UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 2, 2022

Christine Oskin, MBA, RT(R)(m)
Corporate Director, Medical Imaging Services
Charleston Area Medical Center
P.O. Box 1547
Charleston, WV 25326-1547

SUBJECT: NRC INSPECTION REPORT 030-09164/2021-001 AND NOTICE OF VIOLATION

Dear Ms. Oskin:

This letter refers to the announced inspection conducted the week of November 1, 2021, with follow-up on November 16, 2021, at your facilities in Charleston, West Virginia, with an in-office review through March 24, 2022. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with your staff following the conclusion of the onsite portions of the inspection on November 5 and 16, 2021. A final exit briefing was conducted telephonically with Tuanya Layton, Dr. Kim Lowe, and Patricia Williamson of your staff on May 3, 2022. The enclosed reports present the results of the inspection (Enclosure 3).

Based on the results of the inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited and described in the enclosed Notice of Violation (Notice)(Enclosure 1) because they were identified by the NRC during the inspection.

In addition, the NRC has determined that three Severity Level IV violations of NRC security requirements occurred that involved NRC security requirements, and thus are cited and described in the non-public Notice of Violation (Notice)(Enclosure 2).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website

Enclosure 2 and Attachment 1 and 2 of Enclosure 3 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 2 and Attachment 1 and 2 of Enclosure 3, the cover letter and the remainder of the document is decontrolled.

at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. Information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC's review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

If Security-Related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, Enclosure 1, and your response, to the extent possible, will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. However, the material in Enclosure 2 and Attachment 1 and 2 of Enclosure 3 contain Security-Related Information as described above. Therefore, the material in these enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). To the extent possible, your response should not include any personal privacy information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Ms. Robin Elliott of my staff at (610) 337-5076, or the undersigned at (610) 337-5078.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2022.06.02 16:36:23 -04'00'

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Docket No. 030-09164
License No. 47-15473-01

Enclosures:
1. Notice of Violation (Public)
2. Notice of Violation (Nonpublic)
3. NRC Inspection Report 030-09164/2021-001 (Attachment 1 & 2 Nonpublic)

cc (w/Enclosure 1):
Tera Patton, State of West Virginia

NRC INSPECTION REPORT 030-09164/2021-001 AND NOTICE OF VIOLATION– DATED JUNE 2, 2022.

Distribution:
R1Enforcement

☒SUNSI Review: By: JEV | ADAMS: ☒ Yes ☐ No | Non-Publicly Available ☒ Publicly Available | ☒ Non-Sensitive Sensitive | Keyword:

OFFICE	RI:DRSS	RI:DRSS	RI:DRSS	RI:DRSS		
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NOTICE OF VIOLATION (PUBLIC)

Charleston Area Medical Center
Charleston, WV

Docket No. 030-09164
License No. 47-15473-01

During a routine inspection conducted on November 1, 2, 4, and 16, 2021, with in-office review through March 24, 2022, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. License Condition 20 of License No. 47-15473-01, Amendment 83, requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated November 11, 2016, (ADAMS Accession No.: ML16337A027). The application dated November 11, 2016, requires the licensee, in part, to follow written procedures for monitoring occupational dose. The licensee's written procedure for Radioactive Iodine-131 Handling, No. 30AA01023 requires, in part, that bioassays are required for any individual handling liquid radioiodine in millicurie quantities.

   Contrary to the above, on July 21, 2020, the licensee did not conduct their program in accordance with statements, representations, and procedures contained in the Application dated November 11, 2016. Specifically, the licensee did not perform a bioassay for an authorized user who administered 103.2 millicuries of I-131.

   This is a Severity Level IV violation (Enforcement Policy 6.7.d).

B. 10 CFR 20.1502(a)(1) requires that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR 20.1201. At a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in one year form sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201.

   In addition, License Condition 20 of License No. 47-15473-01, Amendment 83, requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated November 11, 2016, (ADAMS Accession No.: ML16337A027). The application dated November 11, 2016, requires the licensee, to implement procedures for the safe use of unsealed byproduct materials. The licensee's responsive procedure, "Safe Use of Radioactive Materials," dated May 9, 2019, required, in part, that: "personnel monitoring devices are to be worn at all times while in areas where radioactive materials are used or stored."

