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

February 13, 2019

EN 53695
NMED No. 180486 (Closed)

Ms. Danielle Sheen
Director, Environmental Health and Safety
The Regents of the University of Michigan
1239 Kipke Dr.
Ann Arbor, MI 48109-1010

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001988/2018001(DNMS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Dear Ms. Sheen:

On October 22 through 26, 2018, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Ann Arbor campus, with continued in-office review through January 15, 2019. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of information regarding a medical event that occurred during the onsite inspection, including the required written notification of the medical event. Messrs. Robert Gattone and Edward Harvey of my staff conducted a final exit meeting by telephone with Messrs. Byron Bryant, Mark Driscoll, Karl Fischer, Justin Quinn, and Stan Uitti of your staff on January 15, 2019, to discuss the inspection findings. This letter and the enclosed inspection report present the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the licensee's failure to fully implement its written procedure to provide high confidence that each administration of lutetium-177 DOTA^{0}-Tyr^{3}-Octreotate (Lu-177) is in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 35.41(a)(2). Specifically, a nurse, who did not have appropriate training, handled Lu-177, contrary to the licensee's written procedure to provide high confidence that each Lu-177 administration is in accordance with the written directive, which ultimately resulted in the occurrence of a medical event. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspectors identified the violation.

The inspectors determined that the root cause of the violation was that the staff member who was most knowledgeable of Lu-177 administrations left the procedure to tend to another patient. As corrective actions to restore compliance and to prevent recurrence the licensee: (1) implemented a policy in which the attending nuclear medicine technologist (NMT) will be responsible only for Lu-177 administrations on days when Lu-177 is administered, until all Lu-177 infusions are complete for the day; (2) committed to formally retrain all nurses attending to Lu-177 therapies on the infusion process, their responsibilities, and general radiation safety; (3) committed to a policy in which, emergency situations notwithstanding, only trained NMTs will handle Lu-177, purge or handle lines during the Lu-177 infusion, or otherwise manipulate components involved in the Lu-177 infusion, until the Lu-177 infusion is complete; (4) committed to train additional NMTs to oversee Lu-177 therapies; and (5) implemented a policy in which all staff entering the restricted area where Lu-177 infusions occur should wear two pairs of shoe covers and discard the outer pair before stepping out of the restricted area.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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.

Please feel free to contact Mr. Gattone if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01988
License No. 21-00215-04

Enclosures:
1. Notice of Violation
2. IR 03001988/2018001(DNMS)

cc w/encl: State of Michigan

Letter to Danielle Sheen from Aaron McCraw dated February 13, 2019.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO.03001988/2018001(DNMS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

DISTRIBUTION:
Darrell Roberts
John Giessner
Mohammed Shuaibi
Christine Lipa
Jamnes Cameron
Paul Pelke
MIB Inspectors

ADAMS Accession Number: ML19044A655

OFFICE	RIII-DNMS		RIII-DNMS		RIII-DNMS			
NAME	EHarvey:cl via email		RGattone		AMcCraw MKunowski for			
DATE	2/12/2019		2/12/2019		2/13/2019			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

The Regents of the University of Michigan
Ann Arbor, Michigan

License No. 21-00215-04
Docket No. 030-01988

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 22 through 26, 2018; with continued in-office review through January 15, 2019, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* Section 35.41(a)(2) requires that, for each administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> The licensee's written procedure to provide high confidence that each $DOTA^{0}$-Tyr^{3}-Octreotate (Lu-177) administration is in accordance with the written directive was the clinical sponsor's information/instruction package. Section 4.15 of the clinical sponsor's information/instruction package states, in part, that Lu-177 must be stored, handled, and administered only by qualified/authorized personnel.
>
> Contrary to the above, on October 25, 2018, the licensee failed to fully implement its written procedure to provide high confidence that each administration of Lu-177 is in accordance with the written directive. Specifically, a nurse, who did not have appropriate training, handled Lu-177.
>
> This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was or will be achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice) and its enclosed inspection report (Enclosure 2). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03001988/2018001(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, 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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 13th day of February 2019.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01988
License No.	21-00215-04
Report No.	03001988/2018001(DNMS)
EN No./NMED No.	EN53695 / 180486
Licensee:	The Regents of the University of Michigan Radiation Safety Service: Occupational Safety & Environmental Health, University of Michigan
Facility:	1239 Kipke Drive Ann Arbor, MI 48109-1010
Inspection Dates:	October 22-26, 2018; with continued in-office review through January 15, 2019
Exit Meeting Date:	January 15, 2019
Inspectors:	Robert G. Gattone, Jr., Senior Health Physicist Edward F. Harvey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

The Regents of the University of Michigan Radiation Safety Service: Occupational Safety & Environmental Health, University of Michigan
NRC Inspection Report No. 03001988/2018001(DNMS)

On October 22 through 26, 2018, with continued in-office review through January 15, 2019, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of The Regents of the University of Michigan Radiation Safety Service: Occupational Safety & Environmental Health, University of Michigan (licensee). The licensee is authorized under NRC Materials License No. 21-00215-04 to conduct medical broad scope activities that includes the use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee used licensed materials for medical applications and research and development.

