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

March 30, 2020

EA-20-003

Mr. David Flicek
President and Chief Executive Officer
Avera McKennan
1325 South Cliff Avenue
Sioux Falls, SD 57117-5045

SUBJECT: NRC INSPECTION REPORT 030-11252/2019-002

Dear Mr. Flicek:

This letter refers to the unannounced routine inspection conducted on November 18-22, 2019, at your facilities in Sioux Falls and Mitchell, South Dakota, with in-office reviews through February 27, 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 and Avera McKennan's management team during daily debriefs conducted while the inspectors were onsite. A final exit briefing was conducted telephonically on March 12, 2020, with Avera McKennan management and staff representatives.

Based on the results of this inspection, the NRC has determined that six 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 failure to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (2) submit a written report to the NRC within 30 days of discovery of an incident covered under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2203, specifically occupational exposures in excess of the annual limits in 10 CFR 20.1201; (3) implement certain elements of your radiation protection program; (4) provide instructions regarding radiation safety, specifically involving the proper use of dosimeters, to certain radiation workers; (5) provide occupational exposure reports to certain radiation workers; and (6) ensure that an authorized user of each type of use permitted by the license was represented on the Radiation Safety Committee. These apparent violations were identified by the NRC during the unannounced inspection on November 18-22, 2019.

Note: On March 10, 2020, the NRC completed a license amendment requested by Avera McKennan that separated the licensee's operations into two NRC licenses. This report and any follow-up communication regarding EA-20-003 will be placed within both NRC dockets.

Based on the preliminary results of the NRC's inspection, and based on our independent assessment of your calculations, we determined that the individuals of concern had not received occupational exposures in excess of the regulatory limits in calendar years 2016 through 2018, or year-to-date 2019 (through the date of the inspection). Nevertheless, the NRC determined that because of the programmatic failures associated with the dosimetry program, the individuals 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 either request a pre-decisional 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. If you decide to participate in a PEC or pursue ADR, please contact Ms. Patricia A. Silva at 817-200-1455 within 10 days of the date of this letter. 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 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 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 third-party neutral. 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 the NRC's ADR 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,

Mary C. Muessle

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Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket: 030-11252, 030-39216
License: 40-16571-01, 40-16571-02

Enclosure:
NRC Inspection Report 030-11252/2019-002

cc w/Enclosures:
John Priest
Sr. Health Facilities Surveyor-radiation
South Dakota Dept. of Health
Licensure & Certification
4101 W. 38th St.
Sioux Falls, SD 57106

NRC INSPECTION REPORT 030-11252/2019-002; NOTE: NEW AVERA MCKENNAN LICENSE 40-16571-02, DOCKET 030-39216 - DATED 03/30/2020

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

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OFFICIAL RECORD COPY

Mary C. Muessle

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-11252
License:	40-16571-01
Report:	2019-002
EA No:	EA-20-003
Licensee:	Avera McKennan
Locations Inspected:	Avera McKennan Hospital 1325 South Cliff Avenue, Sioux Falls, South Dakota Avera McKennan Mobile Medical Garages 901 East 17th Street, Sioux Falls, South Dakota 705 S. 6th Avenue, Sioux Falls, South Dakota 819 S. 6th Avenue, Sioux Falls, South Dakota Avera Heart Hospital 4500 West 69th Street, Sioux Falls, South Dakota Avera Heart Hospital - North Central Heart 4520 West 69th Street, Sioux Falls, South Dakota Avera Cancer Institute, Prairie Center 1000 East 23rd Street, Sioux Falls, South Dakota Mitchell Clinic, Ltd. 818 West Havens Street, Mitchell, South Dakota
Inspection Dates:	November 18-22, 2019, with in-office review through February 27, 2020
Exit Meeting Date:	March 12, 2020
Inspectors:	Jason vonEhr, Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety, Region IV Robin Elliott, Health Physicist Medical and Licensing Assistance Branch Division of Nuclear Materials Safety, Region I
Approved By:	Patricia A. Silva, Chief Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment 1:	Authorized Users' Dosimeter Summaries
Attachment 2:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Avera McKennan
NRC Inspection Report 030-11252/2019-002

On November 18-22, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an unannounced routine inspection of Avera McKennan at its facilities in Sioux Falls and Mitchell, South Dakota, with in-office reviews through February 27, 2020. 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.

