

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

December 1, 2022

Shereef Elnahal, M.D. Under Secretary for Health U.S. Department of Veterans Affairs 810 Vermont Avenue, NW Washington, DC 20420

SUBJECT: NRC INSPECTION REPORT NO. 03034325/2022014(DRSS) – DEPARTMENT OF VETERANS AFFAIRS

Dear Dr. Elnahal:

This refers to the announced U.S. Nuclear Regulatory Commission (NRC) biennial team inspection conducted on October 17 through 21, 2022. The purpose of the inspection was to review the activities authorized under the Department of Veterans Affairs (DVA) Master Materials License (MML). At the conclusion of the inspection on October 21, 2022, the NRC's findings were discussed with John Nord, M.D., Deputy Chief Officer, Specialty Care Services; David Bushnell, M.D., Ph.D., Chair of the DVA National Radiation Safety Committee (NRSC); other members of the NRSC; and members of the DVA's National Health Physics Program (NHPP) staff.

This inspection consisted of an examination of activities conducted under the DVA's 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. The NRC determined that overall, the DVA implemented its MML in accordance with NRC licensing and inspection policies and procedures, and in a manner that protected the public health and safety. Based on the results of this inspection, no violations of NRC requirements were identified.

S. Elnahal

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

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

Sincerely,

Signed by Nick, Joseph on 12/1/22

Joseph L. Nick, Acting Chief Material Licensing Branch Division of Radiological Safety and Security

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

Enclosure: IR 03034325/2022014(DRSS) Letter to Shereef Elnahal, M.D. from Joseph Nick dated December 1, 2022.

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NAME	JNick				
DATE	12/1/22				

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Region III

Docket No.:	030-34325
License No.:	03-23853-01VA
Report No.:	03034325/2022014(DRSS)
Licensee:	Department of Veterans Affairs
Location:	National Health Physics Program North Little Rock, Arkansas
Inspection Dates:	October 17 through 21, 2022
Inspectors:	Bryan A. Parker Senior Health Physicist Project Manager of the Department of Veterans Affairs Master Materials License (MML) Region III
	Allyce Bolger Health Physicist Region IV
	Robin Elliott Senior Health Physicist Region I
	Frank Tran Health Physicist Region III
Approved by:	Joseph L. Nick, Acting Chief Materials Licensing Branch Division of Radiological Safety and Security Region III

EXECUTIVE SUMMARY

Department of Veterans Affairs Master Materials License NRC Inspection Report No. 03034325/2022014(DRSS)

This announced U.S. Nuclear Regulatory Commission (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). This was a routine biennial inspection of the MML that included: (1) an assessment of the DVA's implementation of its centralized control program; (2) an evaluation of the DVA's permitting, inspection, and incident response and allegation programs; (3) an evaluation of the adequacy of the DVA's technical staffing and training; (4) a review of the results of NRC independent inspections of DVA permittee facilities conducted during the review period; and (5) 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 November 9, 2019, through October 21, 2022, were reviewed during this inspection.

Through interviews and discussions with the DVA staff, an 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, inspection, allegation and incident response programs were adequate and implemented in a manner that protected the health and safety of workers and the general public.

No violations of NRC requirements were identified.

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

Management Oversight

The team determined that the DVA had centralized control over the radioactive materials program and provided adequate management oversight of the implementation of the MML. The team concluded that the National Health Physics Program (NHPP), with oversight from the NRSC, conducted and controlled the DVA's licensed activities in a manner that ensured overall compliance with the conditions and commitments of the MML and associated Letter of Understanding (LOU), the DVA's Standard Operating Procedures (SOPs), and the NRC's regulations.

The team reviewed ongoing efforts in DVA's response to a Confirmatory Order (CO) issued during the review period related to a willful violation identified at VA-Greater Los Angeles. Safety culture webinars had been conducted in accordance with the CO and the NHPP was planning further actions to comply with other commitments in the CO.

Technical Quality of Inspections

The team concluded that the DVA's inspection program was conducted in a manner that was compatible with NRC inspection policies, procedures, and guidelines. The team also concluded that the NHPP Program Managers (PMs) were properly prepared for inspections and conducted inspections in a manner that was consistent with NRC policies and procedures, and successfully integrated safety culture reviews into their inspection program.

Status of Materials Inspection Program

The team concluded that the DVA completed inspections of permittees at intervals in accordance with the frequencies established in NRC Inspection Manual Chapter (IMC) 2800, except for 18 inspections that were deferred as authorized under a temporary exemption that was granted by the NRC in a letter dated May 19, 2020, and extended in letters dated December 15, 2020, June 29, 2021, September 24, 2021, December 14, 2021, and June 29, 2022. The team also noted that the DVA was in the process of updating its procedures to incorporate the latest revisions to IMC 2800.

Technical Staffing and Training

The team concluded that at the time of the biennial inspection, the DVA had a qualified and experienced technical staff to implement the day-to-day operations of its radioactive materials program.

The NHPP completed its training qualification program for four full-time PMs and continued to make progress in fully qualifying the one remaining interim-qualified PM who is on track to complete the training program by the end of fiscal year 2023.

The team also concluded that the NHPP achieved a successful balance in the acquisition and scheduling of staff training and management of the permitting and inspection workload, while effectively implementing a centrally controlled program.

Technical Quality of Permitting Program

The team concluded that the DVA conducted quality technical reviews that were based on sound health physics practices. In addition, the DVA processed permits in a manner that was consistent with NRC licensing policies, procedures, and guidance. The team also concluded that the DVA effectively integrated safety culture into its permitting review process, and in routine communications with permittees.

Status of Permitting Program

The team concluded that the DVA processed permitting actions in accordance with NRC approved procedures. The process and procedures for reviewing and issuing permitting actions by the DVA was efficient, with timely issuance of permitting actions and no backlog.

Allegation and Incident Handling Programs

The team concluded that the DVA processed allegations in accordance with the terms and conditions of the MML. The team noted that the licensee received seven allegations during the review period; three were from the NRC for investigation and follow-up, and the remaining four the licensee received directly from concerned individuals (CIs). Four cases were still open at the time of the inspection. Five allegations were carried over from the last inspection period and were evaluated by the team. The team confirmed that all five were investigated, documented, and closed in accordance with SOP 06. This closes the violations issued in the 2017 and 2019 biennial inspections.