   Contrary to the above, from at least March 30, 2018, through November 16, 2021, the licensee failed to monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR 20.1201. Specifically, for numerous physicians, the licensee failed to monitor exposures to radiation resulting from the performance of nuclear cardiac stress tests in violation of both the licensee's "Safe Use of Radioactive Materials" procedure and the abovementioned CFR requirement, and, in one instance, failed to monitor a physician's

exposure to radiation from both nuclear medicine operations and cardiac catherization laboratory operations. In numerous instances, the subject physicians' reconstructed radiation exposures were in excess of the 10 CFR 20.1201(a)(1) 10% threshold to require monitoring.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

C. 10 CFR 20.1201(f) requires the licensee to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, from at least March 30, 2018, through November 16, 2021, the licensee failed to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the licensee failed to account for occupational exposures received by at least nine physicians from at least four facilities external to the licensee.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

D. 10 CFR 20.1101(a) requires that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

The licensee's radiation protection program, represented in part by the procedure "Radiation Safety ALARA Program" dated May 20, 2019, required a number of actions by CAMC, including:

a. The delegation of enforcement of the ALARA concept to the Radiation Safety Officer (RSO);
b. The quarterly review by the RSC of occupational radiation exposure, with "particular attention to instances in which [ALARA investigation limits] are exceeded;"
c. The principal purpose of the [quarterly] review is the assessment of trends in occupational exposure and decide if action is warranted;
d. The investigation, by the RSO, of all instances of deviation from good ALARA practices and, if possible, determine the causes; and,
e. The investigation, by the RSO, in a timely manner the causes of all personnel doses exceeding Investigation Level II, and presentation to the RSC at the first available RSC meeting, including documentation in the minutes of the details of these reports.

Contrary to the above, from at least March 30, 2018, through November 16, 2021, the licensee failed to adequately implement the radiation safety program in accordance with 10 CFR 20.1101(a) and the "Radiation Safety ALARA Program" procedure dated May 20, 2019. Specifically: (a) the enforcement of the ALARA concept was, in practice, delegated further from the RSO who was not involved; (b) the RSC did not perform an adequate review of occupational exposure, with appropriate attention to, instances when ALARA investigation limits were exceeded, with a total 56 instances of licensee staff exceeding Level II investigation levels noted in calendar year 2020; (c) the licensee failed to identify trends in ALARA practices, including widespread instances of badge policy noncompliance; (d) the licensee failed to have the RSO perform investigations into instances of deviation from good ALARA practices and determination of causes, both

due to the inadequacy of investigations and delegation of these actions from the RSO to unit managers and, at times, senior staff; and (e) the failure to perform adequate investigations into instances of individuals exceeding ALARA Investigation Level II occurred, including the failure to present these instances and associated investigations to the RSC, which in-practice was presented a unit-level summary with no further action.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d).

Pursuant to the provisions of 10 CFR 2.201, Charleston Area Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406-1415, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violations, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that have been or will be taken; and (4) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be made available electronically for public inspection in the NRC Public Document Room and on the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, it should, therefore, not include any personal privacy or proprietary information so that it can be made publicly available without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 2nd day of June 2022

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket: 030-09164

License: 47-15473-01

Report: 2021-001

Licensee: Charleston Area Medical Center

Locations Inspected: 3200 MacCorkle Avenue, S.E., Charleston, WV
501 Morris Street, Charleston, WV

Inspection Dates: November 1, 2, 4, and 16, 2021, with in-office review through March 24, 2022

Inspectors: Robin L. Elliott
Digitally signed by Robin L. Elliott
Date: 2022.06.02 15:27:10 -04'00'

Robin Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Jason E. VonEhr
Digitally signed by Jason E. VonEhr
Date: 2022.06.02 15:58:13 -04'00'

Jason vonEhr, Health Physicist
Commercial, Industrial, Research and Development, and Academic Branch
Division of Radiological Safety and Security

Netra S. Patel
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Date: 2022.06.02 16:08:33 -04'00'

