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

December 17, 2019

EA-19-126

Mr. Todd Forkel
Regional President and Chief Executive Officer
Avera St. Luke's
dba Avera St. Luke's Hospital
305 South State Street
Aberdeen, SD 57401

SUBJECT: NRC INSPECTION REPORT 030-13778/2019-001

Dear Mr. Forkel:

This letter refers to the unannounced routine inspection conducted on July 30-31, 2019, at your facility in Aberdeen, South Dakota, with in-office review through November 14, 2019. 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 and Avera St. Luke's executive management team at the conclusion of the onsite portion of the inspection on July 31, 2019. A final exit briefing was conducted telephonically with you and Mr. Tony Kallas, Director of Radiology Services, on December 2, 2019.

Based on the results of this inspection, the NRC has determined that three 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 workers from licensed and unlicensed sources of radiation; (2) develop and implement certain elements of your radiation protection program; and (3) submit a written report to the NRC within 30 days of discovery of a situation covered under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2203, specifically an occupational exposure in excess of the annual limits in 10 CFR 20.1201. These were identified by the NRC during the July 30-31, 2019, unannounced inspection.

Based on the results of the NRC's inspection and on our independent assessment of your calculations, we determined that the individual of concern had not received occupational exposures in excess of the regulatory limits in calendar year 2018, or year-to-date 2019. Nevertheless, the NRC determined that because of the programmatic failures associated with

the dosimetry program, the individual had a substantial potential to exceed NRC occupational exposure limits. Additionally, there is no information to suggest that any members of the public may have been exposed to radiation doses in excess of the regulatory limits as a result of any of these apparent program deficiencies.

Before the NRC makes its enforcement decision, we are providing you an opportunity to request a predecisional enforcement conference (PEC) or 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 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 presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. 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 at: http://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR 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 (the “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 the NRC’s program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR 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.

In addition, 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.

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 Agencywide Documents Access and Management System (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,

/RA/

Michael C. Hay, Acting Director
Division of Nuclear Materials Safety

Docket: 030-13778
License: 40-18000-01

Enclosure:
NRC Inspection Report 030-13778/2019-001

cc w/enc.
John Priest, South Dakota Dept. of Health

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-13778
License:	40-18000-01
Report:	2019-001
EA No:	EA-19-126
Licensee:	Avera St. Luke's dba Avera St. Luke's Hospital
Location Inspected:	305 South State Street Aberdeen, South Dakota
Inspection Dates:	Onsite July 30 through 31, 2019, with in-office review through November 14, 2019
Exit Meeting Date:	December 2, 2019
Inspectors:	Jason vonEhr, 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

Avera St. Luke's
NRC Inspection Report 030-13778/2019-001

On July 30-31, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an unannounced routine inspection at Avera St. Luke's Hospital at its facility in Aberdeen, South Dakota, with in-office reviews through November 14, 2019. The scope of the inspection was to examine the activities conducted under the license as they relate to public health and safety and to confirm compliance with the NRC's rules and regulations and with the conditions of the 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 inspection additionally focused on the oversight and implementation of the licensee's yttrium-90 microsphere program as a new medical modality initially authorized under the NRC license in February 2018. This report describes the findings of the inspection.

Program Overview

Avera St. Luke's was authorized under NRC Materials License 40-18000-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulations* (10 CFR) Part 35 at its facility in Aberdeen, South Dakota. (Section 1)

Inspection Findings

During an unannounced routine inspection, three apparent violations were identified which involving the licensee's failure to: (1) monitor occupational exposure of a worker from licensed and unlicensed sources of radiation; (2) develop and implement certain elements of the radiation protection program; and (3) submit a written report to the NRC within 30 days of discovery of a situation covered under 10 CFR 20.2203, specifically an overexposure involving an adult occupational worker. (Section 3)

Dose Assessment

The licensee conducted an occupational exposure reconstruction for an individual of concern who was identified as being inadequately monitored for occupational exposure, which was completed and submitted to the NRC. The NRC independently reviewed and concurred with the reconstruction, with no concerns identified with respect to the methodology, assumptions, or final result provided by the licensee. The licensee concluded that an upper-limit estimate of the occupational whole-body deep dose equivalent to be 2,627 millirem for the individual for calendar year 2018 and 3,391 millirem for year-to-date 2019. (Section 4)

Corrective Actions

The licensee immediately conducted an assessment of the individual's occupational exposure for calendar year 2018 and year-to-date 2019. In addition, the licensee has taken steps to develop additional training specifically for interventional radiology and conduct in-house assessments of As-Low-As-Reasonably-Achievable practices and procedures. (Section 5)

REPORT DETAILS

1. Program Overview (87131)

1.1. Program Scope

Avera St. Luke's was authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License 40-18000-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulation* (10 CFR) Part 35 at its facility in Aberdeen, South Dakota.