The team concluded that the DVA's program for responding to incidents was effectively implemented and complied with the conditions of the MML and applicable NRC regulations. The events were appropriately reported to the NRC in accordance with NRC requirements.

NRC Independent Inspections of DVA Permittees

The NRC inspected 13 DVA permittees during the review period. Two Severity Level IV violations were identified on one of the inspections. Based on the overall results of the NRC's independent inspections, the team concluded that permitted activities were conducted in a manner that protected the health and safety of permittee staff and the public.

Report Details

1. **Program Overview**

The DVA is authorized under the MML No. 03-23853-01VA to issue byproduct radioactive material permits and inspect DVA permitted facilities throughout the United States. At the time of the inspection, the DVA managed 115 permittees. The DVA's MML was issued on March 17, 2003, and does not have an expiration date.

The DVA has centralized control over its radioactive materials program through the NRSC. The NRSC is responsible for providing oversight of the DVA's implementation of its MML and associated permitted activities. The NRSC has delegated the authority to manage the day-to-day operations of the DVA's radioactive materials program to the NHPP, which includes budgeted resources for one Director, six Project Managers (PMs), and four administrative staff members. The NHPP is responsible for issuing permits, conducting inspections, implementing enforcement, and responding to events, incidents, and allegations.

2. Management Oversight

2.1 Inspection Scope

The team evaluated the licensee's organization and management oversight activities to determine whether the DVA, through the NRSC and the NHPP, adequately controlled the use of radioactive materials, as required by the MML and NRC requirements, in a manner that protected the public health and safety. The evaluation included a review of program documentation including internal and external assessment reports, observations of NRSC quarterly meetings and meeting minutes, and discussions with cognizant licensee representatives.

The team reviewed the licensee's program for updating the National Source Tracking System (NSTS) which included how the information was entered into the NSTS database, how the DVA communicated with the NRC regarding NSTS matters, how DVA personnel identified sources of concern, and the responsible individuals for entering the information into NSTS. The team also assessed communications between the permittees and the NHPP to evaluate the effectiveness and timeliness of the DVA's updates to the NSTS.

The team also reviewed ongoing efforts in DVA's response to a Confirmatory Order (CO) issued on April 21, 2022. The CO was a result of an enforcement action that was resolved through the NRC's Alternative Dispute Resolution (ADR) option (EA-21-059). The ADR held on March 2, 2022, was a result of a willful violation identified at VA-Greater Los Angeles by the permittee in July 2021. In addition to the corrective actions already taken by the DVA, the NRC and the DVA agreed to the terms of the CO, which included that the DVA; 1) conduct a safety culture survey of VA employees nationwide, 2) conduct safety culture training for Radiation Safety Officers (RSOs) and certain nuclear medicine personnel, and 3) "re-energize" its employee concerns program to focus more on safety culture.

2.2 Observations and Findings

The NRSC delegated authority to the NHPP to manage the DVA's day-to-day operations

of its radioactive materials program. This included maintaining an adequate level of staff to execute the radioactive materials program, training and qualifying the NHPP staff, implementing the permitting, inspection, and enforcement programs, maintaining, and updating the NSTS, and responding to events, incidents, and allegations. During the previous review period, the NHPP faced significant challenges regarding both technical and administrative staffing. During this review period, the NHPP made great strides in filling open positions and getting personnel fully trained and qualified. Administrative staffing is discussed in this section below. The technical staffing is discussed in detail in the "Technical Staffing and Training" section (Section 5).

The NRSC was composed of senior DVA managers and representatives from DVA headquarters and field offices. The NRSC met quarterly to provide oversight of the DVA's radioactive materials program and discussed issues raised by the NHPP. Based on observations made by the NRC staff in attendance at each meeting and a review of the NRSC meeting minutes, the inspection team verified that the NRSC met its minimum requirements for establishing a quorum at each meeting and for conducting business.

The NHPP is responsible for maintaining six Standard Operating Procedures (SOPs) that are essential in implementing the MML. The SOPs address processing permits, conducting inspections, taking enforcement action, training PMs in inspection and permitting activities for formal PM qualification, responding to incidents, and managing allegations. During the review period, significant revisions were made to SOP 05, "Incident Response" (Amendment 18 of the MML), and SOP 01, "Permitting" and SOP 06, "Allegations" (Amendment 19 of the MML). Additionally, the NHPP maintained and implemented 27 detailed internal procedures that are designed to ensure compliance with the SOPs.

The NHPP has a total of four permanent administrative support positions which provide assistance to the PMs and support several programs within the MML. At the time of the inspection, there were three administrative staff to support the program and the one vacancy was open and expected to be filled by the end of 2022. All four permanent administrative staff positions are based out of the NHPP Headquarters, located in North Little Rock, Arkansas.

During the review period, the DVA had one individual in the NHPP who was credentialed and authorized to access and update the NSTS. In early January each year, the NHPP requested by email for permittees to update the information in the NSTS. The NHPP staff member transferred permittee data to the NSTS during the annual reconciliation effort prior to the January 31 deadline each year. The NHPP staff communicates with the NRC regarding NSTS matters and information via telephone or facsimile. If the NHPP has a problem with NSTS, they contact the NSTS help desk for assistance. The NHPP plans to submit one final NSTS update in January 2023 now that all Part 37 material has been removed from the MML (see Section 3.2).

The team reviewed the NRSC's and the NHPP's tools and methods for communicating items of interest to its permittees. The primary methods of communication were through the NHPP website and the "Scatterings" newsletter, including periodic special editions of the newsletter that focus on specific topics of interest. The newsletters were typically issued monthly to quarterly over the review period. The team reviewed the content of the NHPP website and the newsletter and determined that important issues are communicated to the permittees in a timely and efficient manner.

In addition, the NHPP enhanced their communications with the permittees by holding periodic (typically every other month) webinars on specific topics of interest. During the review period, the NHPP sponsored several webinars. Permittee RSOs and nuclear medicine staff attended the webinars, which included various discussion topics. The webinars also provided the NHPP the opportunity to communicate any current "hot topics" that have recently occurred or are expected to evolve. Examples of topics covered during these webinars included, but were not limited to, patient release under 10 CFR 35.75, safety culture, changes in NRC regulations, and incident response. The NHPP also used specific Users Group email (i.e., HDR users, seed users, prostate users, Y-90 users, Part 37 security users, etc.) to distribute specific topics of interest to these user groups, as appropriate.