In addition, the inspection focused on assessing the status of the nuclear medicine program in consideration of the significant enforcement initiated in November 2017 and the findings from the follow-up inspection in June 2018. Within the scope of these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

Program Overview

Avera McKennan was authorized under NRC Materials License 40-16571-01 to possess and use byproduct material for diagnostic and therapeutic medical uses under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, at its facilities in Sioux Falls, Mitchell, and Parkston, South Dakota, as well as mobile medical operations at temporary job sites in areas of NRC jurisdiction. (Section 1)

Inspection Findings

During an unannounced routine inspection, six apparent violations were identified involving the licensee's failure to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (2) submit a written report to the NRC within 30 days of discovery of an incident covered under 10 CFR 20.2203, specifically occupational exposures in excess of the annual limits in 10 CFR 20.1201; (3) implement certain elements of Avera McKennan's radiation protection program; (4) provide instructions regarding radiation safety, specifically involving the proper use of dosimeters, to certain radiation workers; (5) provide occupational exposure reports to certain radiation workers; and (6) ensure that an authorized user of each type of use permitted by the license was represented on the Radiation Safety Committee. (Section 3)

Dose Assessment

The licensee conducted an occupational exposure reconstruction for the individuals of concern, which was initially completed and submitted to the NRC within 2 weeks of the conclusion of the on-site inspection. The NRC inspectors independently reviewed and concurred with the reconstruction, with no concerns identified with respect to the methodology, assumptions, or the final results provided by the licensee. The licensee concluded that an upper-limit estimate of the occupational whole-body deep dose equivalent was below 5 Rem (50 mSv) for each of the individuals of concern for each applicable calendar year. (Section 4)

Corrective Actions

The licensee immediately conducted an assessment of the individuals' occupational exposure for applicable calendar years 2016 through year-to-date 2019. In addition, the licensee initiated 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, 87132)

1.1. Program Scope

Avera McKennan was authorized under U.S. Nuclear Regulatory Commission's (NRC's) Materials License 40-16571-01 to possess and use byproduct material for numerous diagnostic and therapeutic medical uses under Title 10 of the *Code of Federal Regulations* (10 CFR), Part 35, at its facilities in Sioux Falls, Mitchell, and Parkston, South Dakota, as well as mobile medical operations at temporary job sites in areas of NRC jurisdiction.

On March 10, 2020, the NRC completed a license amendment request for Avera McKennan that cleaved the licensee's operations into two NRC licenses. The original license 40-16571-01 would maintain most of the oncology aspects of the license, including authorizations for 10 CFR 35.600 remote afterloader unit and 10 CFR 35.1000 gamma stereotactic radiosurgery. Meanwhile, the new license 40-16571-02 would authorize the nuclear medicine modalities: 35.100 uptake, dilution, and excretion studies, 35.200 imaging and localization studies, 35.300 use of unsealed byproduct material requiring a written directive, 35.400 manual brachytherapy, and both 35.1000 yttrium-90 microsphere authorizations.

1.2. Inspection Scope

On November 18-22, 2019, the NRC performed an unannounced routine inspection of Avera McKennan at its facilities in Sioux Falls and Mitchell, South Dakota, with in-office reviews through February 27, 2020. 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.

In addition, the inspection focused on assessing the status of the nuclear medicine program in consideration of the significant enforcement initiated in November 2017 and the findings from the follow-up inspection in June 2018. The inspection had an additional focus on the oversight and implementation of the licensee's new Flexitron remote afterloader brachytherapy unit, which was approved for medical use in October 2018, after the previous NRC inspection. Due to time constraints and the flexibilities allowed under Inspection Manual Chapter 2800, Revision 1, the inspection did not review the safety or security aspects of the licensee's Elekta Model Leksell Gamma Knife Perfexion unit.

