

POLICY ISSUE (Notation Vote)

May 6, 2004

SECY-04-0076

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: DEPARTMENT OF VETERANS AFFAIRS (DVA) IMPLEMENTATION OF ITS
MASTER MATERIALS LICENSE (MML)

PURPOSE:

To provide the Commission with a status report on the DVA's implementation of its MML following completion of the first year of the U.S. Nuclear Regulatory Commission's (NRC's) increased oversight plan, and to request Commission approval of the staff's recommendation to modify the NRC's increased oversight plan based on the DVA's performance.

SUMMARY

The staff has completed one year of increased oversight of the DVA's implementation of its MML. This included two comprehensive team inspections using Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," criteria to assess DVA performance; NRC independent inspections of 60 percent of the DVA's higher priority permittees, i.e., priority 2 and 3 programs; and two accompaniments by NRC staff of each DVA inspector. Based on the integrated results of these NRC oversight activities and the DVA's demonstration that it continues to effectively manage its centrally controlled program, the staff recommends that the increased oversight program be maintained for the second year, but at a reduced level.

BACKGROUND:

The purpose of an MML is to consolidate a number of NRC licenses each held by single entities which are part of a large federal organization into a single master license, while maintaining adequate NRC oversight and licensee management control to assure the safe use of licensed materials. Under the MML, the DVA currently oversees 115 permitted DVA Medical Centers located throughout the United States. In addition to the DVA, the NRC has issued MMLs to two other Federal organizations: the Department of the Air Force (1985) and the Department of the Navy (1987).

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A determining factor the NRC uses to evaluate an applicant's ability to manage an MML program is whether the applicant has established, and is maintaining, adequate centralized control of activities to ensure the safe use of byproduct materials under specific licenses of broad and limited scope, i.e., a centrally controlled program. The NRC recommends that applicants for an MML have at least five years experience in implementing a centrally controlled program.

Initially, the DVA requested an MML in 1996. From 1996 through 1999, the staff reviewed the DVA's submissions and evaluated the DVA's implementation of its program. Based on the results of these reviews and evaluations, the staff concluded that the DVA's existing program was deficient because it lacked adequate central control. Additionally, the staff concluded that the DVA's proposed plan to establish a sustainable central control program was not adequate. These conclusions precluded issuance of an MML.

The DVA submitted a revised application on September 21, 1998, which reflected substantive improvements, including: 1) a specific internal delegation of authority; 2) specific long-term MML funding; 3) re-establishment of the director's position for the DVA National Health Physics Program (NHPP); 4) independence of the radiation safety program for all DVA permittees implemented by the NHPP; 5) revised DVA National Radiation Safety Committee (NRSC) Standard Operating Procedures; and 6) program commitments that resolved many of the previously identified deficiencies. The staff concluded that the DVA had proposed an adequate central control program to effectively manage an MML.

From September of 1998 through early 1999, the staff assessed the DVA's program implementation, and on May 4, 1999, informed DVA management that it had not yet established and implemented an adequate central control program. The staff requested that the DVA conduct an internal assessment of its central control program and develop a plan, with milestones, and a schedule for establishing an adequate program. The DVA agreed to respond to this request.

The DVA proceeded with its assessment and implementation plan. The NRC and DVA management met on June 1, 2000, to discuss DVA's efforts and accomplishments since May of 1999. On October 26, 2000, the DVA notified the NRC that the needed changes and improvements to its program had been implemented.

In response to the DVA's notification and in order to assess its stated improvements, NRC staff conducted an independent readiness review using the IMPEP assessment criteria. The review was conducted from January through June 2001, and a report was issued on August 20, 2001. The readiness review team concluded that the DVA had implemented an adequate central control program to effectively manage an MML.

The NRC staff concluded that the DVA met all of the criteria for an MML, with the exception that the DVA lacked the recommended five years of experience in implementing and maintaining a centrally controlled program. As a result, the NRC staff concluded that it could not recommend issuance of an MML to the DVA without an initial period of increased NRC oversight, and presented the following three licensing options to the Commission: 1) deny the application until the DVA obtained the five years experience in implementing a centrally controlled program;

2) issue a two-phase MML: the first phase would include the lower-risk licensees with the intent of considering the second phase of the MML for higher-risk licensees at a later date; or 3) issue a full MML, consolidating all licenses, with increased NRC oversight while the DVA more fully established itself as an MML licensee.

On August 28, 2002, the staff recommended that the Commission approve Option 3, to issue the DVA a full MML, with increased staff oversight during a two-year period. The elements of the plan for increased NRC oversight, which includes comprehensive semi-annual team inspections, are described in Enclosure 1 to this paper.

The Commission informed the staff via a Staff Requirements Memorandum (SRM) dated October 15, 2002, in response to SECY-02-0160, "Department of Veterans Affairs Application for a Master Materials License," that it had approved Option 3. The SRM also directed the staff to provide the Commission with a status report at the end of the first year of increased NRC oversight. On March 17, 2003, the staff issued the MML to the DVA, conditional on increased NRC oversight of program implementation for a two-year period.

DISCUSSION

The staff considered the following two elements in its assessment of the DVA's implementation of its MML: I) the effectiveness of the DVA's centrally controlled program; and II) the results of the first year of semi-annual team inspections with detailed analysis of the specific focus elements used to review the DVA's MML during both NRC inspections.

I. Effectiveness of the DVA's Centrally Controlled Program

Since the MML was issued on March 17, 2003, the DVA, through its NRSC and NHPP, has demonstrated that it continues to effectively operate a centrally controlled program. The NRSC is comprised of various medical and research specialists, administrative staff, and upper level management representatives. The NRSC has delegated the management of day-to-day licensed activities to the NHPP. The NHPP includes a director, five program managers strategically located throughout the United States, several administrative staff, and an information technology specialist. The NHPP reports directly to the NRSC, which conducts Committee meetings on a quarterly basis.

Effective implementation of the DVA's MML rests heavily on the ability of the NHPP to centrally manage the activities of the 115 DVA permittees to ensure program consistency, and translate NRSC direction into appropriate action. This also requires effective two-way communication between the NHPP and NRSC. During the first year of increased oversight, NRC staff focused on the ability of the DVA, through its NHPP, to maintain centralized control of MML activities. The NRSC frequently assigns specific tasks to the NHPP at its quarterly meetings. The NHPP Director and staff report on MML activities at these meetings, providing updates on the status of these tasks at each subsequent meeting until the issue is closed per majority vote by the Committee.

Essential elements of an effective centrally controlled program are a clear understanding by the master materials licensee staff of NRC regulations, as well as licensing and inspection policies and guidance; and an ability to make necessary and timely adjustments to the MML program as policies change. Based on the results of the

NRC's oversight activities, the staff has concluded that the DVA, through its NHPP understands NRC regulations, and has effectively implemented NRC licensing and inspection policies. The NHPP actively monitors the NRC web site for any changes in inspection and licensing policies and procedures, reviews its procedures to determine if any modifications to its procedures are necessary, trains DVA staff in the changes, and notifies its permittees of the changes electronically through its web site (see below for a discussion of the NHPP web site). Based on NRC independent inspections and a thorough review of NHPP permitting actions, the staff concluded that these communications have been effective.

The staff also noted that the NHPP uses the NRC's NUREG-1556 series in reviewing permitting actions. In an effort to improve consistency in applications received from its permittees and maintain timeliness in completing permits, the NHPP developed permitting templates for renewal applications. These templates are electronically transmitted to permittees six months before a permit expiration date and are used by permittees in preparing applications for permit renewal. All applications for amendment and renewals, follow-up deficiency letters, and completed actions are transmitted electronically between permittees and the NHPP. As a result, the NHPP has an average timeliness of 12 days in completing permitting casework.

The NHPP effectively controls the DVA's inspection program by using NRC inspection guidance and making timely adjustments to keep current with NRC policy. The NHPP adopted NRC's inspection frequencies as defined in Temporary Instruction 33 for NRC Manual Chapter (MC) 2800, "Revised Materials Inspection Program," when the MML was issued on March 17, 2003. When MC 2800 was finalized by the NRC in November 2003, the priority for Program Code 2120 was changed from five years to three years. The inspection team noted that the NHPP adjusted the priority of all of its permits that had a program code of 2120 from five years to three years. This resulted in approximately 17 permittee inspections that were then immediately overdue. A discussion with the NHPP Director indicated that the DVA's plan was to perform all of the overdue inspections by the end of calendar year 2004. All other inspections were completed by the required due dates. The NHPP has averaged 24 days to complete its inspections and issue its reports. The DVA, through the NHPP, has demonstrated control over its inspection program by completing all of its inspections on time, identifying revisions that the NRC made to MC 2800, and developing a plan to complete inspections that were affected by these changes.

The NHPP and its administrative staff have been using electronic media very effectively to communicate with its permittees and the NRSC. In 1997, the NHPP developed its "NHPP Scatterings" newsletter, which is distributed to DVA permittees on a bimonthly basis. The newsletter advises permittees of recent violations that have generic applicability, the status of the DVA permitting and inspection programs, changes in NRC regulations and guidance, guidance on security of permitted material, frequently asked questions (FAQs), etc. In addition, on an as-needed basis, the NHPP issues special edition newsletters.

In 1999, the NHPP established an Intranet web site (www.nhpp.med.va.gov), and in 2002 it developed an Internet web site (www.vamcl.org/nhpp). The Intranet web site is

accessible to all DVA employees and contains current permits for all DVA permittees, NHPP inspection reports, NRC Inspection Reports, NRSC meeting minutes, etc. The Internet web site is available to the general public and contains the NHPP's "Scatterings" newsletter, a link to frequently asked questions (FAQs), a list of NHPP contacts and telephone numbers, and MML information. It also instructs the user on how to report radiation safety concerns.

Based on the results of both semi-annual team inspections, NRC independent inspections, accompaniments of NHPP inspectors by NRC staff, random NRC interviews of permittee staff members, as well as NRC observations of quarterly meetings between the DVA's NRSC and NHPP staff, the NRC staff has concluded that the DVA continues to operate its MML in a manner that exhibits a functioning centrally controlled program which fosters effective communication between the NRSC, NHPP, and DVA permittees.