The team reviewed the DVA's practice of routinely monitoring its own performance through internal and external assessments. The team determined that the NRSC submits an annual report to the Under Secretary for Health, who is the highest-ranking official named on the MML. The NRSC's annual report is comprised of an internal audit conducted by the NHPP staff utilizing Internal Procedure No. 17, external audits conducted by independent consultants, and an NRSC working group review of the program. The annual report is based on the core performance indicators established by the NHPP to monitor its performance. Due to the significant staffing issues just prior to the review period, the annual report for calendar year (CY) 2018 was delayed. The CY 2018 and 2019 annual reports were presented to the NRSC in May 2020 and then provided to the Under Secretary. The CY 2020 and 2021 reports were presented to the NRSC in February of 2021 and 2022, respectively, and then provided to the Under Secretary.

The content and program assessments of the audit are determined during the February NRSC meeting each year. Recommendations with respect to the DVA's performance against the established indicators are tracked to completion during each NRSC meeting. The NHPP uses the core performance indicators to identify apparent trends, generic issues, and possible root causes, as well as to assess overall performance results. Examples of core performance indicators include results and numbers of inspections conducted, quality and timeliness of permitting actions, response to incidents, and processing of allegations.

The team noted that the NHPP staff monitored NRC event reports, Federal Register Notices, and NRC's Agencywide Document Access and Management System (ADAMS) regularly, to benchmark its program with other NRC licensees, and NRC policy and decision-making. The NHPP updates and revises its policies, procedures, and practices as part of their continuous improvement initiative, as appropriate. This approach provides the NHPP the opportunity to identify relevant regulatory issues in a timely and efficient manner and communicate such information to its permittees, thereby enhancing the DVA's regulatory oversight of the MML.

During the review, it was noted that safety culture webinars had been conducted in accordance with the CO in August and September of 2022 with more than 90 percent of the target audience trained to date. In addition, the NHPP continued it efforts to plan and conduct the required safety culture survey VA-wide and significant emphasis had been applied to the employee concerns program with updated postings, etc. at all VA permittee facilities.

The team reviewed the activities at the DVA's only waste burial site located at the VA Greater Los Angeles Healthcare System, Los Angeles, California. The burial site has been inactive since the early to mid-1980s. The DVA is required by Condition No. 14 of the LOU to seek NRC approval for any change in the status of the site. Based on a review of the status of the burial site and interviews with the NHPP Director, the team determined that there had been no change in the status of the burial site.

2.3 <u>Conclusion</u>

The inspection team concluded that the NHPP, with oversight from the NRSC, conducted and controlled the DVA's activities in a manner that ensured compliance with the conditions of the MML commitments and associated LOU, the DVA's SOPs, and the NRC's regulations. The inspection team determined that the DVA had centralized control over the radioactive materials program and provided adequate management oversight of the implementation of the MML.

The team concluded that the licensee's program for maintaining and updating the NSTS was adequate and implemented effectively. The team also concluded that the NHPP provided sufficient oversight of the waste burial site to ensure compliance with the LOU and NRC requirements.

3. Technical Quality of Inspections

3.1 Inspection Scope

The team reviewed inspection plans, inspection reports and records, enforcement documents, and correspondence associated with inspections conducted by the NHPP staff during the review period to determine if the NHPP inspections were consistent and conformed with the NRC's inspection procedures. In addition, the team interviewed PMs to evaluate how they prepared for and conducted inspections. This included a review of the permit, permitting related documents, and regulatory requirements. During the review period, the NRC accompanied the two PMs not accompanied during the previous review period, to evaluate the technical quality of inspections being conducted by the NHPP staff.

3.2 Observations and Findings

The NHPP conducted approximately 135 inspections of permittees during the review period, including routine, special, and initial inspections of permittees adding yttrium-90 activities. During the review period, approximately 40 severity level IV violations were identified and issued as notice of violations or non-cited violations. The inspections covered different categories of permittees, including: (1) medical broad scope; (2) medical institution-written directive not required; (3) medical institution-written directive required; (4) research and development broad scope programs; and (5) self- shielded irradiators. The PMs reviewed permits, permittee files, previous inspection records and correspondence in developing inspection plans. Inspection plans were generated by the PMs for each inspection and were reviewed and approved by the NHPP Director prior to the inspection.

The team noted that the plans incorporated applicable NRC Inspection Procedures as described in the NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." The PMs also annotated inspection plans to incorporate operational experience, generic issues, and regulatory changes identified as important to review during the inspection. This included precautions for lutetium-177 therapies, evaluating issues identified in the NRC Nuclear Material Events Database (NMED), incident reporting, assessing safety conscious work environment, reporting safety concerns, compliance with regulations and permit conditions, follow-up on items identified in the permit file, permittee reporting structure for the RSO, oversight by the permittee's radiation safety committee, and permittee executive management roles and responsibilities.

During the review period, the NHPP permitted two cesium-137 blood irradiators that were subject to 10 CFR Part 37 requirements. The PMs integrated the security inspections with the routine core inspections. On June 10, 2021, and October 1, 2022, the blood irradiators were transferred to SWRI as a part of the Department of Energy/National Nuclear Security Administration's cesium irradiator replacement project. For both transfers, the NHPP engaged with the permittees to ensure there was adequate coordination and preparations for the transfer. No issues were identified, and as of the date of this review, the licensee did not permit material requiring the implementation of Part 37.

The team assessed the technical quality of inspections by reviewing 19 completed inspection reports (Attachment 2). The team observed that the NHPP inspection reports and records appropriately documented those areas reviewed by the PMs, and that inspection plans were followed in conducting the inspections. In addition, the PMs effectively integrated safety culture into their inspections. The team also observed that inspection findings were based on health and safety matters and were well founded and properly documented.

The NHPP dispositioned violations in accordance with the current NRC Enforcement Policy and Guidance. Violations were issued to permittees on a form similar to the NRC's Form 591M Part 1, or in a Notice of Violation. In general, inspection reports and records were complete, and adequately discussed inspection results and supported violations or conclusions.

Based on information obtained by NRC staff during the accompaniments of two PMs, the team determined that the PMs conducted performance-based inspections that focused on health and safety. The team also noted that each PM was accompanied by the NHPP Director at the proper frequency.

3.3 <u>Conclusion</u>

The team concluded that the licensee's inspection program was conducted in a manner that was consistent with NRC inspection policies, procedures, and guidelines. The team also concluded that the PMs were properly prepared for inspections, conducted inspections in a manner consistent with NRC policies and procedures, and effectively integrated security and safety culture into their inspections.