Within the areas identified above, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

2. Background

2.1. 2017 NRC Enforcement

Following an investigation by the NRC into transportation practices at Avera McKennan as they related to Class 7 (radioactive) hazardous materials, the NRC determined that six apparent violations were identified, which were issued to the licensee in a letter dated November 7, 2017 (NRC Inspection Report 030-11252/2017-001, NRC's Agencywide Documents Access and Management System (ADAMS) Accession ML17278B205). Avera McKennan attended a predecisional enforcement conference with the NRC on December 1, 2017 (see ADAMS Accessions ML17325A140 for the Meeting Notice and ML17340B113 for the Conference Summary).

The apparent violations included the failures to: (1) properly package shipments of radioactive material that were transported on public highways; (2) describe the hazardous material on shipping papers; (3) mark each package containing hazardous material for shipment; (4) label packages for shipment; (5) secure packages containing radioactive material to prevent shifting during normal transportation conditions; and (6) monitor the external surfaces of labeled packages for radioactive contamination upon receipt.

The investigation and enforcement conference led to the issuance of four violations (see (1) through (4) above), which were grouped as a Severity Level III problem, and the issuance of two separate Severity Level IV violations (see (5) and (6) above), in a letter dated December 21, 2017 (ADAMS Accession ML17355A491). The violations grouped as a Severity Level III problem were deemed significant as a result of several of the licensee employees' deliberate misconduct regarding compliance with NRC and U.S. Department of Transportation regulations.

Although the 2018 NRC inspection scope was specifically to follow-up on these deficiencies at Avera McKennan, the August 2, 2019, inspection (2019-001) and November 19-22, 2019, inspection (2019-002) also reviewed these requirements as they were applicable to determine if the licensee's corrective actions were lasting and effective. The inspectors did not identify any recurrences in these deficiencies across all program areas.

2.2. 2018 NRC Inspection Follow-Up

On June 12-14, 2018, the NRC conducted an unannounced inspection (NRC Inspection Report 030-11252/2018-001, ADAMS Accession ML19026A003) which, in part, reviewed the licensee's actions as they related to the 2017 enforcement described above. The inspection determined that adequate corrective actions were taken that prevented a recurrence of the violations discussed in 2017 but determined that the licensee's "failure to anticipate the consequences of [its] corrective actions resulted in the identification of additional noncompliances."

The 2018 inspection resulted in the identification of three Severity Level IV violations, which involved the failures to: (1) certify that hazardous Class 7 (radioactive) materials were offered for transport in accordance with applicable requirements; (2) monitor packages containing Class 7 (radioactive) materials as soon as practical after receipt; and (3) for mobile medical services, obtain a letter signed by the management of each

client that permits the use of byproduct material and clearly delineates the authority and responsibility of the licensee and the client.

The 2019-001 and 2019-002 inspections' review of operations in nuclear medicine and other modalities, as far as these requirements crosscut other program areas, demonstrated the lack of recurrence of the violations identified above. Moreover, the licensee's program changes and training provided to staff provided a basis for confidence that recurrence of the above violations was unlikely. Based on these reviews and conclusions, which are discussed in greater detail in Section 3 below, the inspectors closed out the three violations that were identified during the June 2018 inspection.