1.2. Inspection Scope

On July 30-31, 2019, the NRC inspector performed an unannounced, routine inspection at Avera St. Luke's at its facility in Aberdeen, South Dakota, with in-office reviews through November 14, 2019. The scope of the inspection was to examine the activities conducted under the license as they relate to public health and safety, to confirm compliance with the NRC's rules and regulations and with the conditions of the 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 inspection additionally focused on the oversight and implementation of the licensee's yttrium-90 microsphere program as a new medical modality initially authorized under the license in February 2018.

2. Background

2.1. 2018 Licensing Actions

Since the most recent NRC inspection in March 2016, the licensee had amended its license five times. These amendments removed a satellite field office (North Central Heart Clinic), removed gadolinium-153 and strontium-90 sealed source authorizations, revised the list of authorized users, and amended the radiation safety officer listed on the license.

In addition, the licensee requested in a nonpublic letter dated November 1, 2017, to amend the NRC license to add a new medical modality; the use of Sir-Spheres yttrium-90 ceramic microspheres for therapeutic administrations under 10 CFR 35.1000. This amendment request was approved, and NRC license 40-18000-01, Amendment 37 was issued on February 1, 2018.

2.2. Fluoroscopy and NRC Dosimetry Requirements

The use of yttrium-90 microspheres involves the use of fluoroscopes, which is an x-ray generating machine that is capable of outputting significant quantities of radiation with the purpose of imaging patients during different types of procedures. Besides yttrium-90 administrations, these devices are used in cardiology and interventional radiology. Most of the generated radiation is directed along a primary beam from the x-ray generating tubes and deposited either in the patient or in the imaging intensifier, where the image is generated (see Figure 1). Medical personnel who participate in procedures using these

devices generally have personal radiation exposure predominantly as a result of radiation scatter from the beam's interactions with the patient and table.

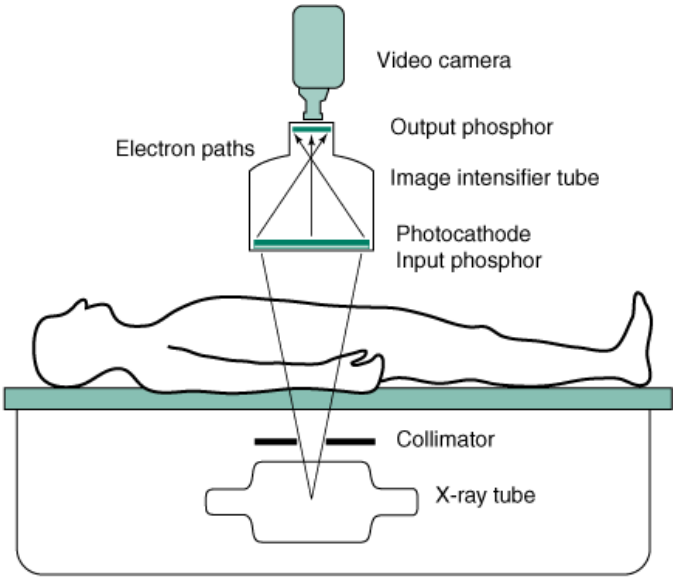

Figure 1 - Basic diagram of a fluoroscope.
Source: Chen MYM, Pope TL, Ott DJ: *Basic Radiology, 2nd Edition:* http://www.accessmedicine.com

As a result of any licensee's staff's participation in yttrium-90 microsphere administrations, an NRC-regulated activity, his or her occupational radiation exposure from both NRC-licensed and unlicensed forms of radiation, such as exposure received while performing fluoroscopy, falls within the purview of the NRC's radiation monitoring requirements in 10 CFR 20.1502.

3. Observations and Findings

The July 30-31, 2019, unannounced routine inspection included review of the entirety of the Avera St. Luke's NRC-licensed operations, which included diagnostic and therapeutic use of unsealed byproduct material for nuclear medicine administrations, therapeutic use of sealed sources for manual brachytherapy, and the yttrium-90 microsphere program.