4. Status of Materials Inspection Program

4.1 Inspection Scope

The 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 the NHPP PMs and management and compared the licensee's inspection due dates posted in its tracking system against the actual dates that inspections were completed.

4.2 Observations and Findings

The NHPP Inspection Procedure was contained in NRSC SOP 02, dated January 20, 2015, and assigned inspection frequencies as delineated in a previous version of NRC IMC 2800, dated November 15, 2010. However, the current version of IMC 2800 provided more flexibility regarding inspection timeliness and therefore the NHPP's process did not impact their ability to perform inspections timely. Additionally, the NHPP had established a more restrictive inspection frequency "Priority 3/5" for permit types that the NRC had established as a "Priority 5". Specifically, the NHPP attempted to perform these inspections at a four-year interval rather than a five-year interval. The licensee had established a tracking system to ensure that inspections were being scheduled appropriately.

The DVA was significantly impacted by the COVID-19 public health emergency and requested a temporary exemption on April 23, 2020, to defer inspections, as necessary, and to announce inspections. On May 19, 2020, the NRC granted the requested exemption for the remainder of calendar year 2020. The DVA continued to renew the exemption, most recently on April 12, 2022, which was approved on June 29, 2022, with an expiration on December 31, 2022. During this time, the licensee announced all inspections to ensure that onsite activities not impact patient care or endanger the NHPP and permittee staff or members of the public. Additionally, 18 inspections were deferred due to the onsite conditions of specific permitted facilities. The NHPP established a tracking system to ensure that these facilities were then inspected at the next reasonable opportunity. As of the date of this review, the NHPP had completed all deferred routine inspections and did not expect the need to defer future inspections beyond the established inspection interval.

The team noted that the licensee had several permittees with multiple locations of use listed on their permits. The NHPP staff used Internal Procedure No. 26, "Inspection Scheduling," for guidelines regarding scheduling inspections of permittees with more than one location of use. The procedure was more restrictive than the IMC 2800 and required that all satellite locations within 59 miles of the primary location be inspected while the primary location of use is inspected. Additionally, for those locations greater than 59 miles from the primary location, the PMs attempted to complete inspections of those facilities within the routine inspection frequency.

Six initial inspections were performed for facilities that had added authorizations under 10 CFR 35.1000 to use yttrium-90 microsphere permanent brachytherapy. These initial inspections were performed approximately 12 months after the permittee began

performing activities under the new authorization, which was within 18 months of amending the permit. These initial inspections were often performed at the same time as the routine inspection.

As discussed above, the DVA has not updated NRSC SOP 02 to ensure compatibility with the September 2017 and March 2020 revisions to IMC 2800. However, the NHPP was actively working on a revision to the SOP and planned to submit it to the NRC soon. Among other changes, this revision intends to remove the restriction that all inspections be completed unannounced.

4.3 Conclusion

The team concluded that while 18 inspections were completed beyond the inspection frequencies established in IMC 2800, these were all a result of the implications of COVID-19 at those facilities and the deferral of these inspections were authorized under the temporary exemption granted to the DVA. The team also concluded that the NHPP maintained an inspection tracking system that ensured that inspections were performed consistent with or at a more restrictive interval than established in the current version of IMC 2800.

5. Technical Staffing and Training

5.1 Inspection Scope

The team reviewed the licensee's radioactive materials program staffing level and turnover, and the technical qualifications and training history of the PMs. In evaluating these elements, the team interviewed NHPP staff members, reviewed the DVA's inspector/permit reviewer qualification program described in SOP 04 "NHPP Inspector/Reviewer Qualifications," reviewed records and documentation of NHPP staff training, and evaluated casework related to permitting, inspecting, and responding to incidents and allegations.

5.2 Observations and Findings

The NHPP has a written training and qualification program for its PMs which is described in SOP 04, "NHPP Inspector/Reviewer Qualifications." The procedure is based on NRC IMC 1248, "Formal Qualifications Program in the Federal and State Material and Environmental Management Programs."

As of October 21, 2022, there were no technical staffing vacancies. The NHPP technical staff consisted of one Director and six full-time PMs. The NHPP, through its Director, reported to the Deputy Chief Officer for Specialty Care Services, and to the Chairman of the NRSC. The NHPP Director was located in Mare Island, California. Two PMs were located in Birmingham, Alabama, one PM was located in Round Rock, Texas; one PM was located in Houston, Texas; one PM was located in Pensacola, Florida; and one PM was located in North Little Rock, Arkansas. A part-time PM (retired annuitant) left the program on October 3, 2020, when his one-year authorization expired

The NHPP had a permanent Director who is also fully qualified and five fully qualified PMs, four of whom had become fully qualified during this review period. One PM

became interim qualified during the review period and is on track to complete full qualification by the end of FY 2023.

5.3 <u>Conclusion</u>

The team concluded that, having overcome significant challenges regarding staff turnover just prior to the review period, the DVA now had sufficient qualified and experienced technical staff to implement oversight of the day-to-day operations of the DVA's MML. The NHPP continued to make progress towards achieving full qualification for one interim-qualified PM by the end of fiscal year 2023. The team also concluded that the NHPP achieved a successful balance in the acquisition and scheduling of staff training and management of the permitting and inspection workload, while effectively implementing a centrally controlled program.

6. Technical Quality of Permitting Program

6.1 Inspection Scope

The team assessed the technical quality of the permitting process by reviewing 23 DVA

permitting actions completed by the PMs (Attachment 3). The permitting actions were evaluated to ensure that applicable regulations and guidance documents were reviewed. This evaluation included a review of permit and tie-down conditions, appropriate training and experience authorizations, adherence to sealed source and device registrations, use of operating and emergency procedures for the radionuclides and quantities used, and adequacy of facilities and equipment. Casework was also evaluated for completeness, consistency between PMs, timeliness, supervisory review, and adherence to good health physics practices. The permit files were also reviewed for retention of documents required to support the permitting action.

6.2 Observation and Findings

During the inspection period, DVA completed approximately 277 radioactive materials permitting actions. The inspection team evaluated 23 of those licensing actions. The permitting casework reviewed by the inspection team was selected to provide a representative sample of all permitting actions that were processed during the review period. The permitting actions selected for review included all three renewals, all two terminations, and 18 amendments. There were no new permits issued during the inspection period. The team evaluated casework which included, but not limited to, the following permit types and actions: (1) medical broad scope/research and development (R&D) broad scope; (2) medical institution limited scope; (3) medical institution/R&D limited scope; (4) decommissioning actions; (5) notifications; and (6) new locations of use.