The inspectors reviewed the facts and circumstances of a medical event that occurred during the onsite inspection on October 25, 2018, involving a patient under dose of lutetium-177 $DOTA^{0}$-Tyr^{3}-Octreotate (Lu-177) and determined that one violation occurred concerning the licensee's failure to fully implement written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive, pursuant to 10 CFR 35.41(a)(2). In addition, the inspectors determined that the licensee made all required medical event notifications in a timely manner. The inspectors noted that the licensee took corrective actions to prevent a similar event and violation.

The inspectors reviewed other aspects of the licensee's radiation protection program and the use of licensed materials, with no issues noted.

REPORT DETAILS

1 Program Overview and Inspection History

The Regents of the University of Michigan Radiation Safety Service: Occupational Safety & Environmental Health, University of Michigan (licensee) is authorized under NRC Materials License No. 21-00215-04 to conduct medical broad scope activities that includes use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee maintained a student population of 46,200 at the main campus in Ann Arbor, Michigan. The license also authorizes licensed activities to be conducted at facilities in Dearborn, Flint, Belleville, Brighton, and Pellston, Michigan. The licensee's RPC had designated approximately 190 individuals as authorized users, and about 1,000 people worked as supervised users. The licensee used licensed materials for medical applications and research and development.

The licensee's Radiation Safety Service (RSS), led by the RSO, was located within its Department of Environment, Health & Safety (EHS). The EHS department is overseen by an Executive Director, who reports to the Associate Vice President for Facilities and Operations. Approximately 13 staff members worked in RSS. The RSS staff conducted instrument calibrations, conducted leak tests, and reviewed authorized user applications. RSS technicians were involved with package delivery and receipt, laboratory reviews, confirmatory surveys, laboratory closeouts, and assistance to research and development staff regarding radiation safety matters.

Medical use was conducted at University Hospital (UH), Cardiovascular Center, Kellogg Eye Center, C.S. Mott Children's Hospital and Von Voigtlander Women's Hospital, and the Brighton Center for Specialty Care. At UH, the licensee used licensed materials under the authorities of Title 10 of the *Code of Federal Regulations* (CFR) 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. UH also possessed a self-shielded irradiator for irradiating biological materials until its removal and disposal by the Department of Energy Offsite Source Recovery Project on August 14, 2018.

Radioactive materials for research and development were located at approximately 750 radiation rooms within about 60 buildings. Research and development activities were trending down and primarily involved biological research with millicurie (mCi) quantities of carbon-14, hydrogen-3, iodine-125, phosphorus-32, and sulfur-35. The licensee also maintained and operated three self-shielded cesium-137 (Cs-137) irradiators for research and development.

2 Medical Event

2.1 Inspection Scope

The inspectors reviewed the facts and circumstances of a medical event that occurred at the licensee's UH during the onsite inspection on October 25, 2018, involving a therapeutic administration of Lu-177. The review included observations of event response, interviews with involved licensee personnel, and a review of pertinent licensee documents.

2.2 Observations and Findings

On October 25, 2018, two patients were scheduled to receive administrations of 200 mCi of Lu-177 from the licensee's nuclear medicine department at UH. The treatment protocol for these administrations required concurrent infusion of reno-protective amino acids that are infused at least 30 minutes prior to the Lu-177, and must be continued at a constant rate for at least four hours. The Lu-177 infusion lasts approximately 30 minutes and may be followed by saline flush of the vial to help ensure that any residual dosage is administered to the patient. The licensee delivered these treatments using an infusion pump with two modules; one for the Lu-177, and one for the amino acids. A bag of saline was also integrated into the module with the Lu-177.

The inspectors observed the first administration of Lu-177 with no issues identified. The inspectors observed the nuclear medicine technologist (NMT) assay the unit dose using a dose calibrator, verify the patient's identity, set up the treatment delivery system, administer the Lu-177, and flush the vial with no issues. Following the complete administration of the Lu-177, the NMT collected the vial and treatment catheter to assay them for residual activity to determine the final dose delivered.