During the inspector's review of the licensee's yttrium-90 microsphere program, three apparent violations were identified involving the licensee's failure to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (2) develop and implement certain elements of the radiation protection program; and (3) submit a written report to the NRC within 30 days of discovery of an incident covered under 10 CFR 20.2203, specifically an overexposure involving an adult occupational worker.

3.1. Nuclear Medicine Operations – Imaging and Diagnostic

The inspection began with the radiopharmacy (Cardinal Health Nuclear Pharmacy Services, NRC license 34-29200-01MD) dropping off the nuclear medicine unit doses for

the day's scheduled nuclear medicine studies. The licensee staff were on-site for receipt, as the radiopharmacy driver did not have access to the licensee's hot lab. The inspector observed initial quality assurance and quality control tests on the two nuclear medicine cameras, the use and calibration of hot lab instrumentation, and initial unit dose package receipt. The two full-time nuclear medicine technologists had over 15- and 30-years' experience, respectively, and were very knowledgeable on the licensee's practices and procedures, and NRC license and regulatory requirements. A third technologists was available "as-needed" and was otherwise employed by Avera St. Luke's in other non-NRC licensed medical services.

On the first day of the inspection the licensee had one cardiac rest/stress test, one hepatobiliary iminodiacetic acid (HIDA) study, and two bone scans. The inspector observed each administration and confirmed the technologists' As-Low-As-Reasonably-Achievable (ALARA) occupational exposure practices including use of a syringe shield, lead syringe traveling 'purse,' and absorbent material for IV/sharp administrations.

Security of the hot lab and licensed materials in use was maintained adequately between an automatically locking door on the hot lab and direct surveillance by licensee nuclear medicine staff. Housekeeping staff did not have direct access to the hot lab, and were escorted, when necessary, by the nuclear medicine staff. The inspector also reviewed the licensee's long-term storage area. Following a shipment of unused radioactive sealed sources in October 2016, and disposal of various short-lived materials, the long-term storage area did not contain NRC licensed material.

3.2. Nuclear Medicine Operations – Therapeutic

The licensee's 10 CFR 35.300 unsealed byproduct material therapies included iodine-131 and Xofigo radium-223 administrations. The licensee's radium-223 administrations had slowed considerably, with none conducted in calendar year 2019, and approximately a dozen in 2018. The licensee created written directives for each dose of radium-223 administered and included all necessary information. The licensee's iodine program had five administrations in 2018 and two in year-to-date 2019. All the licensee's iodine administrations were with capsules rather than liquid doses and were all conducted as outpatient procedures. All administrations were below 100 mCi, with one exception.

The licensee adequately prepared exposure estimates for members of the public to justify patient release criteria in accordance with 10 CFR 35.75. The inspector discussed with the technologists the processes for ordering 10 CFR 35.300 therapeutic doses, providing patient instruction, surveys, and waste related to the administrations requiring a written directive, with no issues identified.

3.3. Nuclear Medicine - Other

The licensee employed a third-party consultant that conducted quarterly reviews of the nuclear medicine department operations starting in April 2018. The review included the conduct of inventories, leak tests, linearity and accuracy tests, and written directives, among other activities. The licensee's four survey meters (three Ludlum Model 14C and one Bicron Model 2000) were all appropriately calibrated with staggered dates of calibration for availability. The inspector reviewed samples of records for constancy, linearity, accuracy, and decay-in-storage with no issues identified.

The inspector reviewed the licensee's Conference of Radiation Control Program Director's Source Collection and Threat Reduction (CRCPD SCATR) Program's preparation and certification for shipping of the waste sealed sources (25 sealed sources made of primarily the excessed cesium-137 brachytherapy seeds, but also including small cobalt-57, -60, and iridium-192 sources), which were shipped to a licensed disposal facility in Andrews, Texas in October of 2016. The SCATR Program provided personnel expertise, an appropriate shipping container, and packaged the material for shipment on behalf of the licensee.

Nuclear medicine personnel wore a ring dosimeter in addition to the use of a whole-body dosimeter. The ring dosimeter was largely a legacy from when the licensee used molybdenum/technetium generators rather than unit doses. For the nuclear medicine technologists, the maximum recorded occupational exposures were below 300 mrem whole-body and 1,000 mrem extremity for each calendar year 2017, 2018, and year-to-date 2019 through April.