2.3. Regarding 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.

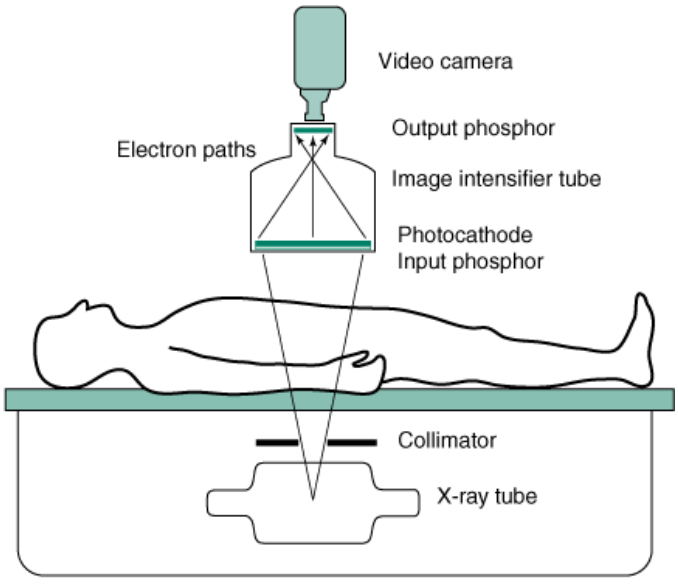

Figure 1 - Basic diagram of a fluoroscope.
Source: Chen MYM, Pope TL, Ott DJ: *Basic Radiology, 2nd Edition:* http://www.accessmedicine.com

As a result of any licensee's staff's participation in yttrium-90 microsphere administrations, an NRC-regulated activity, the staff's 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 November 18-22, 2019, unannounced routine inspection reviewed Avera McKennan's NRC-licensed operations except for the safety and security elements associated with the licensee's Elekta Model Leksell Gamma Knife Perfexion unit. This review included diagnostic and therapeutic use of unsealed byproduct material for nuclear medicine administrations, therapeutic use of sealed sources for remote afterloader brachytherapy, and the yttrium-90 microsphere program.

During the inspector's review of the licensee's yttrium-90 microsphere program, six apparent violations were identified involving the licensee's failure to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (2) submit a written report to the NRC within 30 days of discovery of an incident covered under 10 CFR 20.2203, specifically occupational exposures in excess of the annual limits in 10 CFR 20.1201; (3) implement certain elements of Avera McKennan's radiation protection program; (4) provide instructions regarding radiation safety, specifically involving the proper use of dosimeters, to certain radiation workers; (5) provide occupational exposure reports to certain radiation workers; and (6) ensure that an authorized user of each type of use permitted by the license was represented on the Radiation Safety Committee.

3.1. Nuclear Medicine Operations – Imaging and Diagnostic

The licensee was authorized for 10 CFR 35.100 and 35.200 imaging and diagnostic studies at a number of fixed locations in addition to mobile medical operations (see Section 3.2 below) in areas of NRC jurisdiction. The fixed locations that were staffed on a daily basis during the week and on call otherwise, included the main Avera McKennan Hospital and North Central Heart, both located in Sioux Falls, South Dakota. The Heart Hospital of South Dakota (essentially co-located with North Central Heart, but with a separate hot lab), Avera St. Benedict Hospital in Parkston, South Dakota, and Mitchell Clinic, Ltd. in Mitchell, South Dakota, were staffed on an as-needed basis.

The licensee's imaging and diagnostic activities were largely based on technicium-99m studies, but included other more rarely-used medical isotopes such as thallium-201, iodine-123, indium-111, and xenon-133. In addition, the licensee had a separate organizational group for Positron Emission Tomography – Computed Tomography (PET/CT) studies at the Avera Cancer Institute/Prairie Center in Sioux Falls, which used fluorine-18 for imaging studies.

The PET/CT group was staffed with two to three nuclear medicine technologists, who usually performed between six to nine studies daily and generally operated from 7:30 a.m. to 4:30 p.m., Monday through Friday. Unit doses of fluorine-18 fluorodeoxyglucose (FDG) were obtained from Cardinal Health Nuclear Pharmacy Services (NRC License 34-29200-01MD) to primarily conduct whole-body or eyes-to-thighs scans. Brain scans and cardiac studies were also performed to a lesser degree. Unit doses of Axumin fluorine-18 Fluciclovine were obtained from the manufacturer PETNET (Minnesota Licenses 1017, (radioisotope production) and 1228 (radioisotope preparation and transfer)) in Minneapolis for prostate studies. These studies involved the administration of the material to the patient followed by a scan approximately 4 minutes after the administration.

The PET/CT facilities included the hot lab, a scan room using a Discovery IQ camera, and three quiet rooms, one of which was used in practice for storage. The dose calibrator was used to verify patient dose prior to administration. The inspector observed patient interviews and dose preparation, administration, scanning, package receipt and preparation for return to pharmacy, use of appropriate dosimetry, waste management, surveying, and material security. The inspector conducted independent surveys of the hot lab, control room, quiet rooms and areas immediately outside the quiet rooms. The results of the surveys were consistent with the licensee's postings and within regulatory limits. No issues concerning PET/CT were identified.

