UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

July 13, 2020

EA-20-050

Ms. Kelly Hefti
Executive Director, Heart & Vascular
Sanford Medical Center
dba Sanford USD Medical Center
P.O. Box 5039
Sioux Falls, SD 57117-5039

SUBJECT: NRC INSPECTION REPORT 030-03249/2020-001 AND EXERCISE OF ENFORCEMENT DISCRETION

Dear Ms. Hefti:

This letter refers to the unannounced routine inspection conducted on February 3-4, 2020, at your facility in Sioux Falls, South Dakota, with in-office review through June 9, 2020. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and 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 enclosed report presents the results of the inspection.

The preliminary inspection findings were discussed with you at the conclusion of the onsite portion of the inspection on February 4, 2020. Preliminary information was provided on February 11, 2020, and the NRC requested further dosimetry data and analysis. You provided further analysis on May 1, 2020 and specific requested follow-up data on May 8, 2020 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession ML20133K099). A final exit meeting was conducted telephonically on July 1, 2020.

Based on the results of this inspection, four apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failures to: (1) monitor occupational exposure of one worker from unlicensed sources of radiation; (2) implement elements of your radiation protection program in accordance with procedures regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures; (3) provide instruction to the worker on the requirement to monitor exposures from unlicensed sources of radiation; and (4) make a written report to the NRC in 2014 when that worker's annual occupational dose of record exceeded 5 rem, even though their annual total effective dose equivalent did not exceed 5 rem.

The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with your staff at the inspection exit meeting on July 1, 2020. The NRC determined, through independent assessment of your calculations, that the worker who was not properly monitored for occupational exposure from unlicensed sources of radiation did not receive occupational exposures in excess of the regulatory limits. However, because the worker did not properly wear dosimetry, there was a substantial potential for the worker to exceed the NRC's occupational exposure limits.

Before the NRC makes its enforcement decision, we are providing you an opportunity to:(1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request a predecisional enforcement conference (PEC), or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Ms. Patricia Silva at 817-200-1455 within 10 days of the date of this letter to inform us of your decision to participate in a PEC or ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-03249/2020-001; EA-20-050," and should include for the apparent violations: (1) the reason for the apparent violations or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response.

Your written response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and emailed to R4Enforcement@nrc.gov, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that an enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up

misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Although a violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.60 and a violation of 10 CFR 35.63 were identified and the issues were discussed with you during the telephonic exit meeting, your program met all the criteria in Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013, for the use of enforcement discretion. Therefore, the NRC is exercising enforcement discretion and, will not issue any enforcement action for these violations.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," 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 Public Document Room and from the NRC's ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Ms. Patricia Silva of my staff at 817-200-1455.

Sincerely,

Mary C. Muessle

Digitally signed by Mary C. Muessle
Date: 2020.07.13 16:51:52 -05'00'

Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket No.: 030-03249
License No.: 40-12378-01

Enclosure:
NRC Inspection Report 030-03249/2020-001

cc w/encl.:
John Priest, Sr. Health Facilities
Surveyor-radiation
South Dakota Dept. of Health

NRC INSPECTION REPORT 030-03249/2020-001 AND EXERCISE OF ENFORCEMENT DISCRETION DATED July 13, 2020

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☒ SUNSI Review: By: JCD | ADAMS: ☒ Yes ☐ No | ☐ Non-Publicly Available ☒ Publicly Available | ☒ Non-Sensitive ☐ Sensitive | Keyword: NRC-002

OFFICE	DNMS:MLIB	DNMS:C:MIB	RIV:ACES	RC	D:DNMS	
NAME	JDykert	PASIlva	JRGroom	DMCylkowski	MCMuessle	
SIGNATURE	/RA/	/RA/	/RA/ JGK for JRG	/RA/	Mary C. Muessle Digitally signed by Mary C. Muessle Date: 2020.07.13 16:55:34 -05'00'	
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report 030-03249/2020-001

Docket:	030-03249
License:	40-12378-01
Report:	2020-001
Licensee:	Sanford Medical Center *dba* Sanford USD Medical Center
Location Inspected:	1305 West 18th Street Sioux Falls, South Dakota
Inspection Dates:	February 3 and 4, 2020 with in office review through June 9, 2020
Exit Meeting Date:	July 1, 2020
Inspector:	Jason Dykert, Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety
Approved by:	Patricia A. Silva, Chief Materials Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

NRC Inspection Report 030-03249/2020-001
Sanford Medical Center dba Sanford USD Medical Center

Program Overview (Section 1)

Sanford Medical Center is located in Sioux Falls, South Dakota, and was authorized for diagnostic and therapeutic nuclear medicine, manual brachytherapy, yttrium-90 (Y-90) microsphere and high dose-rate afterloader (HDR) brachytherapy by NRC license 40-12378-01, as described in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 and 35.1000, for medical use.