As of the date of the inspection, the licensee had regular Positron-Emission Tomography/Computed Tomography ("PET/CT") imaging mobile services provided by DMS Health Technologies (NRC license 40-32477-01) on site every Wednesday.

3.4. Manual Brachytherapy

The licensee's 10 CFR 35.400 brachytherapy program has had no licensed activities since at least February 2008. With no activities conducted more recent than the date of the last NRC inspection in March 2016, no further reviews were conducted with regard to this program. The inspector encouraged the licensee to provide booster or refresher training to applicable personnel should it decide to restart this long-idled program.

3.5. Yttrium-90 Microspheres

The licensee had conducted nine administrations of yttrium-90 since receiving initial approval from the NRC in February 2018, only one of which was in year-to-date 2019. The inspector conducted a 100 percent review of the yttrium-90 administrations. The licensee's training, inventory, labeling, and waste disposal practices were found to be in accordance with the NRC's February 12, 2016, Revision 9 licensing guidance concerning the use of microspheres, as committed to in the November 1, 2017, amendment request (Amendment No. 38, Corrected Copy, License Condition 15.C,).

Nuclear medicine personnel were involved with the yttrium-90 administrations. The technologists participated in the ordering, manipulating and measuring of the yttrium-90 dose, radiological monitoring of personnel entrances and exits from the catheterization (cath) lab during the procedure, and taking contamination wipes following the procedure.

The nine yttrium-90 written directives were inconsistent in identifying the target site (i.e. the liver or which lobe of the liver was the intended target) of the administration. However, the inspector was able to obtain sufficient supplemental information in records generated prior to each yttrium-90 administration, when lacking, to reasonably determine the target site, and therefore the noncompliance was deemed minor in significance. The licensee committed to more clearly and consistently identify the target for the administration in future written directives.

3.6. Dosimetry Program

The inspector reviewed the licensee's dosimetry program with special attention to the juncture between cath lab and nuclear medicine operations. With the initiation of the yttrium-90 microsphere program, cath lab personnel involved with yttrium-90 procedures became involved with NRC-licensed activities, and therefore their radiation exposures must be monitored in accordance with the requirements of 10 CFR Part 20.

Cath lab personnel, including the principle responsible physician/NRC authorized user, wore dedicated lead aprons with two radiation dosimeters. These dosimeters included one worn above the lead-shielded apron at the collar and one worn below the lead apron at the waist, and were exchanged on a monthly basis. The licensee's dosimetry vendor used a lead correction formula, "EDE1," to determine the whole-body exposure, shown below:

Whole-Body Assigned Dose = 0.04(Collar Dosimeter) + 1.5*(Chest Dosimeter)*

However, in the inspector's review, only the principle yttrium-90 authorized user had this lead correction applied to his dosimeter results. All other cath lab personnel reviewed had a whole-body exposure assigned directly from the collar dosimeter, without adjustment. This necessarily overestimated the radiation exposure to the employees, as it discounts the shielding provided by the lead apron.

The nuclear medicine personnel who assisted in the procedure wore a "guest" lead apron when inside the cath lab and wore their single dosimeter above the lead apron near the collar. As with the other cath lab personnel, this portion of the nuclear medicine technologists' occupational radiation exposure would result in a reported exposure above what the staff actually received.

In the inspector's review of the cath lab personnel's recorded occupational radiation exposures, the inspector observed that the dose of record for the yttrium-90 authorized user had exceeded NRC regulatory requirements in calendar year 2018, with a total occupational exposure assignment of 16,327 mrem. The authorized user's exposures were unevenly distributed through the year, with four months with no recorded exposures (listed in the dosimetry vendor's reports as "M" for minimal exposures recorded), and three months with assigned whole-body exposures in-excess of 1,000 mrem. The authorized user's collar dosimeter, chest dosimeter, and assigned whole-body exposure is shown below.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
January 2018	M	M	M
February 2018	M	M	M
March 2018	830	M	33
April 2018	1,374	888	1,387
May 2018	(missing)	11,641	11,641(1)
June 2018	712	237	384
July 2018	997	1055	1,622
August 2018	882	(missing)	882(1)
September 2018	M	M	M
October 2018	504	93	160
November 2018	156	141	218
December 2018	M	M	M
CY2018 total	**5,455**	**14,055**	**16,327**

Table 1 – Authorized user's dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure at the time of the inspection. All whole-body assigned exposures are using the "EDE1" lead correction formula, with exceptions of those with a (1) indicated.