II. Overview: First Year of Increased Oversight

From September 15 - 19, 2003, the NRC conducted its first semi-annual review of the DVA's performance in implementing its MML. The associated team inspection was led by Region III and included representatives from Region II, Region III, and the Office of Nuclear Material Safety and Safeguards (NMSS). The review also incorporated the results of NRC independent inspections of 14 DVA permittees, representing 30 percent of DVA's higher risk programs, i.e., priority 2 and 3 programs, as well as NRC accompaniments of each NHPP inspector.

The NRC staff completed the first year of its increased oversight plan when it conducted the second semi-annual team inspection from March 2 - 5, 2004. The team inspection was led by Region III, and included representatives from Region III, Region IV, and NMSS. Similar to the first semi-annual review effort culminating with the September 2003 team inspection, this second six-month review effort also incorporated the results of NRC independent inspections of 14 DVA permittees, representing 30 percent of DVA's higher risk programs, i.e., priority 2 and 3 programs, and NRC accompaniments of each NHPP inspector.

Both semi-annual reviews were conducted in accordance with Manual Chapter (MC) 2810, "Master Materials License Inspection Program." The elements of each review, as described in Inspection Procedure (IP) 87129, "Master Materials Program," included: 1) Management Oversight; 2) Technical Staffing and Training; 3) Status of Materials Inspection Program; 4) Technical Quality of Inspections; 5) Technical Quality of Materials Permitting Actions; and 6) Response to Events or Incidents and Safety Concerns or Allegations.

No violations of NRC requirements were identified in either semi-annual team inspection, and both inspection teams concluded that the DVA implemented its MML in accordance with NRC licensing and inspection policies and procedures, and that, overall, the DVA is implementing its permitting and inspection programs in a manner that adequately protects health and safety of workers and the general public. Enclosures 2 and 3 are copies of the semi-annual inspection reports.

A. Staff Assessment: Management Oversight

As part of its ongoing assessment of the DVA's program, NRC staff attends each NRSC quarterly meeting to evaluate the NRSC's performance in exercising its MML oversight function. The staff has observed focused involvement by the NRSC in issues pertaining to implementation of the DVA's MML. The staff has also observed NRSC interaction with NHPP staff and management at the quarterly Committee meetings, and confirmed that the Committee was actively engaged in, and effectively provided oversight and direction on, issues raised by the NHPP. For example, at the January 2004 NRSC meeting, the Deputy Under Secretary for Health communicated his concerns regarding two Severity Level III violations that the NRC had issued to the DVA between October 2003 and February 2004.¹ The Director of Safety for the DVA, at the request of the Deputy Under Secretary, also attended this meeting and provided additional insight on ways to improve the security of radioactive materials. In addition, the NRSC discussed potential security issues related to permittees that have obsolete sealed sources in storage. As a result, the NRSC tasked the NHPP to develop additional guidance addressing security of radioactive materials that would include guidance for permittees that continue to store obsolete sealed sources.

The results of NRC independent inspections of DVA permittees were also considered by the staff in its assessment of DVA oversight of its permittees' safe use of radioactive materials. From March 2003 through March 2004, the NRC conducted independent inspections of 28 DVA permittees. During this one-year period, the NRC issued two Severity Level III violations and three Severity Level IV violations. Each permittee coordinated with the NHPP to develop and implement both immediate and long-term corrective actions for each Severity Level IV violation that was cited by the NRC. In all cases, corrective action was either immediately taken or planned for implementation within 30 days.

The staff also reviewed the corrective actions implemented by the DVA in response to each violation to determine if the corrective actions were timely, comprehensive, and effective. Regarding the two Severity Level III violations, both were considered isolated and non-programmatic in nature, consequently no civil penalties were issued. The involved DVA permittees took prompt corrective action. In addition, the DVA submitted a written response to each violation, describing acceptable long-term corrective actions. During an NRC six-month follow-up inspection for the first Severity Level III violation, the staff verified that the permittee implemented appropriate corrective actions. A six-month follow-up inspection for the second Severity Level III violation is scheduled for August 2004.

In summary, NRC staff have concluded that the DVA, through its NRSC and NHPP, has conducted operations in accordance with the MML, DVA's Standard Operating Procedures, and NRC regulations. The NRSC and the NHPP were effective in providing oversight of the DVA's radiation safety and regulatory compliance program.

¹ The two violations involved failure to secure from unauthorized removal or limit access to licensed materials located in: a) a nuclear medicine department's hot laboratory; and b) a storage room located within a radiation safety office.

B. Staff Assessment: Effectiveness of the DVA's Inspection Program

Two key factors in the staff's evaluation of the DVA's inspection program were the results of NRC accompaniments of DVA NHPP inspectors and an assessment of the DVA's inspection findings. During the first year of increased NRC oversight, the staff accompanied each NHPP inspector twice and reviewed all of the NHPP's inspection reports and violation citations. Based on direct observations from NRC staff who accompanied the NHPP inspectors, and the results of the staff's review of DVA inspection documentation, both semi-annual inspection teams concluded that the NHPP inspectors conducted performance-based inspections and issued inspection reports and violations in a manner that was consistent with NRC policies and procedures.

The NRC staff also assessed the effectiveness of the DVA's inspection program by comparing the results of DVA inspections at permittee facilities to the results of inspections conducted by NRC Region III staff at non-VA facilities with identical program codes. Department of Veterans Affairs inspection activities involved permittees with the following program codes: 1) 2120 (Medical Institution - Written Directive Required); 2) 2121 (Medical Institution - Written Directive Not Required); 3) 2110 (Medical Institution Broad); and 4) 3610 (Research and Development Broad - Type A). The data gathered from NRC inspections at non-VA facilities related to the same types of programs. Enclosure 4 contains the NRC and DVA data used in the comparison.

Enclosure 4 (Table A) compares the results of all DVA inspections conducted from March 17, 2003, through February 27, 2004, to the results of NRC Region III inspections at non-VA facilities over the same time period. The last two columns provide a comparison of the ratio of the number of violations issued to the number of inspections conducted by both agencies. Of the two categories where both institutions issued violations, i.e., Program Codes 2120 and 2110, the DVA had a higher rate of violations issued per inspection conducted.

Enclosure 4 (Table B) compares the results of all DVA inspections to an equivalent number of inspections conducted by the NRC Region III Office at non-VA facilities. In compiling the NRC data, the staff reviewed the results of the last 14 inspections at non-VA facilities with Program Code 2120, 1 inspection at a Program Code 2121 facility, 10 inspections of Program Code 2110 facilities, and 2 inspections of Program Code 3610 facilities.

The data from Enclosure 4 illustrates that the DVA is identifying and issuing violations, and at a higher rate than the NRC. Based on review of the DVA's inspection reports, the staff noted that the types of violations being cited include issues related to training, survey programs, posting and labeling, and security, which is consistent with the types of findings documented in NRC inspection reports. All of the violations cited have been at a Severity Level IV. Based on a review of the DVA's inspection reports, the NRC staff concurred with the DVA's findings and citations.

In order to gain further insight into the effectiveness of the DVA's inspection program, the staff also reviewed Region I inspection data. Region I provided Region III with a listing of non-VA materials inspections it conducted from March 2003 through December 2003, along with the inspection results. The comparison of Region I's inspection results

to the DVA's inspection results of the same program codes, inspected over the same time frame, resulted in very similar findings to the comparison between the Region III and DVA inspections illustrated in Enclosure 4.

As the DVA continues to gain experience implementing its MML, the NRC staff expects that the rate of cited violations will decrease as the DVA's inspection program matures into a more risk-informed and performance-based program.

C. Staff Assessment: Effectiveness of DVA's Permitting Program

During the first year of increased NRC oversight, the staff reviewed 37 permitting actions completed by the NHPP. This review included interviews of NHPP staff during both semi-annual team inspections to determine whether the DVA's permitting program was consistent with NRC licensing policies and procedures. Permitting actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permit actions. Casework was also evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The NRC staff also evaluated the DVA's permitting process to determine if permitting actions were conducted pursuant to the MML. This process review also included an assessment of the effectiveness of the licensee's permitting tracking system. Based upon the results of both semi-annual team inspections, the NRC staff concluded that the DVA, through its NHPP, processed permitting actions in a manner consistent with NRC licensing policies, procedures, and guidance. The NRC staff also concluded that the NHPP staff conducted quality technical reviews that were based on sound health physics practices. The staff further determined that the issuance of permitting actions by the DVA was efficient and timely, with no permitting actions held in backlog.

D. Staff Assessment: Allegation and Incident Handling Programs

The NRC staff reviewed the DVA's programs for incident response and the handling of allegations. This included a review of all permittee incidents and any allegations received by the DVA to determine applicability to NRC reporting requirements, the effectiveness of the DVA's incident response and allegation programs, and the effectiveness of associated communications between the NHPP and the NRSC. The staff evaluated five incidents involving the disposal of radioactive materials to landfills, an unusually high TLD reading assigned to a permittee staff member, possession of byproduct material by an unlicensed DVA medical center, and two medical events reported to the NRC by the DVA. Based upon interviews with NHPP staff involved in the response to each non-medical incident, the NRC staff concluded that the events were not reportable and that the DVA responded to each incident in accordance with the MML. The NRC staff also reviewed the circumstances surrounding both medical events and concluded that each event was reported in accordance with 10 CFR Part 35.

During the first six months of the NRC's increased oversight effort, the NRC referred one allegation to the NHPP for follow-up in late June of 2003. The NHPP initiated its investigation in mid-July. Information concerning the allegation was forwarded in early July to the NRSC Chairman by the Director of the NHPP. However, as of September 15, 2003, the allegation had not been communicated to the NRSC membership. The NRC staff concluded that this lack of communication was an oversight on the part of the NHPP and the NRSC Chairman. The allegation was presented to the NRSC membership during the October 30, 2003, Committee meeting. An NRSC working group reviewed the details and conclusions of the investigation conducted by the NHPP. Based on its review of the NHPP investigation, the working group will be making a recommendation to the NRSC to close the allegation since the allegation was not substantiated. The NRC staff concluded that despite the lapse in communication with the NRSC membership, the allegation was processed in accordance with the MML.

