the number of seeds observed in the treatment site on the post-implantation images. A revision of the WD after implantation, but before completion of the procedure, can lead to an apparent disconnect in the regulations, because there is no longer any valid dose value upon which to determine whether or not a medical event occurred. Some NRC staff members, as well as some licensees, believe that it is appropriate to compare the number of seeds and activity implanted. With regard to determining the endpoint, NRC regulations do not specify how licensees should make this determination. Likewise, there is no guidance to the licensees or the NRC staff on acceptable methods to comply. Licensees use various criteria for ascertaining dose. To assess dose to the prostate, these criteria include D90 (dose to 90 percent of the prostate volume), D80 (dose delivered to 80 percent of the prostate volume), and V100 (percent of prostate volume receiving at least 100 percent of the prescribed dose). Other methods and criteria are used to assess dose to nearby tissues and organs.

One Agreement State recently issued an information notice to its licensees regarding post-implant verification of permanent brachytherapy procedures. The information notice reminded its licensees of the need to perform dose-based reviews of all permanent brachytherapy procedures. It further stated that licensees should ensure that AUs and authorized medical physicists are trained on the medical event criteria and reporting requirements. It encouraged licensees to be aware of the recommendations of the American Association of Physicists in Medicine made in the Task Group 137 Report for post-implant verification of the dose to the prostate. This report suggests the use of D90 and V100 for the dosimetric evaluation when comparing the prescribed dose to the dose delivered to the prostate.

The VATG believes that any proposed changes to the regulations in this area will not be effective and that these situations will recur if the NRC does not provide useful guidance to its staff and licensees regarding implementation of the requirements. Any revisions to the

regulations in this area are likely many months away. In the meanwhile, the NRC staff cannot continue indefinitely to perform inspections in this area using TAR responses as inspection guidance. Likewise, the guidance in NUREG-1556, Volume 9, Appendix S, does not provide sufficient guidance for licensees regarding acceptable methods of compliance.

The lack of guidance for NRC and Agreement State licensees has clearly led to confusion regarding implementation of the requirements for WDs, procedures, and reports of medical events involving prostate brachytherapy. Because the NRC staff has little to no guidance in this area, it is likely that it is not performing appropriate evaluations during inspections or in response to reported medical events. It is the VATG's position that the use of TAR responses as inspection guidance has led to inconsistency among NRC regional inspection programs.

### 3.6.2 Recommendations

The VATG made the following recommendations:

- The NRC should make every effort to provide NRC licensees and inspectors with: definitions for relevant terms (e.g., treatment site, completion of procedure), guidance regarding complying with NRC's requirements related to written directives, and guidance regarding acceptable criteria for evaluating prostate brachytherapy medical events. The implementation guidance could be transmitted to licensees in an information notice or perhaps a regulatory issue summary. The inspection guidance could be transmitted to NRC inspectors in an addendum to IP 87132, "Brachytherapy Programs," dated December 5, 2005. The NRC should share both the guidance to licensees and inspectors with Agreement State Radiation Control Programs. The guidance to inspectors should also be shared with the MMLs.

- The NRC should not finalize any changes or revisions to the regulations in this area without accompanying guidance on licensee implementation and NRC inspection and licensing.

- FSME management should communicate to the regional offices that, unless specifically stated, they should not use TAR responses as generic inspection or licensing guidance. If it intends certain TAR responses to be used as generic inspection or licensing guidance, FSME management should to transmit this information in a suitable format to the regional offices so that it can be used consistently across the NRC Regions. Although TAR responses are typically not publicly available, the information contained in TAR responses that are intended for generic use should be shared with Agreement State Radiation Control Programs and MML programs, as applicable.

## 3.7 Guidance for Initiating Special Inspections

### 3.7.1 Discussion

As noted earlier, on August 22, 2008, the Director, DNMS, NRC Region III, chartered an SIT in response to the numerous medical events that NHPP reported for brachytherapy procedures performed at PVAMC. As described in its charter, the team consisted of the DVA MML PM and two senior health physicists. The charter documented that the circumstances surrounding the medical events were reviewed against the criteria in MD 8.3, "NRC Incident Investigation Program," dated March 27, 2001, and MD 8.10, "NRC Medical Event Assessment Program,"

dated July 6, 1994. It furthermore stated that based on preliminary NRC inspection findings and the number of reported events, the NRC considered this to be a significant event.

MD 8.3 describes different types of incident investigations. One type, the incident investigation team (IIT), can be considered the NRC's most serious response to an incident. MD 8.3 prescribes members of an IIT to have not had previous significant involvement in inspection and licensing activities at the affected site. IITs report directly to the EDO and are independent of HQ and Regional management. The next type of investigation is the augmented inspection team (AIT), which consists of technical experts from the Region in which the incident took place and is augmented by personnel from HQ, other regional offices, or contractors. Members of AITs may have had prior involvement with licensing and inspection of the affected facility. AITs report directly to the appropriate Regional Administrator. According to MD 8.3, an SIT is similar to an AIT, except that the group is generally smaller and not augmented by personnel from NRC HQ, other regions, or contractors. SITs report directly to the appropriate Regional Administrator.

MD 8.3 describes a significant operational event as any radiological, safeguards, or other safety-related operational event at an NRC-licensed facility that poses an actual or potential threat to public health and safety, property, or the environment. It further notes that the NRC evaluates significant operational events for materials licensees on the basis of deterministic criteria to define the level of NRC investigatory response.

MD 8.3 provides criteria for which an IIT should be considered for significant operational events. In the materials arena, the criteria that are pertinent for consideration of an IIT for medical events include: (1) medical use of byproduct material that may have resulted in deterministic effects to a significant number of patients over a long period of time (months or years), (2) medical use of material that resulted in the potential exposure of a significant number of individuals above the occupational or public dose limits, (3) use of byproduct material that may have resulted in a fatality, or (4) circumstances sufficiently complex, unique, or not well enough understood that an investigation would serve the needs and interests of the Commission. The criteria provided in MD 8.3 for AITs do not include any that directly or indirectly pertain to medical use of byproduct material or medical events.

Although MD 8.3 does not specifically refer to it, MD 8.10 includes more specific criteria for determining whether an IIT or AIT is warranted for a medical event assessment. Specifically, MD 8.10 states that the following criteria should be considered for an IIT: (1) a medical event involving a significant number of patients or individuals over a long period (months or years) that may have resulted in deterministic effects, (2) a medical event resulting in the potential exposure of a significant number of individuals above the occupational or public dose limits, or (3) a medical event involving circumstances sufficiently complex, unique, or not well enough understood that an investigation would serve the needs and interests of the Commission. Additionally, MD 8.10 provides criteria to be considered when deciding whether an AIT is warranted: (1) a medical event in which a medical consultant determined that the event directly contributed to a fatality, (2) a medical event involving a device failure, including computer software, such as treatment planning systems or other support systems, with possible adverse generic implications, (3) a medical event that is complicated and with probable causes that are unknown or difficult to understand, or (4) a medical event with consequences to the patient(s) or other potentially exposed individuals that require HQ or special contractor support to evaluate.

The criteria in MD 8.3 and MD 8.10 are inconsistent. In MD 8.3, the NRC should consider an IIT for a significant materials event involving byproduct material that may have resulted in a fatality,

whereas, in MD 8.10, it should consider an AIT for a medical event in which a medical consultant determined that the event directly contributed to a fatality.

The VATG interviewed managers from FSME and Region III to ascertain how they determined the scope and level of NRC's inspection actions. No prostate implant brachytherapy procedures were performed at PVAMC after June 2, 2008, and the Director, PVAMC, voluntarily suspended the PVAMC prostate implant brachytherapy program on June 11, 2008. Region III initially conducted a reactive inspection at PVAMC on July 23-25 and September 9-12, 2008. During and after this time, PVAMC and NHPP continued to review prior PVAMC prostate implant brachytherapy procedures and NHPP continued to report to NRC medical events that had been identified at PVAMC. This contributed to the decision by the Director, DNMS, Region III, to charter an SIT on August 22, 2008. By that time, NHPP had reported 55 medical events at PVAMC. On October 8, 2008, Region III began conducting inspection activities at the 13 DVA facilities that had prostate brachytherapy programs, as well as at the NHPP program office. According to the DVA MML PM, the inspections at PVAMC, the 13 other permitted facilities, and the NHPP program office were all considered part of the SIT charter.

The scope of the NRC's overall inspection effort related to DVA's prostate brachytherapy program was quite large. Region III dedicated a number of resources to the response, including a branch chief, the DVA MML PM (a senior health physicist), and two other inspectors (one a senior health physicist and the other a health physicist) who were essentially engaged in a full-time effort regarding these issues. One other Region III senior health physicist participated in the inspection of the NHPP program office, and a staff member from FSME participated in one inspection at PVAMC. Additionally, a medical consultant reviewed selected cases and participated in one site visit to PVAMC.

When comparing the criteria in MD 8.3 and MD 8.10, the circumstances of the reported medical events at PVAMC warrant consideration for an IIT or an AIT. The inspection activities at the 13 other DVA facilities seem to bolster consideration for an AIT or IIT. For example, the reported medical events at PVAMC occurred over a long period of time (2002–2008) and involved a significant number of patients (97 patients out of 114 treated). The circumstances of the events were complex, given that the criteria for what constitutes a medical event and how to evaluate medical events is an ongoing subject of much agency and stakeholder debate. The reported events involved characteristics of an investigation that would best serve the needs and interests of the Commission, as evidenced by the ongoing debate regarding the central issues and continued review of the NRC's actions in this case.

Region III appropriately performed reactive inspection activities and recognized the need to escalate to an SIT. It is arguable that, at the time the NRC chartered the SIT, it should have considered an AIT or even an IIT instead. Assuming that only a special inspection was warranted at that time, the circumstances of the case continued to evolve. NHPP continued to report additional medical events. Likewise, the NRC's inspection activities expanded to multiple facilities. At what point did the NRC need to take a step back and reassess its inspection posture and consider escalating to an AIT or an IIT? Both MD 8.3 and MD 8.10 are silent on this issue. Both of these documents essentially assume that all of the major information about the event is known, and thus the NRC could consider initiating an AIT or IIT at the onset of the event response. However, in the case of the DVA events, additional information was still being developed and the scope of the inspection was expanding over time. Perhaps there was no clear, logical point for the NRC to reevaluate the inspection posture and reassess whether it had dedicated the proper resources to perform the inspection in a timely, coordinated, and thorough manner.

The VATG asked Region III managers and staff and FSME managers and staff why an AIT or IIT was not initiated. It was argued by some that Region III basically had an AIT, although not in name. According to MD 8.3 and MD 8.10, it is the Office Director, NMSS (now FSME, but the MDs are not current), who is responsible for making recommendations and coordinating with the appropriate Regional Administrator on events that may warrant investigation by an AIT but it does not address who is responsible for making recommendations regarding events that may warrant an investigation by an IIT. No interviewee from FSME could recall asking Region III whether it should consider officially initiating an AIT or IIT.

Had the NRC initiated an AIT or higher level inspection, it could have dedicated additional resources. For example, the NRC completed onsite inspection activities at the NHPP program office on December 12, 2008; at the 13 other DVA facilities on April 24, 2009; and at PVAMC on October 16, 2009. The VATG acknowledges that these types of inspection activities often necessitate an in-office review following the site visit. The NRC held a PEC with DVA on December 17, 2009, but it only addressed activities at PVAMC. It addressed the programmatic issues related to NHPP's oversight and the issues with the 13 other DVA facilities at another PEC on June 20, 2010. The VATG recognizes that the root causes of the events at the other 13 DVA facilities perhaps differed from those at PVAMC and that might have warranted separating the issues. The programmatic issues of NHPP's oversight were common to all sites, however. The VATG discussed this matter with Region III managers and staff. Several interviewees indicated that they were so busy trying to respond to inquiries from the media, the U.S. Congress, and other NRC offices that they could not combine all of the issues into one IR or one PEC. They also noted that there was a great deal of pressure to resolve the PVAMC issues and, therefore, they could not delay any further. These issues raise questions as to whether additional resources from HQ or other regional offices could have augmented the regional inspection staff to provide support for bringing the issues to completion in a more comprehensive and timely manner.

### 3.7.2 Recommendations

The VATG made the following recommendations:

- With respect to events involving medical uses of byproduct material, the NRC should revise the portion of MD 8.3 related to significant operational events to refer specifically to MD 8.10 and should clearly state that MD 8.10 contains further guidance and criteria to be used when considering activation of an IIT or AIT for medical events.

- Because the NRC has not revised either MD 8.3 or MD 8.10 since it created FSME, it should revise both of these documents to reflect the responsibilities of the Director, FSME, or other FSME managers, with respect to materials events.

- The NRC should revise MD 8.3 and MD 8.10 for consistency as to whether to consider an IIT or an AIT for a medical event involving byproduct material that may have resulted in a fatality.

- MD 8.10 should include criteria for determining when to consider an SIT, AIT, or IIT for medical events involving underdoses or unintended doses to the skin or other organs or tissues.

- The NRC should provide further guidance with respect to materials events in MD 8.3 and medical events in MD 8.10 regarding the decisionmaking process to initiate an SIT, IIT, or AIT. The process should include an initial review by the appropriate regional office, determination of the significance of the event, and consideration by the Region, in consultation with FSME (as necessary), of an SIT, AIT, or IIT. The guidance should address conditions under which it might be necessary to reassess the situation and upgrade the NRC's response posture, as warranted. For materials events, the NRC should document MD 8.3 and MD 8.10 decisions and determinations and place them into ADAMS. The development and inclusion of a form in the MDs, such as a "decision documentation form," would document the decisionmaking process, facilitate consistency among the regional materials programs, better ensure that necessary items are given due consideration, and that an appropriate level of NRC management approves the final decision.

## 3.8 Evaluating Performance of Licensee Contractors

### 3.8.1 Discussion

As noted in its Enforcement Policy, the NRC generally holds licensees responsible for the acts of their contractors and for maintaining control and oversight of their contractor and subcontractor activities. NRC managers and staff are aware of this policy; however, it is unclear whether the agency reviews contractor activities adequately and consistently during NRC inspections at some types of materials licensee facilities.

The VATG reviewed the IPs that pertained to the materials inspection program (e.g., industrial, medical, academic). Of the IPs reviewed, only three discussed contractor activities: IP 87125, "Materials Processor/Manufacturer Programs"; IP 87126, "Industrial/Academic/Research Programs"; and IP 87127, "Radiopharmacy Programs." These three procedures include the following inspection guidance: "Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee." Therefore, inspectors are only instructed to verify the radiation safety training of contractors for these few program types. However, many types of licensees, including academic, industrial, and medical, use the services of contractors to perform licensed activities under the licensee's license.

During the NRC's routine inspection of licensed activities at PVAMC in 2001 (NRC IR 030-14526/2001-001), the inspector documented in the inspection record that "Radiation oncology is done through an arrangement with the University of Pennsylvania radiation oncology group. No sealed source therapy has been done since the last inspection, but it is planned that iodine-125 seed implants will begin about January 2002." Despite having no inspection guidance to inquire about the use of contractors, the inspector did identify the use of contractors for this licensed activity. It is unknown if the NRC explored these issues further during the inspection. For example, it is unknown whether the NRC made any inquiries regarding contractor oversight, responsibilities, or training. The NRC did not document any issues regarding the use of contracted radiation oncology personnel in the February 2003 reactive IR nor in the inspection record for the August 2003 independent NRC inspection at PVAMC.

The use of contracted radiation oncology staff played a critical role in the PVAMC medical events that were reported in 2008. As documented in the DVA Office of the Inspector General's report, the University of Pennsylvania was contracted in 2002 to provide prostate brachytherapy

services to PVAMC. It is noted in the Inspector General's report that it is DVA's policy to maintain the responsibility of monitoring the quality of services provided by academic affiliates under contract to DVA. The Inspector General's report notes that there were "substantial deficiencies in PVAMC's quality oversight of its prostate brachytherapy program," which implies that DVA did not have proper oversight of its contractor. The Inspector General's report documented that there was no delineation of responsibility for reviewing brachytherapy procedures and that there was no evidence of PVAMC case review by the University of Pennsylvania. In fact, during a period of several months, post-treatment prostate brachytherapy studies were not performed because of bureaucracy and hardware or software problems. All of these problems point to gaps in responsibility between DVA and its contractor.