During the initial interviews with the authorized user, the missing May 2018 dosimeter noted in Table 1 was discovered on the authorized user's desk and was promptly submitted to the dosimetry vendor for processing. The dosimeter was determined by the dosimetry vendor on August 19, 2019, to have a recorded exposure of 1,298 mrem.

The inspector also reviewed year-to-date 2019 occupational radiation exposure reports for the authorized user, without any significant anomalies noted in the data. The inspector further noted that the licensee's dosimetry data for March 2018 included a dosimeter for the authorized user from October 2017 that was provided to the dosimetry vendor nearly a year-and-a-half late. While this dosimeter's monitoring month was prior to the authorized user and the cath lab personnel's involvement in NRC licensed activities, the dosimeter reported an exposure of 29,158 mrem. The licensee stated that this dosimeter had been found after an unknown period of time on the cath lab floor, and subsequently submitted a correction to the authorized user's dosimetry record.

Of the remaining cath lab personnel reviewed, no other employees were observed to have exceeded NRC regulatory requirements for occupational dose limits. Nonetheless, the lack of application of the lead correction factor (the "EDE1" formula) resulted in all other cath lab personnel receiving assigned radiation exposures in excess of actual received dose.

3.6.1. Apparent Violation 1 - 10 CFR 20.1502(a)(1)

The licensee failed to adequately monitor the physician's occupational exposure. During months when the authorized user received minimal radiation exposures, the licensee failed to recognize the implausibility of these results compared with the authorized user's known type and frequency of work involving radiation. Furthermore, when the authorized user received elevated exposure results, or had missing badges reported by dosimetry vendor, the licensee was required under its own program to have investigated

these anomalies and, based on the results of those investigations, corrected the employee's occupational dose record. The apparent violation is listed below:

> 10 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 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 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 February 2018, through July 30, 2019, the licensee failed to adequately monitor an individual's occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, a licensee's failure to properly monitor an authorized user's radiation exposure resulted in the authorized user having a significant potential to exceed the NRC's annual limit of 5 rems total effective dose equivalent in 10 CFR 20.1201(a).

The licensee's failure from February 2018 through July 30, 2019, to adequately monitor exposure to radiation and radioactive material from exposures received at Avera St. Luke's was identified as an apparent violation of 10 CFR 20.1502(a)(1). (030-13778/2019-001-01)

3.6.2. Apparent Violation 2 – 10 CFR 20.2203(a)

The licensee was required to have provided a written report to the NRC within 30 days of the discovery or learning of an occupational overexposure in accordance with 10 CFR 20.2203(a). The authorized user's cumulative calendar year 2018 occupational radiation exposure exceeded the NRC's annual limit with the receipt of the May 2018 dosimeter's exposure. The May 2018 dosimeter was provided to the dosimetry vendor late, and therefore the resulting report was received by the licensee on October 3, 2018. The dosimetry vendor highlighted the exposure of the authorized user as elevated beyond certain administrative limits either set by the vendor by default or customized by the client. Therefore, the licensee was required to have provided a written report within 30 days, or by November 3, 2018. No such report was provided to the NRC between initial discovery in October 2018 to the date of the inspection in July 2019.

The lack of a written report significantly impacted the NRC's regulatory processes. Specifically, the licensee's failure to submit a report deprived the NRC the opportunity to conduct a reactive inspection to review the facts and circumstances in a timelier manner. The apparent violation is listed below:

> 10 CFR 20.2203(a) requires, in part, that each licensee shall 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.
>
> Contrary to the above, from November 3, 2018, through July 30, 2019, 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,

the licensee was notified by the dosimetry vendor on October 3, 2018, of an exposure exceeding the NRC's annual exposure limits for an authorized user working under the NRC license, and the licensee failed to provide any notification to the NRC prior to the NRC's inspection on July 30-31, 2019.

The licensee's failure from November 3, 2018, through July 30, 2019, to submit a written report within 30 days of the discovery of a authorized user overexposure was identified as an apparent violation of 10 CFR 20.2203(a). (030-13778/2019-001-02)

3.6.3. Apparent Violation 3 - 10 CFR 20.1101(a)

The licensee had a written radiation protection program which was captured in a series of protocols, procedures, and policies. These documents included: RS-01 "Radiation Safety Committee," RS-02 "Responsibility of Authorized Users," RS-03 "Responsibilities and Authority of [the] Radiation Safety Officer," RS-04 "ALARA Program," and RS-06 "Proper Wear and Care of Individual Radiation Monitoring Devices." The licensee had numerous responsibilities, authorities, and obligations under its written radiation protection program that provided the guidance and methods that should have provided preventative actions against, identification of, and responsive or corrective actions to potential occupational radiation overexposures of staff.