Inspection Findings (Section 2)

A routine inspection performed on site February 3-4, 2020, and a review of dosimetry analyses through June 9, 2020, identified four apparent violations; the first three involved an Interventional Radiologist (IR) not consistently wearing dosimetry. The fourth involved a reporting requirement.

The first apparent violation involved a failure to monitor exposure to machine-produced ionizing radiation. The IR was an Authorized User (AU) of Y-90 on the NRC license, but was not properly wearing assigned dosimeters when performing non-NRC licensed fluoroscopy or computed tomography (CT) procedures. The second apparent violation involved a failure to implement a radiation protection program commensurate with the scope and extent of licensed activities, specifically to have procedures for identifying when minimal or very low exposures existed on IR dosimetry records. The third apparent violation involved failing to provide training regarding the NRC requirement to monitor exposures from unlicensed sources.

The fourth apparent violation involved a failure to submit a written report to the NRC in 2014, when the AU's as-measured deep dose equivalent (DDE) from a single dosimeter worn on the outside of a lead apron exceeded the NRC's annual limit of 5 rem for an occupational whole body dose. Prior to the as-measured DDE exceeding 5 rem, the licensee used an approved effective dose equivalent (EDE) calculation to account for the lead apron and demonstrated that the AU's Total Effective Dose Equivalent (TEDE) did not actually exceed the annual limit. However, the AU's dose of record had not been updated since 2014 and his lifetime dose record included the as-measured DDE in excess of the limits from the single dosimeter.

Corrective Actions (Section 3)

During the onsite inspection the licensee immediately provided training to the entire staff in IR and nuclear medicine, to correct the known issue and to ensure dosimetry was properly worn. Additional supervision and a "time-out" dosimetry badge check was instituted for all IR doctors who were performing work with non-NRC licensed sources, such as fluoroscopy or CT.

Following the onsite inspection, the licensee implemented several corrective actions to address the personnel dosimetry deficiencies. These corrective actions included adding a requirement for analysis of unused and minimal dosimeter readings for physicians with fluoroscopy privileges in each department, with a referral to the radiation safety officer and radiation safety committee to investigate if repeat issues are identified.

REPORT DETAILS

1. Program Overview (Inspection Procedure 87131, 87132)

1.1. Program Scope

Sanford Medical Center (Sanford) is a large medical hospital in Sioux Falls, South Dakota, that performed routine diagnostic and therapeutic nuclear medicine, and also utilized a Bracco CardioGen® rubidium-82 dose generator and fluorodeoxyglucose (FDG) for positron emission tomography (PET) imaging. A high dose-rate afterloader (HDR) and yttrium-90 microspheres were used routinely for various cancer treatments, but manual brachytherapy implants were not utilized for many years. Written Directives (WD) were required and used for all activities performed under 10 CFR 35.300, 35.400, 35.600, and 35.1000.

The main hospital campus primarily utilized radioisotopes under the radiology department (nuclear medicine) and at the cancer center (HDR and PET imaging), and in the interventional radiology department for Y-90 microspheres, with locations in License Conditions (LC) 10.A, B, C, and E. The other location of use, LC 10.D, in Aberdeen, South Dakota, performed diagnostic and therapeutic nuclear medicine.

The radiation safety officer (RSO) was an Authorized User on the license for nuclear medicine studies, was board certified in both nuclear medicine and radiology, also worked in the cancer center, and had chaired the radiation safety committee (RSC) for 10 years at Sanford. The assistant RSO provided direct oversight and management for the nuclear medicine departments. Both RSOs reported to the Executive Director for Heart & Vascular and the management representative to the RSC.

1.2. Observations

The previous two inspections, in June 2015 and September 2017, did not identify any violations. At the main hospital campus, there were two hot labs, one in the nuclear medicine department and one in the cancer center HDR/PET imaging and treatment area. The licensee's hot labs were secured using keycard access doors. Unit doses and bulk FDG were delivered to the nuclear medicine hot lab by Cardinal Health Sioux Falls.