Netra Patel, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By: Anne E. DeFrancisco
Digitally signed by Anne E. DeFrancisco
Date: 2022.06.02 16:36:57 -04'00'

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Attachments: 1 - Security-Related Supplement (Nonpublic)
2.Supplemental Inspection Information (Nonpublic)

Enclosure 3

EXECUTIVE SUMMARY

Charleston Area Medical Center
NRC Inspection Report 030-09164/2021-001

Program Overview

Charleston Area Medical Center (CAMC) is authorized by the U.S. Nuclear Regulatory Commission (NRC) Materials License 47-15473-01 to use a variety of sealed sources and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* 35.100-400, 35.600, as well as a self-shielded irradiator for non-medical use. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Charleston, West Virginia. (Section 1)

Inspection Findings

Four Severity Level IV violations of NRC requirements were identified. These violations included the failures to: (A) follow a written procedure for radioactive Iodine-131 handling; (B) monitor occupational exposure while performing licensed activities; (C) aggregate occupational exposures received by licensee staff outside of CAMC, (D) report an exposure in excess of the regulatory requirements; and (E) implement portions of the radiation safety program as it related to occupational exposure monitoring. (Section 2 and 3)

In addition, three Severity Level IV violations of NRC security requirements were identified. The circumstances surrounding these violations are described in the non-public Attachment 1 of this Inspection Report.

Corrective Actions

Several corrective actions were provided by the licensee following the onsite inspections and the preliminary exits. These actions were communicated to the NRC in teleconferences and letters and are described in Section 4 of Enclosure 3 as they address the non-security-related violations. In brief, the licensee: conducted re-training with the authorized user who failed to submit to a bioassay following the administration of liquid I-131; implemented a multi-facility monitoring program (including non-CAMC facilities); issued additional dosimeters to applicable staff or physicians; performed additional education and training to staff and physicians concerning radiation safety; and implemented a mechanism to improve badge compliance during procedures. (Section 4)

REPORT DETAILS (PUBLIC)

1. Program Overview (Inspection Procedure 87130, 87131, and 87132)

CAMC is authorized by the NRC Materials License 47-15473-01 to use a variety of sealed sources and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100-400, 35.600, as well as a self-shielded irradiator for non-medical use. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Charleston, West Virginia.

Information pertaining to the NRC review of CAMC's security program (Inspection Procedure 87137) is documented in the non-public Attachment 1 of this inspection report.

2. Initial Observations and Findings

2.1. Inspection Scope

The inspection was an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the CAMC license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

2.2. Observations and Findings

This inspection included observations at the 3200 MacCorkle Avenue, S.E. (General Hospital) and 501 Morris Street (Memorial Hospital), Charleston, WV locations. Since the last inspection in February 2020 a new Cardiac Imaging location began operations in Memorial Hospital, the authorization for 10 CFR 35.400 was removed due to inactivity, and Kim Lowe, Pharm. D. was added as an Associate Radiation Safety Officer. A Best Theratronics Ltd. Gammacell 300 Elan Type I self-shielded irradiator was used by the licensee for the sterilization of blood products.

The inspector toured all areas where licensed material was used in General Hospital and Memorial Hospital observing the following activities: package receipt, dose calibrator morning quality control, dose preparation, injection, patient interaction, scanning, surveying, waste management, and cardiac stress testing. Additionally, independent surveys were performed and found to be consistent with licensee postings and within regulatory limits.

2.2.1. Licensee Oversight

The radiation safety program operated under the direction of a Radiation Safety Committee (RSC) which met quarterly and included the representation required by 10 CFR 35.24. The Radiation Safety Officer (RSO) was an Authorized User (AU) who

received the support of an Associate RSO who performed the annual program reviews, and a physics consultant who performed quarterly audits. The audits included, but were not limited to: equipment calibration, review of written directives, training, records review, ALARA exposure evaluations, and sealed source leak test and inventory.