Following the first administration, the inspectors left the Lu-177 treatment bay to review written directives and observe administrations of other treatments. The inspectors returned to the Lu-177 treatment bay and observed that licensee personnel appeared to be responding to an issue with the second administration. The inspectors noted that the NMT attending to the patient had removed all of the Lu-177 treatment delivery components and terminated the delivery of Lu-177 because there was no additional radiopharmaceutical remaining in the vial. The inspectors followed the NMT to the nuclear medicine hot lab and observed the NMT assay the residual Lu-177 to find that approximately 68.3 mCi of the dispensed 203.2-mCi dose had not been administered to the patient. As a result, the patient received approximately 134.9 mCi of the prescribed 200 mCi dose.

Once the residual radioactivity was assayed, the NMT notified the nuclear medicine lab manager and the physician. The inspectors noticed that the survey instrument in the hot lab appeared to show elevated readings and asked the NMT that she survey herself for contamination. A member of the licensee's radiation safety staff was present and assisted the NMT with personnel surveys, which indicated contamination. The NMT began the decontamination process and additional licensee staff proceeded to check the treatment bay and the path between the bay and the hot lab for contamination. The licensee determined that all contamination was limited to the NMT's clothing and the designated potentially contaminated area of the treatment bay that was covered with protective padding.

The licensee performed a dose assessment and determined that the effective dose equivalent administered to the patient differed from the prescribed dose by 0.13 Gray (Gy), or 13 rem, and that the administered activity differed from the prescribed activity by 32.6 percent. Based on this information, this administration met the criteria for an NRC medical event, as specified in 10 CFR 35.3045(a)(1).

The physician notified the patient of the event and worked with the nuclear medicine staff to order a make-up dose of Lu-177 to be administered the next day. Following the complete infusion of amino acids, the patient was surveyed for contamination and surveys indicated that some articles of clothing had been contaminated. The licensee provided new garments for the patient and held the contaminated clothes for decay in

storage. The patient was released and licensee personnel began the process of decontaminating the treatment bay.

The inspectors interviewed pertinent staff involved with the procedure and determined that the root cause of the medical event was that the NMT who was most knowledgeable of Lu-177 administrations (NMT1) left the treatment bay during the administration to tend to another patient. Before NMT1 left, she had given explicit instructions to another NMT (NMT2) that, if the pump alarms for any reason, to pause the treatment and notify her. While NMT1 was away, a small air bubble had formed in the infusion line, causing the pump to alarm. Contrary to NMT1's instructions, NMT2 attempted to restart the pump, which formed a larger bubble in the line. NMT2 then asked an attending infusion nurse for assistance in purging the air from the line. The nurse had not been trained on purging a line on this particular Lu-177 treatment apparatus, which was previously performed by NMT1. As such, the nurse was unaware that fully concentrated Lu-177 was still in the line. The nurse drained the line of Lu-177 by emptying it into an emesis basin believing it was saline and then observed that the saline line was closed. NMT1 then returned to the treatment bay and terminated the infusion of Lu-177. The licensee's written report, submitted to the NRC on November 9, 2018, confirms these details.

Title 10 CFR 35.41(a)(2) requires that, for each administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's written procedure to provide high confidence that each Lu-177 administration is in accordance with the written directive was the clinical sponsor's information/instruction package. Section 5 of the licensee's permit authorizing the nuclear medicine department to use Lu-177 states, in part, "Only individuals qualified by training and experience in the safe handling and administration of radiopharmaceuticals will be authorized to handle Lu-177." Section 6 of the licensee's permit authorizing the nuclear medicine department to use Lu-177 states, in part, that personnel handling and/or administering Lu-177 must follow all precautions specified in the clinical sponsor's information/instruction package. Section 4.15 of the clinical sponsor's information/instruction package states, in part, that [Lu-177] must be stored, handled, and administered only by qualified/authorized personnel.

The nurse intervening and handling a catheter containing Lu-177, without the required training, constitutes a failure to fully implement the licensee's written procedure to provide high confidence that each administration is in accordance with the written directive, and therefore, is a violation of 10 CFR 35.41(a)(2). The NRC has determined that the root cause of this violation was that NMT1, who was most knowledgeable of Lu-177 administrations, left the procedure to tend to another patient.