The inspector observed radioactive materials packages being received, then followed the unit dose handling all the way to patient administration and noted that procedures were followed. Dose activity was verified by a certified nuclear medicine technologist in the hot lab prior to administration. Dose calibrators, survey instruments, and well counters were maintained and calibrated by an in-house health physicist. The hot lab has a fume hood to maintain negative pressure in the room for storing xenon-133 and iodine-131 as needed. Several imaging rooms maintained negative pressure which is tested quarterly. Room clearance times are posted if a spill were to occur. Weekly wipe tests occurred on Thursdays, and daily surveys occurred in every room where radioisotopes were handled or could have been used.

A majority of the regulatory records were kept in the nuclear medicine department; many of the records were kept in paper copy as well as electronically. The RSC meeting minutes (quarterly), calibration or quality assurance records for survey instrumentation and dose calibrators, staff bioassays, sealed source inventories, leak test records, Written Directives (WD), etc., were reviewed and no issues were identified. Other records, such as receipt and disposal of unit doses or weekly wipes and daily surveys, were kept in the licensee's software system.

The iodine-131 WDs include a calculation and basis for patient release, and the WDs for Y-90 have a pre- and post-treatment activity entered onto the form. Lutathera® WDs contained the requisite information for therapies per treatment fraction.

Lutathera® was administered using a Medfusion® 3500 syringe pump along with an Alaris® infusion pump for the amino acid uptake and the anti-nausea or other medications if needed. Nursing staff followed written procedure guidance to ensure the amino acid uptake was adequate before administration. The licensee sent the vials, shielded containers, and other packaging back to the manufacturer.

The HDR source is changed out quarterly and shipped back to the manufacturer. Waste brokers are used for TheraSpheres® disposal in case of long-lived contaminants, but SIR-spheres® are primarily utilized for treatments. Nuclear medicine materials primarily were held for decay-in-storage and separated into short lived and long lived isotopes, both with half-lives less than 120 days.

All decay-in-storage materials were surveyed at the most sensitive setting with calibrated instruments before documenting that radioactivity was not detectable and then passed through a sensitive radiation portal monitor before leaving the hospital. Environmental services staff were given basic radiation safety training and were able to contact the radiation safety manager if the portal monitor alarmed.

Rubidium-82 (Rb-82) was utilized for PET imaging via a Bracco-CardioGen® dispensing cart. The dispensing cart system measured the prescribed dose and was checked by a trained technologist prior to administration. All users of the Rb-82 cart, the assistant RSO, and RSO were trained by the manufacturer to use the cart. Sanford used Bracco-CardioGen® procedures to ensure infusion pump flow rate was consistent, accurate activity was measured, and that the radiation detector in the unit was working properly. Bracco-CardioGen® performed annual maintenance on the cart and provided annual training at that time. The calibration records and the daily use records, including the column wash, strontium-82 and strontium-85 breakthrough tests, the dose calibration factors, and the training records were reviewed without issues. These records were kept in the PET imaging console area.

The HDR unit was secured with two independent barriers and was only accessible by individuals with adequate safety training for the unit. The inspector observed daily testing performed by the medical physicist, including opening the HDR door while the source was out, and testing of unit power failure for source retraction. Primalert® testing, intercom and video testing, console power loss test, a catheter misconnect test, position verification tests, emergency response equipment availability, survey meter calibration, verification of date and time on the console, timer accuracy, proper source retraction and source output verification were observed satisfactorily.

Emergency drills were performed annually, emergency procedures were posted, and the keys were secured out of the area of the console. The authorized medical physicist, an authorized user, and nursing staff were present for all treatments as described in the written directives. Full calibrations and current leak tests were completed quarterly with each source exchange.

The inspector performed independent surveys with a Ludlum® 12 analog survey meter, serial number 22750, connected to a Ludlum® 44-9 GM pancake detector, serial No. PR7882, in each of the hot labs, dose administration areas, dose delivery carts, waste storage, and radioactive

materials use areas. All surveys indicated that minimal dose rates were present, the areas would not exceed regulatory limits, and that licensee postings were adequate.

The inspector identified inspection findings during a dosimetry record review. The AU for TheraSpheres® and SIR-spheres® microsphere brachytherapy Y-90 treatments did not have any recorded exposures on their 2019 IR personnel exposure monitoring badges (dosimetry), and some dosimetry readings were incomplete at various times throughout years 2013 - 2018.