The staff reviewed the DVA's SOP for handling allegations and concluded it described an adequate program. However, the staff could not make a determination regarding the DVA's overall effectiveness in implementing its allegation program because the DVA has only received and processed one allegation since the license was issued in March 2003.

E. Staff Assessment: Technical Staffing and Training

The NRC staff evaluated the DVA's staffing level for its radioactive materials program, as well as the technical qualifications and training history of the NHPP staff. In evaluating these elements, the staff interviewed NHPP management, reviewed the DVA training program, and examined the job position requirements related to permitting, compliance, and inspection. The NHPP is staffed with a director, five program managers, and administrative personnel. There has been no staff turnover since the issuance of the MML on March 17, 2003.

The NHPP developed a written training program for its technical staff based on the requirements specified in NRC Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area." The program includes qualification journals and oral qualification boards. All program managers have completed the NRC "Fundamentals of Inspection" and "Licensing Practice and Procedures" courses, as well as equivalent NRSC approved courses. The NHPP schedules its program managers for other core NRC courses as space becomes available. The NRC staff concluded that the DVA has a well-balanced, sufficiently qualified staff to perform the regulatory duties of an MML. The NHPP has successfully balanced the acquisition of training with the accomplishment of the permitting and inspection function, while successfully implementing a centrally controlled program.

INCREASED OVERSIGHT: OPTIONS

Based on the results of the NRC's assessment of the DVA's effectiveness in implementing its MML, the staff considered the following options regarding NRC oversight of the DVA:

- A. **Option 1:** Maintain the current level of increased NRC oversight of the DVA's implementation of its MML for a second year.
- B. **Option 2:** Reduce the level of increased NRC oversight of the DVA's implementation of its MML from semi-annual reviews to an annual review.
- C. **Option 3:** Terminate the current level of NRC oversight and implement the standard bi-annual review frequency for MMLs as described in Manual Chapter (MC) 2800, "Materials Inspection Program."

ANALYSIS OF OPTIONS

- A. Under **Option 1**, the NRC would maintain the current level of increased oversight of the DVA's implementation of its MML for another year, as originally proposed by the staff to the Commission in SECY-02-0160. The staff has concluded that the DVA has demonstrated adequate centralized control of its MML, such that maintaining the same level of increased NRC oversight for one more year would not result in measurable added value or benefit to the agency in terms of effective resource utilization.
- B. Under **Option 2**, the NRC would reduce its level of oversight from semi-annual to annual reviews. The NRC accompaniments of DVA inspectors would be reduced from twice per year per inspector, to once per year per inspector. The NRC independent inspections would be reduced from 60 percent of the DVA's higher risk programs per year to 30 percent per year, and the next comprehensive team inspection would be conducted in one year instead of in 6 months. While this option would result in reduced oversight relative to the level of oversight originally proposed by the staff in SECY-02-0160, it represents an increased level of oversight relative to the standard bi-annual frequency for conducting reviews of MML programs, as described in MC 2800. In addition, NRC independent inspections would be conducted at 30 percent of the DVA permittees per year compared to 10 percent per year under the bi-annual review program.

The results of the two semi-annual reviews of the DVA's performance in implementing its MML indicate that the DVA is effectively exercising a centrally controlled program. However, as noted in the background section of this paper, at the time the MML was issued, the staff was concerned that the DVA lacked the recommended five years of experience in implementing and maintaining a centrally controlled program. Consequently, the MML was issued conditional upon the staff providing the current level of increased oversight. The staff considers it prudent, given the difficulties experienced by the DVA in the past in establishing a centrally controlled program (refer to discussion in background section) to maintain a level of oversight that is above the level of oversight described in MC 2800 for another year. At that point, the staff will again assess the DVA's performance as it relates to maintaining a centrally controlled program and recommend an appropriate level of oversight based on the results of that assessment. Reducing the current level of oversight to the level described in this option acknowledges the DVA's performance to date, while addressing the fact that the DVA does not have five years of experience in successfully implementing and maintaining a centrally controlled program. In the staff's view, this graded approach to the level of

NRC oversight of the DVA's MML program will give the staff further confidence in the DVA's ongoing ability to manage its MML. Assuming the DVA continues to perform in the manner represented by the results of the last two semi-annual reviews, NRC oversight at the normal level for an MML prescribed in MC 2800 would appear warranted.

- C. Under **Option 3**, the NRC would terminate its program of increased oversight altogether and evaluate the DVA's implementation of its MML on the standard bi-annual review frequency outlined in MC 2800. Given that the DVA will not have obtained the recommended 5 years of experience in implementing its centrally controlled program until 2005 and for the reasons discussed in option 2, this option is not recommended by the staff

RESOURCES

- A. Under **Option 1**, maintaining the current level of increased NRC oversight would require an expenditure of approximately 0.60 FTE.
- B. Under **Option 2**, reducing the level of NRC oversight by 50 percent would require an expenditure of approximately 0.30 FTE.
- C. Under **Option 3**, eliminating increased NRC oversight would reduce FTE expenditure to approximately 0.20, which is the estimated FTE expenditure for managing an MML under the routine inspection program outlined in MC 2810.

RECOMMENDATION

The staff recommends that the Commission approve Option 2. Staff notes that all of the options are within the current allocated resources.

COORDINATION

The Office of the General Counsel has reviewed this Commission Paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource impacts and has no objections.

/RA Luis A. Reyes for/

William D. Travers
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- Enclosures:
1. Plan for Increased Oversight
 2. NRC Inspection Report No. (IR 030-34325/2003-015(DNMS))
 3. NRC Inspection Report No. (IR 030-34325/2004-002(DNMS))
 4. DVA and NRC Inspection Data

PLAN FOR INCREASED OVERSIGHT

The purpose of this plan is to provide the NRC staff a means of evaluating the Department of Veterans Affairs' (DVA's) initial implementation of its Master Material License (MML) program. Since the DVA does not meet the recommended criterion of having a centrally controlled program (CCP) for five years, a plan for increased NRC oversight is appropriate in order to assure effective implementation of their program. This plan provides for a two-year increased oversight of the DVA's MML activities and is based on the integrated materials performance evaluation program (IMPEP)-type criteria developed for the DVA Readiness Review.

This approach for increased oversight differs from oversight provisions contained in NRC Inspection Manual Chapter (MC) 2810, "Master Material License Inspection Program." MC 2810 describes an annual review that includes conducting one or more independent inspections of MML permit holders per Region per year, accompanying MML inspectors at least once annually, and inspecting DVA management oversight at the MML's primary facility on an annual basis. In addition to performing the required MC 2810 reviews and inspections, a semi-annual review, including team inspections, of the DVA MML activities will be performed using the elements listed below.

The staff proposal for increased oversight differs from the current MC 2810 by adding several specific areas of review and conducting the review on a semi-annual basis for the two-year increased oversight.

- I. Status of the Materials Permitting Program (tracking systems, timeliness of permitting and inspections, etc.)
 - A. MC 2810 does not directly address this, but the inspection process reviews this item.
 - B. Increased DVA oversight will include a review of their timeliness in issuing permitting actions and conducting inspections.
- II. Technical Quality of Permitting Program
 - A. MC 2810 does not directly address this, but the inspection process reviews this item.
 - B. Increased DVA oversight will include independent NRC review of permit amendments and renewal applications, associated deficiency letters, and completed permits to verify consistency with NRC policies and procedures.
- III. Technical Quality of Inspections
 - A. MC 2810 addresses this element by requiring one or more assist (independent) inspections per year in each Region and NRC accompaniments of each MML inspector once per year.

- B. Increased oversight will involve independent NRC inspections of 30 percent of the higher risk DVA permittees, i.e., priority 1 and 2 programs, and accompaniments of each National Health Physics Program (NHPP) inspector semi-annually. The project manager will also receive and review all NHPP inspection reports and enforcement actions.

NOTE: Current MML project managers for the Air Force and Navy coordinate independent inspections totaling about 10 percent of the higher risk programs over the course of 1 year and accompany each MML inspector at least one time per year.

IV. Status of Training of Technical Staff

- A. MC 2810 does not directly address this, but the technical competency of the staff is evaluated.
- B. Increased oversight will involve NRC review of the status of DVA's progress in the training of their technical staff.

V. Implementation of DVA's Allegation and Incident Handling Programs

- A. MC 2810 does not address allegations, but incident response is evaluated during the inspection process.
- B. Increased oversight will involve NRC review of DVA's handling and processing of allegations.

VI. Management Oversight

- A. MC 2810 addresses this element by requiring an annual inspection of the MML's primary facility to include inspection of management oversight.
- B. In addition to the standard practice of performing a full review of the DVA National Radiation Safety Committee (NRSC) meeting minutes, activities, and staff attendance at quarterly NRSC meetings, increased oversight will include a visit to the NHPP office in Little Rock, Arkansas at the time of the IMPEP, and other semi-annual visits.

In addition to the above semi-annual program, and in accordance with the Letter of Understanding, it is important to note that the DVA will be required to submit all of their completed permitting actions to the Region III project manager for review.

After the first year of increased oversight, the NRC will conduct an assessment to decide what level of augmented oversight should be completed in the second year. If the DVA's performance begins to show decline, the initial level of augmented oversight or even an increased level of oversight will be performed for the second year. If the DVA shows acceptable performance, the augmented oversight will be lessened accordingly for the second year. Once the two year period of augmented oversight is over, regulation of the DVA should follow that of an established MML. However, if deficiencies are noted during the oversight period, the NRC should decide what course of action is appropriate at that time. In addition, the staff will send a

letter to the DVA to remind them of the importance of management attendance at the NRSC meetings and active management participation in the MML program. The letter will also emphasize that a lack of management participation and involvement could lead to escalated enforcement with possible civil penalty and loss of the MML.

April 8, 2004

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Department of Veterans Affairs
Washington, DC 20420

SUBJECT: NRC INSPECTION REPORT (IR 030-34325/2004-002(DNMS))

Dear Dr. Roswell:

This refers to the announced team inspection conducted on March 2 through 4, 2004. The purpose of the inspection was to review the activities authorized under the Department of Veterans Affairs (DVA) Master Materials License (MML), and the inspection is the second comprehensive semi-annual NRC inspection of DVA activities, covering the period from September 22, 2003 through March 4, 2004. At the conclusion of the inspection on March 4, 2004, the NRC's findings were discussed with Thomas Holohan, M.D., Chairman, DVA MML National Radiation Safety Committee, and with the DVA's National Health Physics Program staff.