The VATG asked inspectors about following up with contractors, especially regarding medical modalities. Several inspectors noted that they did not routinely inquire as to whether medical licensees used contractors. One inspector noted that, in a hospital setting, he always assumes that the personnel are contractors because medical facilities these days rarely have their own staff. The inspector further noted that this was even more true for DVA facilities, which tend to have mostly contractors and very few actual DVA employees. A few inspectors noted that medical physics services are often performed under contract but acknowledged that they often do not follow up with these individuals during inspections. In many cases, contracted medical physicists are not physically located at the licensee facility being inspected but rather at another medical facility (perhaps a different licensee's facility). Also, it is often the case in these situations that the records related to the patient treatment procedures, including post-treatment verification, are at the contracted medical physicist's facility rather than at the licensee's facility. Sometimes physical distances between the facilities or time constraints were barriers to inspectors following up on these activities. The inspectors noted that, unless there was a compelling reason or a suspected problem in this area, they probably would not follow up on contracted activities.

If there is a problem or deficiency associated with licensed activities being performed by a contractor, additional attention may be warranted. In the PVAMC case, the contractor (University of Pennsylvania) was itself an NRC licensee (and later became a Commonwealth of Pennsylvania licensee when Pennsylvania became an Agreement State). If contractors are not performing licensed activities properly for a particular client, it is likely that they are not performing licensed activities properly elsewhere. If a deficiency is identified, attention should be paid to determining the extent of conditions, because the problem might be occurring at other associated facilities. If deficiencies are suspected for associated facilities in Agreement States, this information should be shared with the respective State Radiation Control Programs for their review and followup, as appropriate.

### 3.8.2 Recommendations

The VATG made the following recommendation:

- The NRC should revise the following medical IPs to include a discussion about contractors: IP 87131, "Nuclear Medicine Programs, Written Directive Required," dated October 24, 2002; IP 87132, "Brachytherapy Programs," dated December 6, 2005; IP 87133, "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs," dated October 24, 2002; and IP 87134, "Medical Broad-Scope Programs," dated September 28, 2005. The discussion should include guidance for licensees' oversight responsibility, when it might be necessary to follow up on contractor activities, and if problems or deficiencies are identified, the necessity to determine the extent of

conditions and possible implications for other licensees of the Commission or Agreement States. The staff should review the remaining materials IPs to determine if a discussion of contractors is applicable.

## 4. NRC TRAINING PROGRAM

The NRC asked the VATG to assess the adequacy of the training programs for NRC inspectors and license reviewers (and MML inspectors and permit reviewers) to identify, respond to, evaluate, and disposition medical events.

### 4.1 Discussion

The NRC describes its training and qualification requirements for materials inspectors and license reviews in IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Arena," dated January 5, 2001. The training programs consist of self-study, formal coursework, and on-the-job training. NRC inspectors (referred to in IMC 1246 as "materials health physics inspectors") and license reviewers (referred to in IMC 1246 as "materials license reviewers") must successfully complete the requirements in IMC 1246 for those areas before being qualified to act independently in them.

In the area of medical uses of byproduct material, there are two NRC-sponsored courses:

- Diagnostic and Therapeutic Nuclear Medicine Course (H-304)
- Brachytherapy, Gamma Knife, and Emerging Technologies Course (H-313)

Both of these courses are provided under a contract administered by the NRC. The latter course is relevant to this review, since it covers prostate implant manual brachytherapy. It is a "core" course for both materials license reviewers and materials health physics inspectors, meaning that this course is one of the minimum formal classroom courses necessary to obtain qualification. IMC 1246 contains options for demonstrating equivalency for formal courses.

Formal courses alone cannot, nor are they expected to, completely teach an inspector how to perform inspections involving medical uses of byproduct material. Formal courses are only part of the qualification process. It is the qualification process, which includes self-study, formal coursework, and on-the-job training, that prepares individuals to review licenses or conduct inspections.

Following formal qualification, the NRC requires materials license reviewers and materials health physics inspectors to have refresher training. IMC 1246 requires that, every 3 years following initial qualification, license reviewers take a Health Physics Topical Review Course (H-401) and other courses as determined by management. IMC 1246 also requires that, every 3 years following qualification, materials health physics inspectors receive an IP update briefing, in addition to taking a Health Physics Topical Review Course (H-401) and other courses as determined by management.

The H-313 course was previously called "Teletherapy and Brachytherapy Course." In 2004, a working group composed of NRC (HQ and regional) and Agreement State personnel recommended changes to the Teletherapy and Brachytherapy Course. The working group proposed modifying the course contents to focus on brachytherapy, gamma stereotactic radiosurgery, and other emerging medical modalities; suggested a course outline; and made

several other recommendations. These included adding a new Chapter 11, "Basic Dosimetry Calculations in Brachytherapy," to the revised course. The working group provided a suggested outline for Chapter 11, which included methods for post-implant dosimetry, dose-volume histograms, and parameters for the evaluation of prostate implants (D90, V100). The working group also proposed having "expert regulators" from the NRC or an Agreement State present a session (suggested time allotted, 8 hours) to share their experience on both licensing and inspection activities for the various modalities.

The VATG contacted the NRC Technical Training Center (TTC) and spoke with the Chief of the Specialized Training Branch and a senior health physicist regarding the H-313 course. They stated that the contractor revised the course in 2005, and they provided the VATG with a copy of the most recent materials from the March 2010 offering of the course. The VATG reviewed Chapter 11, but it did not appear to include any detailed discussion regarding methods for brachytherapy post-implant dosimetry, dose-volume histograms, or the parameters that can be used in the evaluation of prostate brachytherapy implants, although the working group had recommended that the chapter include these topics.

Because Chapter 11 did not include this information, the VATG reviewed the remaining chapters of the contractor-led portion of the course. In particular, Chapter 19, "Brachytherapy Treatment Case Studies," an otherwise excellent description of prostate implant brachytherapy technology and techniques, is not comprehensive when discussing post-implant dose determination methodologies and techniques. For example, this chapter only includes one slide that uses the terms "D90" and "V100," and then only as headings in a table; the slide did not provide an actual written definition or description of these terms. The VATG noted that the course agenda did not include Chapter 19. The VATG discussed this matter with the TTC Senior Health Physicist, who followed up with the course contractor. The course contractor indicated that Chapter 19 is not formally reviewed during the course but is, instead, provided as reference material for the students.

The VATG recognized that perhaps issues such as methods for brachytherapy post-implant dosimetry were discussed verbally during the course rather than included in the written course materials. Accordingly, the VATG interviewed two NRC attendees that had recently taken the H-313 course. Both individuals indicated that the instructors did not address these issues (e.g., parameters that can be used in the evaluation of prostate brachytherapy implants) during the contractor-led portions of the course. One interviewee, who has an extensive background in medical use of byproduct material, further noted that, because attendees had asked questions about prostate brachytherapy, the instructor "read" the slides for Chapter 19. The instructor did not elaborate on the slides or provide the attendees with additional details. The other interviewee, who attended a different offering of the course, noted that the instructor only reviewed items from Chapter 19 that attendees were expected to know for the course exam. None of the questions addressed brachytherapy post-implant dosimetry. Both interviewees noted that the lecturer who "reviewed" these topics during the course had no expertise in prostate brachytherapy, did not possess a functional knowledge of this area, and could not answer any questions related to the subject.

After revising the course, the contractor implemented the 2004 working group's recommendation to bring expert regulators from the NRC or an Agreement State to the H-313 course to share their experience on both licensing and inspection activities. A health physicist (materials inspector/license reviewer) from Region I provided the NRC portion. The VATG interviewed this individual, who, although initially allotted 8 hours, thought that 4 hours was sufficient time to discuss the relevant subject matter. TTC told the individual to discuss

licensing and inspection but provided no detailed guidance or specific list of topics. The individual developed the lecture materials independently, and a supervisor reviewed them. (Note: The VATG could not review these slides because the electronic file had become corrupted, and TTC did not separately maintain them.)

After one or two offerings of the course, a change in work assignments resulted in a different health physicist (materials inspector/license reviewer) from Region I leading the NRC portion of the H-313 course. TTC also did not provide this individual with detailed guidance or a specific list of topics to cover. Despite no specific guidance, the individual extended significant effort and independently developed introductory slides as well as sets of slides covering several therapeutic modalities, including prostate implant brachytherapy. These slides, which the VATG reviewed, were well-developed, and provided a definition for D90, inspection pointers, and information on how to review and ask questions of the licensee regarding medical events. The individual also independently developed, and provided to the course attendees, one-and-a-half pages on key issues and an inspection checklist for prostate implant brachytherapy to assist the attendees in conducting inspections for this activity. The slides used in the most recent version of the course also discussed the recommended changes to the definition of "medical event" that were proposed by the NRC's ACMUI. The VATG interviewed individuals who had taken the H-313 course since its revision. The interviewees felt that the information provided during the NRC-led portion of the course, including the handouts provided by the NRC presenter, was valuable and should be continued.

The requirement for qualified individuals to have refresher training every 3 years recognizes that training does not stop with initial qualification. When the H-313 course was significantly revised, those NRC and Agreement State personnel who had previously taken the course were not required to take the revised course. Likewise, those who had previously taken the H-313 course were not given an "update" of changes to the course. According to IMC 1246, refresher training should be made available for experienced inspectors and license reviewers on the basis of need, special circumstances, and the necessity of keeping current with inspection and licensing programs. The specific 3-year requirement for a Health Physics Topical Review Course is rather broad and could involve any of several dozen topics in the health physics arena. A routine refresher in the medical arena is not specifically required for inspectors and license reviewers but could be beneficial if it discusses changes in medical technologies and new modalities.

## 4.2 Recommendations

The VATG made the following recommendations:

- As the 2004 working group recommended, the brachytherapy portions of the contractor-led portion of the "Brachytherapy, Gamma Knife, and Emerging Technologies Course" (H-313) should discuss brachytherapy post-implant dosimetry, dose-volume histograms, and parameters for the evaluation of prostate implants (e.g., D90, V100). The H-313 course should be modified to include these terminologies as well as others that explain post-implant dose verification techniques for prostate implant brachytherapy. These topics should be defined and discussed in the contractor-led portion of the course, instead of being defined and introduced for the first time by the NRC or Agreement State lecturer. Furthermore, the contractor lecturer who presents these materials should have a strong familiarity or some level of expertise with these topics and be able to answer questions on the subject matter.

- In general, expert regulators from the NRC or Agreement States who lead portions of NRC-sponsored courses should receive some guidance, expectations, or list of topics to cover during the time allotted for their portions of the course. This could consist of a bulleted list developed with input from TTC, the regional offices, and FSME. Specifically with respect to the H-313 course, the scope of topics for the NRC or Agreement State lecturer should not be too broad, as currently the course allots only 4 hours (including breaks) for this portion, which is expected to discuss both licensing and inspection. The NRC or Agreement State-led portion of the course should focus on licensing and inspection, as appropriate, and should not spend significant time repeating topics that were covered in the "technology" (contractor-led) portion of the course.

- In general, NRC-sponsored courses should exercise caution in discussing or teaching attendees regarding proposed regulations. These topics could be confusing and might lead to inspection against proposed regulations that have not been finalized or implemented. TTC should develop guidance for course lecturers to use as reference when discussing proposed regulations.

- When NRC-sponsored courses are significantly revised, consideration should be given to either: (1) requiring previous attendees who are still qualified inspectors/license reviewers to take the revised course in a reasonable timeframe (e.g., 2 to 3 years) or (2) having the "new" or significantly revised material taught in a shorter session (e.g., fewer than 2 days) that can be taught by the contractor or TTC personnel, as appropriate, in an NRC regional office or hosted by an Agreement State.

- Due to continuous changes in the medical technology and techniques, IMC 1246 should include refresher training for license reviewers and inspectors in this area. The NRC should require this training in addition to the H-401 refresher training requirement. A contractor or appropriately qualified NRC personnel should provide this training on a specified periodic basis or as new treatment technologies or dose determination methodologies are developed and implemented. This recommendation applies to all NRC-regulated therapeutic modalities, not just prostate brachytherapy. The TTC should standardize the training and course content so that license reviewers and inspectors across the NRC receive consistent training. Such training should also be offered to Agreement State personnel and MML inspectors and permit reviewers.

## 5. NRC MEDICAL CONSULTANT PROGRAM

The task group was charged with assessing whether NRC policies and procedures adequately define the use of medical consultants and whether the use of a medical consultant (in accordance with NRC policies and procedures) is appropriate for this type of medical event.

### 5.1 Discussion

MD 8.10, "NRC Medical Event Assessment Program," dated July 6, 1994. which describes the NRC's use of medical consultants, states that the group reviewing a medical event must be composed of at least one qualified NRC inspector and an NRC medical consultant, if warranted. It further notes that a physician consultant must be a member of the group if the misadministration (presently "medical event") resulted in an overexposure to the patient and that medical consultants can be used for other events at the regional management's discretion.

Medical consultants are Special Government Employees appointed by the NRC to serve in that capacity.

MD 8.10 provides a generic listing of the responsibilities of the medical consultant. For medical event reviews, these are: (1) preparing a report summarizing evaluations and assessments, (2) providing an estimate of the radiation dose to the exposed individual and the probable error associated with the estimation of the dose, (3) comparing the prescribed dose to the dose received to determine medical or biological significance, (4) evaluating the justification for not informing the patient, (5) evaluating the licensee's plan for patient followup, and (6) reviewing licensee reports submitted pursuant to regulatory requirements. IMC 1360, "Use of Physician and Scientific Consultants in the Medical Consultant Program," dated November 2, 2006, contains a more detailed description of the responsibilities of the medical consultant.

The objective of the NRC's medical consultant program is to have a scientific or physician consultant assist the NRC staff in evaluating radiation exposure incidents (including medical events). The type of assistance or support to be provided by medical consultants includes, but is not limited to the following areas: (1) expert and independent medical evaluations of the probable deterministic effects of radiation exposures, (2) interpretation of bioassay results and other data related to a radiation exposure, (3) calculation of internal and external radiation doses, (4) participation in NRC inspections and investigations to determine the root cause of the radiation exposure incident and the nature and probable deterministic effects of the radiation exposure on the exposed person(s), (5) evaluation of reports the licensee submits to the NRC and to the exposed individual after a radiation exposure incident or medical event, (6) provision of expert testimony regarding inquiries or hearings and, as requested by the NRC, participation in selected conferences on the biological effects of radiation and radioactive materials, and (7) provision of technical support to the NRC as necessary (e.g., rulemaking activities, validation and verification of research results).

IMC 1360 establishes guidelines for circumstances under which the NRC obtains the services of medical consultants, which are as follows:

a. Incidents where an individual has received one or more of the following doses:

    1. A suspected total effective dose equivalent of 0.25 Sv or more.
    2. A suspected lens of the eye dose equivalent of 0.75 Sv or more.
    3. A shallow-dose equivalent to the skin or extremities of 2.5 Gy or more.
    4. A suspected committed effective dose of 2.5 Sv or more to any individual organ or tissue other than the lens of the eye.

b. Incidents where an individual is demonstrating physical symptoms (erythema, nausea, vomiting, etc.) consistent with radiation syndromes, and the source of the radiation may be attributable to NRC-licensed radioactive material.

c. Incidents where NRC staff believes permanent functional damage to an organ or a physiological system is possible.

d. Incidents where a nursing infant or an embryo/fetus may have been inadvertently exposed to radiation or radioactive material as a result of

the intentional or unintentional exposure of the mother of the nursing infant or an embryo/fetus to radiation or radioactive material.

e. A medical consultant shall be contacted for all medical events involving an overexposure in accordance with Management Directive 8.10, "NRC Medical Event Assessment Program."

According to IMC 1360, the NRC may also use medical consultants for any incident where the staff believes that their assistance would be beneficial to fulfilling the NRC's mission.