2. Inspection Findings

2.1. Observations

The AU had two sets of dosimetry badges separated by department, Y-90 procedures had dosimetry badges provided by nuclear medicine, and fluoroscopy and CT procedures had dosimetry badges provided by the IR department. Yttrium-90 is licensed by the NRC; fluoroscopes are x-ray generating machines and are not licensed by the NRC, but they are used in Y-90 and interventional radiology treatments.

The inspector noted that the AU's Y-90 nuclear medicine badges had exposures as expected, but the IR badge set for 2019 did not have any recorded exposures, even though many fluoroscopy (fluoro) procedures had been performed. The AU confirmed, that for procedures that did not involve Y-90 but did involve only fluoro or CT, that his dosimetry was not always worn correctly. The AU indicated a lack of awareness about the specific NRC requirement to monitor exposures from non-NRC licensed machines. The AU indicated that he always wore dosimetry for Y-90 procedures, which was independently confirmed by the inspector through interviews and a comparison of Y-90 treatment dates and correlating dosimetry reports.

After realizing the dosimetry data for the AU's IR badge set was not accurate, the inspector requested an analysis of the radiation dose to the AU from both fluoro and Y-90 treatments since 2013, when the AU started working for the licensee. A preliminary overview of 2018 and 2019 dosimetry data was provided on February 11, 2020, and a complete analysis was provided on May 1, 2020, with requested follow-up information on May 8, 2020.

The inspector reviewed the licensee's complete analysis, including the approach, assumptions, calculations, and data, and determined that the licensee's methodology resulted in reasonable yet still conservative results. The licensee's estimated occupational deep dose equivalent (DDE) describing the external whole body exposure to the AU for each year was acceptable and ranged from 1.05 rem per year to 2.07 rem per year.

Calendar Year	Measured annual DDE from IR badge set (mrem)	Measured annual DDE from Y-90 badge set (mrem)	Estimated annual occupational TEDE with lead apron/ EDE corrections applied (mrem)
2013	5612	22	1899
2014	2156	40	2068
2015	638	7	1466
2016	150	29	1920
2017	100	47	1050
2018	152	35	1166
2019	0	25	1518

Table 1: Summary of annual occupational dose to the Authorized User

The complete dose analysis provided by the licensee for the AU, dated May 1 and 8, 2020, provided a written explanation and 5 tables with data for each year, 2013 - 2019.

The tables included (1) a comparison of the number of procedures performed by the AU and the other two IR doctors; (2) an estimated maximum dose for each procedure, including data for the dosimeter worn outside the lead apron, a dose amount for each IR procedure for each physician, a calculated maximum dose for every Y-90 procedure performed by the AU, and a nationally recognized publication's maximum expected dose range for each IR procedure performed; (3) the dose determined for each procedure actually performed, with EDE calculations for each IR physician; (4) the AU's IR dosimetry results, with EDE values and/or IR partner doses calculated into the whole body dose received; and (5) a roll up table noting the IR procedure counts, Y-90 procedure counts, conservative EDE calculated dose for each procedure, and the total estimated occupational DDE to the AU for each year.

The estimated occupational DDE indicated that the AU had not exceeded any occupational dose limits. However, an issue was revealed during the inspector's review involving the AU's permanent dose records for 2013. The AU's as-measured DDE exceeded the NRC's annual limit of 5 rem for the whole body, and this dose of record had not been updated.

The inspector found that in early 2013, during the first few months of employment, the AU was assigned only a single dosimeter worn on the outside of a lead apron. Because lead aprons provide shielding to the whole body, an EDE calculation applied to the as-measured DDE is appropriate to give a realistic TEDE for the AU's whole body.

In September 2013, the AU's as-measured DDE was approximately 4.9 rem and the licensee immediately investigated the issue. An ALARA 1 (as low as reasonably achievable) investigation performed by the RSO and medical physicist determined that the AU's actual total whole body dose, through appropriate EDE calculations, was actually approximately 1.3 rem. The inspector reviewed documentation of the investigation and the related calculations without issue but noted that the licensee did not update the AU's permanent dose record in 2013 with the realistic TEDE calculated at that time. The AU's lifetime dose records in 2020 still included the 2013 DDE that was in excess of the limits.