The NRC is implementing a program of increased oversight of the DVA, which includes semi-annual inspections of the DVA's MML program over a two-year period. Each semi-annual inspection involves an evaluation of MML activities conducted by the DVA over a six-month period.

This semi-annual inspection consisted of an examination of activities conducted under your MML as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the MML. Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of activities in progress, and interviews with personnel.

Based upon the inspection, no violations of NRC requirements were identified. The NRC determined that the DVA implemented its MML in accordance with NRC licensing and inspection policies and procedures, and that, overall, the DVA is implementing its permitting and inspection programs in a manner that protects public health and safety. The inspection team also confirmed that the DVA took appropriate action to address two issues that were identified by an NRC inspection team during the first semi-annual inspection conducted in September 2003. The two issues pertained to updating standard operating procedures and informing the DVA's National Radiation Safety Committee of an allegation that was being processed by the National Health Physics Program.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The ADAMS system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

R. Roswell

-2-

We will gladly discuss any questions you have concerning this inspection.

Sincerely

/RA/

Marc L. Dapas, Director
Division of Nuclear Materials Safety

Docket No.: 030-34325
License No.: 03-23853-01VA

Enclosure: NRC Inspection Report No. 030-34325/2004-002(DNMS)

cc w/encl: E. Lynn McGuire, Director
DVA National Health Physics Program

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REGION III

Docket No.: 030-34325

License No.: 03-23853-01VA

Report No.: 030-34325/2004-002(DNMS)

Licensee: Department of Veterans Affairs (DVA)

Location: National Health Physics Program
Little Rock, Arkansas

Inspection Dates: March 2 - 4, 2004

Inspectors: Kevin G. Null, Senior Health Physicist and
Project Manager for DVA Master Materials License
(MML), Region III

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Region III

Approved by: John Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety
Region III

EXECUTIVE SUMMARY

Department of Veterans Affairs Master Materials License

NRC Inspection Report No. 030-34325/2004-002

This announced NRC team inspection was conducted to evaluate the Department of Veterans Affairs (DVA) implementation and administration of activities conducted under the Master Materials License (MML). The inspection included an assessment of the DVA's implementation of its centralized control program, an evaluation of the DVA's radioactive materials permitting and inspection programs, a review of the results of Nuclear Regulatory Commission (NRC) inspections of DVA permittee facilities conducted during the six-month assessment period, and an examination of the National Radiation Safety Committee's (NRSC's) oversight of activities authorized by the MML. Licensed activities conducted during the period of September 22, 2003 through March 4, 2004, were reviewed during this inspection.

Through interviews and discussions with DVA staff, evaluation of the DVA's response to an NRC questionnaire, reviews of documents related to MML activities, and observations of DVA staff in the performance of their duties, the NRC inspection team concluded that, overall, the DVA's permitting and inspection programs were adequate and being implemented in a manner that protects the health and safety of workers and the general public.

The program areas assessed during this team inspection are summarized below:

Management Oversight

- The team concluded that the NRSC, through its National Health Physics Program (NHPP) staff, conducted operations in accordance with the MML and associated Letter of Understanding, DVA's Standard Operating Procedures, and NRC regulations. The NRSC was effective in executing its responsibility and provided appropriate oversight of the DVA's radiation safety and regulatory compliance program.

Technical Quality of Inspections

- The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures. In addition, the team determined that the DVA's inspection program is compatible with NRC's inspection policies, procedures, and guidelines, and in accordance with the MML.

Status of Materials Inspection Program

- The inspection team concluded that NHPP management appropriately assigned program codes and inspection due dates for its permittees. The NHPP has developed an acceptable plan to complete 17 inspections by the end of calendar year 2004 for those permittees whose required frequency of inspection was reduced from five years to three years when Manual Chapter 2800, "Revised Materials Inspection Program" was revised in November 2003. Notwithstanding this issue, the inspection team determined that all other inspections that were due during this six-month review period were completed in a timely manner.

Technical Staffing and Training

- The inspection team concluded that the DVA has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a master materials licensee. The NHPP has developed a plan to complete its inspector training program by the end of calendar year 2006. The team also concluded that the NHPP has successfully balanced the acquisition and scheduling of staff training and management of the permitting and inspection workload, while successfully implementing a centralized control program.

Technical Quality of Permitting Program

- The inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures, and guidance. In addition, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

Status of Permitting Program

- The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The process for reviewing and issuing permitting actions by the DVA was efficient, with timely issuances of permitting actions and a zero backlog.

Allegation and Incident Handling Programs

- No allegations have been received by the DVA (either via NRC referral or direct receipt from permittee staff or members of the public) during the second semi-annual review period, i.e., since September 2003. The NHPP has completed its investigation of an allegation that was forwarded by the NRC to the NHPP on June 29, 2003. An NRSC working group appointed by the Committee has reviewed the results of the NHPP investigation, and will be making a recommendation to close out the unsubstantiated allegation at the next NRSC meeting scheduled for April 29, 2004. The inspection team concluded that the DVA continues to process the allegation it received from the NRC in June 2003, in accordance with the MML.
- The inspection team concluded that the DVA's program for responding to incidents was in compliance with the MML conditions and applicable NRC regulations and was being implemented effectively. Two medical events were reported during this review period.

NRC Independent Inspections of DVA permittees

- The NRC inspected 14 DVA permittees during the review period. One Severity Level III and two Severity Level IV violations were identified. Based on the overall results of the independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

Report Details

1.0 Program Overview

The Department of Veterans Affairs (DVA) is authorized under NRC Master Materials License (MML) number 03-23853-01VA, to issue byproduct radioactive material permits and inspect DVA medical facilities throughout the United States. The DVA oversees approximately 115 permittees. The license was issued on March 17, 2003, and does not have an expiration date.

The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The Committee has delegated the authority to manage the DVA radiation safety program and DVA day-to-day operations to its National Health Physics Program (NHPP), which includes a program director and five program managers who are responsible for issuing permits, conducting inspections, and investigating incidents and allegations.

2.0 Management Oversight

a. Inspection Scope

The NRC inspection team evaluated the licensee's NRSC organization and management oversight activities to determine whether the Committee and its NHPP office adequately controlled the use of licensed materials, as required by the MML and NRC regulations, in a manner that protects the public health and safety. The assessment included observations of NRSC meetings, a review of notes from quarterly NHPP program managers' meetings, discussions with cognizant licensee representatives, and a review of program documentation, including an internal audit report.

b. Observations and Findings

The NRSC meets quarterly and is comprised of senior DVA managers and DVA headquarters and field representatives. During the six-month review period, the NRSC met twice. Based on observations by NRC staff in attendance at both meetings and a review of the NRSC minutes, NRC staff confirmed that the Committee met its minimum requirements for establishing a quorum. The NRC Project Manager and Nuclear Materials Safety and Safeguards (NMSS) MML Project Coordinator observed NRSC interaction with NHPP staff and management at both meetings, and confirmed that the Committee was actively engaged in, and effectively provided oversight and direction on, issues raised by the NHPP.

Through NRC attendance at the NRSC's quarterly meetings, observations by NRC staff during their accompaniments of NHPP inspectors, and an evaluation of the results of NRC independent inspections of DVA permittees, the NRC inspection team determined that the NHPP has been effective and timely in communicating important issues to its permittees. Examples include communication of issues related to security, inspection findings of generic interest and applicability, revisions to DVA MML procedures, results of NRC inspections, and NHPP inspection reports and permitting actions. The NHPP relies heavily on electronic forms of communication in transmitting inspection reports, permitting actions, and informational newsletters to permittees. However, the NHPP also communicates directly with permittees via telephone, as necessary.

During the January 29, 2004, NRSC meeting, the Committee and members of the NHPP actively discussed two security violations identified by the NRC. One was identified at the McGuire VA Medical Center, Richmond, Virginia, and the other was identified at Hines VA, Hines, Illinois. The Deputy Under Secretary for Health, accompanied by the Director of Safety, attended the meeting as a result of the recent security findings. Both expressed their concern over the lapse in security at the two institutions and emphasized the importance of making improvements at all levels within the DVA in the areas of prevention and identification of security related problems. As a result, the DVA is exploring ways to assist its permittees in disposing of old, unused sealed sources in storage (“disused sources”) and to incorporate additional engineering controls to improve security of licensed material.

In addition, the NHPP and NRSC are analyzing ways to improve: 1) identification of security weaknesses through surveillance by permittee safety/police staff); 2) restricting accessibility to material by unauthorized individuals through the use of two methods to secure material, i.e., keeping material in a locked safe and storing the safe in a locked storage room; and 3) response to breaches in security through coordination with permittee safety/police staff. In addition, as a baseline approach in its efforts to improve security, the NHPP, through delegation given to it by the NRSC, is developing a centralized sealed source inventory program for all sealed sources (used and “disused”). Using documents from the International Atomic Energy Agency and the National Council on Radiation Protection, the NHPP is working with members of the NRSC to draft a definition of a “disused source,” which will be provided to all of its permittees.

The NRSC remains committed to delegating authority to the NHPP to manage the DVA’s radiation safety program and its day-to-day operations. This includes implementation of the permitting and inspection programs, incident and allegation follow-up responsibilities, obtaining training for staff, and maintaining an acceptable level of staff to execute the program. The NHPP is responsible for six standard operating procedures (SOPs), which are essential in implementing the MML. The SOPs include reference to procedures for processing permits, conducting inspections, taking enforcement action, training inspectors, responding to incidents, and managing allegations. In addition, the NHPP developed and implemented detailed internal procedures that are designed to assure compliance with the SOPs.

During the first semi-annual inspection conducted in September 2003, the team noted that the DVA’s SOPs had not been updated to reflect the revised 10 CFR Part 35 issued in October 2002. Any changes to SOPs, including administrative changes, require an amendment to the MML. In the Letter of Understanding (LOU) between the NRC and the DVA, the DVA is required to update its policies and procedures to reflect the most current NRC regulations. The NRC inspection team concluded, however, that even though it had not updated its SOPs, the DVA, through its NHPP staff and DVA permittees, was well aware of the changes and had used the revised 10 CFR Part 35 and related NRC guidance in conducting inspections and issuing permitting actions, as well as to guide permittee activities/operations.