Outside of PET/CT operations, the licensee had approximately 18 nuclear medicine technologists devoted to nuclear imaging and diagnostic studies who were assigned on a rotating basis through the satellite sites, mobile operations, and the fixed facilities in Sioux Falls. The inspectors conducted extensive reviews of the licensee's operations at the Avera McKennan Hospital and North Central Heart, a division of Heart Hospital of South Dakota. These two operations represented the majority of the nuclear medicine operations conducted at fixed facilities for the licensee.

The inspectors observed start-of-day activities including the use of sealed sources for calibration and constancy of equipment, flood sources for quality assurance and quality control of imaging equipment, and dose check-in from the radiopharmacy. The inspectors interviewed numerous nuclear medicine staff, observed the preparation and administration of licensed radioactive material to patients, and confirmed the adequate use of as-low-as-reasonably-achievable (ALARA) techniques.

As in the PET/CT area, the inspectors observed patient interviews and dose preparation, administration, package receipt and preparation for return to pharmacy, use of appropriate dosimetry, waste management, surveying, and material security. The inspectors conducted independent surveys of the hot lab, control room, injection rooms and areas immediately outside the injection rooms. The results of the surveys were consistent with the licensee's postings and within regulatory limits. No issues were identified.

The operations at Avera McKennan Hospital typically started at around 6 to 6:30 a.m., and at 6 a.m. at North Central Heart. Depending on patient loads, the licensee could expect three deliveries of radioactive materials, all in the form of unit doses from the radiopharmacy, with deliveries at approximately 6, 9:30, and 11:30 a.m., with add-on and on-call options for unscheduled demands. Doses were delivered directly from the radiopharmacy drivers. At each of the two facilities, staff estimated normal patient loads between 15-20 patients daily.

During the 2018 NRC inspection, two Severity Level IV violations were cited for activities involving the transportation or receipt of radioactive materials for imaging and diagnostic nuclear medicine. The first violation involved the use of a third party's certification on shipping papers for transportation of Class 7 (radioactive) material following the initial third party's shipment. The second violation involved the failure to provide timely monitoring of received packages containing radioactive material.

During the 2019 NRC inspection, the inspectors were able to review outgoing shipments of radioactive material at the fixed facilities for empty radioactive packages or unused administrations, as well as the receipt and follow-up shipment at intermediate locations

(namely at the “Wee Care” mobile medical garage) of similar packages containing radioactive unit doses. The licensee clearly demonstrated the use of and self-certification of shipping papers for follow-up shipments of greater-than-exempt quantities of radioactive materials, and timely monitoring of packages received by the licensee, even in cases where they would be further transported to other locations.

In addition, the inspectors considered the results of NRC Inspection Report 030-11252/2019-001, which documented the lack of recurrence of the 2017 and 2018 violations at the mobile medical site, but did not conclude that the limited inspection conducted at the temporary job site was a sufficient basis for closing out the 2018 violations. Based on these observations, interviews with staff, supervisors, and managers, as well as the observations made during the August 2019 NRC inspection at a temporary job site in Watertown, South Dakota, the two violations described above were closed (030-11252/2018-001-01 and 030-11252/2018-001-02).

The third and final violation identified in June 2018 is discussed below in Section 3.2 regarding the licensee’s mobile nuclear medical operations.

3.2. Nuclear Medicine – Mobile Medical Operations

The inspectors conducted a review of the licensee’s mobile nuclear medicine operations. These activities were performed at approximately 12 temporary job sites across South Dakota, and other sites in Agreement State or non-NRC jurisdictions. The temporary job sites were serviced by four mobile medical coaches and five licensee-owned cars. There were three garages (as of Amendment 79: License Condition 10.C, 10.H(ii), and 10.H(iii)) that housed mobile coaches in Sioux Falls and one garage (License Condition 10.H(i)) in Watertown that likewise housed a mobile coach. The principal Sioux Falls garage and associated facilities (License Condition 10.C, colloquially known as the “Wee Care” garage) included a well counter and survey meters used for performing package surveys in accordance with U.S. Department of Transportation requirements, and storage lockers for packages and supplies.