As immediate corrective action, the licensee ordered a supplemental dose of Lu-177 that was properly administered to the patient on October 26, 2018. As long-term corrective actions to prevent recurrence of a similar event and violation, the licensee: (1) implemented a policy in which the attending NMT will be responsible only for Lu-177 administrations on days when Lu-177 is administered, until all Lu-177 infusions are completed for the day; (2) committed to formally retrain all nurses attending to Lu-177 therapies on the infusion process, their responsibilities, and general radiation safety; (3) committed to a policy in which, emergency situations notwithstanding, only trained NMTs will handle Lu-177, purge or handle lines during the Lu-177 infusion, or otherwise manipulate components involved in the Lu-177 infusion, until the Lu-177 infusion is complete; (4) committed to train additional NMTs to oversee Lu-177 therapies; and

(5) implemented a policy in which all staff entering the restricted area where Lu-177 infusions occur should wear two pairs of shoe covers and discard the outer pair before stepping out of the restricted area.

2.3 Conclusions

The inspectors reviewed the facts and circumstances of the medical event that occurred on October 25, 2018, and determined that one violation occurred concerning the licensee's failure to fully implement written procedures to provide high confidence that each administration is in accordance with the written directive, pursuant to 10 CFR 35.41(a)(2). The inspectors noted that the licensee took corrective actions to prevent a similar violation/event.

3 Licensee Notifications

3.1 Inspection Scope

The inspectors interviewed licensee staff and management concerning both the initial notification of the medical event to the NRC and the required written report. The inspectors also reviewed the documentation of the notifications for required information.

3.2 Observations and Findings

The licensee discovered that the Lu-177 administration met the criteria for a reportable medical event on October 26, 2018, and subsequently notified the NRC Headquarters Operations Center on the same day. This met the requirement to report the medical event to the NRC by no later than the next calendar day after discovery, in accordance with 10 CFR 35.3045(c).

In addition, the licensee notified the patient and the patient's referring physician of the medical event the same day of discovery. This met the 24-hour reporting requirement described under 10 CFR 35.3045(e).

On November 9, 2018, the NRC received the licensee's written report regarding the medical event. The licensee's written report was received within 15 days of the discovery of the medical event, as required by 10 CFR 35.3045(d). The inspectors reviewed the report and determined that it contained all of the required information. A copy of the licensee's written report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Number ML18324A824.

3.3 Conclusions

The inspectors determined that the licensee made all of the medical event required notifications in a timely manner.

4 Other Areas Inspected

4.1 Inspection Scope

The inspectors reviewed other areas of the licensee's radiation protection program by interviewing select staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspectors, and reviewing selected records. Areas reviewed included, in part, dosimetry, high dose-rate remote afterloader brachytherapy (HDR) treatments, yttrium-90 (Y-90) microspheres treatments, intravascular brachytherapy treatments (IVBTs), samarium-153 (Sm-153) Quadramet treatments, nuclear medicine imaging, and calibrator device use.

4.2 Observations and Findings

Dosimetry

The inspectors reviewed dosimetry records and noted that the highest whole body and extremity doses for radiation workers for 2017 were 2,480 millirem (mrem), and 27,166 mrem, respectively. In addition, the inspectors noted that the highest whole body and extremity doses for radiation workers for 2018, through August,18, 2018, were 3,775 millirem (mrem), and 21,505 mrem, respectively. The inspectors noted that the highest hydrogen bioassay dose for 2017 was 3.2 E-2 mrem. In addition, the inspectors noted that the highest bioassay iodine-125 total organ dose equivalent was 37.7 mrem, and the highest committed effective dose equivalent was 0.4 mrem. The inspectors noted that radiation workers were adequately monitored for internal and external radiation doses and that all recorded doses were within regulatory limits.

HDR Treatments

The licensee's radiation oncology department administered HDR treatments to 52 patients for a total of 198 fractions in 2017. A majority of the treatments were gynecological with occasional prostate treatments.

The inspectors observed the administration of an HDR treatment in which a vaginal cylinder applicator was used. The inspectors observed the licensee: (1) perform all of the required spot checks prior to the administration; (2) verify the correct treatment plan was loaded into the treatment console; (3) verify the patient's identity; (4) survey the patient both before and after treatment; and (5) secure the HDR device after the treatment was complete.

The inspectors also reviewed a sample of pertinent HDR records including written directives, treatment plans, daily spot checks, full calibrations, and source exchanges with no issues identified.

Y-90 Microspheres

The licensee conducted 52 Y-90 TheraSpheres treatments in 2017. The inspectors reviewed records showing that a selected authorized user physician, who conducted Y-90 microspheres treatments, completed technical Y-90 TheraSpheres treatment training. In addition, the inspectors reviewed records showing that a selected

Interventional Radiologist (IR) who was approved by the Subcommittee on the Human Use of Radioisotopes (SHUR) for Y-90 microspheres, including Y-90 SIR Spheres treatments. The inspectors reviewed records showing that the IR had training on injections by arterial infusion.