On December 18, 2003, the DVA received an amendment to its MML, which authorized the DVA to make administrative changes to its SOPs without requiring an amendment to the MML. Subsequent to that amendment, the NHPP modified its SOPs to be consistent with the new 10 CFR Part 35. Draft revisions to applicable SOPs were forwarded to the Region III Project Manager for review. Final versions of the SOPs were provided to the inspection team for review during the second semi-annual team

inspection. The inspection team noted that the SOPs were consistent with the new 10 CFR Part 35.

c. Conclusion

The inspection team determined that the NRSC and NHPP provided adequate oversight of DVA implementation of its MML, and conducted and controlled DVA activities in a manner that assured compliance with the MML, DVA's SOPs, and NRC regulations. The team also concluded that the DVA, through its NRSC and NHPP, demonstrated an acceptable level of centralized control of licensed activities, and maintained a functioning centralized administrative structure.

The inspection team determined that the NHPP adequately addressed issues identified in the September 2003 semi-annual inspection related to the updating of its SOPs to reflect current NRC regulations pertaining to 10 CFR Part 35.

3.0 Technical Quality of Inspections

a. Inspection Scope

The NRC inspection team reviewed inspection plans, inspection reports, and enforcement documents and correspondence associated with inspections conducted by the NHPP during the review period to determine if NHPP inspections were consistent and in conformity with NRC inspection procedures. In addition, the team interviewed NHPP inspectors to evaluate how they prepared for inspections. This included a review of the permit (or previous NRC license), licensing-related documents, and regulatory requirements. The team also evaluated the DVA's use of supporting documents (e.g., permitting files, regulatory guides, and regulations), and equipment and instrumentation provided to the DVA inspectors for conducting inspections.

b. Observations and Findings

The NHPP staff conducted 19 inspections of permittees during the review period. The inspections were routine inspections covering different types of permittees, including medical broadscope; medical institutions, written directive not required; medical institutions, written directive required; and research and development broadscopes. Inspection plans were generated by NHPP inspectors for each inspection and were reviewed and approved by the NHPP Director. The inspection team noted that the plans incorporated applicable NRC Inspection Procedures as described in the NRC Inspection Manual Chapter 2800, "Materials Inspection Program."

The inspection team observed that NHPP inspection reports appropriately documented those areas reviewed by the inspectors and that the inspection plans were followed in conducting the inspections. The inspection team also concluded that inspection findings were based on health and safety matters, and were well-founded and properly documented. The team noted that inspection reports were complete; that the inspection findings were reviewed by the NHPP Director, a good quality assurance practice; and that the reports were completed in a timely manner. The team also noted that NHPP inspectors were evaluated during an accompaniment by the NHPP Director at the proper frequency.

Each NHPP inspector was accompanied by an NRC inspector during the review period. The purpose of the accompaniment was to evaluate the technical quality of inspections being conducted by NHPP inspection staff. In addition, the NRC Project Manager accompanied the NHPP Director while the Director observed an inspection being conducted by one of his inspectors.

c. Conclusion

The team concluded that the licensee's inspection program was conducted in a manner that was compatible with the NRC's inspection policies, procedures, and guidelines. The team also concluded that NHPP inspectors were properly prepared for inspections, were provided with the necessary tools for conducting inspections, and conducted performance-based inspections in a manner that was consistent with NRC policies and procedures. Based on feedback from interviews with DVA inspectors, the team was informed that the NHPP Director's accompaniment of inspectors provided an opportunity for constructive feedback and added value to the inspection process.

4.0 Status of Materials Inspection Program

b. Inspection Scope

The NRC inspection team reviewed the licensee's program for assigning inspection frequencies to permittees, and its timeliness in completing inspections based on inspection due dates. The team interviewed NHPP inspectors and management, and compared the licensee's inspection due dates posted in its tracking system against the actual dates that inspections were completed.

c. Observations and Findings

The NHPP adopted NRC's inspection frequencies as defined in Temporary Instruction 33 for NRC Manual Chapter (MC) 2800, "Revised Materials Inspection Program," when the MML was issued on March 17, 2003. When MC 2800 was finalized by the NRC in November 2003, the priority for Program Code 2120 was changed from five years to three years. The team noted that the NHPP adjusted the priority of all of its permits that had a program code of 2120 from five years to three years. This resulted in approximately 17 permittee inspections that were then immediately overdue. A discussion with the NHPP Director indicated that the DVA's plan was to perform all of the overdue inspections by the end of calendar year 2004. All other inspections were completed by the required due dates.

d. Conclusion

The inspection team concluded that NHPP management appropriately assigned program codes and inspection due dates for its permittees, and that all inspections that were due during this six-month review period were completed in a timely fashion. Also, the team concluded that the licensee's plan to inspect the 17 overdue inspections that resulted from changes in MC 2800, was acceptable.

5.0 Technical Staffing and Training

a. Inspection Scope

The NRC inspection team reviewed the licensee's radioactive materials program staffing level and turnover, as well as the technical qualifications and training history of the NHPP staff. In evaluating these elements, the team interviewed program management staff and reviewed the DVA training program, job position requirements, and casework related to licensing, compliance, and inspection.

b. Observations and Findings

The NHPP personnel are assigned as headquarters-level staff reporting to the Chief of Patient Care Services. There have been no changes in the technical or administrative staffing of the NHPP since the first semi-annual review was completed in September 2003.

The NHPP is staffed with a director, five program managers, and administrative personnel. The director and one program manager are located in Little Rock, Arkansas. The remaining four program managers are located in the Eastern, Midwestern, Northwestern, and Southwestern United States.

The director of the NHPP continues to function as the communication link between the NRSC and program managers, and has sole signature authority for all permitting actions. However, each program manager is responsible for conducting independent technical reviews of permitting actions, resolving deficiencies with permittees, and forwarding completed reviews to the director for review and signature.

The director and program managers are all qualified to perform permitting reviews and conduct inspections. Additionally, each program manager is expected to develop expertise in specific assigned areas, e.g., there are specialists in the areas of decommissioning and high dose-rate remote brachytherapy. The administrative support staff are also cross-trained to perform all administrative functions.

The NHPP developed a written training program for its technical staff based on the requirements specified in NRC Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The program includes qualification journals and oral qualification boards. The NHPP has also developed a plan to complete all core training for its staff by calendar year (CY) 2006, pending availability of training courses. In addition to all technical staff completing NRC's "Fundamentals of Inspection" and "Licensing Practices and Procedures" courses, several staff have also completed training in root cause analysis and are scheduled to complete "Diagnostic/Therapeutic Nuclear Medicine" and "Teletherapy/Brachytherapy" training courses by the end of March 2004. Three of the five program managers have completed the course entitled "Inspecting for Performance." The other two program managers will be attending this course in CY 2005, as it is not scheduled for CY 2004.

c. Conclusion

The inspection team concluded that the DVA has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a master materials licensee. The team also concluded that the NHPP has successfully balanced the acquisition and scheduling of

staff training and management of the permitting and inspection workload, while successfully implementing a centralized control program.

6.0 Technical Quality of Permitting Program

a. Inspection Scope

The NRC inspection team reviewed 22 DVA permitting actions completed by the NHPP program managers. Permitting actions were evaluated for completeness, consistency, proper isotopes and quantities authorized, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permit actions. Casework was also evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authority. The permit files were reviewed for the retention of necessary documents and supporting data.

b. Observations and Findings

The permitting casework reviewed by the inspection team was selected to provide a representative sample of all the permitting actions that were processed for DVA permittees during the six-month review period. The sampling included the following types of permits: medical broadscope, limited medical institution, and research and development broadscopes. The types of permitting actions selected for evaluation included 16 amendments to existing permits, five renewals, and one termination. No new permit requests or actions with potential significant environmental impact or complex decommissioning activities were processed during the review period.

Based on the review of the subject permitting casework, the inspection team concluded the NHPP staff followed appropriate NRC NUREGs, policies, procedures, and directives to ensure that the submitted information supported the permittee's request. The team noted that the technical reviews were complete and comprehensive, and that checklists were used for each type of permit program action reviewed. This resulted in consistency between the reviewers. Deficiencies identified were addressed in letters, e-mails and/or documented telephone conversations. The team also determined that deficiency correspondence contained appropriate regulatory language, was detailed, and provided the necessary information to support the action. All permitting actions were reviewed for technical content and signed by the NHPP Director. The actions were also forwarded to the NRC on a monthly basis.

c. Conclusion

The inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures, and guidance. In addition, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

7.0 Status of Permitting Program

a. Inspection Scope

The NRC inspection team examined the licensee's permitting process to verify that permitting actions were handled and processed as described in the license. The team also evaluated the effectiveness of the licensee's tracking system.

b. Observations and Findings

The NHPP is responsible for approximately 115 medical and medical/research permittees. All five regional NHPP program managers are authorized to review permitting actions, which are ultimately signed by the NHPP Director. Since the issuance of the MML on March 17, 2003, the NHPP has processed approximately 100 permitting actions. The NHPP did not receive any requests for new permits during this six-month review period. The program managers processed and/or completed all permitting actions well within the DVA's general timeliness goal of 30 calendar days.

The NHPP enters permitting action requests it receives from permittees into its Records Tracking Management System (RTMS). The RTMS is a system that is used to track casework status and is maintained in an electronic, centrally controlled file database. The actions are entered into the database, scanned, electronically filed, and archived. After processing by the administrative officer, the permit action requests are electronically provided to a program manager's office for review.

The RTMS also provides the NHPP staff access to documents supporting the permitting process (e.g., permit files, guidance criteria, inspection history, etc.). In addition, the tracking system provides NHPP staff with the capability to follow the status of any permitting action from start to completion. The inspection team also noted that information is readily retrievable from the system for staff use and program assessments.

c. Conclusion

The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures (SOPs). In addition, the inspection team determined that the process for reviewing and issuing permitting actions by the DVA was efficient, with timely issuances of permitting actions and a zero backlog.