The RSO had discussed the calculational EDE correction at an RSC meeting but failed to update the dose of record with the dosimetry provider. In January 2014, the dosimetry provider reported that the AU's annual occupational DDE was approximately 5.6 rem, but a written report regarding the dose record in excess of the annual limit was not provided to the NRC. Instead, the RSO and ARSO indicated that the documentation was available for review during an NRC inspection. Because the AU's lifetime dose on record was incorrect and was not updated, a written report regarding the DDE in excess of limits should have been submitted.

In regard to the AU not properly wearing dosimetry when using a fluoroscope, the RSO did not identify this issue because past reviews were only for the AU's separate Y-90 nuclear medicine dosimetry reports, on a monthly basis. The AU had reasonably corresponding dose to the Y-90 procedures performed, and the RSO did not expect any difference in the IR dosimetry set for fluoroscope use. Prior to this inspection the RSO was not responsible for reviewing fluoro (IR dosimetry set) results.

The IR department manager had been responsible for reviewing the IR dosimetry set reports on a quarterly basis. In 2019 when the AU had zero recorded exposures on the IR dosimetry set, the department manager had an opportunity to identify the issue, but no procedures existed to direct licensee personnel to look for minimal or unexpected low doses to licensee staff who are

likely to have exposures from fluoro or other radiation sources. The IR department manager, the AU, and most licensee staff did not receive training on the NRC requirement that exposures from unlicensed sources must be monitored.

The RSC's protocol used to include a review of all of the licensee staff's dosimetry reports for high dose levels and ALARA action levels on a quarterly basis. Because the AU's dosimetry did not exceed action levels, and the minimal exposures for the three quarters in 2019 were not identified as a problem, the RSC did not address the improper use of dosimetry for fluoro procedures.

Based on the inspection observations, four apparent violations were identified, involving requirements in: 10 CFR 20.1502(a)(1) failure to monitor exposures; 10 CFR 20.1101(a) failure to develop and implement elements of the radiation protection program, including developing procedures to address unexpected low doses; 10 CFR 19.12(a)(3) failure to provide instructions or training, including the requirement to monitor exposures from unlicensed sources; and 10 CFR 20.2203(a)(2)(i), failure to submit a written report.

In addition to these findings, 10 CFR 35.60 and 10 CFR 35.63 require a licensee to calibrate the dose measuring instrument (dose calibrator) and to determine the activity of each dose prior to administration. The dose calibrator requirement mandates following a nationally recognized or manufacturer procedure, but for calibrating this Rb-82 cart, which must be calibrated in the dynamic mode (i.e., while liquids are flowing by the detector), there are no nationally recognized or manufacturer procedures thus compliance with 10 CFR 35.60 is not possible.

The Rb-82 cart directly infuses the dose into the patient due to the short half-life of Rb-82 (76 seconds); therefore, the activity of the dose is not determined prior to administration, but rather at the same time as administration. Thus, compliance with 10 CFR 35.63 also is not possible.

A violation of 10 CFR 35.60 and a violation of 10 CFR 35.63 was identified during this inspection. In accordance with the NRC Enforcement Policy, these violations would normally be characterized at Severity Level IV. However, in accordance with NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations.

2.2. Apparent Violations

Apparent Violation 1: The licensee did not ensure that exposure to radiation from unlicensed sources was monitored. The AU did not always wear dosimetry correctly when working with fluoroscopes or CT scanning equipment. (AV 030-03249/2020-001-01)

Title 10 of CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor 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 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from 2013 to February 3, 2020, the licensee failed to monitor an individual's occupational exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. Specifically, for one Authorized User, the licensee failed to monitor the occupational exposure to radiation from unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by the Authorized User, who received, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Apparent Violation 2: The licensee's radiation protection program did not have a procedure in place to address situations where dosimeters had unexpectedly low exposures. (AV 030-03249/2020-001-02)

Title10 of CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

Contrary to the above, from January 1, 2013 to February 3, 2020, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee failed to provide instructions regarding actions to be taken when dosimeters were less than the licensee's ALARA Investigational Levels, such as those dosimeters that were returned unused or had unexpectedly low exposures.

Apparent Violation 3: The licensee did not provide training to department managers or the AU on the NRC requirement to monitor exposures from unlicensed sources. (AV 030-03249/2020-001-03)

Title 10 of CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the workers' control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, from April 28, 2013 to February 3, 2020, the licensee failed to require that an individual who in the course of employment was likely to receive in a year an occupational dose in excess of 100 mrem be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation. Specifically, the licensee failed to provide adequate instructions regarding the proper use of personnel dosimeters to an Authorized User who was likely to receive in a year an occupational dose in excess of 100 mrem.