2.2.2. Nuclear Medicine

The Nuclear Medicine program utilized approximately 20 Nuclear Medicine Technologists across the seven locations. Written procedures and policies were in place for all activities conducted in nuclear medicine. Radiopharmaceuticals were obtained in unit dose form primarily from the CAMC radiopharmacy operating under a separate NRC license. CAMC obtained I-131 from Pharmalogic, based in Huntington, WV, and Positron Emission Tomography (PET) radiopharmaceuticals from Precision Nuclear based in Gray, TN. Dose calibrators were used at each location to assay doses prior to administration. All nuclear medicine therapies were performed at the General Hospital and included: I-131, Lu-177, Ra-223, and Sm-153. In 2021, the following therapies were performed: 19 greater than 30 millicuries I-131 and 51 less than 30 millicuries I-131, 6 Ra-223 treatments, 6 Lu-177 administrations, and a single Sm-153 treatment.

The nuclear medicine program provided written instructions to all patients; however, no release calculations were performed for Lu-177, Sm-153, or Ra-223 administrations as required by 10 CFR 35.75. The licensee performed the calculations subsequent to the on-site inspection and found that all were within the public dose limits. In accordance with the NRC Enforcement Policy, Section 2.3.1, this was determined to be a minor violation, and is not cited or described in Enclosure 1.

Since the last inspection, there were three in-patient administrations of I-131. Surveys were performed and all nursing staff that cared for the patients were trained and monitored. An administration of 103.2 millicuries of liquid I-131 occurred on July 21, 2020. A bioassay was obtained for the nuclear medicine technologist that assisted, but the AU who administered the dose did not have a bioassay in accordance with the licensee's written procedure. This was cited as a Severity Level IV violation and is described in Enclosure 1.

2.2.3. Sealed Sources

CAMC possessed a total of 96 sealed sources when summed over all the areas of use designated on the license. They were all inventoried during the consulting physicist's quarterly audit and leak tested as appropriate. The reports of the leak testing did not include information regarding the equipment used to analyze the samples, the limit of detection of the equipment, or the associated equipment calibration to assure compliance with 10 CFR 35.67(c). Subsequent to the on-site inspection, the licensee verified with the consultant that the equipment used was appropriately calibrated and capable of measuring 0.005 microcuries. As a result, this was considered a minor records violation and was not formally cited. The licensee agreed to modify their reports to include the equipment used and its calibration information.

The inspector toured the Cs-137 self-shielded irradiator and verified that an adequate health and safety program was in place to protect workers using the device. Operational tests, radiation surveys, maintenance logs, leak tests, and physical security issues were all in order. Blood bank staff were knowledgeable of the aspects of the radiation safety program and in proper operation of the unit. No health and safety concerns were noted.

2.2.4. Identification of Dosimetry Issue

While observing cardiac stress testing the inspector discovered that the AU was not wearing dosimetry. Upon investigation of this issue, the inspector learned that the AU only wore dosimetry during x-ray procedures and not during the cardiac stress tests performed with NRC licensed materials. Additionally, this AU had appeared to exceed the occupational dose limit for calendar year 2020. The over-exposure had been reported to the State of West Virginia; however, since the exposure was primarily due to state-regulated machine-produced radiation, the licensee was unaware of the responsibility to report this to the NRC. A follow-up inspection was conducted to investigate the extent of condition of the problems related to the dosimetry program and is described in Section 3 below.

2.2.5. Independent Radiation Surveys

Independent radiation surveys were conducted in the irradiator room and in the blood bank entrance leading into the irradiator room; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits. The inspector's surveys were performed with a Ludlum Model 2401-P, serial number 281353, calibration date April 12, 2021.

2.3. Conclusions

The NRC inspection identified one violation of greater-than-minor significance related to the licensee's implementation of its radiation safety program, specifically dealing with the performance of a liquid I-131 therapeutic administration and the failure to perform a bioassay of the administering AU in accordance with the licensee's written procedure. This deficiency is described in the accompanying Enclosure 1.