8.0 Allegation and Incident Handling Programs

a. Inspection Scope

The NRC inspection team reviewed the DVA's program for handling allegations and responding to incidents. This included a review of all incidents (reportable and non-reportable) and allegations to determine applicability to NRC reporting requirements, the effectiveness of the DVA in handling allegations and responding to incidents, and the

status of any open allegations. The team also assessed communications between the NHPP and the NRSC to determine if allegations are communicated to the NRSC.

The team evaluated five cases documented in the licensee's event/incident files and tracking system for reportability requirements, and interviewed key licensee personnel involved with each case. These cases involved three instances where radioactive material originating from the VA permittees was discovered in landfills, and two medical events.

b. Observations and Findings

The inspection team reviewed the details of each event involving radioactive material found in a landfill and determined that none of the events were reportable. One event involved non-NRC regulated material. A second event involved waste from a patient who had been treated with iodine-131 and was released from the VA Medical Center in accordance with 10 CFR Part 35. The third landfill event involved the inadvertent disposal by a permittee of two containers of medical waste: one containing thallium-201 (Tl-201) (non-NRC regulated material), and the other containing technetium-99m (Tc-99m). The permittee, as required by the NHPP, conducted an investigation and determined that the amount of Tc-99m in the container was less than the reportable quantity as defined in 10 CFR Part 20.2201(a)(ii).

The DVA reported two medical events to the NRC during the six-month review period (September 2003 and March 2004). The first event occurred on December 29, 2003, and was identified by the NRC during an independent inspection at the VA Ann Arbor Medical Center on January 21, 2004. It was reported to the NRC by the NHPP on January 22. The licensee's 15-day written report was submitted on February 4, 2004. The referring physician was notified within 24 hours. The event involved a failure to administer a radiopharmaceutical in accordance with a written directive that prescribed 4.0 millicuries of strontium-90. The prescribing physician's intent was to administer strontium-89, which is what the technologist did in fact order and administer. The NRC issued a Severity Level IV violation to the DVA for failing to verify that the drug administered to the patient was as prescribed in the written directive (reference NRC IR 030-34325/2003-022(DNMS)).

The second medical event was identified by Boston VA Medical Center and reported to the NHPP on January 29, 2004. The NHPP reported the event to the NRC on January 30, 2004. The written report was submitted to the NRC on February 12, 2004, and the referring physician was notified within 24 hours of the discovery of the event. The event involved the administration of approximately 500 microcuries of iodine-131 to an elderly nursing home patient, instead of the prescribed 5 microcuries. On the same day that the event was discovered, the patient was administered potassium iodide (KI) to block uptake of iodine-131 by the thyroid. Preliminarily, the permittee calculated a committed dose equivalent (CDE) to the thyroid of approximately 86 rem, and does not expect the dose to have any adverse effect on the patient. The NHPP staff completed a reactive inspection (accompanied by NRC staff) on February 4, 2004, and are in the process of completing an assessment of the radiation dose to the patient. The NRC staff will continue to follow this case as the DVA completes its investigation and evaluates this event for safety and enforcement consequences.

The NHPP has not received any allegations since the first semi-annual review was completed. During the first semi-annual inspection, the inspection team identified that information regarding the receipt of an allegation by the NHPP from the NRC was forwarded to the NRSC chairman, but not to the rest of the NRSC membership. As a result of this finding by the inspection team in September 2003, the NHPP reported this allegation to the Committee at the October 2003 NRSC meeting. An NRSC working group was tasked to review the results of the NHPP's investigation, which indicated that the allegation was unsubstantiated. The working group plans to recommend that the allegation be closed at the next NRSC meeting scheduled for April 29, 2004.

c. Conclusion

The team determined that there were two reportable medical events during this review period. Both events were reported to the NRC in accordance with 10 CFR Part 35. The inspection team concluded that the DVA's program for responding to incidents was in compliance with the MML conditions and applicable NRC regulations and was being implemented effectively.

Regarding the DVA's allegation program, the inspection team noted that the DVA has almost completed its review of the allegation it received from the NRC in June 2003, and that DVA staff continue to process the allegation in accordance with the MML conditions.

9.0 NRC Independent Inspections of DVA Permittees

a. Inspection Scope

During this six-month review period, the NRC conducted independent inspections of DVA permittees to assess the adequacy of their radiation safety programs and compliance with NRC regulations and the MML. The NRSC's corrective actions were reviewed for accuracy, completeness, timeliness, and effectiveness.

b. Observations and Findings

During the period from September 22, 2003 through March 4, 2004, the NRC conducted 14 independent inspections of DVA permittees. The NRC focused its inspections on programs with high risk radioactive materials applications, i.e., priority 2 and 3 programs, e.g., medical broad scope programs, etc. The NRC identified two Severity Level IV violations (reference NRC IR 030-34325/2003-022(DNMS) and NRC IR 030-34325/2003-027(DNMS)), and one Severity Level III security violation (no civil penalty)(reference NRC IR 030-34325/2003-024(DNMS)).

The inspection team reviewed the licensee's immediate and long-term corrective actions for the violations and concluded that they were sufficient to address the issues and prevent recurrence.

c. Conclusion

Based on the overall results of the independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

10.0 Exit Meeting

An exit meeting was held with DVA representatives on March 4, 2004. The overall scope and findings of the inspection were discussed. The DVA participants did not identify any information as being proprietary in nature.

LIST OF PERSONS CONTACTED

Licensee Personnel

#A. Bierenbaum, Director of Safety and Technical Services
#T. Holohan, M.D., Chief Patient Care Services Officer and NRSC Chairman
#M. Hughes, Acting Associate Chief Patient Care Services Officer
#M. King, Registered Nurse, Office of Patient Care Services
*E. Leidholt, Ph.D., Program Manager, NHPP Southwest Office
K. Mayo, Information Technologist, NHPP Headquarters
*L. McGuire, Director, NHPP Headquarters
J. McNew, Program Support Assistant, NHPP Headquarters
*L. Offutt, Administrative Officer, NHPP Headquarters
M. Simmons, Program Manager, NHPP Northwest Office
*G. Williams, Program Manager, NHPP Headquarters
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NRC Personnel

*U. Bhachu, Mechanical Engineer, NMSS/IMNS
*A. Gaines, Sr. Health Physicist, Region IV
*K. Null, Sr. Health Physicist, Region III
*G. Shear, Acting Deputy Director, DNMS, Region III
*T. Simmons, Health Physicist, Region III

*Attended March 4, 2004, exit meeting
#Attended March 4, 2004, exit meeting by telephone

In addition, numerous permittee staff were interviewed during the independent inspections conducted by the NRC during the review period September 22, 2003 through March 4, 2004.

LIST OF ACRONYMS, ABBREVIATIONS

CFR	Code of Federal Regulations
DVA	Department of Veterans Affairs
IMNS	Industrial and Medical Nuclear Safety
IP	Inspection Procedures
LOU	Letter of Understanding
MML	Master Materials License

NHPP	National Health Physics Program
NMSS	Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
QMP	Quality Management Program
RSO	Radiation Safety Officer
RTMS	Records Tracking Management System
SOP	Standard Operating Procedure
VA	Veterans Affairs

October 31, 2003

Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
Washington, DC 20420

SUBJECT: NRC INSPECTION REPORT NO. (IR 030-34325/2003-015 (DNMS))

Dear Dr. Roswell:

This refers to the announced team inspection conducted on September 15 through 19, 2003, and is the first semi-annual inspection, which includes a period of review from March 17, 2003, through September 19, 2003. The purpose of the inspection was to review the activities authorized under the DVA's MML. At the conclusion of the inspection, the findings were discussed with Ms. Mari Horak, Associate Chief, Patient Care Services, and the DVA's National Health Physics Program (NHPP) staff during an exit meeting on September 19, 2003.

The NRC is implementing a program of increased oversight of the Department of Veterans Affairs (DVA) Master Materials License (MML). The increased oversight includes semi-annual inspections of the DVA's program over a 2-year period. Each inspection will include a review of DVA MML activities conducted over a 6-month period.

This inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of activities in progress, and interviews with personnel.

Based upon the inspection, no violations of NRC requirements were identified. Furthermore, the NRC found that the DVA's implementation of its MML to be adequate and consistent with NRC licensing and inspection policies and procedures.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>.

R. Roswell

-2-

We will gladly discuss any questions you have concerning this inspection.

Sincerely

/RA by G. Shear Acting for/

Marc L. Dapas, Director
Division of Nuclear Materials Safety

Docket No.: 030-34325
License No.: 03-23853-01VA

Enclosure: NRC Inspection Report No. 030-34325/2003-015 (DNMS))

cc w/encl: E. Lynn McGuire, Director
DVA National Health Physics Program

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REGION III

Docket No.: 030-34325

License No.: 03-23853-01VA

Report No.: 030-34325/2003-015

Licensee: Department of Veteran Affairs (DVA)

Location: National Health Physics Program
Little Rock, Arkansas

Inspection Dates: September 15 - 19, 2003

Inspectors: Kevin G. Null, Senior Health Physicist and
Project Manager for DVA Master Materials License
(MML), Region III

Ujagar Bhachu, Mechanical Engineer and
MML Project Coordinator
NMSS/IMNS

José M. Díaz Vélez, Health Physicist
Region II

Toye Simmons, Health Physicist
Region III

Approved by: John Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

**Department of Veterans Affairs Master Materials License
NRC Inspection Report No. 030-34325/2003-015**

This announced NRC team inspection was conducted to evaluate the Department of Veterans Affairs (DVA) implementation and administration of activities conducted under the Master Materials License (MML). The inspection included a review of the DVA's implementation of its centralized control program, radioactive materials permitting and inspection programs, results of Nuclear Regulatory Commission (NRC) inspections of DVA permittee facilities conducted during the review period, and a review of the National Radiation Safety Committee's (NRSC's) oversight of activities authorized by the license. Licensed activities conducted during the period of March 17, 2003, through September 19, 2003, were reviewed during this inspection.

Through discussions with DVA staff, reviews of documents, and observations of DVA staff in the performance of their duties, the NRC inspection team found the DVA's overall permitting and inspection program to be adequate to protect the health and safety of workers and the general public.

The program areas reviewed during this team inspection are summarized below:

Management Oversight

- The NRSC conducted operations in accordance with the MML, DVA's Standard Operating Procedures and NRC regulations. The NRSC was effective in performing its responsibility and providing adequate oversight of the DVA's radiation safety and regulatory compliance program.