The team noted that the PM's properly addressed health and safety issues and were thorough and complete in their review of permitting casework. For most cases reviewed, the files contained appropriate documentation to support each permitting action. In addition, each permitting action had a technical report that was completed by the respective PM. The technical report documented a summary of the action, cited the guidance and regulatory basis for approving the action, and identified deficiencies and

responses received. The technical reports and the final permitting actions were reviewed and signed by the NHPP Director or his designees.

The team reviewed two permit termination actions and four decommissioning actions (Groups 1 and 2) for the inspection period. The team noted that the PM obtained appropriate information required for the release of locations and areas of use and conducted a historical assessment of the affected areas and evaluated final status survey results.

The team confirmed the licensee performs readiness reviews prior to approving permit amendments to add permanent implant brachytherapy procedures and uses permitted by 10 CFR 35.1000. To demonstrate readiness, permittees must address "Start-up Criteria" developed by the NHPP, which performs a readiness review or evaluation prior to the issuance of the amendment. Permittees must respond to any issues identified during the NHPP evaluation. Upon a satisfactory response, the permit is amended to authorize permanent implant brachytherapy procedures described in 10 CFR 35.400 or Y-90 microspheres authorized under 10 CFR 35.1000. There was an increase of interest in the use of Y-90 microspheres within the DVA. There were nine permittees requested authorization for Y-90 microspheres in the inspection period. To cope with permitting this medical emergent technology, the NHPP has developed and deployed for use a Y-90 microspheres' amendment template, a list of commitments the permittee would need to abide by, and additional permitting guidance for permittees to facilitate amendment requests to add microspheres.

The team continued seeing a large turnover for permit RSOs as noted in the previous inspection report. There were 62 amendments involved the change of an RSO in the previous inspection period. In this inspection period, there were 64 amendments involved the change of an RSO. This posed a weakness to the continuity of the program. In response, the NHPP improved the orientation checklist to include a PowerPoint presentation to provide to new RSOs explaining their role and responsibilities. The NHPP contacts the RSO following the presentation of the PowerPoint to complete the checklist with the new RSO, which is included in each permit action file, to assure they understand the material. In addition, the NHPP has extended the permit condition for the RSO to include a requirement for a need to have a qualified RSO on the permit for the continuity of the radiation safety program.

The team observed that several of the permit conditions were not up to date in accordance with the NRC standard license conditions or that the permit conditions were not applicable to the scope of the program authorized in the permits. These were discussed with the NHPP staff. In response, the NHPP began reviewing the list of current NRC materials standard license conditions and the updated NUREG-1556, Volume 20, Revision 1 dated November 2020 posted on the NRC website and were updating the permit conditions, if applicable, to align with the NRC standard license conditions. The team noted that a significant number of permits were coming due for renewal in the near future and the NHPP indicated it would review and update the permits in their entirety that time.

6.3 <u>Conclusion</u>

The technical quality of the permitting program was determined to be thorough, well documented, and consistent. The program implemented by the NHPP enabled the permitting process to be reproducible based on the use of standard permit conditions and NRC guidance documents. Effective communication between the PMs and the NHPP Director enhanced the consistency of the permitting process. The team concluded that the NHPP staff processed permits in a manner that was consistent with current NRC licensing policies, procedures, and guidance.

7. Status of Permitting Program

7.1 Inspection Scope

The team evaluated the effectiveness of the licensee's tracking system for permit requests. The team also examined the licensee's permitting process to verify that permitting actions were handled and processed as required by the MML and LOU.

7.2 Observations and Findings

At the time of the inspection, the NHPP had 115 permittees, primarily medical and medical/research programs. Utilizing the NRC NUREG-1556 series guidance documents, the NHPP issued all renewal permits with a 10-year expiration date.

Most of the completed permitting actions were signed by the NHPP Director. Permitting actions limited to simple requests or notification requirements in 10 CFR 35.14 may be signed by two PMs who are qualified and have been delegated in writing by the NHPP Director. The NHPP Director retains the authority to sign for permits associated with new licenses, renewals, terminations, changes of RSO, new uses of radioactive material, and complex decommissioning actions. At the time of the inspection, all six PMs were qualified to independently review permitting actions and as noted above, two PMs had signature authority. During the review period, the NHPP processed approximately 277 permitting actions.

At the time of the inspection, there were eight pending permitting actions (routine amendment requests). The PMs processed and completed most permitting actions within DVA's timeliness goal of 30 calendar days or less. Many amendment requests were completed within 10 days from the date the requests were received.

The NHPP entered permit requests received from permittees into its spreadsheet for tracking permitting actions. The spreadsheet contains, but is not limited to, permittee's name, program code, description of the request, amendment number, date of request, date received, date assigned, assigned PM, date approved, date issued, and metric date. The permitting manager monitors the status of all permitting actions from start to completion.

7.3 <u>Conclusion</u>

The team determined that the process for reviewing and issuing permitting actions by the licensee was efficient and timely, with no backlog of casework. The team concluded that the NHPP processed permitting actions in accordance with the MML and current NRC policies and procedures.

8. Allegation and Incident Handling Programs

8.1 Inspection Scope

The team reviewed the licensee's program for handling allegations and responding to incidents. This included a review of incidents and allegations to determine applicability of NRC reporting requirements, the effectiveness of the NHPP staff in handling allegations and responding to incidents, and the status of any open allegations. The team interviewed the NHPP staff regarding incidents and allegations and assessed communications between the NHPP and the NRSC to determine if allegations were communicated to the NRSC.

The team reviewed SOP 05, "NHPP Incident Response Procedure" and seven of the 10 incidents that were reported to the NRC (Attachment 4). The team also reviewed SOP 06, "NHPP Allegation Management Program," and four allegations that the NRC forwarded to the NHPP for investigation, and four allegations that the NHPP received directly from concerned individuals (CIs).

8.2 Observations and Findings

a. Incidents/Events

The NHPP staff reported 10 events to the NRC during the review period. Six events were medical events (one retracted), and two events involved packages received at permitted facilities with removable surface contamination levels that exceeded Department of Transportation contamination limits. The remaining two events involved a leaking source, and an exposure rate in excess of public dose limits in an unrestricted area.