3. Follow-up Observations and Findings

3.1. Inspection Scope

During the follow-up inspection performed on November 16, 2021, the NRC performed a focused examination of activities conducted under the NRC license as they related to occupational exposure and dosimetry practices at CAMC. Within these areas, the inspection consisted of a focused examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

3.2. Observations and Findings

The follow-up inspection initially focused on the physician identified during the initial inspection as having failed to wear occupational monitoring dosimetry during a cardiac stress test and having a recorded occupational exposure in excess of the requirements in 10 CFR 20.1201. The inspectors interviewed the individual, observed the performance of additional cardiac stress tests, and reviewed dosimetry records associated with this individual. As later described in Section 3.2.3, this scope was expanded to include other physicians with similar responsibilities and activities involving both NRC-licensed radioactive materials and state-licensed machine-produced X-rays.

3.2.1. Original Physician

The inspectors identified that the licensee's occupational monitoring program (and the associated dosimetry vendor) had not performed an adjustment to account for the wearing of the physician's lead during operations in the catherization laboratory (cath lab). For the wearing of a single dosimeter at the collar outside the lead shielding, the dosimetry may be adjusted downward by 70 percent, in accordance with the dosimetry vendor's accepted EDE2 ("Effective Dose Equivalent") equation. As a result, the initially identified overexposure of 5,223 millirem for calendar year 2020 was reduced to 1,567 millirem (excluding the component of the occupational exposure incurred during nuclear medicine operations, which were unmonitored prior to the NRC's inspection).

3.2.2. Reportability of Physician Overexposure

The licensee received, from the dosimetry vendor, a report on February 3, 2021, which included the overexposure of this first physician. The licensee did not perform any calculation, evaluation, or assessment to revise this exposure following receipt. Since this individual participated in NRC-licensed activities, specifically in nuclear cardiac stress tests, the licensee was therefore obligated to report the overexposure to the NRC within 30 days of learning of the overexposure. The licensee prepared and submitted a report to the State of West Virginia, dated March 17, 2021, describing this overexposure, but failed to provide the same to the NRC. As a result, the NRC first learned of this overexposure through the performance of the routine inspection activities on November 1, 2, and 4, 2021.

Following the initial NRC observation that the physician was involved with and exposed to NRC-licensed activities, the licensee prepared and submitted a written report in accordance with 10 CFR 20.2203(a)(2)(i), dated November 8, 2021 (non-publicly available). With the NRC's observations noted above in Section 3.2.1 related to the failure to account for the use of additional shielding, the licensee performed a dose reconstruction which concluded the physician's true occupational exposure from all occupational sources of radiation was approximately 1,857 mrem, and therefore retracted the overexposure report in writing on February 3, 2022.

3.2.3. Expansion of Initial Scope

In interviewing the physician described above, the inspectors identified other physicians at CAMC that performed similar types of split work: work that involved occupational exposure in both the cath lab and in nuclear medicine. The inspectors interviewed two further physicians on-site and understood that they had a similar deficiency in their occupational monitoring: the physicians wore their dosimetry during cath lab operations, but not during nuclear medicine operations. As a result, the inspectors requested from CAMC, and received, a list of 24 physicians that performed hybrid cath lab and nuclear medicine work. These physicians represented a mixture of individuals named on the CAMC NRC license as AUs (11) and non-AUs (13). The NRC inspectors performed remote interviews with six of these physicians (in addition to the 3 previously interviewed physicians) between November 19 and 24, 2022.

Out of the nine interviewed physicians: six described wearing dosimetry only in the cath lab, while also participating in nuclear medicine operations (one stated this dosimetry was not issued by CAMC), two described wearing dosimetry in both the cath lab and nuclear medicine, and one physician stated that they only wore dosimetry during nuclear medicine (but not in the cath lab), and that this dosimetry was not issued by CAMC. In addition, four physicians described performing activities at non-CAMC facilities that involved occupational exposure to radiation, including other NRC-licensed facilities. Five further physicians, beyond the nine interviewed by the inspectors, were also named in interviews as performing work involving occupational exposure to radiation outside of CAMC. The licensee staff and administrators implementing the monitoring program were unaware of these external facility exposures and failed to aggregate the exposures incurred at these facilities with the exposures recorded at CAMC.