The FSME coordinator for the medical consultant program maintains the list of appointed consultants. At the time that the NRC initially used a medical consultant to evaluate the medical events at PVAMC (fiscal year 2008), the list contained five medical consultants of various disciplines, including one radiation oncologist, two nuclear medicine physicians, one medical physicist, and one physician specializing in radiation exposures. The NRC expanded the list in fiscal year 2009 to add a previous ACMUI member who specialized in brachytherapy, including prostate implant brachytherapy. In fiscal year 2010, the agency added another radiation oncologist specializing in gamma stereotactic radiosurgery. According to IMC 1360, the NRC staff may also ask ACMUI members to serve as consultants if those individuals from the approved list are not available.

The VATG reviewed the NRC's medical consultant program and identified a number of problems involving qualifications of medical consultants, their selection and hiring, and the quality of their reports. These deficiencies are described below.

The NRC does not currently document the functions for each medical consultant discipline. The list of medical consultants maintained by FSME provides the names of the approved individuals under broad headings. For example, currently, three individuals are listed under the heading "Radiation Therapy." As a result, it is not clear what specializations, these physicians have (e.g. high-dose rate remote afterloader brachytherapy (HDR), prostate implant brachytherapy, gamma stereotactic radiosurgery), or if they are generalists. It would be beneficial to Regional staff to have access to a current list of approved NRC medical consultants, with a description of each of their specific specialties.

The VATG observed that in several instances medical consultants declined to provide their services because they believed that they lacked the expertise in a particular modality or because they were too busy. The VATG believes that the NRC does not have enough depth in its medical consultant list. While the current list covers all of the various disciplines in 10 CFR Part 35, the agency would be better served to have more than one medical consultant available to cover each type of NRC-regulated modality in radiation therapy (e.g., two HDR brachytherapy physicians, two permanent implant manual brachytherapy physicians). The VATG acknowledges that the hiring of medical consultants is challenging. These challenges include: (1) physicians' demanding schedules do not afford sufficient time to provide services to the NRC, (2) NRC compensation rates are low relative to a full-time position, (3) the NRC hiring process and completion of security paperwork is viewed as too onerous, and (4) physicians are reluctant to provide services related to complex or controversial cases. The staff should consider solicitation for nominations in the FR or through advertisements in professional journals, and should request assistance from professional societies.

The VATG observed that the NRC has no criteria on which candidates are appointed to serve as medical consultants. There are no formal qualifications, selection criteria, review panel, or

approval by the Office or Division Director. While challenges for hiring medical consultants exist, the VATG believes that policy should be established that specifies the qualifications, selection criteria, and formal selection process for hiring medical consultants

During the VATG interview process, an NRC staff member acknowledged that one of the physicians who performed some of the brachytherapy administrations that resulted in medical events at PVAMC had previously served as a medical consultant for the NRC. This was confirmed through a review of FSME medical team records. During the NRC's review of the medical events at PVAMC, this physician appeared to lack knowledge of the NRC's medical event criteria or how to apply those criteria to prostate brachytherapy events. This further supports the need to have selection criteria and a more rigorous selection process for the NRC's medical consultants.

By letter dated September 28, 2008, the NRC Region III staff retained the services of a medical consultant to evaluate the events at PVAMC. By letter dated October 21, 2008, the NRC asked the consultant to review additional PVAMC cases. Region III sent the medical consultant a request for additional services on July 6, 2009. During interviews, the VATG asked Region III staff and managers why they selected this particular consultant from the list of approved consultants. The medical consultant was selected, in part, because Region III had worked with the individual on previous cases and were familiar with his work. Furthermore, of the other approved consultants, one individual had a reputation for not being available for consulting when requested, and several interviewees believed another individual had a predisposition to certain views related to prostate brachytherapy.

The NRC's medical consultant issued two reports, on December 22, 2008, and November 9, 2009. The consultant based the reports on a review of documents, interviews with individuals, and a site visit to PVAMC, which was conducted August 27–28, 2009. The medical consultant's first report for the selected patients described the patients' history obtained from their records and the prescribed dose compared to the actual administered dose as provided by the licensee. For the cases reviewed, the medical consultant noted qualitative statements such as "numerous seeds outside of correct region," "most of the seeds are outside of the prostate," "patient doing well and tumor free," or "seed placement in these cases is quite erratic." The medical consultant stated, "My independent dose estimates generally agree with those provided by the licensee." However, it is not apparent that the medical consultant provided actual independent dose estimates in his report. Furthermore, it is unclear what methodology, if any, the medical consultant used to obtain dose estimates. The medical consultant's report indicated that, in one case, the increased radiation dose could have contributed to ulcerative colitis and that most of the overdose cases seemed not to result in any significant adverse reactions.

The medical consultant's second report examined additional cases selected by NRC Region III and provided a brief review of a Microsoft Excel spreadsheet from NHPP of all of the cases identified up to August 6, 2009. Similar to the first report, the second report summarized data provided by the licensee. The medical consultant again stated, "My independent dose estimates generally agree with those provided by the hospital." However, it is not apparent that the medical consultant provided actual independent dose estimates in the report. Furthermore, it is unclear what methodology, if any, the medical consultant used to obtain dose estimates. Of the cases reviewed in the second report, the medical consultant indicated that one case showed radiation proctitis, and in another case, a colonoscopy showed benign vascular signs of radiation dose.

According to MD 8.10, “The medical consultant should have expertise in the area being reviewed.” It appears that the medical consultant who evaluated the PVAMC medical events did not demonstrate sufficient proficiency in the area of permanent implant manual brachytherapy to adequately evaluate these events. Many staff members who were interviewed felt that the selected medical consultant lacked the expertise to evaluate prostate brachytherapy implants, because he is not a radiation oncologist. Given the scope and the visibility of the PVAMC medical events, perhaps review by a panel of experts or by multiple medical consultants (e.g., radiation oncologist, medical physicist), one of whom would be a prostate implant brachytherapy physician, would have been warranted.

The DVA Office of the Inspector General conducted an internal investigation to review PVAMC’s practice of prostate brachytherapy. Its May 3, 2010, report, “Healthcare Inspection Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania, and Other VA Medical Centers,” provided an assessment of patient complications, which addressed the potential for short- and long-term complications and compared expected outcomes with observed outcomes for the patients involved. The Inspector General’s report provided significant details on an assessment of the observed complications, specifically urinary and rectal toxicity because of the vulnerability of these organs to radiation injury and because the outcomes had clear endpoints. In contrast to the Inspector General’s report, it is the VATG’s view that neither of the two reports submitted by the NRC’s medical consultant provided detailed medical evaluations of actual or expected patient complications; the NRC medical consultant’s reports simply lacked the necessary detail to meet the objectives of the NRC’s medical consultant program.

Upon interviewing regional staff, some staff felt that medical consultants did not provide the assessment that the staff sought. The VATG found that medical consultants, on occasion, did not abide by the charter guidelines. The VATG notes that there should be more clearly defined guidance regarding the necessary information that a medical consultant’s reports should include to support the NRC’s needs, as well as to meet staff expectations. The VATG acknowledges, however, that consultants are challenged with the difficult task of determining biological significance and evaluating long-term effects for delivered doses that differ from the prescribed doses by perhaps as little as 20 percent.

Medical consultants are responsible for submitting final written reports to the appropriate regional office within 30 days of completing the case review. The staff does not receive a draft version for review before receipt of the final report. Some staff expressed that there was no clear mechanism to obtain additional information from the consultants when there were questions about the consultants’ reports..

IMC 1360 instructs the regional staff to provide the ADAMS accession numbers for the consultant’s report and the IR to the FSME Coordinator; however, this information is not consistently forwarded to the FSME Coordinator. The FSME Coordinator does not maintain a log of the consultants used and the cases (licensee name and general description of the event(s)) they were asked to review, nor the ADAMS accession numbers for all of the consultant reports and related IRs. For example, the VATG wished to review the two consultant reports related to a similar prostate brachytherapy case involving 21 medical events that occurred in 2001 at Robert Packer Hospital, Guthrie Healthcare System. However, neither of these reports could be located in ADAMS, and it appears that regional practice at the time was to not place the consultant reports into ADAMS. Hard copies of the reports may have been placed in the licensee’s docket folder, but the NRC transferred these records to the Commonwealth of Pennsylvania when it became an Agreement State. At Region I’s request, the Commonwealth

of Pennsylvania searched the docket folder but could not locate the reports. Likewise, HQ could not locate the reports. The VATG contacted the Region I inspector involved with the case, who was able to locate copies of the consultants' reports in her office inspection files and provide them to the VATG for review. A central log of ADAMS accession numbers for all consultant reports and related IRs would have been helpful in this regard. These consultants' reports were subsequently placed into ADAMS.

## 5.2 Recommendations

The VATG made the following recommendations:

- A current list of approved NRC medical consultants, with a description of each of their specific specialties, should be made available to FSME and regional staff. This could be accomplished by posting the list in an easily accessible area on FSME's internal web site.

- The NRC should have more medical consultants available to the staff. Specifically, the NRC should have more than one medical consultant available to cover each type of NRC-regulated modality in radiation therapy. To obtain a more comprehensive list of qualified consultants, the staff should consider soliciting for nominations through the FR, as well as advertisements in professional journals, and should ask professional societies to nominate qualified candidates.

- The NRC should revise IMC 1360 to specify the qualifications, selection criteria, and formal selection process for hiring medical consultants. The policy currently practiced for the selection of ACMUI members should be used as a suitable guide in the development of a policy for the NRC's medical consultant program. When hiring medical consultants, the NRC should use a formal selection process, to include a selection panel and approval of the medical consultant by the FSME Office Director or Director, MSSA. The revisions to IMC 1360 should also provide clear guidance on the basis for renewal of consultants' appointments.

- The staff should identify all cases on which XXXXXXXXXXXXXXXXXXXXXX served as an NRC medical consultant. (XXXXXXXXXXXXXX, a former NRC medical consultant, was also involved as an AU in some of the PVAMC medical events.) These cases in which XXXXXXXXXXXXXX served as an NRC medical consultant should be reviewed by the staff and, as necessary, independently reviewed by a different medical consultant who is qualified in the modality or modalities being reviewed.

- Both the confirmation letter and the charter should explicitly state the tasks NRC medical consultants are to perform so that they produce more useful reports that meet the objectives of the NRC's medical consultant program.

- The NRC should revise IMC 1360 to allow both regional and HQ staff to review the medical consultant reports in draft before the reports become final, so the staff can ask clarifying questions and provide feedback on inadequate assessments. This would also provide the medical consultant an opportunity to ensure that the report includes information that is useful to the NRC staff.

- For the purpose of tracking, the FSME Coordinator should maintain a log of the consultants who are used and the cases to which they are assigned. The FSME Coordinator should ensure that ADAMS accession numbers for medical consultant reports and associated NRC IRs are received and maintained on file.

## 6. MASTER MATERIALS LICENSE PROGRAMS

The NRC asked the VATG to review several areas with respect to MML programs, such as assessing the adequacy of NRC policies and procedures related to initial MML programs, including turnover of historical licensing and inspection information and turnover of duties between NRC MML PMs. The NRC also asked the VATG to assess the adequacy of its policies and procedures and the framework agreed to in LOUs with MMLs regarding the assignment of responsibilities between the MML and the NRC for: (1) evaluating and responding to medical events, (2) performing inspection activities, including reactive inspections, and (3) processing and dispositioning inspection findings, including any subsequent escalated enforcement actions. Finally, the NRC asked the VATG to assess the adequacy of NRC policies, procedures, and applicable training programs for inspectors and license reviewers to properly administer and maintain oversight of MML programs.

### 6.1 Initial MML Programs

#### 6.1.1 Discussion

The NRC developed the guidance in NUREG-1556, Volume 10, for reviewing initial MML applications in parallel with the agency's initial review of the DVA MML application. The NUREG incorporated guidance from NMSS Policy and Guidance Directive 6-02, Revision 1, "Standard Review Plan for License Applications for Master Materials Licenses," dated September 25, 1997. The guidance in the NUREG defines the criteria that the NRC should use to evaluate an initial MML application. As the cornerstone, the applicant should have at least five years of experience as a centrally controlled program. The guidance also recommends that the NRC review the application to determine the operational and administrative readiness of the centrally controlled radiation safety program and the MML applicant's readiness to fulfill its responsibilities under an MML.

IMC 2810 defines the term "NRC MML Project Coordinator" as the NRC staff member located in a regional office and assigned project responsibility for an MML. In practice, this position has been referred to as the "NRC MML Project Manager." IMC 2810 further states that the lead region for the MML shall assign a staff member as the NRC MML PM. The initial DVA MML PM participated in the review of the application but retired from the agency before the issuance of the MML. Region III reassigned the DVA MML PM duties, including participation on the MML application review team, to another Region III staff member starting in 1998.

Section 1.1 of NUREG-1556, Volume 10, provides an overview of the NRC's review process and criteria for MML applications. It does not specify that a PM will be appointed during the application review process, nor does it specify that the PM will be a member of the MML application review team. It does, however, recommend that the MML application review team members will be selected from HQ and regional staff, including at least one former or current PM for an existing MML. The guidance further recommends that the team leader be from the region in which the MML will be issued.

It is important that NRC MML PMs become engaged early in the MML application review process, well before a license is issued. When involved early, the NRC MML PM can better capture ongoing issues that may need to be addressed or tracked following the issuance of the MML. During the application review process, it is critical that the NRC MML PM be aware of all correspondence from all NRC offices to the MML, as well as from the MML to the NRC. The MML application review process represents a critical time when the MML is trying to demonstrate central control, yet all of its facilities are still independent NRC licensees.

The VATG did not identify any formal NRC policy or procedure that addressed specific guidance for processing casework or handling licensee docket folders and correspondence that would eventually be transferred to an MML as part of an initial MML program. Region III developed an action plan, dated December 23, 2002, addressed to all regional offices. The action plan provided guidance to the regions before the issuance of the MML, for handling licensing, inspection, enforcement, allegations, and investigations. However, the action plan did not provide any guidance for tracking ongoing event response or handling any new event reports.

During the DVA MML application review process, each regional office had a designated point of contact (POC) to track activities related to the transition from individual NRC licensees to issuance of the MML. In the case of the February 3, 2003, event at PVAMC, the DVA MML PM recalled that he was probably aware of the event through regional interoffice communications or through routine contact with the NHPP, but could not specifically recollect the circumstances of the event or the outcome of NRC's inspection and followup. The VATG did not identify any documentation to indicate that the DVA MML PM was engaged in any of the followup activities or discussions involving the results and followup related to Region I's reactive inspection at PVAMC. MML PMs should be aware of all events reported for their respective MML applicant facilities as well as any NRC Regional event response and related inspection activities, in order to have effective oversight of MML activities prior to issuance of the MML and during the time period that follows.

NUREG-1556, Volume 10, contains guidance for MML applicants on providing appropriate information in their application and provides NRC staff guidance in evaluating the application; however, it does not include a procedure for the NRC to process the application. Because the NRC has received only three MML applications, the most recent one almost 10 years ago, it is important that the NRC capture the process in a procedure. This would aid in the NRC's knowledge management should it receive another MML application from a Federal agency. Although MMLs are not Agreement States, FSME procedure SA-700, "Processing an Agreement," dated July 19, 2007, is a suitable reference as a starting point for processing an MML application.

Because the MMLs are licensees, the NRC has the ability to suspend or revoke an MML. Likewise, a licensee could voluntarily turn the MML back to the NRC, terminate or modify its centrally controlled radiation safety program, and request that, instead of an MML, the NRC issue individual specific licenses to each of its facilities. Revocation of an MML, or a turn-back of an MML, would have an impact on NRC resources, particularly with respect to regional licensing and inspection. It was previously estimated that the NRC would have a resource savings of 1–1.5 FTE when DVA received the MML. If the NRC had to assume full authority for any of the three MMLs, it might require 1–2 FTE, with perhaps more FTE necessary at the onset. Although the resource impact on the NRC might not be significant, if the NRC were to revoke an MML or if a licensee were to turn back its MML, there is no contingency plan, policy, or procedure for the NRC to resume full responsibility for licensing, inspection, allegations, enforcement, and event response.