Apparent Violation 4: The licensee failed to submit a written report when the AU's dose of record, DDE without EDE calculations, exceeded 5 rem. The licensee applied corrective EDE calculations to the AU's DDE, recorded by a single dosimeter worn on the outside of a lead apron, in October 2013, prior to the DDE exceeding the limit. However, the corrections weren't applied, and the DDE exceeded the limit on a January 2014 dosimetry record. A written report was not submitted to the NRC after the licensee learned that the dose of record was in excess of the limits. (AV 030-03249/2020-001-04)

Title 10 of CFR 20.2203(a)(2)(i) requires, in part, that each licensee shall submit a written report within 30 days after learning of doses in excess of the occupational dose limits for adults in 10 CFR 20.1201.

Contrary to the above, from January to February 2014, the licensee failed to submit a written report within 30 days after learning of a dose in excess of the occupational dose limits for adults in 10 CFR 20.1201. Specifically, an Authorized User's deep dose equivalent exceeded 5 rem and a written report was not submitted to the NRC.

3. Corrective Actions

As described in the Executive Summary to this report and the licensee's publicly available analysis (ADAMS Accession No. ML20133K099), the licensee immediately gave training to the entire staff in IR and nuclear medicine during the onsite inspection, to correct the known issue and to ensure dosimetry was properly worn. Immediately after the onsite inspection, additional supervision and a "time-out" dosimetry badge check was instituted for all IR doctors starting work with fluoroscopy or CT equipment.

The NRC requested a dose analysis be performed, and a full analysis of the AU's historical work with x-ray generating equipment and Y-90 microspheres demonstrated that no occupational limits were exceeded. The licensee has administratively revised the AU's calculated amount of exposure for each year. The RSO has reviewed exposure reports for similar issues without finding any other individuals whose reports indicated they weren't wearing dosimetry. The licensee has also instituted improved training for each AU and department head regarding dosimetry use. A radiation protection program requirement for analysis of unused and minimal dosimeter readings has been added for physicians with fluoroscopy privileges for each department, with a referral to the RSO and RSC to investigate.

4. Exit Meeting Summary

The preliminary inspection findings were discussed at the conclusion of the onsite portion of the inspection on February 4, 2020. On July 1, 2020, a final telephonic exit meeting was conducted with Bridget O'Brien-Johnson, Director of Nuclear Medicine; Dr. Christopher Fischer, RSO; and Jennifer Stapleton, Assistant RSO.

The NRC inspector described the apparent violations, and the licensee acknowledged the inspection findings and did not dispute any of the details discussed. Timelines for a response to the inspection report were discussed and the licensee acknowledged a response was required and understood the timelines required for the response options.

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Kelly Hefti, Executive Director for Heart & Vascular
Bridget O'Brien-Johnson, Director of Nuclear Medicine
Dr. Christopher Fischer, RSO
Jennifer Stapleton, Assistant RSO

INSPECTION PROCEDURES USED

87131 Nuclear Medicine Programs, Written Directive Required
87132Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03249/2020-001-01	AV	Failure to monitor exposures; (10 CFR 20.1502(a)(1))
030-03249/2020-001-02	AV	Failure to develop and implement elements of the radiation protection program, including developing procedures to address unexpected low doses; (10 CFR 20.1101(a))
030-03249/2020-001-03	AV	Failure to provide instructions or training, including the requirement to monitor exposures from unlicensed sources; (10 CFR 19.12(a)(3))
030-03249/2020-001-04	AV	Failure to submit a written report; (10 CFR20.2203(a)(2)(i))

Closed
None

Discussed
None

ACRONYMS

ALARA - As Low As Reasonably Achievable	DDE - Deep Dose Equivalent
CFR - Code of Federal Regulations	EDE - Effective Dose Equivalent
NRC - U.S. Nuclear Regulatory Commission	HDR - High Dose Rate Afterloader
RSO - Radiation Safety Officer	Y-90 - Yttrium 90
AU - Authorized User	Rb-82 - Rubidium 82
IR - Interventional Radiologist	CT - Computed Tomography
RSC - Radiation Safety Committee	FDG - Fluorodeoxyglucose
TEDE - Total Effective Dose Equivalent	PET - Positron Emission Tomography
EGM – Enforcement Guidance Memorandum	WD - Written Directive