In addition, the licensee's written radiation protection program did not provide any list of events or triggers when it would be required to provide a notification and/or written report to the NRC. This lack of development with respect to the licensee's notification requirements contributed, in part, to Apparent Violation 2 described in Section 3.6.2, involving 10 CFR 20.2203(a). The apparent violation is listed below:

> 10 CFR 20.1101(a) requires, in part, that each licensee develop 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 policies and procedures captured in Radiation Safety, or "RS" procedures, documented the licensee's radiation protection program. The procedures in RS-01 "Radiation Safety Committee," RS-02 "Responsibility of Authorized Users," RS-03 "Responsibilities and Authority of [the] Radiation Safety Officer," RS-04 "ALARA Program," and RS-06 "Proper Wear and Care of Individual Radiation Monitoring Devices" collectively documented the licensee's requirement to (1) adequately review occupational radiation dose records of all personnel working with byproduct material; (2) recommend remedial actions to correct any deficiencies identified in the radiation safety program; (3) maintain and update the Radiation Safety Manual; (4) conduct a quarterly review of occupational radiation exposures to assess trends in occupational exposure as an index of ALARA program quality; and (5) conduct of reviews or investigations of individuals exceeding licensee-set ALARA Level I (310 mrem/calendar quarter) and Level II (930 mrem/calendar quarter) occupational exposures.
>
> Contrary to the above, from February 2018, through July 30, 2019, the license failed to develop 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.

Specifically, the licensee failed to include in its radiation protection program the reporting requirements under 10 CFR Part 20, Subpart M.

In addition, the licensee failed to implement portions of its radiation protection program, including, but not limited to, the failures to conduct the program requirements listed in (1) through (5) described above.

The failure to develop and implement portions of the licensee's radiation protection program was identified as an apparent violation of 10 CFR 20.1101(a). (030-13778/2019-001-03)

4. Dose Reconstruction

As a result of the deficiencies identified in Avera St. Luke's occupational dosimetry program, the NRC determined that it was necessary to reconstruct the authorized user's occupational exposure history. Since the authorized user began conducting work under the NRC license in February 2018, the NRC determined that the reconstruction needed to include calendar year 2018 forward.

The licensee aggregated the reconstruction's raw data primarily from the authorized user's work with fluoroscopy and other x-ray generating machines. At Avera St. Luke's, the fluoroscopy and other x-ray generating machines captured certain useful parameters from the patient procedures, such as information on how long the x-ray beam was on, penetrating power of the produced beam, and the machine-calculated patient exposure. Other x-ray generating machines captured beam time, which could be used with some additional modeling.

4.1. Licensee Reconstruction

The licensee reconstructed the subject physician's occupational exposure history from 2018 forward. The licensee utilized a physicist within Avera's corporate umbrella to conduct the reconstruction.

The licensee's physicist conducted physical radiation surveys with a phantom (patient-equivalent device used to simulate radiation scatter, normally for calibration purposes) with radiation measuring equipment on the actual devices that the authorized user would have utilized. The physicist used a RaySafe X2 solid state survey meter, serial number 230047, with a calibration date of November 2, 2018, to complete these measurements.

Through a series of calculations and conservative assumptions regarding shielding and authorized user's positioning relative to the x-ray generating machine and the theoretical patient, the licensee's physicist determined a ratio between the machine recorded patient exposure, or beam time (dependent on the machine in question), which in turn could be used to calculate the authorized user's occupational exposure using the aggregated raw data on procedures from Avera St. Luke's.

The physicist produced a report dated August 13, 2019 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession ML19231A278) to describe and document the efforts and methodologies, as well as to produce the initial estimates for the subject physician's occupational exposure for the calendar year 2018. A subsequent

report was submitted to revise the authorized user's year-to-date exposure information for calendar year 2019. This second report was dated September 4, 2019 (ADAMS Accession ML19261A159).

The licensee's reports referenced above utilized a dosimetry methodology to back calculate the authorized user's exposure histories. This methodology was to calculate the occupational radiation exposure that a single dosimeter placed on the collar of the physician would have been exposed to.