The transition of docket folders (hard copies of license files) is similar to the activities performed when a non-Agreement State becomes an Agreement State. When an Agreement is issued, the NRC's license files are transferred to the new Agreement State. However, an MML is different, because the licensee remains under the NRC's authority, in that the individual licensees become MML permittees. In the case of MMLs, there is not a complete transfer of regulatory jurisdiction. The VATG found that, concurrent with the issuance of the DVA MML, the license docket folders for the individual specific DVA licenses were transferred to the NRC archives. Because DVA does not have the docket folders, it has, on occasion, asked the NRC for copies of certain files because it needed some historical information about the permitted facilities. The NRC has retrieved these documents from its archives without any difficulty and provided them to DVA. MD 3.53, "NRC Records and Document Management Program," dated March 15, 2007, describes the policy for handling NRC-generated records and states that NUREG-0910, "NRC Comprehensive Records Disposition Schedule," issued March 2005, provides the guidance for the authorized disposition of documents. Licenses issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," are considered permanent and will continue to be retrievable. It was noted that the Air Force and Navy license docket folders were transferred to the respective MMLs for their use and retention, until such time as the MML is terminated or transferred back to the NRC. While the NRC gave the Air Force and Navy their docket folders, it transferred its docket folders for DVA facilities to the archives.

It is indeterminate whether the docket folder for PVAMC and the other DVA facilities would have been beneficial to DVA. Licensees have record retention requirements and, therefore, DVA might not have gained much information, had it been provided the NRC's docket folders. With the exception of historical information and some sensitive information, the NRC maintains its licensing and inspection records in ADAMS, to which DVA has access and which it uses routinely.

Instead of transferring the docket folders to the NRC archives or providing them to the MML, another option would be for the other regional offices to transfer the docket folders to the lead region for the MML. If the docket folders were transferred to the lead region, the MML PM would have ready access to the historical licensing and inspection information contained in the folders. Region I interviewees acknowledged that PVAMC was known to be a "problem licensee" and related that there were performance and safety culture problems at PVAMC before it became a DVA permittee. The VATG could not ascertain whether the DVA MML PM was aware of the extent of the problems at PVAMC. Presumably, had the docket folders been transferred to the lead region, the DVA MML PM could have reviewed the information and made informed decisions regarding DVA facilities that perhaps needed additional NRC and/or DVA oversight.

For any future MMLs, the handling and disposition of docket folders should be evaluated on a case-by-case basis. The NRC's decision may be influenced by storage limitations or requirements for handling sensitive information, or at the specific request of the MML applicant.

### 6.1.2 Recommendations

The VATG made the following recommendation:

- The NRC should develop a procedure for processing an MML application. A suitable starting point is SA-700. At a minimum, the procedure should include guidance for:

(1) providing a timeline for appointing an MML PM, (2) describing the makeup of the MML application review team, (3) describing the roles and responsibilities of regional and HQ POCs, (4) processing and tracking all actions, including licensing, inspections, incidents or events, allegations, investigations, and enforcement, (5) identifying MML licensees with a history of health and safety issues or programmatic concerns, and (6) transferring or archiving NRC license docket folders for terminated MML facility licenses.

## 6.2 Letters of Understanding with MMLs and Assignment of Responsibilities

### 6.2.1 Discussion

There are three MMLs, which include the Air Force, issued in 1985; the Navy, issued in 1987; and the DVA, issued in 2003. A key component of an MML is the mutually agreed upon LOU. The LOU assigns the responsibilities between the NRC and the MML; contains the commitment by the MML for implementing areas of its program to reflect the NRC's policies and procedures; and identifies certain exclusionary activities that the MML cannot conduct, unless specifically authorized under the license. The LOU is issued formally and becomes a part of the MML ("tied down").

The three MML LOUs are unique, because they were adopted at different times and without a standard template. Because the Air Force was the initial MML, its LOU is very short and does not address all of the program areas and responsibilities. For example, approximately 1 year after the NRC issued the MML to the Air Force, a significant radiological contamination event occurred at an Air Force installation. However, the Air Force LOU did not specifically address the NRC reporting requirements, and it was not clear whether the MML was required to report the event to the NRC or whether it was sufficient for the permittee to report to the MML, since the MML was acting in the role of a regulator. Subsequent amendments to the license conditions for the Air Force MML addressed these types of program changes and expectations of the MML. Another example of an item perhaps not clearly articulated in all LOUs is the assignment of decommissioning responsibilities between the NRC and the MML. As a result of a TAR related to the Air Force MML, the program office determined the decommissioning responsibilities that may be assigned to the MML. As a result, these responsibilities were incorporated into the Air Force MML by license condition. The DVA LOU incorporated a number of the Air Force MML lessons learned. However, the Navy LOU has not been updated and does not incorporate the delineation of responsibilities for some of these areas, such as decommissioning.

The three MMLs do not have expiration dates and, therefore, there is no formal mechanism to renew them. During an NRC MML counterpart meeting, regional and HQ staff recommended that each MML submit a license amendment in its entirety to update the LOU and license conditions, as applicable. However, because there is no expiration date on the license, it would be incumbent upon the MML to support the degree of effort it would take to submit a license amendment in its entirety. The Air Force agreed to the NRC's request, and in May 2008 they submitted a license amendment request to NRC. This submittal was not a "renewal" but was an amendment of the Air Force MML in its entirety. The NRC decided to review the Air Force's amendment request using a team approach with the expertise of each of the three MML PMs, the HQ MML PM, and an HQ representative from the original DVA license review team. The team was tasked with: (1) developing a standard template LOU, (2) reviewing the Air Force's amendment request, and (3) reviewing and revising, as necessary, the guidance in NUREG-1556, Volume 10. The NRC sent the draft LOU to the Air Force on March 5, 2010, for

its review and concurrence. Because the LOU must be agreed upon and signed by both parties, a consensus is required as to the specific wording of the delineated responsibilities.

The VATG asked interviewees whether the MMLs should have expiration dates. Many interviewees felt that the MMLs should, indeed, have expiration dates, with several individuals noting that a 5-to-10-year timeframe would be appropriate. Several interviewees expressed concern that licenses of this magnitude and responsibility should not be issued "indefinitely." One interviewee noted that, if the NRC had an expiration date on a license of very low risk significance, such as gas chromatographs, then it seemed unreasonable that a license of such high risk significance did not have an expiration date. One interviewee suggested that, although there should be a required renewal or "refresh," it should not be "in entirety" but rather should comprise a subset of issues or items that would be renewed on a periodic basis. Some interviewees felt that MMLs should not have expiration dates. These individuals pointed out that the renewal process would be time-consuming for the MML as well as for the NRC staff and could negate the resource savings derived from having an MML. A suggested compromise was that the MMLs have no expiration date but that the LOUs have an expiration or "renegotiation" date. The feasibility of imposing expiration dates could require a legal analysis from OGC. Likewise, the VATG did not perform an analysis to determine the resources necessary for different MML renewal options (e.g., in entirety, partial renewal, or LOU only). The frequency of MML renewals (e.g., 5 years, 10 years) would also require some type of resource analysis by the staff that would consider the NRC resources necessary for a team to renew an MML, as well as the MML resources necessary for the renewal application and process.

### 6.2.2 Evaluating and Responding to Medical Events

The NRC has policies and procedures for responding to medical events. Each of the MMLs has agreed to implement its respective inspection program in accordance with IMC 2800. Each of the MMLs has responded to events; however, DVA is the only MML to have responded to multiple medical events at any one time. DVA has multiple brachytherapy programs; however, the Navy has only one and the Air Force has recently implemented two.

The inspector training program is different between each of the MMLs. The DVA and Navy inspectors are qualified in a program that reflects IMC 1246, and the staff positions perform both inspection and permitting activities. The DVA NHPP is comprised of five Program Managers, one of which is vacant, and a Director. The NHPP Program Managers are typically assigned by geographical locations. The training for NHPP Program Managers includes the use of qualification journals and oral qualification boards. The Navy MML is comprised of two Technical Support Centers, in which staff personnel have the job titles of Radiation Program Managers. The Navy Radiation Program Managers are trained as inspectors and license reviewers simultaneously. The Naval Radiological Affairs Support Office oversees the industrial program and has seven Radiation Program Managers who are civilian employees. The Navy and Marine Corps Public Health Center oversees the medical program and has three Radiation Program Managers, where two are civilian employees, with one Officer-in-Charge. The Air Force MML program has separate inspection and permitting activities. The Air Force MML program performs permitting and enforcement activities, but not inspections. Instead, the Air Force inspector is from the Air Force Inspector General's Office and performs inspections on behalf of the Air Force MML program. The inspector is qualified under the Air Force's modified IMC 1246 program, because there is only one Air Force inspector and the position typically rotates every 2 to 3 years.

The NRC has experience in responding to events through its depth of resources, including inspectors and management experience, regional and HQ staff input, training, and an enforcement program office. The depth of experience of MMLs to respond to events is limited because of their limited resources, staff size, and the infrequent occurrence of events that can be used to develop "event-response" skills. Therefore, the depth of experience for MMLs to respond to events cannot be expected to be equivalent to that of the NRC. Although the MMLs are expected to implement an inspection and enforcement program that is equivalent to the NRC's program, the MML PMs and regional management stated that outreach in this area is required for the MML to successfully implement an equivalent program. This outreach is provided through routine communications, review of incident and allegation responses by the MML PMs, and the MML PM's requests for additional information as part of the NRC's oversight of the MML's response to events.

### 6.2.3 Performing Inspection Activities, Including Reactive Inspections

Each of the MML programs has expertise in the medical arena that can be used in responding to medical events. The Air Force MML is organized under the Office of the Surgeon General, has access to certified medical physicists and physicians through its Radioisotope Committee, and has successfully used independent dose assessment specialists for consultation in response to medical events. The Navy and Marine Corps Public Health Center implements the Navy's medical program, which includes drafting medical permits, conducting inspections, and issuing enforcement actions. Therefore, the Navy also has resources available, through its staff and programs, to evaluate a medical event. NHPP has expertise available throughout DVA to assist in responding to a medical event. However, several NRC interviewees related that the medical events identified at PVAMC were so numerous that the NHPP appeared to be overwhelmed; it was disorganized in assessing the data and did not use the expertise and resources available within DVA until the NRC encouraged and guided it in that direction. DVA subsequently organized a blue ribbon panel to evaluate the medical events.

The VATG recognized that each MML was unique and that the command and control exhibited by DVA contrasted sharply with the military structure of command and control exhibited by the Air Force and Navy MML organizations. The DVA hospitals are under their own structure, and there was an apparent lack of central coordinated effort under the leadership of NHPP in response to multiple medical events at PVAMC. The NRC's concerns during the MML application review process related to DVA's lack of a centrally coordinated program. This concern appears to be borne out in DVA's response to the medical events at PVAMC.

### 6.2.4 Processing and Disposition of Inspection Findings, Including any Subsequent Escalated Enforcement Actions

Responsibility for enforcement activities is divided between the NRC and the MML through the LOU. The MML must have a program that commits to following NRC's Enforcement Policy to ensure that actions taken by the MML are consistent with those of the NRC. The NRC Enforcement Manual, Section 8.12, allows the MML to process escalated enforcement, such as SL III, II, or I violations. The MML must inform the respective NRC MML PM when it identifies potential violations that could result in escalated enforcement. Each regional office typically allows the MML to proceed with its enforcement process. According to the NRC Enforcement Manual, the NRC has the discretion to mitigate an escalated enforcement action if the MML has conducted a thorough investigation and has reported its finding to the MML PM. The NRC would typically hold an Enforcement Panel to review the MML's process and determine whether the NRC should exercise this discretion or take its own enforcement action.

The VATG determined that the MML's lack of depth and experience in processing escalated enforcement actions may contribute to its lack of understanding of the sometimes subtle differences between SL III and SL IV violations or between SL II and SL III violations. In particular, these subtle differences involve identifying what constitutes a substantial programmatic failure or identifying what is considered "significant" as it affects a SL. The VATG found that the experience and training the NRC provided to the MMLs was lacking in the area of processing enforcement actions and responding to large or multiple events. This lack of experience would probably be more apparent in the other MMLs if they had to respond to multiple events across multiple facilities, as the DVA MML has had to do.

The VATG believes that the oversight of the MML program could be enhanced if each MML developed a corrective action program to provide the planning and forethought that would be beneficial in responding to, and evaluating events. A corrective action program would establish a process that should promptly identify conditions adverse to quality or safe radiation protection practices or events. In addition, the programmatic procedure should guide the MML to determine the cause(s); develop corrective actions to preclude recurrence; and evaluate the extent of conditions, method of documentation, dissemination within the program, and reporting to management. The corrective program should enable the MML to perform trend analyses and self-assessments of its program. The incorporation of the corrective action program into the NRC biennial review process would provide a measure of confidence that each MML is effectively detecting, correcting, and preventing problems that could affect the overall cornerstone, which is to protect the health, safety, and security of the public and the environment.

### 6.2.5 Recommendations

The VATG made the following recommendations:

- It was beyond the scope of the VATG mandate to fully explore whether MMLs should have expiration dates. The staff should consult with OCG to determine the feasibility of imposing expiration dates on the three existing MMLs and should also develop a policy regarding expiration dates for new MMLs. The staff should analyze the options to renew MMLs (e.g., in entirety, partial renewal, LOU only) that also takes into consideration different potential renewal frequencies (e.g., 5 years, 10 years). The staff's analysis should examine the NRC resources necessary to perform such a renewal using a team approach, as well as the impact of such a renewal on MMLs.

- The NRC should revise its Enforcement Manual to specify that MMLs may process enforcement actions for SL III and below, while the NRC should process escalated enforcement actions that are potentially SL II and above. In addition, the Enforcement Manual should specify that the NRC reserves the right to process any enforcement actions whenever it deems it appropriate and, in particular, when there are multiple events or potential programmatic issues or issues with MML oversight that contributed to the violations.

- The NRC should clarify the Enforcement Manual and the MML LOU to state that the MML is responsible for informing the NRC when it first identifies a potential escalated enforcement action and for keeping the NRC MML PM informed of the progress of the

enforcement action, so that the NRC can make an informed decision on its responsibility to process enforcement actions as necessary.

- The NRC should develop a presentation for the MMLs to describe the NRC's enforcement process. This should provide examples of SLs and the nuances between them, describe what constitutes minor and noncited violations, discuss the importance of reviewing the extent of conditions and implementing corrective actions, and provide guidance for identifying causal factors.

- The NRC should require MMLs to have a corrective action program as one of the elements of the MML program. This element should be included in the revision to NUREG-1556, Volume 10. The corrective action program would be reviewed both by the licensing Region and as part of the NRC's biennial inspection. The corrective action program should, at a minimum, address the following items: (1) identify performance indicators or a matrix for the program, (2) specify trending analysis parameters that will be evaluated for the MML oversight and inspection program, (3) commit to performing causal analysis and develop a procedure for implementing the program, and (4) identify performance improvement recommendations for the program. The corrective action program should be a risk-informed and graded approach for determining overall safety for the different modalities authorized by the MML.

## 6.3 Oversight of MML Programs

### 6.3.1 Discussion

The NRC has both formal and informal mechanisms to oversee MML programs. A more informal mechanism of oversight is for the assigned NRC PM for the MML program to communicate and routinely interact with the MML. Formal mechanisms for NRC oversight include independently inspecting MML permittees, accompanying MML inspectors, and inspecting MML programs biennially. IMC 2810 describes the program for the NRC's oversight of MML performance. The NRC first issued IMC 2810 in February 2000 and, in Change Notice 03-034, revised it on September 15, 2003, to include new procedures that the NRC has implemented since it granted DVA an MML.

### 6.3.2 Project Management

Although not specifically prescribed in any procedure or policy, the NRC would typically be expected to select an initial NRC MML PM during the MML application review process so that he or she could participate in the license application review. The NRC has no official policy or procedure to prescribe the frequency of "changing out" a PM. Instead, these decisions are made locally at the regional level, which the VATG considers to be an acceptable practice. The VATG noted that the length of time that one remained as the PM for an MML varies among the regions but that the PM typically maintains that role for several years. There is one region-based MML PM for each MML.