The inspectors reviewed the dosimetry records associated with the interviewed physicians. The two physicians noted above did not have dosimetry issued by the cath lab unit or any other organizational unit at CAMC. In addition, the inspectors observed that the dosimetry vendor did not apply the lead correction factor (the “EDE2” equation) to all the physicians. It was not ultimately determined why all of the staff in the cath lab (where the wearing of a lead apron was a routine requirement) did not have this lead correction factor. In contrast to the cath lab, lead aprons were not normally worn in the nuclear medicine department.

3.2.4. Licensee Monitoring Program Oversight

Finally, the inspectors reviewed the licensee’s program, with an emphasis on the dosimetry program implementation and its associated oversight. The licensee provided records associated with the ALARA program, RSC meeting minutes, and ALARA investigations performed by licensee personnel. The licensee established administrative exposure limits, called ALARA Investigation Levels, to assist in the implementation of a radiation safety program. When CAMC personnel exceeded the higher of the two ALARA Investigation Levels, the associated procedure required a timely investigation by the RSO and presentation of the investigation at the next RSC meeting.

In practice, the licensee RSO was not performing these investigations or otherwise actively involved in the implementation of the ALARA program. Instead, unit managers and other senior staff were documenting the investigations. The investigations themselves were limited to a short questionnaire pre-prepared and filled out by the subject individual being investigated, without follow up or extension of the scope of the investigation beyond the questionnaire to identify a common or root cause when appropriate. The inspectors identified 56 instances of CAMC staff exceeding ALARA Investigation Level II in calendar year 2020, and 37 instances in calendar year 2021 through the end of Quarter 3. The RSC review of these instances was limited to a report of the organizational origin (e.g. “cardiac catherization lab”) and the number of instances within that unit. In no instance reviewed by the NRC did the RSC discuss these investigations, identify or discuss potential trends, document the investigations themselves, or otherwise cause actions to be taken in response to these instances.

The inadequate oversight of and by the radiation safety program directly contributed to the inability of the program to react in a timely manner and with comprehensive actions to the escalating exposure received by the original physician, and to the deficient monitoring of the other physicians.

The licensee implemented certain actions with respect to the original physician (who incurred the apparent overexposure) in an attempt to reduce the physician’s occupational exposure. The licensee purchased and installed additional shielding in the cath lab, including mobile shields, full-body shields, light and moldable shields that can be placed on the patient, and leaded glasses for the physician. The physician took two weeks of leave from the hospital in December 2020 to further reduce occupational exposure. However, the dosimetry vendor would typically take between two weeks and a month to return an exposure report, leading to a one-to-two-month delay between the radiation exposure occurring and the report documenting said exposure being published. While the licensee’s actions appear to have had some effect on the resulting exposures – reducing the average monthly exposure from 685 millirem in the period from January through October 2020 to 213 millirem in November and December 2020), it was insufficient to prevent the non-lead corrected exposure from apparently exceeding 5,000 millirem whole-body, the NRC regulatory annual limit.

In addition, dosimeters were worn for multi-month interval (with interim badges being unused), creating an additional delay between the physician’s exposure and the associated results in a report. The issue of badge compliance, both the timely return of dosimetry and the wearing of dosimetry, was a general issue across multiple sub-units at CAMC and was consistently seen across the interviewed physicians. Across the seven physicians that the inspectors interviewed that had CAMC-issued dosimetry, 24 out of 84 badges in calendar year 2020 were either: (1) returned in an untimely manner; (2) not returned; or, (3) returned and reported as “unused.” During 2021, these same physicians had 30 badges out of 56 returned and reported as “unused” (the licensee’s internal administrative goal was a timely return of 95% of issued dosimeters).

3.2.5. Violations Associated with the Follow-up Inspection

The above account of the review during the November 16, 2021, follow-up inspection and the remote review that followed resulted in the identification of four violations of NRC requirements. The exposures that went unmonitored were primarily nuclear medicine exposures received while in the vicinity of NRC-licensed materials, which the licensee conservatively estimated would result in a radiation exposure no-greater-than 290 millirem per year per applicable physician. As a result, the violation associated with these failures is appropriately characterized as a Severity Level (SL) IV violation.