In responding to events, the NHPP implemented SOP 05, "NHPP Incident Response Procedure." The procedure requires that each MML permittee report events to the NHPP in accordance with NRC regulations. When the NHPP staff received an event report from a permittee, the event was documented with the information as noted on the Incident Information Form included in SOP 05.

The NHPP reviewed the information and determined whether the event was reportable to the NRC. If reportable, the NHPP staff notified the NRC as required. In accordance with SOP 05, the Director evaluated each event to ensure that inspections were conducted within the established time frame in accordance with NRC policies and procedures, and to determine if an immediate reactive inspection

was required, or if follow-up on the event could be conducted during the next routine inspection. In most cases, an investigation was immediately initiated via phone or email and follow-up inspections scheduled as needed.

The team reviewed inspection plans and inspection reports for the five medical events and the two contaminated package events, evaluated the licensee's incident files and tracking system for reporting requirements, and interviewed the NHPP staff. The team determined that the events were reported to the NRC as required by NRC regulations. The team also noted that the NHPP inspection reports adequately described the circumstances surrounding the events, as well as actions taken by the permittees to prevent recurrence.

b. Allegations

The team reviewed eight of the 12 allegations on the NHPP tracking list which included files that were not completed from the last biennial inspection and additional files processed during the review period. There were three allegations open and in-process at the time of the inspection. The team noted that SOP 06 was updated since the last inspection and included a change in how the person reporting the allegation was referred to from "alleger" to "concerned individual (CI)", which also carried over into the allegation files. A separate folder was maintained for each allegation and labelled as containing sensitive material. These files were kept in a locked file cabinet. Electronic files were also maintained which were in restricted folders and were password protected. Only the Director, the program manager, and those with a need to know had the keys to the locked file cabinet or access to the electronic records. Each allegation file contained a chronology that began when the allegation was received and documented all communications and decisions until the file was closed.

Four allegations that were reviewed, were initially received by the NRC and forwarded to the NHPP for investigation. In these cases, the NRC submitted a Request for Information (RFI) to the NHPP. Responses from the NHPP were timely and satisfied the NRC in all cases. For all four cases reviewed where the NHPP received allegations directly from CIs, the NHPP implemented SOP 06, and reported its findings to the NRSC which reviewed the case and voted on closing out the allegation.

During the previous two biennial inspections, violations were issued for failures to issue close-out letters to the CI as required by License Condition No. 18 of the MML that requires the licensee to conduct its program in accordance with the procedures contained in application dated September 21, 1998. The September 21, 1998, application includes six SOPs. Item No. 9 of SOP 06, "NHPP Allegation Management Program", requires, in part, that when an allegation has been resolved, a close-out letter is provided to the CI, which provides the details of the NHPP and NRSC actions to resolve the allegation. The team found that for all the files reviewed for which the NHPP had contact information for the concerned individual, close out letters were issued. In the one case where the CI did not want a close out letter, they were contacted and informed of the outcome of the investigation. This finding closes out the previous violations of this requirement.

8.3 <u>Conclusion</u>

The team concluded that the licensee's program for responding to incidents and events complied with the MML and applicable NRC regulations and SOP 05 and was implemented effectively. The seven events reviewed were appropriately reported to the NRC in accordance with NRC regulations. The team concluded the licensee's program for investigating and documenting allegations complied with the MML and applicable NRC regulations and SOP 06 and was implemented effectively. The eight allegations reviewed were appropriately investigated or referred to the NRC in accordance with NRC regulations.

9. NRC Independent Inspections of DVA Permittees

9.1 Inspection Scope

During the 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 corrective actions to violations were reviewed for accuracy, completeness, timeliness, and effectiveness.

9.2 Observations and Findings

During the period from November 9, 2019, through October 21, 2022, the NRC staff inspected 13 DVA permittees. The NRC inspections focused on programs that the NRC had not recently inspected since the MML was issued. Three of the 13 permittees that were inspected by the NRC had a primary program code of 2110 (medical institution-broad scope), six had a primary code of 2120 (medical institution – written directive required), and the remaining four had a primary program code of 2121 (medical institution – written directive not required). Three permittees also had a secondary program code of 3610 (R&D broad – type A), and one had a tertiary program code of 2240 (medical therapy – other emerging technology).

The NRC identified two Severity Level IV violations at the VA-Muskogee, Oklahoma. The violations involved 1) a failure to name a permanent RSO in a timely manner, and 2) a failure to properly document the release of a patient under 10 CFR 35.75. The team reviewed the permittee's immediate and long-term corrective actions for the violation and noted no concerns.

9.3 <u>Conclusion</u>

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

10. Exit Meeting

An exit meeting was held with DVA representatives on October 21, 2022. The overall scope and findings of the inspection were discussed. The DVA participants did not identify any information as being proprietary in nature.

ATTACHMENTS:

- 1. Supplemental Information
- 2. Inspection Casework Reviews
- 3. Permitting Casework Reviews
- 4. Incident Časework Reviews

SUPPLEMENTAL INFORMATION

LIST OF PERSONS CONTACTED

Licensee Personnel

*C. Abell, Program Manager, NHPP
#D. Barrickman, NRSC Member
*K. Boyd, Program Manager, NHPP
*J. Bravenec, Program Manager, NHPP
#D. Bushnell, M.D., Ph.D., Chair, National Radiation Safety Committee (NRSC)
#J. Chenowith, M.D., NRSC Member
#M. DeGrandi, J.D., NRSC Member
*M. Edwards, Administrative Officer, NHPP
*T. Huston, Ph.D., Program Manager, NHPP
*C. Kidwell, Administrative Support Assistant, NHPP
*J. Kwasniewski, Program Manager, NHPP
#P. Malloy, M.D., NRSC Member
*E. Leidholdt, Ph.D., Director, NHPP
*J. Nord, M.D., Deputy Chief Officer, Specialty Care Services
*T. Sidell, Program Specialist

*K. Wiebeck, Program Manager, NHPP

NRC Personnel

- *A. Bolger, Health Physicist, Region IV
- *D. Curtis, Director, Division of Radiological Safety and Security, Region III
- *R. Elliott, Sr. Health Physicist, Region I
- #J. Nick, Acting Chief, Materials Licensing Branch, DRSS, Region III
- *B. Parker, Sr. Health Physicist, Region III
- *F. Tran, Health Physicist, Region III
- #S. Xu, Health Physicist, Nuclear Material Safety and Safeguards

*Attended October 21, 2022, exit meeting #Attended October 21, 2022, exit meeting by telephone

In addition, numerous permittee staff were interviewed during the independent inspections conducted by the NRC during the review period November 9, 2019, through October 21, 2022.