IMC 2810 does not describe the roles and responsibilities of an NRC MML PM, but it does describe the responsibilities for the lead Region. It describes the lead Region as the Region that is assigned project responsibility for the MML and the region in which the respective NRC MML PM is located. IMC 2810 describes one of the responsibilities of the lead Region as "routine oversight." The description includes reviewing permits, IRs, and event notifications and

reports issued by the MML, as well as attending MML RSC meetings. However, IMC 2810 does not discuss an important aspect of oversight: informal communications and routine interactions with the MML. During interviews with current and former NRC MML PMs, the interviewees underlined the importance of routine interactions with their MML counterparts. One interviewee described informal, routine communication with the MML as "critical" to effective oversight of the MML. Current and former MML PMs noted that the types of communications (telephone, e-mail) and frequency of communication varied depending on the situation. Sometimes they would want to communicate information to the MML, such as new NRC initiatives. Sometimes they would want to solicit information from the MML, such as the status of a special or ongoing project. Some PMs noted that they made an effort to at least "touch base" with their MML counterparts with a specified frequency, such as every 2 weeks. Several interviewees noted that the type and frequency of informal communications was also somewhat dependent on the willingness of their MML counterparts to participate in these communications.

It is also important that the MML PM communicate with the MML counterpart regarding the formal oversight processes, as described in Section 6.3.3. For example, coordination of independent NRC inspections and accompaniments of inspectors, as well as the scheduling and preparation for the biennial inspection, are all important. It is also important to communicate with MML counterparts regarding the results of independent NRC inspections and inspector accompaniments. The exchange of information between the NRC MML PMs and their counterparts is essential for the NRC to maintain proper oversight of the MML, as well as for the MML to maintain proper oversight of its permittees.

When an MML PM is rotated out or leaves the position and is replaced with a new PM, it is incumbent upon the outgoing PM to provide a sufficient turnover of the duties and responsibilities to the incoming PM. In addition, turnover of any ongoing activities of interest should be discussed. This typically takes place when both PMs attend the quarterly MML RSC meetings, visit with the MML staff, accompany MML inspectors, inspect the permitted facilities of high risk significance, and discuss or turn over issues with the program office, as applicable.

To better define the roles and responsibilities of an NRC MML PM, the Region IV office developed a Regional policy guide to ensure that Regional oversight of the subject MML is performed in accordance with IMC 2810 and to prescribe Regional DNMS procedures for carrying out oversight of the MML. The Regional policy guide provides a list of responsibilities of the MML PM, including having regular communication with MML counterparts and providing the MML with information regarding updates to relevant NRC policies and procedures, upcoming NRC-sponsored courses, briefings, and correspondence with the HQ MML PM.

The HQ MML PM could be described as an individual from the program office in HQ who has a role in the NRC's oversight of all the MMLs. It appears that the NRC has had some type of HQ MML PM dating back to the issuance of the first MML. Several individuals have served in this role over the years. Interviewees noted that the amount of effort expended by the HQ MML PM has varied greatly, with some HQ MML PMs being much more engaged than others. This is somewhat understandable, because IMC 2810 has no description of the position of HQ MML PM, nor could the VATG find a description of the role and responsibilities of the HQ MML PM in any other NRC policy or procedure. When the current HQ MML PM was selected, because there was no clear guidance on what this position encompassed, and there was no real turnover from the previous HQ MML PM, the individual took the initiative to become engaged in the program. The current NRC HQ MML PM has been identifying best practices involving MMLs, disseminating relevant information to the MML PMs, attending MML RSC meetings, organizing

counterpart meetings involving the MML PMs, participating in the Air Force LOU refresh, and serving on the team reviewing NUREG-1556, Volume 10.

### 6.3.3 Formal Oversight Mechanisms

Formal mechanisms for the NRC's oversight of MMLs include independently inspecting MML permittees, accompanying MML inspectors, and inspecting MML programs biennially.

*6.3.3.1 Independent NRC Inspections of MML Permittees*

The purpose of performing independent inspections of MML permittees is to help monitor licensee and permittee regulatory performance. According to IMC 2810, the lead Region should annually request a "sufficient number" of independent inspections from the regions in which the permittee is located. It furthermore states that the lead Region should choose a "representative sample" of the MML permittees to be inspected, placing less emphasis on activities that have less potential for health and safety problems. Independent inspections include routine and reactive inspections.

An issue that the VATG discussed with interviewees was requesting assistance from the other regional offices. One MML PM stated that, for this year, the Region intended to conduct all of the independent routine inspections with staff from its own regional office and not request assistance from the other regional offices. The MML PM stated that keeping the inspections in-house helped her have a better understanding of the MML program. Other interviewees stated that having the routine independent inspection conducted by inspectors from different regional offices was useful and often provided valuable additional perspectives. One interviewee noted that, if the MML PM is a qualified materials health physics inspector, it is also important to conduct some independent routine inspections to see licensee and permittee activities firsthand.

Regarding reactive inspections, several interviewees noted that the preference was for an inspector from the lead Region to conduct the reactive inspection, regardless of the physical location of the MML facility. Other interviewees suggested that there would be no problem if an inspector from another regional office performed the reactive inspection, if the MML facility was not physically located in the lead Region. One interviewee suggested that, depending on the scope of the reactive inspection, if it occurred at an MML facility not physically located in the lead Region, an inspector from another regional office could conduct the reactive inspection but that the MML PM should also consider participating in the inspection or having an inspector from the lead Region supplement the inspection.

IMC 2810 is vague in providing guidance regarding the number and type of independent NRC inspections. A "sufficient number" of independent inspections should be performed, choosing a "representative sample" of permittees to be inspected. Each of the three MMLs engages in different programmatic activities, and therefore a "sufficient number" of inspections will be quite different for each MML program. The overall performance of the MML should be taken into account when making a determination of a "sufficient number" of independent inspections. If MML performance is generally acceptable, perhaps fewer independent inspections need to be conducted but if MML performance is problematic, perhaps additional independent inspections are necessary.

*6.3.3.2 Accompaniments of MML Inspectors*

The NRC accompanies MML inspectors to evaluate their performance and determine whether they are inspecting permittees in accordance with the NRC's policies and procedures. According to IMC 2810, the lead Region should "coordinate annual accompaniments of the MML inspector(s)." Current and former MML PMs noted that they preferred to perform inspection accompaniments themselves, although it would be acceptable for other NRC inspectors, including those from other Regions, to perform the inspector accompaniments. The number of inspectors varies quite significantly among the MMLs. The Air Force MML has only one inspector, whereas DVA has five and the Navy has approximately 7–10. As noted above, IMC 2810 indicates that each of these inspectors is to be accompanied every year. This does not take into consideration the difference in the number of inspectors. It would be very time consuming for the Navy MML PM, for example, to accompany 10 inspectors every year. It would be more manageable to accompany 10 inspectors over the biennial review period. On the other hand, the Air Force has only one inspector, and it would be fairly easy to accompany this individual every year or once during the review period.

*6.3.3.3 Biennial Review of MML Programs*

IMC 2810 describes the biennial review of MML programs as a comprehensive review of the MML's management of its centralized radiation control program that integrates the results of the MML PM's routine oversight, the biennial review inspection, the independent NRC inspections, and the accompaniments of MML inspectors. The biennial inspection is conducted over a one week period; however, it incorporates the results of the formal and informal reviews of the MML program that take place during the two-year review period. According to IMC 2810, the methodology for conducting the biennial review inspection shall be performed in accordance with IP 87129, "Master Materials Program," currently dated September 15, 2003. The methodology in IP 87129 is largely based on the framework of the NRC's IMPEP for Agreement States and regional programs. It should be clear that MMLs are not Agreement States, in that MMLs are licensees and the NRC does not discontinue its regulatory authority when it issues an MML. The systematic approach of the biennial inspection is to determine whether the MML is conducting licensed activities in a manner that is protective of health and safety and is in accordance with the NRC requirements and the LOU. Similar to an IMPEP review, the biennial inspection of an MML is conducted by a team that reviews several focus elements: (1) management oversight, (2) technical staffing and training, (3) status of materials inspections, (4) technical quality of materials inspections, (5) technical quality of materials permitting actions, and (6) response to events or incidents and safety concerns or allegations. Also similar to an IMPEP review, before conducting the biennial inspection, the NRC gives the MML a questionnaire containing information it should provide to the inspection team in advance of the inspection or make available to the team during the inspection.

IMC 2810 states that the lead Region should "lead the biennial inspection." Interviews with current and past MML PMs indicated that the biennial inspections are always led by the MML PMs for their respective MMLs. Several of the interviewees and MML PMs expressed that the MML PM, who has been performing the routine oversight of the MML program, is most familiar with their respective MML program, and therefore, is in the best position to lead the biennial inspection team. It is interesting to compare this practice with that used during the conduct of IMPEP reviews of Agreement States, considering that the biennial inspection is based on the IMPEP framework. During the conduct of an IMPEP review of an Agreement State, the team leader is not the respective Regional State Agreements Officer (RSAO) for the Agreement State being reviewed, although this is the individual that is most familiar with the program and with the

program personnel. The respective RSAOs are, however, included as IMPEP team members for their Agreement States, can assist the team as a resource, and can provide any necessary information about the Agreement State program. Having the person most familiar with the program not function as the team leader provides some level of objectivity. Additionally, the IMPEP PM assigns a different team leader for each review of a particular Agreement State program, allowing for a fresh set of eyes to review the program each time. Furthermore, having RSAOs lead the IMPEP reviews of their respective Agreement States could strain the relationship between the RSAOs and their Agreement State counterparts when findings or problems are discussed during the conduct of the review. Because of the relationship between the RSAOs and their respective Agreement States, RSAOs could be reluctant to point out issues or perhaps might not be as critical. The VATG discussed these matters with the interviewees to hear their perspective. Most indicated that these issues were not a problem and felt that the MML PMs should lead their respective MML's biennial inspections. Other interviewees were receptive to the idea of having someone other than the MML PM lead the biennial inspection and indicated that there was value in having another person take an objective, critical look at the program. Options for team leaders other than the respective MML PM include any number of qualified NRC technical staff, as well as the other MML PMs and the HQ MML PM.

IMC 2810 states that the lead Region should "assemble the inspection team." Neither IMC 2810 nor IP 87129 provides further guidance on the size of the inspection team. IP 87129 discusses the qualifications of team members under each focus area. Some focus areas have more detailed qualification requirements than others. For example, to review the focus area "Status of Materials Inspection Program," the principal reviewer should meet the appropriate requirements specified in IMC 1246 for a materials radiation specialist inspector; however, to review the focus area "Response to Events or Incidents and Safety Concerns or Allegations," no specific qualifications listed are listed. The VATG asked interviewees how they decided how many people were needed or how they identified qualified team members for the focus areas. Several interviewees noted that they would ask someone experienced and qualified in licensing and inspection from their own region, or perhaps someone they were familiar with from another region. Having a team member with past experience as an MML PM or some familiarity with the MML program was also considered when selecting team members.

The appendices in IP 87129 provide guidance for the review of each of the six focus elements identified above. The guidance includes review details for each area to be reviewed during the inspection. As a comparison to IMPEP reviews, MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004, contains evaluation criteria for review areas (called "performance indicators" in IMPEP). IMPEP review teams use these criteria to evaluate the performance of Agreement States and regional programs and make a finding of either "satisfactory," "satisfactory but needs improvement," or "unsatisfactory." In evaluating MML programs through the biennial inspection process, some of the focus elements in IP 87129 refer to the IMPEP evaluation criteria in MD 5.6. Although the readiness review for DVA used the term "satisfactory" to describe the results of the focus elements reviewed, biennial inspections of MMLs do not make determinations of "satisfactory," "satisfactory but needs improvement," or "unsatisfactory" for the focus elements reviewed. Instead, NRC applies its Enforcement Policy for dispositioning findings related to biennial inspections of MMLs just as it is used for independent NRC inspections of MML permittees. Consistent use of NRC's Enforcement Policy is important because it reinforces NRC's expectations of MMLs given that, as described in Section 6.2.4, MMLs commit to following NRC's Enforcement Policy for their inspections.

There is no prescribed format for biennial IRs. Interviewees noted that they followed a standard narrative type of IR, consistent with regional guidelines. Unlike IMPEP reports, biennial IRs do not typically provide appendices that list IRs reviewed, accompaniments performed, independent NRC inspections conducted, permits reviewed, or incident and event casework reviewed. Instead, biennial IRs may state, in the narrative section, "10 inspection reports reviewed," "15 permitting actions reviewed," and "14 independent inspections were performed." Also, biennial IRs do not routinely document which team member reviewed which focus elements and who performed the independent inspections and inspector accompaniments.

The biennial inspection serves not only as a wrapup of oversight activities conducted throughout the review period but also as an opportunity to review overall programmatic issues, including MML management and oversight. Since the NRC issued the MML to DVA in February 2003, there have been four "biennial-type" inspections, because DVA was in a period of increased oversight when the NRC first issued the license. The NRC conducted program reviews in September 2003, March 2004, March 2005, and April 2007. Two different DVA MML PMs led biennial inspection teams between 2003 and 2007. The NRC scheduled a biennial inspection in 2009, but the lead Region postponed it, in part, because of ongoing inspection activities related to the prostate brachytherapy program. The biennial inspection was scheduled to be performed sometime after the May 2010 extent-of-condition IR was issued.

The first biennial-type inspection of the DVA MML reviewed the period from March 17–September 19, 2003. The team's report did not discuss the February 2003 prostate brachytherapy event at PVAMC. Although the event occurred before the review period, IP 87129 notes that it "applies to all event or incident responses…that are ongoing or occurred during the review period." The inspection team's overall conclusion was that DVA conducted its program for handling incidents in accordance with the MML.

The second biennial-type inspection reviewed the period from September 22, 2003, to March 4, 2004. The team's report reviewed several medical events at different DVA permittees, but none of the events involved prostate brachytherapy. The inspection team's overall conclusion was that DVA conducted its program for responding to incidents in compliance with the MML conditions and applicable regulations and was implementing it effectively.

The third biennial-type inspection reviewed the period from March 5, 2004, to March 17, 2005. The team's report documented the review of three medical events at different DVA permittees, two of which involved prostate brachytherapy. In the first event, at DVA Greater Los Angeles, 31 of 109 seeds were inadvertently placed in the bladder, resulting in an underdose to the prostate. NHPP's inspection determined that the event resulted from a misidentification of the base of the prostate during ultrasound imaging. In the second event, at DVA Durham, several seeds were placed into the fatty tissue surrounding the prostate but could not be removed because of potential consequences to the patient. NHPP had initiated an inspection but its report had not yet been issued at the time of the NRC's review. The team's conclusion was that DVA conducted its program for responding to incidents in compliance with the MML conditions and applicable regulations and was implementing it effectively.

After it terminated the period of increased oversight, the NRC conducted the first true "biennial inspection" of the DVA MML and reviewed the period from March 17, 2005, to April 20, 2007. The team's report documented the review of four medical events, two of which involved prostate brachytherapy. The first event was the continuation and followup of the previously reported event at DVA Durham. The NRC inspection team reviewed the NHPP IR during the biennial inspection and concluded that the NHPP staff properly reviewed the reported medical event.

The second event was on October 5, 2005, at PVAMC. The team's report noted that DVA had retracted the event, because the regulations allowed the AU to modify the WD after implantation but before completion of the procedure. The team reviewed NHPP's IR and concluded that the NHPP staff properly reviewed the event. The inspection team's overall conclusion was that DVA conducted its program for responding to incidents in compliance with the MML conditions and applicable regulations and was implementing it effectively.

The NRC's inspections of the DVA MML program were not effective in identifying the programmatic issues that were the subject of PECs held with DVA. The prostate brachytherapy events reviewed during the DVA MML program office inspections represent missed opportunities for the NRC to interact with the MML program staff and gain a better understanding of how the MML responds to and evaluates such events. The NRC and NHPP staff could have discussed programmatic issues, ways to share lessons learned across the fleet of DVA facilities, responses to and evaluations of medical events, and approaches to ensure fleet-wide performance and compliance.