Technical Quality of Inspections

- The DVA's inspection program was conducted in a manner that was compatible with NRC's inspection policies, procedures, and guidelines, and in accordance with the MML. The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures.

Status of Materials Inspection Program

- The inspection team concluded that the NHPP management appropriately assigned program codes and inspection due dates to its permittees, and that all inspections that were due during this review period were completed in a timely fashion.

Technical Staffing and Training

- The inspection team concluded that the DVA's MML program has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a Master Materials Licensee.

Technical Quality of Permitting Program

- Overall, the inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures and guidance. Furthermore, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

Status of Permitting Program

- The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The issuance of permitting actions by the DVA was found to be efficient and timely with no permitting actions held in backlog.

Allegation and Incident Handling Programs

- The NHPP is currently processing one allegation forwarded by the NRC to the NHPP on June 29, 2003. The DVA's allegation program was conducted in a manner that was in accordance with the MML.
- There were no reportable incidents during this review period. The DVA's program for handling incidents was conducted in a manner that was in accordance with the MML.

NRC Independent Inspections of DVA permittees

- The NRC inspected 14 DVA permittees during the review period. Two violations were identified at two separate permittee facilities. Based on the overall results of independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

Report Details

1.0 Program Overview

The Department of Veterans Affairs (DVA) is authorized under NRC Master Materials License (MML) number 03-23853-01VA, to issue radioactive material permits and inspect DVA medical facilities throughout the United States. The DVA oversees approximately 118 permittees. The license was issued on March 17, 2003, and does not have an expiration date.

The DVA National Radiation Safety Committee (NRSC) has the responsibility for oversight of the MML and its permittees. The Committee has delegated the day-to-day operations to its National Health Physics Program (NHPP), which includes a Program Director and five Program Managers who are responsible for issuing permits, conducting inspections, and investigating incidents and allegations.

2.0 Management Oversight

a. Inspection Scope

The NRC inspection team reviewed the licensee's NRSC organization and management oversight activities to determine whether the Committee and its NHPP office, adequately controlled the use of licensed materials as required by the MML and NRC regulations, and in a manner that protects the public health and safety. The review included observations of NRSC meetings, discussions with cognizant licensee representatives, and a review of program documentation,

b. Observations and Findings

The team determined that the NRSC was organized as required and had implemented management oversight procedures to control the authorized use of licensed materials.

The NRSC meets quarterly and is comprised of senior DVA managers, and DVA Headquarters and field representatives. During the review period, the NRSC met twice. Based on attendance at both meetings and a review of the NRSC minutes, NRC representatives confirmed that the Committee met its minimum requirements for establishing a quorum. The NRC Project Manager and Nuclear Materials Safety and Safeguards (NMSS) Project Coordinator observed NRSC interaction with the NHPP at both meetings, and confirmed that the Committee engaged in several issues raised by the NHPP.

The NRSC delegates authority to the NHPP to manage the radiation control program and its day-to-day operations. This includes implementation of the permitting and inspection programs, incident and allegation follow-up, maintaining staffing at acceptable levels, and training of NHPP staff. The NHPP is required to implement six standard operating procedures (SOPs). The SOPs establish the essential programmatic elements for implementation of the program. The SOPs describe procedures for processing permits, conducting inspections, taking enforcement action, training inspectors, responding to incidents and managing allegations. In addition, the NHPP developed and implemented detailed internal procedures that are linked and designed to assure compliance with the SOPs.

Item 3.b of the Letter of Understanding (LOU), which is considered an adjunct to the license between the NRC and DVA, requires that the DVA update policies and procedures to reflect the most current NRC regulations. Further, Item 3.b also requires that changes or updates to NRC regulations be incorporated and distributed to staff within 90 days for immediate implementation. In October of 2002, the NRC revised 10 CFR Part 35, "Medical Use of Byproduct Material." As of September 15, 2003, the DVA SOPs had not been updated to reflect the revised 10 CFR Part 35. However, the team determined that the revised NRC regulations were distributed to NHPP staff, and licensee inspectors were aware and utilized the revised 10 CFR Part 35.

In a January 2003 document that described results of an internal audit, the NHPP documented and communicated to the NRSC the need to revise its SOPs to reflect the revised 10 CFR Part 35. The document further stated that this should be done after the NRC completed its first semi-annual inspection of the DVA's program, so that the NHPP could also incorporate additional changes into the SOPs that might be necessary as a result of the NRC inspection.

The team determined that the DVA and its permittees have implemented the revised 10 CFR Part 35. Failure to update the SOPs did not negatively impact the DVA or its permittees in implementing and complying with the revised regulations. Prior to completion of this inspection on September 19, 2003, the NHPP began to make the necessary revisions to its SOPs, and indicated they plan to request an amendment to its MML that would allow them to make non-safety related revisions to SOPs internally, without requesting approval from the NRC.

Item 5 of the LOU requires the DVA to follow NRC inspection criteria to ensure consistency between NRC and DVA inspection programs. The team determined that the DVA has implemented NRC inspection criteria. However, the team also noted that there was no link or reference in the DVA's inspection field notes or its intranet web site, to NRC inspection criteria/procedures. As of September 19, 2003, the NHPP addressed this issue by updating its web site and IPs to include references to relevant NRC IPs and inspection criteria.

c. Conclusion

Overall, the inspection team found that the NRSC conducted operations in accordance with the MML, DVA's SOPs and NRC regulations. The NRSC was effective in performing its responsibility and providing adequate oversight of the DVA's radiation safety and regulatory compliance program.

3.0 Technical Quality of Inspections

a. Inspection Scope

The NRC inspection team reviewed inspection plans, inspection reports, enforcement documents and correspondence associated with inspections conducted by the NHPP during the review period to determine if NHPP inspections were consistent and in conformity with NRC inspection procedures. In addition, the team interviewed NHPP inspectors to evaluate their process in preparing for inspections, including study of the permit (or previous NRC license), licensing related documents, and regulatory requirements. The team also evaluated their use of supporting documents (e.g.,

permitting files, regulatory guides, and regulations), and the equipment and instrumentation provided to the inspectors for performing inspections.

b. Observations and Findings

The team determined that NHPP inspectors properly prepared for inspections, and were provided with the necessary tools for performing their inspections.

The NHPP staff performed 10 inspections of permittees and one inspection of a non-permittee during the review period. The inspections were routine inspections as well as reactive, covering different types of permittees, including Medical Broad, Medical Institutions QMP (Quality Management Program) not required, Medical Institutions QMP required, and Research and Development. The team determined that for all inspections performed, the inspectors generated inspection plans which were reviewed and approved by the NHPP Director. The inspection team determined that inspection plans used, followed the typical areas of applicable NRC Inspection Procedures as described in the NRC Inspection Manual Chapter 2800, Materials Inspection Program.

The inspection team determined that NHPP inspection reports documented areas reviewed by the inspectors and that inspection plans were followed to perform the inspections. The inspection team noted that inspection findings were based on health and safety matters, and were well-founded and properly documented. The team found that inspection reports were complete, and that the review of inspection findings performed by the NHPP Director was in accordance with NRC practices, and completed in a timely manner. The team also noted that each NHPP inspector was evaluated during an accompaniment over the review period by the NHPP Director.

Each NHPP inspector was also accompanied by a NRC inspector during the review period. The purpose of the accompaniment was to evaluate the technical quality of inspections being performed by NHPP inspection staff. In addition, the NRC Region III Project Manager accompanied the NHPP Director while the director observed an inspection being performed by one of his inspectors.

c. Conclusion

The inspection team concluded that the licensee's inspection program was conducted in a manner that was compatible with NRC's inspection policies, procedures, and guidelines. The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures.

4.0 Status of Materials Inspection Program

a. Inspection Scope

The NRC inspection team reviewed the licensee's program for assigning inspection frequencies to permittees, and its timeliness in completing inspections based on inspection due dates. The team interviewed NHPP inspectors and management, and compared the licensee's inspection due dates posted in its tracking system against the actual dates that inspections were completed.

b. Observations and Findings

The NHPP adopted the NRC's inspection frequencies for its permittees when the MML was issued on March 17, 2003. The team noted that the NHPP adjusted and reassigned program codes to 17 permittees. This resulted in changes to inspection frequencies for each of these permitted facilities. The majority of these changes resulted in new inspection frequencies that were more conservative. For example, some permittees were reclassified from a standard medical program (program code 2120) to a research and development Type A broad scope program (program code 3610). Some permittees inspection frequencies were modified based on the NRC's revision to its inspection frequency program. All inspections were completed by required due dates and there were no overdue inspections.

c. Conclusion

The inspection team concluded that the NHPP management appropriately assigned program codes and inspection due dates to its permittees, and that all inspections that were due during this review period were completed in a timely fashion.

5.0 **Technical Staffing and Training**

a. Inspection Scope

The NRC inspection team reviewed the licensee's radioactive materials program staffing level and turnover, as well as the technical qualifications and training history of the NHPP staff. In evaluating these elements, the team examined the DVA's response to the NRC's questionnaire relative to this indicator, interviewed program management staff, and reviewed the DVA training program, job position requirements, and casework related to licensing, compliance and inspection. The team also conducted accompaniments of qualified NHPP inspectors.

b. Observations and Findings

The NHPP personnel are assigned as headquarters-level staff reporting to the Chief of Patient Care Services. The NHPP is staffed with a Director, five Program Managers, and administrative personnel. The Director provides a two-way vertical conduit for interaction and communication of information between the NRSC and Program Managers, and has the sole signature authority for permit issuance. There has been no staffing turnover since the issuance of the MML on March 17, 2003.

The program has built in flexibility as the Director and Program Managers are all qualified to perform both permitting reviews and inspections. Additionally, each Program Manager is expected to develop expertise in specific assigned areas. For instance, there are specialists in the areas of decommissioning and high dose-rate remote brachytherapy. The administrative support staff are also cross-trained to perform all administrative functions.

The NHPP developed a written training program for its technical staff based on the requirements specified in NRC Inspection Manual Chapter 1246. The program includes qualification journals and oral qualification boards. All Program Managers have completed the NRC Fundamentals of Inspection and Licensing Practice and Procedures courses, as well as some of the other NRC and equivalent NRSC approved courses.