The resulting exposure on the collar badge would then be used to input into the Webster Equation. The Webster Equation in general seeks to calculate the Total Effective Dose Equivalent to the human body by compartmentalizing the body into sections and aggregating the resulting exposure by weighting each section of the body, with the additional knowledge that a personal lead apron will cut down on the exposure to the shielded portions of the body. This is similar to the dosimetry vendor's "EDE1" equation, with the difference being the single dosimeter input rather the dual dosimeters. The result of the compartmentalization of the body and the non-uniform exposure to the body as a result of the lead apron is the following equation:

Whole-Body Assigned Dose = 0.3(Collar Dosimeter)*

4.2. Licensee Results

The licensee's final results for calendar year 2018 for the authorized user were a conservative estimate of 2,627 mrem. The licensee also produced an estimate that took into account additional details that the licensee judged reasonable to assume but impractical to demonstrate in practice; examples included the use of a 'typical' clinical technique rather than the maximum [beam] technique, taking into account a larger distance to where the physician would stand (75 cm) rather than a conservative 50 cm distance. This more refined estimate concluded a total 2018 occupational exposure of 762 mrem.

The NRC conducted an independent review of the licensee's methodology, assumptions, and mathematical results, with no significant deficiencies identified. The NRC concluded that the licensee's upper-estimate was reasonable given the data at hand, the results of interviews conducted with the physician and involved staff, and review of the radiation producing equipment and shielding available at the facility.

5. Corrective Actions

Upon identification by the NRC during the July 30-31, 2019, inspection, the licensee immediately arranged for an occupational exposure reconstruction for the authorized user covering calendar year 2018 and year-to-date 2019. Following the NRC's review of the licensee's report, the licensee submitted a letter to the dosimetry vendor to formally request the revision of the authorized user's dose of record based on the results of the licensee's physicist's conclusions.

In addition, the licensee's Radiology Director conducted a review of staff being occupationally exposed in the cath lab by observing and interviewing staff with respect to ALARA practices and procedures associated with radiation safety measures and

practices. A training program focused specifically on interventional radiology procedures was being developed.

6. Exit Meeting Summary

On July 31, 2019, the NRC inspector provided the preliminary inspection findings at the conclusion of the on-site portion of the inspection. Avera St. Luke's was represented at the preliminary exit meeting by:

- Todd Forkel - Chief Executive Officer
- Tess Moeller – Quality, Innovation, and Strategy
- Deborah Streier – Vice President of Operations
- Tony Kallas – Director of Radiology Services

On December 2, 2019, the NRC and Avera St. Luke's conducted a final telephonic exit briefing. Avera St. Luke's was represented by Mr. Todd Forkel and Tony Kallas, with their titles noted above.

The licensee acknowledged the inspection findings and did not dispute any of the details presented during the call.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Todd Forkel – Chief Executive Officer
Tess Moeller – Quality, Innovation, and Strategy
Deborah Streier – Vice President of Operations
Kellie Fischer – Chief Nursing Officer
Tony Kallas – Director of Radiology Services
Leslie Lenter, M.D. – Radiation Safety Officer
David Martin – Lead Certified Nuclear Medicine Technologist
Lanette Huebaer – Certified Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

87131 - Inspection of Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-13778/2019-001-01	AV	Failure to monitor occupational exposure to radiation and radioactive material from exposures received at Avera St. Luke's. (10 CFR 20.1502(a)(1))
030-13778/2019-001-02	AV	Failure to submit a written report to the NRC within 30 days of the discovery or identification of an occupational exposure in excess of the annual limits set forth in 10 CFR 20.1201 (10 CFR 20.2203(a))
030-13778/2019-001-03	AV	Failure to develop portions of and failure to implement portions of the Avera St. Luke's written radiation protection program. (10 CFR 20.1101(a))

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALARA	As-Low-As-Reasonably-Achievable
AV	Apparent Violation
CFR	*Code of Federal Regulations*
CRCPD	Conference of Radiation Control Program Directors
CT	Computed Tomography
HIDA	Hepatobiliary Iminodiacetic Acid
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
PET	Positron-Emission Tomography
PRN	*Pro Re Nata*
SCATR	Source Collection and Threat Reduction Program

NRC INSPECTION REPORT 030-13778/2019-001 - DATED DECEMBER 17, 2019

ADAMS ACCESSION NUMBER: ML19352D339

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

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