### 6.3.4 Recommendations

The VATG made the following recommendations:

- The NRC should revise IMC 2810 as follows:
  - The IMC would be more appropriately entitled "MML Oversight Program" and should establish the NRC's oversight program applicable to MMLs. This oversight includes both formal and informal oversight mechanisms..
  - The IMC should specify the general roles and responsibilities of the (region-based) NRC MML Project Coordinator/Manager. This should include a discussion of the importance of routine communications with the MML. However, regional offices should be responsible for establishing policies and procedures that define roles and responsibilities and should provide implementation guidance that is specific to their respective MML programs.
  - The IMC should specify the roles and responsibilities of the HQ MML PM.
  - The IMC should discuss the expected types of interactions and exchanges of information between the region-based MML PMs and the HQ MML PM. This should also include a discussion of the frequency and organization of NRC MML counterpart meetings and the responsibility for resolving action items.
  - The IMC should provide guidance for turnover duties when a new individual assumes the responsibilities of the MML PM.
  - The IMC should provide further guidance on what constitutes a "sufficient number" and "representative sample" of independent inspections. This guidance should consider that the MMLs have different numbers of permittees and that those permittees vary significantly in health and safety as well as security significance. The guidance should have flexibility to allow increases or decreases in the number of independent inspections, based on overall MML performance.

- The IMC should provide further guidance regarding accompaniment inspections. Consideration should be given to whether the accompaniments should be conducted on an annual basis or over the biennial review period. The number of inspector accompaniments should be based on the total number of qualified MML inspectors. As applicable, priority should be given to accompanying newly qualified inspectors and those inspectors who have not been accompanied during the previous review period. Priority should be given to conducting inspection accompaniments at facilities that involve activities of higher health and safety or security significance.

- The IMC should provide further guidance on leading biennial inspection teams. Specifically, consideration should be given to having someone other than the MML PMs assigned as team leaders for biennial inspections for their respective MMLs. Although the MML PM should continue to be a member of the biennial inspection team, options for team leaders other than the respective MML PM include any number of qualified NRC technical staff, as well as the other MML PMs and the HQ MML PM.

- The IMC should provide further guidance on: (1) determining the number of team members necessary to conduct the inspection, and (2) identifying qualified team members. A suggested approach is for the lead region to solicit qualified team members through the regional DNMS Division Directors and FSME before conducting a biennial inspection. Consideration should be given to including the HQ MML PM as a biennial inspection team member.

- The NRC should revise IP 87129 as follows:

  - The NRC should consider the intent of the biennial inspection findings. It is not clear whether the findings should be compared to some criteria (either those in MD 5.6,"Integrated Materials Performance Evaluation Program," or something else) to determine whether the MML performance is satisfactory and/or NRC's Enforcement Policy should be applied.

  - The IP should provide guidance on the content and format of biennial IRs. Specifically, biennial IRs should include appendices regarding the review of inspection casework, permitting actions, and incident/event casework, and should list inspector accompaniments and independent NRC inspections performed during the review period. Independent NRC inspections should also document whether someone from the MML program was present. Biennial IRs should also document the team member reviewed who reviewed each focus element, as well as who performed the independent NRC inspections and inspector accompaniments. This would allow all of the pertinent information about the review period to be captured in one document.

  - The IP should provide additional guidance on the identification of programmatic issues, including how MMLs ensure consistency across their programs and share lessons learned with their permittees.

## Appendix A Consolidated Table of Recommendations

| Section | Document Type, Name, and Recommendations |
|---|---|
| **Management Directives** | |
| | **MD 8.3, "NRC Incident Investigation Program"** |
| **3.7.2** | With respect to events involving medical uses of byproduct material, the "Significant Operational Event" portion of MD 8.3 should be revised to refer specifically to MD 8.10 and clearly state that MD 8.10 contains further guidance and criteria to be used when considering activation of an IIT or AIT for medical events. |
| **3.7.2** | Should be revised to reflect the responsibilities of the Director, FSME, or other FSME managers, with respect to materials events. |
| **3.7.2** | In coordination with MD 8.10, should be revised for consistency as to whether to consider an IIT or an AIT for a medical event involving byproduct material that may have resulted in a fatality. |
| **3.7.2** | With respect to materials events, further guidance should be given regarding the decisionmaking process to initiate an SIT, IIT, or AIT. The process should include an initial review by the appropriate regional office, determination of the significance of the event, and consideration by the region, in consultation with FSME (as necessary), of an SIT, AIT, or IIT. The guidance should address conditions under which it might be necessary to reassess the situation and upgrade the NRC's response posture, as warranted. For materials events, the decisions and determinations should be documented and placed into ADAMS. The development and inclusion of a form in the MD, such as a "decision documentation form," would document the decisionmaking process, facilitate consistency among the regional materials programs, better ensure that necessary items are given due consideration, and that an appropriate level of NRC management approves the final decision. |
| | **MD 8.10, "NRC Medical Event Assessment Program"** |
| **3.2.2** | The language should closely mirror the current definitions and regulations in 10 CFR Part 35, addressing both over- and under- exposures as well as unintended doses to the skin or other organs or tissues. When the NRC revises the 10 CFR Part 35 regulations, especially those that relate to the reporting criteria for medical events, it should review MD 8.10 to determine if any changes are necessary. |
| **3.2.2** | Should be revised to discuss the determination of the extent of conditions and whether reported medical events are isolated or programmatic. |
| **3.2.2** | Should provide further guidance regarding the assessment of multiple medical events and how to evaluate potential medical events. |
| **3.7.2** | Should be revised to reflect the responsibilities of the Director, FSME, or other FSME managers, with respect to materials events. |
| **3.7.2** | In coordination with MD 8.3, should be revised for consistency as to whether to consider an IIT or an AIT for a medical event involving byproduct material that may have resulted in a fatality. |
| **3.7.2** | Should include criteria for determining when to consider an SIT, AIT, or IIT for medical events involving underdoses or unintended doses to the skin or other organs or tissues. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| **3.7.2** | With respect to medical events, further guidance should be given regarding the decisionmaking process to initiate an SIT, IIT, or AIT. The process should include an initial review by the appropriate regional office, determination of the significance of the event, and consideration by the region, in consultation with FSME (as necessary), of an SIT, AIT, or IIT. The guidance should address conditions under which it might be necessary to reassess the situation and upgrade the NRC's response posture, as warranted. For materials events, the decisions and determinations should be documented and placed into ADAMS. The development and inclusion of a form in the MD, such as a "decision documentation form," would document the decisionmaking process, facilitate consistency among the regional materials programs, better ensure that necessary items are given due consideration, and that an appropriate level of NRC management approves the final decision. |
| **Inspection Manual Chapters** | |
| | **IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area"** |
| **4.2** | Should include a requirement for refresher training for NRC license reviewers and inspectors regarding changes in medical technology and techniques. This training should be required in addition to the H-401 refresher training requirement. A contractor or appropriately qualified NRC personnel should provide this training on a specified periodic basis or as new treatment technologies or dose determination methodologies are developed and implemented. This recommendation applies to all NRC-regulated therapeutic modalities, not just prostate brachytherapy. The TTC should standardize the training and course content so that license reviewers and inspectors across the NRC receive consistent training. Such training should also be offered to Agreement State personnel and MML inspectors and permit reviewers. |
| | **IMC 1360, "Use of Physicians and Scientific Consultants in the Medical Consultant Program"** |
| **5.2** | Should be revised to specify the qualifications, selection criteria, and formal selection process for hiring medical consultants. The policy currently practiced for the selection of ACMUI members should be used as a suitable guide in the development of a policy for the NRC's medical consultant program. When hiring medical consultants, the NRC should use a formal selection process, to include a selection panel and approval of the medical consultant by the FSME Office Director or Director, MSSA. The revisions to IMC 1360 should also provide clear guidance on the basis for renewal of consultants' appointments. |
| **5.2** | The requested tasks to be performed by NRC medical consultants should be explicitly stated in both the confirmation letter and the charter, to obtain more useful reports that meet the objectives of NRC's medical consultant program. |
| **5.2** | Should be revised to allow both regional and HQ staff to review the medical consultant reports in draft before the reports become final, so the staff can ask clarifying questions and provide feedback on inadequate assessments. This would also provide the medical consultant an opportunity to ensure that the report includes information that is useful to the NRC staff. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| | **IMC 2800, "Materials Inspection Program"** |
| **3.1.2** | Future revisions to inspection priority codes should be carefully implemented, especially when inspection priorities are being extended (e.g., Priority 1 changing to Priority 2). Instead of making changes across the board for a program code, the regional office should review each potentially affected licensee on a case-by-case basis to determine the appropriateness of implementing the change immediately. There may be some cases that warrant delaying implementation, such as the case of significantly expanded licensee programs. |
| | **IMC 2810, "Master Material License Inspection Program"** |
| **6.3.4** | Would be more appropriately titled "MML Oversight Program" and should establish the NRC's oversight program applicable to MMLs. This oversight includes both formal and informal oversight mechanisms. |
| **6.3.4** | Should specify the general roles and responsibilities of the (regional-based) NRC MML Project Coordinator/Manager. This should include a discussion of the importance of routine communications with the MML. However, regional offices should be responsible for establishing policies and procedures that define roles and responsibilities and should provide implementation guidance that is specific to their respective MML programs. |
| **6.3.4** | Should specify the roles and responsibilities of the (Headquarters-based) HQ MML PM. |
| **6.3.4** | Should discuss the expected types of interactions and exchanges of information between the region-based MML PMs and the HQ MML PM. This should also include a discussion of the frequency and organization of NRC MML counterpart meetings and responsibilities for the resolution of action items. |
| **6.3.4** | Should provide guidance for turnover duties when a new individual assumes the responsibilities of the MML PM. |
| **6.3.4** | Should provide further guidance on what constitutes a "sufficient number" and "representative sample" of independent inspections. This guidance should consider that the MMLs have different numbers of permittees and that those permittees vary significantly in health and safety as well as security significance. The guidance should have flexibility to allow increases or decreases in the number of independent inspections, based on overall MML performance. |
| **6.3.4** | Should provide further guidance regarding accompaniment inspections. Consideration should be given to whether the accompaniments should be conducted on an annual basis or over the biennial review period. The number of inspector accompaniments should be based on the total number of qualified MML inspectors. As applicable, priority should be given to accompanying newly qualified inspectors and those inspectors who have not been accompanied during the previous review period. Priority should be given to conducting inspection accompaniments at facilities that involve activities of higher health and safety or security significance. |
| **6.3.4** | Should provide further guidance regarding leading biennial inspection teams. Specifically, consideration should be given to having someone other than the MML PM assigned as team leaders for biennial inspections for their respective MMLs. Although the MML PM should continue to be a member of the biennial inspection team, options for team leaders other than the respective MML PM include any number of qualified NRC technical staff, as well as the other MML PMs and the HQ MML PM. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| **6.3.4** | Should provide further guidance on (1) determining the number of team members necessary to conduct the inspection, and (2) identifying qualified team members. A suggested approach is for the lead region to solicit qualified team members through the regional DNMS Division Directors and FSME before conducting a biennial inspection. Consideration should be given to including the HQ MML PM as a biennial inspection team member. |
| **Inspection Procedures** | |
| | **IP 87129, "Master Materials Program"** |
| **6.3.4** | The NRC should consider the intent of the biennial inspection findings. It is not clear whether the findings should be compared to some criteria (either those in MD 5.6 or something else) to determine whether the MML performance is satisfactory and/or NRC's Enforcement Policy should be applied. |
| **6.3.4** | Should provide guidance on the content and format of biennial IRs. Specifically, biennial IRs should include appendices regarding the review of inspection casework, permitting actions, and incident/event casework, and should list inspector accompaniments and independent NRC inspections performed during the review period. Independent NRC inspections should also document whether someone from the MML program was present. Biennial IRs should also document the team member reviewed who reviewed each focus element, as well as who performed the independent NRC inspections and inspector accompaniments. This would allow all of the pertinent information about the review period to be captured in one document. |
| **6.3.4** | Should provide additional guidance on the identification of programmatic issues, including how MMLs ensure consistency across their programs and share lessons learned with their permittees. |
| | **IP 87131, "Nuclear Medicine Programs, Written Directive Required"**<br>**IP 87132, "Brachytherapy Programs"**<br>**IP 87133, "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"**<br>**IP 87134, "Medical Broad-Scope Programs."** |
| **3.8.2** | Should be revised to include a discussion about contractors. The discussion should include guidance for when it might be necessary to follow up on contractor activities, and if problems or deficiencies are identified, the necessity to determine the extent of conditions and possible implications for other licensees of the Commission or Agreement States |
| | **Multiple Materials IPs** |
| **3.8.2** | The staff should review the remaining materials IPs, for programs that do not require a WD, to determine if a discussion of contractors is applicable. |
| **NUREGs** | |
| | **NUREG-1556, Volume 10, "Program-Specific Guidance About Master Materials Licenses"** |

| Section | Document Type, Name, and Recommendations |
|---|---|
| **6.2.5** | Should be revised to require MMLs to have a corrective action program. The corrective action program would be reviewed by both the licensing Region and as part of the NRC's biennial inspection. The corrective action program should, at a minimum, address the following items: (1) identify performance indicators or matrix for the program, (2) specify trending analysis parameters that will be evaluated for the MML oversight and inspection program, (3) commit to performing causal analysis and develop a procedure for implementing the program, and (4) identify performance improvement recommendations for the program. The corrective action program should be a risk-informed and graded approach for determining overall safety for the different modalities authorized by the MML. |
| **Enforcement** | |
| | **Enforcement Manual** |
| **6.2.5** | Should be revised to specify that MMLs may process enforcement actions for Severity Level III and below and the NRC should process escalated enforcement actions that are potentially Severity Level II and above. In addition, the Enforcement Manual should specify that the NRC reserves the right to process any enforcement actions whenever it deems appropriate and, in particular, when there are multiple events or potential programmatic issues or issues with MML oversight that contributed to the violations. |
| **6.2.5** | In coordination with MML LOUs, should be clarified to state that the MML is responsible for informing the NRC when it first identifies a potential escalated enforcement action and for keeping the NRC MML Project Manager informed of the progress of the enforcement action, so that the NRC can make an informed decision on its responsibility to process enforcement actions as necessary. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| | **General** |
| **6.2.5** | The NRC should develop a presentation for the MMLs to describe the NRC's enforcement process. This should provide examples of SLs and the nuances between them, describe what constitutes minor and noncited violations, discuss the importance of reviewing the extent of conditions and implementing corrective actions, and provide guidance for identifying causal factors. |
| **Guidance to Licensees and Inspectors/License Reviewers** | |
| | **General** |
| **3.6.2** | The NRC should make every effort to provide NRC licensees and inspectors with: definitions for relevant terms (e.g., treatment site, completion of procedure), guidance regarding complying with NRC's requirements related to written directives, and guidance regarding acceptable criteria for evaluating prostate brachytherapy medical events. The implementation guidance could be transmitted to licensees in an information notice or perhaps a regulatory issue summary. The inspection guidance could be transmitted to NRC inspectors in an addendum to IP 87132, "Brachytherapy Programs," dated December 5, 2005. The NRC should share both the guidance to licensees and inspectors with Agreement State Radiation Control Programs. The guidance to inspectors should also be shared with the MMLs. |
| **3.6.2** | The NRC should not finalize any changes or revisions to the regulations in this area without accompanying guidance on licensee implementation and NRC inspection and licensing. |
| **Master Materials License Program** | |
| | **General** |
| **6.1.2** | The NRC should develop a procedure for processing an MML application. A suitable starting point is SA-700. At a minimum, the procedure should include guidance for (1) providing a timeline for appointing an MML PM, (2) describing the makeup of the MML application review team, (3) describing the roles and responsibilities of regional and HQ POCs, (4) processing and tracking all actions, including licensing, inspections, incidents or events, allegations, investigations, and enforcement, (5) identifying MML licensees with a history of health and safety issues or programmatic concerns, and (6) transferring or archiving NRC license docket folders for terminated MML facility licenses |
| **6.2.5** | The staff should consult with OCG to determine the feasibility of imposing expiration dates on the three existing MMLs and should also develop a policy regarding expiration dates for new MMLs. The staff should analyze the options to renew MMLs (e.g., in entirety, partial renewal, LOU only) that also takes into consideration different potential renewal frequencies (e.g., 5 years, 10 years). The staff's analysis should examine the NRC resources necessary to perform such a renewal using a team approach, as well as the impact of such a renewal on MMLs. |
| **6.2.5** | In coordination with the Enforcement Manual, MML LOUs should be clarified to state that the MML is responsible for informing the NRC when it first identifies a potential escalated enforcement action and for keeping the NRC MML Project Manager informed of the progress of the enforcement action, so that the NRC can make an informed decision on its responsibility to process enforcement actions, as necessary. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| **Medical Consultant Program** | |
| | **General** |
| **5.2** | A current list of approved NRC medical consultants, with a description of each of their specific specialties, should be made available to FSME and regional staff. This could be accomplished by posting the list in an easily accessible area on FSME's internal Web site. |
| **5.2** | The NRC should have more medical consultants available to the staff. Specifically, the NRC should have more than one medical consultant available to cover each type of NRC-regulated modality in radiation therapy. To obtain a more comprehensive list of qualified consultants, the staff should consider solicitation for nominations through the *Federal Register*, as well as through advertisements in professional journals, and should ask professional societies to nominate qualified candidates. |
| **5.2** | The staff should identify all cases on which XXX XXXXXXXXXXXXXXXXXX served as an NRC medical consultant. (XXXXXXXXXXXXXX, a former NRC medical consultant, was also involved as an AU in some of the PVAMC medical events.) The cases in which XXXXXXXXXXXXXX served as an NRC medical consultant should be reviewed by the staff and, as necessary, independently reviewed by a different medical consultant who is qualified in the modality or modalities being reviewed. |
| **5.2** | For the purpose of tracking, the FSME Coordinator should maintain a log of the consultants who are used and the cases to which they are assigned. The FSME Coordinator should ensure that ADAMS accession numbers for medical consultant reports and associated NRC IRs are received and maintained on file. |
| **Technical Assistance Requests** | |
| | **General** |
| **3.6.2** | FSME management should communicate to the regional offices that, unless specifically stated, they should not use TAR responses as generic inspection or licensing guidance. If it intends certain TAR responses to be used as generic inspection or licensing guidance, FSME management should to transmit this information in a suitable format to the regional offices so that it can be used consistently across the NRC Regions. Although TAR responses are typically not publicly available, the information contained in TAR responses that are intended for generic use should be shared with Agreement State Radiation Control Programs and MML programs, as applicable. |