LIST OF ACRONYMS USED

- ADAMS Agencywide Documents Access and Management
- System CFR Code of Federal Regulations
- DRSS Division of Radiological Safety and Security
- DVA Department of Veterans Affairs
- IMC Inspection Manual Chapter
- LOU Letter of Understanding
- MOU Memorandum of Understanding
- MML Master Materials License
- NARM Naturally Occurring or Accelerator-Produced Radioactive

Material NHPP	National Health Physics Program
NRC	U.S. Nuclear Regulatory
Commission NRSC	National Radiation Safety
Committee NSTS	National Source Tracking
System PM	Program Manager
R&D	Research and Development
RSO	Radiation Safety Officer
RTMS	Records Tracking Management
System SOP	Standard Operating Procedure
VA	Veterans Administration
VHA	Veterans Health Administration

INSPECTION CASEWORK REVIEWS

File No.: 1 Permittee: Togus VA Medical Center Inspection Type: Routine, Announced Inspection Date: August 3, 2021

No.: 2 Permittee: Montgomery VA Medical Center Inspection Type: Routine, Announced Inspection Date: July 27, 2022

File No.: 3 Permittee: Montgomery VA Medical Center Inspection Type: Routine, Unannounced Inspection Date: January 14-15, 2020

File No.: 4 Permittee: New Mexico VA Healthcare System Inspection Type: Routine, Announced Inspection Date: April 6-7, 2022

File No.: 5 Permittee: VA Central Iowa Healthcare System Inspection Type: Routine, Announced Inspection Date: July 16, 2020

File No.: 6 Permittee: VA Loma Linda Healthcare System Inspection Type: Routine, Announced Inspection Date: November 17-19, 2020

File No.: 7 Permittee: VA Connecticut Healthcare System Inspection Type: Routine, Announced Inspection Date: May 20, 2021

File No.: 8 Permittee: VA Salt Lake City Healthcare System Inspection Type: Routine, Announced Inspection Date: April 8-9, 2021

File No.: 9 Permittee: Miami VA Healthcare System Inspection Type: Routine, Announced Inspection Date: April 20-21, 2021 Permit No.: 18-07561-01 Priority: 3/5 Inspector: CK

Permit No.: 23-08786-01 Priority: 2 Inspector: CK

Permit No.: 23-08786-01 Priority: 2 Inspector: TH

Permit No.: 30-01747-02 Priority: 3 Inspector: CA

Permit No.: 14-03523-02 Priority: 3 Inspector: KB

Permit No.: 04-17862-01 Priority: 3 Inspector: SB/KW

Permit No.: 31-13511-04 Priority: 2 Inspector: CA

Permit No.: 43-03299-01 Priority: 3 Inspector:

Permit No.: 09-00239-06 Priority: 2 Inspector: SB

File No.: 10 Permittee: Miami VA Healthcare System Permit No.: 09-00239-06 Inspection Type: Initial (Y-90), Announced Priority: 2 Inspection Date: January 11, 2020 Inspector: KW INSPECTION CASEWORK REVIEWS File No.: 11 Permittee: Cpl Michael J. Crescenz VA Medical Center Permit No.: 37-00062-07 Inspection Type: Routine, Announced Priority: 2 Inspection Date: September 1-2, 2021 Inspector: CA File No.: 12 Permittee: VA Northern CA Healthcare System Permit No.: 04-02956-02 Inspection Type: Routine/Initial (Y-90), Announced Priority: 2 Inspection Date: May 18-20, 2021 Inspector: KW File No.: 13 Permittee: Herschel Williams VA Medical Center Permit No.: 47-03630-02 Priority: 3 Inspection Type: Routine, Announced Inspection Date: April 14, 2021 Inspector: CK File No.: 14 Permittee: VA Eastern Colorado Healthcare System Permit No.: 05-01401-02 Inspection Type: Routine, Announced Priority: 2 Inspection Date: May 11, 2021 Inspector: TH File No.: 15 Permittee: VA Pittsburg Healthcare System Permit No.: 37-01230-03 Inspection Type: Special, Announced Priority: 3 Inspection Date: May 17, 2021 Inspector: CA File No.: 16 Permittee: San Francisco VA Healthcare System Permit No.: 04-00421-05 Inspection Type: Routine, Announced Priority: 2 Inspection Date: June 29-30, 2020 Inspector: KW File No.: 17 Permittee: VA Medical Center Kansas City, MO Permit No.: 24-00589-01 Inspection Type: Special, Announced Priority: 3 Inspection Date: July 7, 2021 Inspector: CA/SB File No.: 18 Permittee: VA Medical Center Orlando, FL Permit No.: 09-00675-01 Inspection Type: Routine, Announced Priority: 3 Inspection Date: March 7-8, 2022 Inspector: KB File No.: 19 Permittee: VA Medical Center Fayetteville, NC Permit No.: 32-13654-01 Inspection Type: Routine, Announced Priority: 3/5 Inspection Date: April 12, 2022 Inspector: KW

PERMITTING CASEWORK REVIEWS

File No.: 1 Permittee: VA Orlando, FL Type of Action: Amendment Permit Type: Medical Institution – Limited Scope Comment: Remove a location of use

File No.: 2 Permittee: VA Los Angeles, CA Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 3 Permittee: VA Mather, CA Type of Action: Amendment Permit Type: Medical Institution/R&D - Limited Scope

File No.: 4 Permittee: VA Denver, CO Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope Comment: Remove a location of use

File No.: 5 Permittee: VA Albuquerque, NM Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope Comment: Decommissioning Building No. 11

File No.: 6 Permittee: VA Lincoln, NE Type of Action: Termination Permit Type: Medical Institution – Limited Scope

File No.: 7 Permittee: VA Roseburg, OR Type of Action: Amendment Permit Type: Medical Institution – Limited Scope

File No.: 8 Permittee: VA Northport, NY Amendment No.: 55 Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope Permit Reviewer: TH Comment: Remove non-human R&D and decommissioning associated buildings