The inspectors reviewed the circumstances of an incident in March 2018, involving a Y-90 TheraSpheres treatment resulting in significant pooling of blood under the patient table, and ambient exposure rates showed that the blood was radioactive. The bleeding was caused by a wound where the catheter was in the femoral artery. The licensee contained the contamination (i.e., absorbent drapes and several linens). The licensee measured the normal radioactive waste as per the licensee's Y-90 TheraSpheres procedure per 10 CFR 35.41; however, the extra blood contamination was not assessed per the licensee's Y-90 TheraSpheres procedure per 10 CFR 35.41 because the extra blood contamination items were too large to conduct a proper survey to determine what portion of the Y-90 TheraSpheres did not get administered to the patient. To assess the quality of the administration, the licensee used a reconstruction protocol for quantitative Y-90 bremsstrahlung SPECT/CT for the patient in February 2018 to determine the SPECT/CT calibration factor (i.e., gigaBecquerels (GBq)/count). As such, the licensee used that calibration factor to determine the radioactivity that was administered in the treatment site in March 2018, and the licensee's Y-90 TheraSpheres written directives included units of GBq and Gy. The patient's prescribed dose was 2.59 GBq to the treatment site, and the administered dose was 2.5 GBq. This incident did not meet any of the reportability criteria for an NRC medical event.

Overall, the inspectors determined that the licensee adequately conducted Y-90 microspheres treatments, with no issues identified.

IVBT Program

The licensee began performing IVBT treatments on January 15, 2018, and had performed a total of 16 administrations as of the onsite inspection. The inspectors interviewed licensee personnel regarding implementation of the treatment procedures, emergency procedures, source security, source leak testing, and source exchanges. In addition, the inspectors reviewed records of written directives. The inspectors did not identify any issues with the licensee's IVBT program.

Sm-153 Quadramet Treatments

The inspectors interviewed a nuclear medicine pharmacist and an NMT regarding Sm-153 Quadramet treatments. In addition, the inspectors reviewed selected treatment records. The inspectors did not identify any issues with the licensee's use of Sm-153.

Nuclear Medicine Imaging

The inspectors observed an NMT administer a dosage of technetium-99m labeled medronic acid for a bone scan. The inspectors observed the NMT using a syringe shield and a shielded syringe carrier. The inspectors also noted that the NMT read the syringe label to verify that the syringe contained the correct dosage prior to administration. In addition, the inspectors observed that the NMT wore gloves, whole body dosimeter, and extremity dosimeter while handling the dosage. The inspectors observed appropriate radiation safety techniques when handling unsealed licensed material.

Calibrator Device Use

The inspectors observed a senior health physicist demonstrate how a J.L. Shepherd Model 28-8A calibrator containing seven Curies of Cs-137 was used for educational instruction and dosimeter/instrument testing. The inspectors observed how a radiation safety checklist was properly followed. The inspectors reviewed selected leak test records for the J.L. Shepherd Model 28-8A calibrator. The inspectors identified no issues with the licensee's use of the calibrator.

4.3 Conclusions

The inspectors reviewed other areas of the licensee's radiation protection program with no issues identified.

5 Exit Meeting Summary

The inspectors presented preliminary inspection findings following the onsite inspection on October 26, 2018. The final exit meeting was conducted via telephone on January 15, 2019. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Henry Baier, Associate Vice President for Facilities and Operations
#^ Byron Bryant, Health Physicist I, Radiation Safety Service
Kyle Cuneo, M.D., Authorized User for Y-90 microspheres
#^ Mark Driscoll, Director, RSO
#^ Karl Fischer, Senior Health Physicist, Radiation Safety Service
Sean Gray, NMT
Phil Keavey, Radiation Safety Radiation SafetyTechnician
Joe Miklos, Senior Health Physicist
Katherine Oravecz-Wilson, Authorized User of Irradiator
Ruth Nichols, Ph.D., Radiation Policy Committee Chairperson
Dennis Palmieri, Senior Health Physicist
Joann Prisciandaro, Associate Professor
^Justin Quinn, Health Physicist II
Denise Regan, NMT II
Linda Rodriguez, Dosimetry Coordination
Peter Scott, Assistant Professor of Radiology/Director of PET Radiochemistry
Dave Siemenik, Research Specialist
Danielle Sheen, Director, Environmental Health and Safety
^ Stan Uitti, Health Physicist

Attended preliminary exit meeting on October 26, 2018
^ Attended telephone final exit meeting on January 15, 2019

INSPECTION PROCEDURES USED

87103: Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
87134: Medical Broad-scope Programs