The exception to the above description was for the single physician identified with occupational exposure that was not monitored during cath lab operations (while also exposed during NRC-licensed activities in the nuclear medicine department and monitored by non-CAMC dosimetry) and therefore had a significantly higher potential for exposure. In this instance, the licensee performed a dose reconstruction which concluded a total occupational exposure by this physician to be approximately 811 millirem for calendar year 2021. This value was determined after several revisions based on errors identified by the NRC in the initial reconstruction; this violation was appropriately assessed at SL IV. The NRC determined that the facts and circumstances did not meet the threshold described in the NRC Enforcement Policy example 6.7.c.6 for a SL III violation, which describes a “substantial potential for exposures… in excess of the applicable limits in [10 CFR Part 20].”

The licensee failed to aggregate the occupational exposures received by physicians from outside of CAMC with those recorded within. This failure was also appropriately assessed at a SL IV, on account of the very limited occupational exposures expected or realized outside of CAMC due to the type and frequency of activity.

The licensee’s failure to notify the NRC was based on the incorrect conclusion that the original physician experienced an overexposure, which was later determined to not be the case. The licensee would have been required to notify the NRC based on the information in-hand, however in light of the corrected information regarding the lack of an overexposure, the NRC has determined that this was not a violation and is not cited or described in Enclosure 1.

Finally, the licensee failed to implement their written program related to the oversight, investigation, communication, and correction of issues related to the radiation monitoring program. These issues compounded the licensee’s challenges to the radiation monitoring program, inhibited the timely intervention of the apparent overexposure, and resulted in the failure to ultimately identify and correct the other violations of NRC requirements described herein.

The violations associated with the follow-up inspection are cited and described in detail in the accompanying Enclosure 1, and include, in summary:

1. Failure to monitor occupational exposure. This includes the failure to monitor physicians performing activities in the nuclear medicine department (which also was contrary to the licensee’s “Safe Use of Radioactive Materials” procedure), as

well as physicians who had no dosimetry issued by CAMC but were occupationally exposed both in the cath lab and nuclear medicine department.

2. Failure to account for concurrent occupational exposure of physicians at facilities outside of CAMC.

3. Failure to implement certain elements of the licensee's radiation safety program, in particular elements derived from the licensee's "Radiation Safety ALARA Program."

3.3. Conclusions

The licensee experienced a series of compounding challenges in implementing a large occupational monitoring program spanning well over a thousand staff and physicians. The NRC inspection, in an expanding review from a concern regarding a single physician, identified several deficiencies related to the performance and oversight of the radiation safety program as it pertained to occupational exposure monitoring. These deficiencies were summarized into three violations of NRC regulatory requirements and CAMC license conditions and are described in the accompanying Enclosure 1 (in addition to the one violation described in Section 2 of this report).

1. Corrective Actions

In response to the NRC's inspection, both the initial and follow-up inspection, the licensee took comprehensive corrective actions. In some instances, the licensee implemented certain measures as intermediate corrective actions until more effective long-term solutions were able to be implemented.

The licensee summarized its long-term actions in a letter to the NRC dated January 14, 2022 (non-publicly available document). These actions included: (1) implementation of a multi-facility monitoring program (including non-CAMC facilities) through the dosimetry vendor; (2) issuance of additional dosimeters to applicable staff or physicians (to help differentiate nuclear medicine exposure in which lead aprons are not worn, and cath lab exposure, where lead-aprons reduce exposure); (3) additional education and training to staff and physicians concerning radiation safety; and (4) implementation of a mechanism to improve badge compliance during procedures.

After initially reporting the initial physician's overexposure on November 8, 2021, the licensee committed in the above letter to completion of the then in-process final dose reconstruction and, as appropriate, retraction of the overexposure report. These reconstructions were revised several times, with the final version completed and submitted to the inspectors for review on February 28, 2022.

2. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on November 4 and 16, 2021. The licensee acknowledged the findings presented and committed to corrective actions. The NRC conducted a final exit briefing

via teleconference with Tuanya Layton, Medical Imaging Quality Manager, Dr. Kim Lowe, Associate Radiation Safety Officer, and Patricia Williamson, Transfusion Services Operations Manager, on May 3, 2022. The licensee again acknowledged the findings presented and did not dispute any of the facts presented.