The NHPP schedules its Program Managers for other core NRC courses as the space becomes available. The NHPP has successfully balanced the acquisition of training with maintaining the permitting and inspection workload, while successfully implementing a centralized control program.

The team reviewed the formal education and experience of the NHPP Director and technical staff. They all have an undergraduate degree in an applicable discipline, with most possessing a Master's degree, and one manager holding a Doctoral degree. All have served as a Radiation Safety Officer (RSO) for a broad scope material license and have 15-25 years of health physics experience.

c. Conclusion

The inspection team concluded that the DVA's MML program has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a Master Materials Licensee.

6.0 Technical Quality of Permitting Program

a. Inspection Scope

The NRC inspection team reviewed 15 DVA permitting actions completed by the NHPP Program Managers and interviewed the staff to determine whether the DVA's permitting program was consistent with NRC licensing policies and procedures. Permitting actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permit actions. Casework was also evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The casework was selected to provide a representative sample of permitting actions that were processed for DVA permittees during the review period. The sampling included the following types of permits: medical broadscope, limited medical institution, and research and development broadscopes. The types of permitting actions selected for evaluation included 8 amendments to existing permits, 5 renewals, and 2 terminations. No new permit requests or actions submitted with potential significant environmental impact or complex decommissioning activities were processed during the review period.

b. Observations and Findings

The casework evaluation indicated that the NHPP staff follows appropriate NRC NUREGs, policies, procedures and directives during the review process to ensure that the submitted information supports the permittee's request. The team found the technical reviews (checklists) used for each type of program to be complete and

comprehensive. As a result, the team noted significant consistency between the reviewers. Deficiencies identified were addressed in letters and documented telephone conversations. The team also determined that the letters and telephone conversation records contained appropriate regulatory language, were detailed, and provided the necessary information to support the action. All permitting actions were reviewed and signed by the NHPP Director and forwarded to NRC on a quarterly basis.

c. Conclusion

Overall, the inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures and guidance. Furthermore, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

7.0 Status of Permitting Program

a. Inspection Scope

The NRC inspection team reviewed the licensee's permitting process to verify that permitting actions were handled and processed as described in the license. The team also evaluated the effectiveness of the licensee's tracking system.

b. Observations and Findings

The NHPP is responsible for approximately 118 medical and medical/research permittees. Five regional NHPP Program Managers conducted inspections and processed permitting actions. Since the inception of the MML on March 17, 2003, NHPP has processed 49 permitting actions. The NHPP averaged 10 days to issue its permitting actions, which included both renewals and amendments. The NHPP did not issue any new permits during this review period.

The NHPP enters permitting actions it receives from permittees into its Records Tracking Management System (RTMS). The RTMS is a system that is utilized to track casework and is maintained in an electronic, centrally controlled file database. The actions are entered into the database, scanned and electronically filed and archived. After processing by the Administrative Officer, the permit requests are assigned and electronically provided to a Program Manager's office for review.

The RTMS also provides the NHPP staff access to licensing guidance documents (e.g., permit files, guidance criteria, inspection history, etc.). In addition, the tracking system provides NHPP staff with the capability to follow the status of any permitting action from start to completion. The system also assures that information will be readily retrievable for staff use and program assessments.

c. Conclusion

The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The issuance of permitting actions by the DVA was found to be efficient and timely with no permitting actions held in backlog.

8.0 Allegation and Incident Handling Programs

a. Inspection Scope

The NRC inspection team reviewed the DVA's program for handling allegations and incidents. This included a review of all incidents and allegations to determine applicability to NRC reporting requirements, and the effectiveness of handling both incidents and allegations by the NHPP, and communications between the NHPP and NRSC. The team evaluated four cases maintained in the licensee's event/incident file for reportability requirements, and interviewed key licensee personnel involved with each case. These cases involved disposal of radioactive materials to two landfills, an unusually high film badge reading assigned to a permittee staff member, and possession of byproduct material by an unlicensed VA medical center.

b. Observations and Findings

The inspection team determined that there were no reportable events for this inspection period.

One landfill disposal event involved material from a facility in Florida that could not be traced to a VA permittee, and the other event was determined not to be reportable by the DVA, and by the NRC, based on the results of an independent inspection. A special inspection of the high film badge reading conducted by the NHPP, with accompaniment by an NRC inspector, determined that the exposure was to the badge and not the employee. Regarding the unlicensed VA facility, the NHPP discovered that Bath VA Medical Center, New York, was in possession of microcurie amounts of carbon-14 and calcium-45. The material was transferred to a licensed VA facility authorized to possess carbon-14 and calcium-45. The DVA is conducting an investigation to review the circumstances surrounding this case. The NRC will continue to follow the DVA's investigation into this issue.

The NHPP is currently reviewing one allegation. The allegation was initially received by the NRC and forwarded to the NHPP in late June of 2003. The NHPP initiated its investigation in mid-July. Information concerning the allegation was forwarded in early July to the NRSC Chairman by the Director of the NHPP. However, the team determined that as of September 15, 2003, the allegation had not been communicated to the NRSC membership. Furthermore, it was not included as an agenda item for discussion at the most recent NRSC quarterly meeting held on July 31, 2003.

The licensee's Standard Operating Procedure (SOP) 06, "NHPP Allegation Management Program," requires direct involvement of, and interaction with, the NRSC in the receipt and handling of allegations. Based on interviews of NHPP staff, it appears that although the NRSC Chairman was notified of the allegation, neither the NHPP nor the NRSC Chairman informed the NRSC membership of the allegation. The inspection team determined that this lack of communication was an oversight on the part of the NHPP and NRSC Chairman.

Prior to completion of this inspection on September 19, 2003, the NHPP stated that the allegation would be presented to the NRSC during the October 30, 2003, committee meeting.

c. Conclusion

The NHPP is currently processing one allegation forwarded by the NRC to the NHPP on June 29, 2003. The inspection team concluded that despite the lapse in communication with the NRSC membership regarding this allegation, the DVA's allegation program was conducted in a manner that was in accordance with the MML.

There were no reportable incidents during this review period. The DVA's program for handling incidents was conducted in a manner that was in accordance with the MML.

9.0 NRC Independent Inspections of DVA Permittees

a. Inspection Scope

During the period of this inspection, the NRC performed independent inspections of DVA permittees to assess the adequacy of permitted radiation safety programs and compliance with NRC regulations and the MML. The NRSC's corrective actions, through the NHPP, were reviewed for completeness, timeliness and effectiveness.

b. Observations and Findings

During the period from March 17 through September 19, 2003, the NRC conducted 14 independent inspections of DVA permittees. The NRC focused its inspections on the higher risk programs, i.e., priority 1 and 2 programs, e.g., medical broad scope programs, etc. The NRC did not identify any violations in 12 of the 14 inspections that were conducted. Two inspections identified violations associated with security and control of radioactive material (ref. IR 03034325/2003-005 (DNMS) and IR 03034325/2003-004 (DNMS)).

The team reviewed the licensee's immediate and long term corrective actions for the violations and found them to be sufficient to address the issues and prevent recurrence.

c. Conclusion

Based on the overall results of independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

10.0 Exit Meeting

An exit meeting was held with DVA representatives on September 19, 2003. The overall scope and findings of the inspection were discussed. The DVA participants did not identify any information as being proprietary in nature.

LIST OF PERSONS CONTACTED

Licensee Personnel

- #M. Horak, Associate Chief, Patient Care Services
- *E. Leidholt, Ph.D., Program Manager, NHPP Southwest Office
- K. Mayo, Information Technologist, NHPP Headquarters
- *L. McGuire, Director, NHPP Headquarters
- J. McNew, Program Support Assistant, NHPP Headquarters

- *L. Offutt, Administrative Officer, NHPP Headquarters
- *M. Simmons, Program Manager, NHPP Northwest Office
- *G. Williams, Program Manager, NHPP Headquarters
- #J. Wissing, Program Manager, NHPP Central Office
- *P. Yurko, Program Manager, NHPP Eastern Office

NRC Personnel

- *U. Bhachu, Mechanical Engineer, NMSS/IMNS
- *J. Díaz Vélez, Health Physicist, Region II
- *J. Madera, Chief, Materials Licensing Branch, Region III
- *K. Null, Sr. Health Physicist, Region III
- *T. Simmons, Health Physicist, Region III

- *Attended September 19, 2003, exit meeting
- #Attended September 19, 2003, exit meeting by telephone

In addition, numerous permittee staff were interviewed during the independent inspections conducted by the NRC during the review period March 17 through September 15, 2003.

LIST OF ACRONYMS, ABBREVIATIONS

CFR	Code of Federal Regulations
DVA	Department of Veterans Affairs
IMNS	Industrial and Medical Nuclear Safety
IP	Inspection Procedures
LOU	Letter of Understanding
MML	Master Materials License
NHPP	National Health Physics Program
NMSS	Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
QMP	Quality Management Program
RSO	Radiation Safety Officer
RTMS	Records Tracking Management System
SOP	Standard Operating Procedure
VA	Veterans Affairs

DVA and NRC Inspection Data

A. Comparison of total number inspections of the same program codes from, March 17, 2003 through February 27, 2004

Program Code	NHPP Inspections of Permittees	NOV's Issued by NHPP	NRC Inspections of non-VA Facilities	NOV's Issued by NRC	NHPP vio/insp ratio	NRC vio/insp ratio
2120	14	4 (SL IV)	23	3 (SL IV)	28%	13%
2121	1	0	11	0	–	–
2110	10	4 (SL IV)	8	2 (SL IV)	40%	25%
3610	2	0	0	0	–	–
Total	27	8	42	5	29%	12%

B. Comparison of the same number of inspections and program codes

Program Code	NHPP Inspections of Permittees	NOV's Issued by NHPP	NRC Inspections of non-VA Facilities	NOV's Issued by NRC	NHPP vio/insp ratio	NRC vio/insp ratio
2120	14	4	14	2	28%	14%
2121	1	0	1	0	–	–
2110	10	4	10	2	40%	20%
3610	2	0	2	0	–	–
Total	27	8	27	4	29%	18%