Date: 2/19/2020 Permit No.: 09-00675-01 Amendment No.: 32 Permit Reviewer: TH

Date: 11/21/2019 Permit No.: 04-00181-04 Amendment No.: 130 Permit Reviewer: KW

Date: 5/28/2020 Permit No.: 04-02956-02 Amendment No.: 133 Permit Reviewer: KB

Date: 8/19/2020 Permit No.: 05-01401-02 Amendment No.: 69 Permit Reviewer: TH

Date: 9/15/2020 Permit No.: 30-01747-02 Amendment No.: 67 Permit Reviewer: CK/TH

Date: 5/7/2021 Permit No.: 26-16293-01 Amendment No.: 35 Permit Reviewer: KW

Date: 3/3/2020 Permit No.: 36-21137-01 Amendment No.: 52 Permit Reviewer: KW

Date: 6/18/2020 Permit No.: 31-13511-04 File No.: 9 Permittee: VA New Orleans, LA Type of Action: Amendment Permit Type: Medical Institution/R&D – Limited Scope Comment: Add authorization for non-human R&D

File No.: 10 Permittee: VA Albuquerque, NM Type of Action: Renewal Permit Type: Medical Institution/R&D – Broad Scope Comment: Converse a Broad Scope to Limited Scope license

File No.: 11 Permittee: VA Los Angeles, CA Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 12 Permittee: VA North Las Vegas, NV Type of Action: Renewal Permit Type: Medical Institution – Limited Scope

File No.: 13 Permittee: VA Amarillo, TX Type of Action: Renewal Permit Type: Medical Institution – Limited Scope

File No.: 14 Permittee: VA Long Beach, CA Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 15 Permittee: VA Hines, IL Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 16 Permittee: VA Bay Pines, FL Type of Action: Amendment Permit Type: Medical Institution/R&D – Limited Scope

File No.: 17 Permittee: VA San Antonio, TX Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope Date: 11/9/2021 Permit No.: 17-00629-01 Amendment No.: 13 Permit Reviewer: KB

Date: 12/18/2020 Permit No.: 30-01747-02 Amendment: 68 Permit Reviewer: TH/KW

Date: 2/12/2020 Permit No.: 04-00181-04 Amendment No.: 131 Permit Reviewer: KW

Date: 11/21/2021 Permit No.: 27-00593-01 Amendment No.: 12 Permit Reviewer: KW

Date: 5/25/2022 Permit No.: 42-00504-01 Amendment No.: 8 Permit Reviewer: SB/TH

Date: 3/29/2022 Permit No.: 04-00689-07 Amendment No.: 70 Permit Reviewer: JK

Date: 11/3/2019 Permit No.: 12-01087-07 Amendment No.: 92 Permit Reviewer: KW

Date: 9/4/2019 Permit No.: 09-04233-03 Amendment No.: 89 Permit Reviewer: KW

Date: 10/27/2021 Permit No.: 42-15881-01 Amendment No.: 84 Permit Reviewer: CA File No.: 18 Permittee: VA Fayetteville, NC Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 19 Permittee: VA Atlanta, GA Type of Action: Amendment Permit Type: Medical Institution/R&D – Limited Scope

File No.: 20 Permittee: VA East Orange, NJ Type of Action: Amendment Permit Type: Medical Institution /R&D – Broad Scope Comment: Change the area of use for HDR

File No.: 21 Permittee: VA Leavenworth, KS Type of Action: Amendment Permit Type: Medical Institution – Limited Scope

File No.: 22 Permittee: VA Los Angeles, CA Type of Action: Amendment Permit Type: Medical Institution/R&D – Broad Scope

File No.: 23 Permittee: VA Roseburg, OR Type of Action: Termination Permit Type: Medical Institution – Limited Scope Date: 7/19/2022 Permit No.: 32-13654-01 Amendment No.: 56 Permit Reviewer: KW

Date: 9/8/2022 Permit No.: 10-01169-01 Amendment No.: 112 Permit Reviewer: KB

Date: 7/1/2021 Permit No.: 29-04481-01 Amendment No.: 125 Permit Reviewer: JK

Date: 3/30/2022 Permit No.: 15-08114-01 Amendment No.: 55 Permit Reviewer: KB

Date: 4/9/2020 Permit No.: 04-00181-04 Amendment No.: 132 Permit Reviewer: JK

Date: 3/25/2021 Permit No.: 36-21137-01 Amendment No.: 53 Permit Reviewer: CA

INCIDENT CASEWORK REVIEWS

File No. 1 Permittee: N FL/S GA Veterans Healthcare Sys Date of incident: February 27, 2020 Discovery Date: February 27, 2020 Investigation Date: February 27, 2020

File No.2 Permittee: VA Boston Healthcare System California Health Care System Date of Incident: August 5, 2020 Discovery Date: August 5, 2020 Investigation Date: August 11, 2020

File No. 3 Permittee: Robert J. Dole VA Medical Ctr Date of incident: March 5, 2021 Discovery Date: March 5, 2021 Investigation Date: March 5, 2021

File No. 4 Permittee: Oklahoma City VA Healthcare System Permit No.: 35-00526 Date of Incident: April 16, 2021 Discovery Date: August 16, 2021 Investigation Date: August 16, 2021

File No. 5 Permittee: VA San Diego Healthcare System

Date of Incident: July 13, 2021 Discovery Date: November 16, 2021 Investigation Date: November 16, 2021

File No. 6 Permittee: Richard L. Roudebush VA Medical Ctr Date of Incident: July 14, 2021 Discovery Date: July 14, 2021 Investigation Date: July 14, 2021

File No. 7 Permittee: Tibor Rubin VA Medical Center Date of Incident: July 27, 2022 Discovery Date: July 27, 2022 Investigation Date: July 28, 2022

Permit No.: 09-12467-02 NRC Event No.: 54547 Type of Incident: Contaminated pkg

Permit No.: 20-00671-02 NRC Event No.: 54822 Type of Incident: Medical Event

Permit No.: 24-00144-05 NRC Event No.: 55124 Type of Incident: Contaminated pkg

NRC Event No.: 55169 Type of Incident: Medical Event

Permit No.: 04-15030-01 NRC Event No.: 55585 Type of Incident: Medical Event

Permit No.: 13-00694-03 NRC Event No.: 55353 Type of Incident: Medical Event

Permit No.: 04-00689-07 NRC Event No.: 56020 Type of Incident: Medical Event