| Section | Document Type, Name, and Recommendations |
|---|---|
| **Training Program** | |
| | **H-313 course "Brachytherapy, Gamma Knife, and Emerging Technologies Course"** |
| **4.2** | As the 2004 working group recommended, the brachytherapy portions of the contractor-led portion of the course should include a discussion of brachytherapy post-implant dosimetry, dose-volume histograms, and parameters for the evaluation of prostate implants (e.g., D90, V100). The H-313 course should be modified to include these terminologies as well as others that explain post-implant dose verification techniques for prostate implant brachytherapy. These topics should be defined and discussed in the contractor-led portion of the course as opposed to being defined and introduced for the first time by the NRC or Agreement State lecturer. Furthermore, the contractor lecturer who presents these materials should have a strong familiarity or some level of expertise with these topics and be proficient to answer questions on the subject matter. |
| **4.2** | The scope of topics for the NRC or Agreement State lecturer should not be too broad, as currently the course allots only 4 hours (including breaks) for this portion, which is expected to discuss both licensing and inspection. The NRC or Agreement State-led portion of the course should be focused on licensing and inspection, as appropriate, and should not spend significant time repeating topics that were covered in the "technology" (contractor-led) portion of the course. |
| | **General** |
| **4.2** | Expert regulators from NRC or Agreement States who lead portions of NRC-sponsored courses should be provided with some guidance, expectations, or list of topics that are expected to be covered during the time allotted for their portions of the course. This could consist of a bulleted list developed with input from TTC, the regional offices, and FSME. |
| **4.2** | NRC-sponsored courses should exercise caution in discussing or teaching attendees regarding proposed regulations. These topics could be confusing and might lead to inspection against proposed regulations that have not been completed or implemented. TTC should develop guidance for course lecturers to use as reference when discussing proposed regulations. |
| **4.2** | When NRC-sponsored courses are significantly revised, consideration should be given to either (1) requiring previous attendees who are still qualified inspectors/license reviewers to take the revised course in a reasonable timeframe (e.g., 2 to 3 years), or (2) having the "new" or significantly revised material be taught in a shorter session (e.g., fewer than 2 days) that can be taught by the contractor or TTC personnel, as appropriate, in an NRC regional office or hosted by an Agreement State. |

## Appendix B Abbreviations and Acronyms

| | |
|---|---|
| ACMUI | Advisory Committee on the Medical Use of Isotopes |
| ADAMS | Agencywide Document Access and Management System |
| Air Force | Department of the Air Force |
| AIT | augmented inspection team |
| AU | authorized user |
| CFR | *Code of Federal Regulations* |
| CT | computed tomography |
| DNMS | Division of Nuclear Materials Safety |
| DPV | differing professional view |
| DVA | Department of Veterans Affairs |
| EDO | Executive Director for Operations |
| FSME | Federal and State Materials and Environmental Management Programs, Office of (NRC) |
| FR | *Federal Register* |
| FTE | full-time equivalent |
| Gy | Gray |
| HDR | high dose rate remote afterloader brachytherapy |
| H&S | Health & Safety |
| HQ | Headquarters (NRC) |
| IMC | Inspection Manual Chapter |
| IMPEP | Integrated Materials Performance Evaluation Program |
| IIT | incident investigation team |
| IP | inspection procedure |
| IR | inspection report |
| LOU | letter of understanding |
| Navy | Department of the Navy |
| NHPP | National Health Physics Program (DVA) |
| NMSS | Nuclear Material Safety and Safeguards, Office of |
| NRC | Nuclear Regulatory Commission, U.S. |
| NRSC | National Radiation Safety Committee (DVA) |
| mCi | millicurie |
| MD | management directive |
| MML | Master Materials License (Licensee) |
| MSSA | Division of Materials Safety and State Agreements |
| OGC | Office of the General Counsel |
| PEC | Predecisional Enforcement Conference |
| PM | project manager |
| POC | point of contact |
| PVAMC | Philadelphia Veterans Affairs Medical Center |
| RSAO | Regional State Agreements Officer |
| RSC | Radiation Safety Committee |
| SIT | special inspection team |
| SL | severity level |
| Sv | sievert |
| TAR | technical assistance request |
| TI | temporary instruction |
| TTC | Technical Training Center (NRC) |

| | |
|---|---|
| VATG | Department of Veterans Affairs Lessons-Learned Task Group |
| WD | written directive |

## Appendix C List of Documents Reviewed

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| **NRC Papers, Briefings, Memoranda Related to DVA MML Application** | | | |
| | SECY-02-0160, "Department of Veterans Affairs Application for a Master Materials License"<br><br>Attachments | August 28, 2002<br><br>various | ML021790474<br><br>ML021650555 (package) |
| | SRM SECY-02-0160, "Department of Veterans Affairs Application for a Master Materials License" | October 15, 2002 | ML022880080 |
| | Department of Veterans Affairs Master Materials License Action Plan | December 13, 2002 | ML023470667 |
| | NRC Guidelines for Processing DVA Licensing Actions, Open Enforcement and Allegation Cases, and Conducting Overdue Inspections | December 23, 2002 | ML023580103 |
| | NRC License, DVA 03-23853-01VA, issuance of MML | March 17, 2003 | ML030850111 |
| | NRC License Termination, Philadelphia Veterans Affairs Medical Center, License 37-00062-007, Docket 030-14526 | March 17, 2003 | ML030770746 |
| | Department of Veterans Affairs Action Plan; Increased Oversight for March 17, 2003, through September 19, 2003 | April 22, 2003 | ML031140597 |
| | Department of Veterans Affairs Action Plan, Revision 1; Increased Oversight for March 17, 2003, through September 19, 2003 | May 19, 2003 | ML031400426 |
| | SECY-04-0076, "Department of Veterans Affairs (DVA) Implementation of Its Master Materials License (MML)" | May 6, 2004 | ML041180619 |
| | Results of Increased Oversight of DVA MML and Recommendation for Future Oversight | May 23, 2005 | ML051430272 |
| | Department of Veterans Affairs MML Oversight Program | July 27, 2005 | ML052010255 |
| | SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public" | December 27, 2005 | ML053180408 |
| **NRC Management Directives (MDs)** | | | |
| | MD 3.53, "NRC Records and Document Management Program" | March 15, 2007 | ML071160026 |
| | MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)" | February 26, 2004 | ML041410578 |
| | MD 6.8, "Lessons-Learned Program" | August 1, 2006 | ML062220175 |
| | MD 8.3, "NRC Incident Investigation Program" | March 27, 2001 | ML031250592 |
| | MD 8.10, "NRC Medical Event Assessment Program" | July 6, 1994 | ML041410592 |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| **NRC Inspection Manual Chapters (IMCs)** | | | |
| | IMC 1246, “Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area” | January 5, 2001 | ML031280599 |
| | IMC 1301, “Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan” | October 20, 2000 | ML003738375 |
| | IMC 1360, “Use of Physicians and Scientific Consultants in the Medical Consultant Program” | November 2, 2006 | ML062720195 |
| | IMC 2800, “Materials Inspection Program” | December 30, 1999 | ML003680406 |
| | Temporary Instruction 2800/033, “Revised Materials Inspection Program” | April 2, 2002 | ML021070347 |
| | Temporary Instruction 2800/033, Rev. 1, “Revised Materials Inspection Program” | October 21, 2002 | ML023300447 |
| | Temporary Instruction 2800/033, Rev. 2, “Revised Materials Inspection Program” | December 31, 2002 | ML030290124 |
| | IMC 2800, “Materials Inspection Program” | November 25, 2003 | ML033360813 |
| | IMC 2800, “Materials Inspection Program” | September 28, 2005 | ML052730305 |
| | IMC 2810, “Master Material License Inspection Program” | September 15, 2003 | ML032810354 |
| | IMC 2882, “Transfer of Files to Agreement State(s)” | December 3, 2001 | ML013480389 |
| **NRC Inspection Procedures (IPs)** | | | |
| | IP 87103, “Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing” | November 3, 2000 | ML003768339 |
| | IP 87118, “Brachytherapy Programs” | unknown | ML003714637 |
| | IP 87125, “Materials Processor/Manufacturer Programs” | September 28, 2005 | ML052730313 |
| | IP 87126, “Industrial/Academic/Research Programs” | September 28, 2005 | ML052730315 |
| | IP 87127, “Radiopharmacy Programs” | July 1, 2008 | ML080740188 |
| | IP 87129, “Master Materials Program” | September 15, 2003 | ML032810328 |
| | IP 87131, “Nuclear Medicine Programs, Written Directive Required” | October 24, 2002 | ML023370170 |
| | IP 87132, “Brachytherapy Programs” | December 6, 2005 | ML053360542 |
| | IP 87133, “Gamma Stereotactic Radiosurgery and Teletherapy Programs” | October 24, 2002 | ML023370189 |
| | IP 87134, “Medical Broad-Scope Programs” | September 28, 2005 | ML052730319 |
| | IP 93812, “Special Inspection” | March 23, 2009 | ML083370411 |
| **NRC NUREGs** | | | |
| | NUREG-1556, Volume 9, Rev. 2, “Program-Specific Guidance About Medical Use Licenses” | January 31, 2008 | ML073400289 |
| | NUREG-1556, Volume 10, “Program-Specific Guidance About Master Materials Licenses “ | December 31, 2000 | ML010110251 |
| | NUREG-1556, Volume 11, “Program-Specific Guidance About Licenses of Broad Scope” | April 30, 1999 | ML010370193 |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| **NRC Regulatory Guides** | | | |
| | Regulatory Guide 8.33, "Quality Management Program" | October 1991 | ML003739489 |
| **NRC FSME Procedures** | | | |
| | SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements" | June 5, 2009 | ML091190055 |
| | SA-700, "Processing an Agreement" | July 19, 2007 | ML072160018 |
| **NRC Inspection Reports (IR), Enforcement Actions, and Related Documents** | | | |
| | NRC IR 030-14526/2001-001 | August 7, 2001 | ML012200108 |
| | FAX from Region III to Region I re: terminating DVA licenses | March 7, 2003 | NA |
| | NRC IR 030-14526/2003-001 | June 30, 2003 | ML031820592 |
| | Memo: Request for Inspections of Permittees Under DVA MML 03-23853-01VA | May 9, 2003 | ML031320711 |
| | NRC IR 030-34325/2003-003 | September 10, 2003 | ML032580347 |
| | NRC IR 030-34325/2003-015 | October 31, 2003 | ML033040481 |
| | Memo: Request for Inspections of Permittees Under DVA MML 03-23853-01VA | November 5, 2003 | ML033100076 |
| | NRC IR 030-03013/2003-002 (Guthrie) | February 13, 2004 | ML040440117 |
| | Notice of Violation, Notice of Enforcement Discretion, and Closure of Confirmatory Action Letter (Guthrie) | March 19, 2004 | ML040790342 |
| | NRC IR 030-34325/2004-002 | April 8, 2004 | ML041000021 |
| | Memo: Request for Inspections of Permittees Under DVA MML 03-23853-01VA | October 13, 2004 | ML042880146 |
| | NRC IR 030-34325/2005-015 | April 27, 2005 | ML051180082 |
| | Memo: Request for Inspections of Permittees Under DVA MML 03-23853-01VA | December 9, 2005 | ML053460392 |
| | NRC IR 030-34325/2007-001 | May 17, 2007 | ML071380374 |
| | Memo: Requests for Inspections of Permittees Under DVA MML 03-23853-01VA | December 27, 2007 | ML073610234<br>ML073610257 |
| | NRC Special Inspection of the DVA MML for Issues Associated with Multiple Medical Events Involving Permanent Prostate Brachytherapy Treatments at PVAMC, Special Inspection Charter | August 22, 2008 | ML082401826 |
| | NRC Confirmatory Action Letter | October 14, 2008 | ML082880717 |
| | Enforcement Panel Worksheet, EA-09-037 | February 26, 2009 | ML090650700 |
| | Enforcement Panel Worksheet, EA-09-038 | February 26, 2009 | ML090650702 |
| | NRC IR 030-34325/2008-029 | March 30, 2009 | ML090900382 |
| | Letter from NRC to NHPP re: postpone PEC | April 20, 2009 | ML091120160 |
| | Letter from NRC to NHPP re: restart of suspended brachytherapy programs | September 9, 2009 | ML092530710 |
| | Enforcement Panel Worksheet | October 8, 2009 | ML093050004 |
| | Letter from NRC to NHPP re: statute of limitations waiver request | October 22, 2009 | ML092940688 |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| | NRC IR 030-34325/2009-001 | November 17, 2009 | ML093210599 |
| | NRC presentation from December 17, 2009 PEC | December 17, 2009 | ML093490877 |
| | NRC PEC summary | December 23, 2009 | ML093570466 |
| | Letter from NRC to DVA re: PEC | December 24, 2009 | ML093580162 |
| | Memo re: decision to postpone DVA Biennial Inspection | February 8, 2010 | ML100390075 |
| | Notice of Violation and Proposed Imposition of Civil Penalty- $227,500; NRC IR 030-34325/2008-029 and NRC IR 030-34325/2009-001 | March 17, 2010 | ML100710692 |
| | NRC IR 030-34325/2008-030 | May 24, 2010 | ML101440380 |
| | PEC meeting notice | June 14, 2010 | ML101650788 |
| | NRC PEC summary | July 2, 2010 | ML101880329 |
| | NRC letter to DVA re: meeting with Chairman Jaczko | July 8, 2010 | ML101890584 |
| | Notice of Violation and Proposed Imposition of Civil Penalty -$39,000; NRC IR 030-34325/2008-030 | August 23, 2010 | ML102350127 |
| **NRC Regional Policies** | | | |
| | Region I DNMS Directive 0310.1, "Response to Medical Events" | December 28, 2006 | NA |
| | Region I Regional Instruction 0530.4/2, "Self-Assessment Process" | July 18, 2008 | ML082040846 |
| | Region IV Regional Office Policy Guide 0801.4, "Management Directive 8.3 and Inspection Manual Chapter 0309 Reactive Team Inspection Decisions, Implementation and Documentation for Power Reactors" | July 6, 2010 | NA |
| | Region IV Regional Office Policy Guide 9005B.4, "Department of the Air Force Master Material License Project Manager Responsibilities" | July 17, 2007 | NA |
| **NRC News Releases** | | | |
| | No. 08-033, "NRC Begins Special Inspection of the Department of Veterans Affairs due to Multiple Medical Events" | September 9, 2008 | NA |
| | No. III-08-040, "NRC Issues Confirmatory Action Letter to the Department of Veterans Affairs" | October 15, 2008 | NA |
| | No. III-09-033, "NRC Completes Inspection of Medical Errors at Veterans Affairs Hospital in Philadelphia" | November 17, 2009 | NA |
| | No. III-09-036, "NRC to Hold Enforcement Conference Dec. 17 with Department of Veterans Affairs" | December 10, 2009 | NA |
| | No. III-10-005, "NRC Proposes $227,500 Fine Against Department of Veterans Affairs" | March 17, 2010 | NA |
| | No. III-10-027, "NRC to Hold Enforcement Conference June 30 with Department of Veterans Affairs" | June 24, 2010 | NA |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| **NRC Medical Consultant Documents** | | | |
| | NRC letter to XXXXXXXXX re: Guthrie Healthcare Systems | June 25, 2003 | ML031780073 |
| | XXXXXXXXXX report re: Guthrie Healthcare Systems | July 28, 2003 | ML102070026 |
| | NRC letter to XXXXXXXXX re: Guthrie Healthcare Systems | August 20, 2003 | ML032320279 |
| | XXXXXXXXXX report re: Guthrie Healthcare Systems | December 8, 2003 | ML102070041 |
| | NRC letter to XXXXXXXXX re: PVAMC events | September 23, 2008 | NA |
| | NRC letter to XXXXXXXXX re: PVAMC events | October 21, 2008 | ML082950794 |
| | XXXXXXXXXX report re: PVAMC events | December 22, 2008 | ML083650335 |
| | NRC letter to XXXXXXXXX re: PVAMC events | July 6, 2009 | ML091880588 |
| | XXXXXXXXXX report re: PVAMC events | October 12, 2009 | ML093020636 |
| | FSME List of Medical Consultants | January 20, 2010 | NA |
| **DVA Correspondence, Event Reports, Inspection Reports, etc.** | | | |
| | Event Notification, Event 39586 | February 14, 2003 | NA |
| | NHPP written report to NRC, Event 39586 | February 27, 2003 | ML030760515 |
| | NHPP IR 642-04-I01 | February 26, 2004 | ML053340583 |
| | Letter to NRC from NHPP re: terminating DVA licenses | March 4, 2003 | NA |
| | Event Notification, Event 40634 | April 2, 2004 | NA |
| | Event Notification, Event 41443 | February 25, 2005 | NA |
| | Event Notification, Event 42038 | October 5, 2005 | NA |
| | NHPP written report to NRC, Event 42038 | October 19, 2005 | ML052970407 |
| | NHPP site visit report for PVAMC | November 8, 2005 | NA |
| | NHPP IR 642-06-I01 | February 14, 2006 | ML061020613 |
| | Event Notification, Event 44065 | March 15, 2008 | NA |
| | Event Notification, Event 44219 | May 6, 2008 | NA |
| | NHPP written report to NRC, Event 44219 | May 30, 2008 | NA |
| | NHPP written report to NRC, Event 44219 | June 21, 2008 | ML092110542 |
| | NHPP written report to NRC, Event 44219 | July 8, 2008 | ML081970249 |
| | NHPP written report to NRC, Event 44219 | July 15, 2008 | ML081980758 |
| | NHPP written report to NRC, Event 44219 | July 21, 2008 | ML082030634 |
| | NHPP written report to NRC, Event 44219 | July 22, 2008 | ML082041000 |
| | NHPP written report to NRC, Event 44219 | July 30, 2008 | ML082130613 |
| | NHPP written report to NRC, Event 44219 | July 31, 2008 | ML082140835 |
| | NHPP written report to NRC, Event 44219 | August 4, 2008 | ML082190411 |
| | NHPP written report to NRC, Event 44219 | August 7, 2008 | ML082240300 |
| | NHPP written report to NRC, Event 44219 | August 19, 2008 | ML090910694 |
| | NHPP written report to NRC, Event 44219 | August 26, 2008 | ML082410293 |
| | DVA Report of Administrative Board of Inquiry | September 5, 2008 | ML082630821 |
| | NHPP Audit Checklist “Transperineal Permanent Implant Prostate Seed Brachytherapy” | September 13, 2008 | NA |
| | Event Notification, Event 44522 | September 25, 2008 | NA |
| | Event Notification, Event 44524 | September 26, 2008 | NA |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| | Event Notification, Event 44548 | October 7, 2008 | NA |
| | Letter to NRC from NHPP re: medical events | October 12, 2008 | ML082880041 |
| | NHPP written report to NRC, Event 44219 | October 16, 2008 | ML082900902 |
| | Letter to NRC from NHPP re: Administrative Board of Inquiry Exhibits | October 17, 2008 | ML082940582 |
| | Event Notification, Event 44663 | November 18, 2008 | NA |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | December 15, 2008 | ML083590147 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | January 22, 2009 | ML090270296 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | January 23, 2009 | ML092321189 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | January 26, 2009 | ML090270287 |
| | Event Notification, Event 44813 | January 28, 2009 | NA |
| | Event Notification, Event 44853 | February 13, 2009 | NA |
| | Letter to NRC from NHPP re: technical issues pertaining to permanent prostate brachytherapy implants | May 20, 2009 | ML091420564 |
| | Letter to NRC from NHPP re: dosimetry information | July 28, 2009 | ML092110770 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | July 30, 2009 | ML092160344 |
| | FAX to NRC from NHPP re: Confirmatory Action letter | August 4, 2009 | ML092260732 |
| | NHPP written report to NRC, Event 44219 | August 26, 2009 | ML092430206 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | September 22, 2009 | ML092710561 |
| | Letter to NRC from NHPP re: medical event data | October 29, 2009 | ML093080147 |
| | Letter to Chairman Jaczko from DVA | November 9, 2009 | NA |
| | NHPP presentation from December 17, 2009 PEC | December 17, 2009 | ML093490877 |
| | Letter to NRC from DVA re: PEC | January 14, 2010 | ML100150326 |
| | Letter to NRC from NHPP re: retraction of medical events | January 28, 2010 | ML100331994 |
| | Letter to NRC from NHPP re: incident response procedure | February 11, 2010 | ML100470927 |
| | Letter to NRC from NHPP re: Confirmatory Action Letter | February 16, 2010 | ML100491815 |
| | Letter from DVA to NRC re: reply to a Notice of violation | April 8, 2010 | ML101030828 |
| | Letter to Chairman Jaczko from DVA | April 16, 2010 | ML101310160 |
| | NHPP IR 642-09-I02 | April 21, 2010 | ML101410560 |
| | DVA Office of Inspector General, Report No. 09-02815-143, “Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania, and Other VA Medical Centers.” | May 3, 2010 | NA |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| | Letter to NRC from NHPP re: PEC | July 15, 2010 | ML101970407 |
| **Regulations** | | | |
| | 10 CFR 35 | | |
| **Miscellaneous Documents** | | | |
| | NRC Enforcement Manual, Chapter 8.12 "Enforcement Actions Involving Master Materials Licensees" | | |
| | Commission policy statement on medical uses, 65 FR 47654 | | |
| | E-mail from Lanzisera to Williamson re: item for next Part 35 call | February 20, 2003 | NA |
| | E-mail from Henderson to Thompson re: archiving DVA licenses | February 26, 2003 | NA |
| | E-mail from Howe to Chidakel re: brachytherapy medical events | February 28, 2003 | NA |
| | Part 35 Bi-weekly Regional Teleconference Meeting Minutes | February 27, 2003 | NA |
| | Telephone conversation record | March 13, 2003 | ML030730720 |
| | Part 35 Bi-weekly Regional Teleconference Meeting Minutes | March 20, 2003 | NA |
| | Part 35 Bi-weekly Regional Teleconference Meeting Minutes | April 3, 2003 | NA |
| | NRC Form 35, "Records Transfer" | April 10, 2003 | NA |
| | Part 35 Bi-weekly Regional Teleconference Meeting Minutes | May 15, 2003 | NA |
| | Part 35 Bi-weekly Regional Teleconference Meeting Minutes | May 29, 2003 | NA |
| | E-mail from Chidakel to Howe re: Prostate Underdose | June 3, 2003 | NA |
| | E-mail from Zelac to Henderson | June 13, 2003 | ML031840065 |
| | Preliminary Notification PNO-I-03-020 re: Guthrie Healthcare Systems | June 18, 2003 | ML031690271 |
| | Preliminary Notification Update PNO-I-03-020A re: Guthrie Healthcare Systems | July 24, 2003 | ML032050470 |
| | Region I Technical Assistance Request re: Guthrie Healthcare System | November 5, 2003 | ML031681469 |
| | Response to Technical Assistance Request dated November 5, 2003, for Guthrie Healthcare System | January 29, 2004 | ML040330104 |
| | ACMUI Summary Minutes | March 1-2, 2004 | NA |
| | ACMUI Meeting Summary | October 13-14, 2004 | NA |
| | ACMUI Meeting Summary | April 20-21, 2004 | NA |
| | E-mail from Ricci to Selden with attached working group final recommendations table | December 14, 2004 | NA |
| | ACMUI Teleconference Meeting Summary | June 28, 2005 | NA |
| | ACMUI Meeting Summary | April 28-29, 2005 | NA |
| | ACMUI Meeting Summary | July 21, 2008 | NA |

| | Document Title/Description | Document Date | ADAMS Accession Number |
|---|---|---|---|
| | ACMUI Meeting Summary | October 27-28, 2008 | NA |
| | NRC Demand for Information, IA-09-035 | May 26, 2009 | ML091460732 |
| | Response to NRC Demand for Information, IA-09-035 | May 28, 2009 | ML091871017 |
| | NRC Office of Investigations Report, Case No. 3-2009-002, "U.S. Department of Veterans Affairs—Philadelphia" | June 26, 2009 | N/A |
| | Region I Technical Assistance Request re: DVA | December 1, 2009 | ML092810019 |
| | E-mail from P. Pelke to D. White re: NRC assessment of PVAMC doses | December 14, 2009 | NA |
| | Department of Veterans Affairs Lessons-Learned Task Group Charter | January 21, 2010 | ML100200766 |
| | Region III Technical Assistance Request re: University of Pennsylvania | February 26, 2010 | ML100610086 |
| | Memorandum from Xu to Lewis re: Master Materials Licensees Counterpart Meeting Summary | March 10, 2010 | ML100680111 |
| | H-313 course materials from Ragland | March 15, 2010 | NA |
| | List of NRC licenses terminated between January 1, 2003 and December 31, 2003 | April 7, 2010 | NA |
| | State of Wisconsin Information Notice | July 21, 2010 | NA |
| | NRC Region III criteria for reviewing medical events at the PVAMC | Unknown | NA |

## Appendix D List of Persons Contacted

**NUCLEAR REGULATORY COMMISSION**

**Office of Enforcement:**

| | | |
|---|---|---|
| Suzanne Woods | Materials Specialist | Office of Enforcement |

**Office of Federal and State Materials and Environmental Management Programs:**

| | | |
|---|---|---|
| Michelle Beardsley | Health Physicist | FSME/MSSA/ASPB |
| Michele Burgess | Senior Regional Program Coordinator | FSME/MSSA/RSMB |
| Christian Einberg | Chief | FSME/MSSA/RSMB |
| Jack Foster | Chief | FSME/MSSA/LB |
| Donna-Beth Howe, Ph.D. | Health Physicist | FSME/MSSA/RSMB |
| Robert Lewis | Director | FSME/MSSA |
| Ed Lohr | Health Physicist | FSME/DILR/RB-B |
| Aaron McCraw | Health Physicist | FSME/MSSA/ASPB |
| Mark Shaffer | Director | FSME/DILR |
| Dennis Sollenberger | Senior Health Physicist | FSME/MSSA/ASPB |
| Julie Ward | Management Analyst | FSME/PBPA/FMB |
| Duane White | Health Physicist | FSME/MSSA/RMSB |
| Duncan White, CHP | Chief | FSME/MSSA/ASPB |
| Shirley Xu | Health Physicist | FSME/MSSA/LB |
| Ronald Zelac, Ph.D. | Senior Health Physicist | FSME/MSSA/RMSB |

**Office of the General Counsel:**

| | | |
|---|---|---|
| Susan Chidakel | Senior Attorney | Office of the General Counsel |

**Office of Investigations:**

| | | |
|---|---|---|
| Jerome Bigoness | Special Agent | OI/ Region III Field Office |
| Scott Langan | Director | OI/ Region III Field Office |

**Office of Nuclear Reactor Regulation:**

| | | |
|---|---|---|
| Fred Brown | Director | NRR/Division of Inspection and Regional Support |

**Region I:**

| | | |
|---|---|---|
| Marc Dapas | Deputy Regional Administrator | Region I |
| Sandy Gabriel, Ph.D. | Senior Health Physicist | Region I/DNMS/MB |
| Pamela Henderson | Acting Deputy Director | Region I/DNMS |
| John Kinneman | Division Director | Region I/DNMS |
| Penny Lanzisera, CHP | Senior Health Physicist | Region I/DNMS/MB |
| Orysia Masnyk-Bailey | Health Physicist | Region I/DNMS/DB |
| Michael Perkins | Licensing Assistant | Region I/DNMS |
| Randolph C. Ragland, Jr., CHP | Senior Health Physicist | Region I/DNMS/MSIB |
| Thomas Thompson | Senior Health Physicist | Region I/DNMS/CRDB |

| | | |
|---|---|---|
| Sheryl Villar | Licensing Assistance Team Leader | Region I/DNMS |

**Region III:**

| | | |
|---|---|---|
| Cassandra Frasier | Senior Health Physicist | Region III/DNMS/MLB |
| Kenneth Lambert | Senior Health Physicist | Region III/DNMS/MIB |
| Kevin Null | Senior Health Physicist | Region III/DNMS/LB |
| Steven Orth | Enforcement/Investigations Officer | Region III |
| Patricia Pelke | Chief | Region III/DNMS/LB |
| Deborah Piskura | Health Physicist | Region III/DNMS/MIB |
| Steven Reynolds | Director | Region III/DNMS |
| Darrel Wiedeman | Senior Health Physicist | Region III/DNMS/MIB |

**Region IV:**

| | | |
|---|---|---|
| Vivian Campbell | Chief | Region IV/DNMS/NMSB-A |
| Larry Donovan, LMP | Health Physicist | Region IV/DNMS/NMSB-A |
| Anthony Gaines | Senior Health Physicist | Region IV/DNMS/NMSB-A |
| Michelle Hammond | Health Physicist | Region IV/DNMS/NMSB-A |
| Art Howell | Division Director | Region IV/DNMS |
| Richard Leonardi | Senior Health Physicist | Region IV/DNMS/NMSB-A |
| Rick Muñoz | Health Physicist | Region IV/DNMS/NMSB-A |
| Martha Poston-Brown | Health Physicist | Region IV/DNMS/NMSB-A |
| James Thompson | Senior Health Physicist | Region IV/DNMS/NMSB-A |
| Jack Whitten | Chief | Region IV/DNMS/NMSB-B |

**Technical Training Center:**

| | | |
|---|---|---|
| Jeff Griffis | Senior Health Physicist | TTC/ Specialized Technical Training Branch |
| John Ricci, Ph.D. | Chief | TTC/Specialized Technical Training Branch |

**DEPARTMENT OF VETERANS AFFAIRS**

| | | |
|---|---|---|
| Thomas Huston, Ph.D. | Program Manager | DVA/NHPP |
| Gary Williams | Director | DVA/NHPP |