Doses were delivered to the “Wee Care” garage and placed in the lockers by the Cardinal Health Nuclear Pharmacy Services’ pharmacy drivers. Avera McKennan’s staff generally left the garage by 6:15 a.m. to travel to their assigned location. Prior to leaving the garage, a pre-trip vehicle inspection would be performed. Staff generally returned between 3-5 p.m. Three-ply Bill of Lading forms were developed for the transportation of the packages from the garage to the final destination and for the return of any wastes generated to the garage. The licensee’s drivers received U.S. Department of Transportation training every other year.

Some temporary job site locations involved studies performed on mobile coaches dispatched from the Sioux Falls locations and in other locations the scans were performed in fixed facilities provided by the host or client facility. There were 25 agreements on file with the licensee outlining the responsibilities of each party (mostly the receiving party was an Avera-branded facility, and therefore, under the same corporate entity).

The inspector reviewed a sample of the agreements and noted that they contained the appropriate signatures and addressed the use of licensed material in accordance with 10 CFR 35.80. A template was used to create all the agreements following the June 2018

violation. As a result of the reviews described above, the inspectors closed out the previous violation involving the inadequacy of agreements between the host or client site and the licensee providing the mobile nuclear medical service (030-11252/2018-001-03).

Area dosimeters were maintained at each outreach site to confirm public dose limits. The inspector toured the three garages in Sioux Falls, interviewed a nuclear medicine technologist that performed licensed activities with a van, the lead nuclear medicine technologist, and performed independent surveys in each garage location. No issues were identified.

3.3. Nuclear Medicine Operations – Therapeutic

The inspectors conducted a review of the licensee's therapeutic uses of unsealed radioactive material authorized under 10 CFR 35.300. The NRC license authorized this activity only at the Avera McKennan Hospital in Sioux Falls and the neighboring Prairie Center and Avera PET/CT in Sioux Falls. Since the last inspection, the licensee's therapeutic unsealed administrations of radioactive material included iodine-131, Zevalin yttrium-90, and Xofigo radium-223.

The inspectors had the opportunity to observe two therapies involving the administration of iodine-131 in activities of 100 and 150 millicuries. The authorized user (AU) was authorized on the license for 10 CFR 35.100-300 administrations (as of Amendment 79), provided patient instruction both orally and in writing and answered questions from the patients and/or caregivers. The written directives for each administration had been prepared prior to the day of the administration. Each written directive was adequately prepared with the required information and had been signed and dated by an AU permitted on the license under 10 CFR 35.300 prior to the administration. No issues were identified.

The inspectors also conducted a sample review of each the iodine-131 administrations, Xofigo radium-223 administrations, and the sole Zevalin yttrium-90 administration. Over the previous 6 months, the licensee conducted 15 administrations of iodine-131 of 100 millicuries or more, 19 administrations of iodine-131 less than 100 millicuries, and 9 administrations (i.e., fractions) of Xofigo radium-223. In the review of written directives, no issues of greater-than-minor significance were identified. For patients administered greater than 33 millicuries, patient release criteria were adequately determined and documented in the patient files.

The licensee had conducted one in-patient iodine therapy since the last inspection in June 2018. The therapy, conducted in March 2019, involved 153.8 millicuries of iodine-131. The licensee conducted real-time training for nursing staff involved in the care of the patient, in addition to their standard radiation safety training conducted online in nursing education modules. The patient was held in an isolated suite in the corner of the building, with buffers on either side consisting of either empty space or storage related to the care of the radiotherapy patient. Adequate and timely radiation surveys with calibrated instruments were conducted by licensee personnel, patient release criteria determined, and room release surveys completed and documented. No issues of greater-than-minor significance were identified.

3.4. Manual Brachytherapy

The licensee's 10 CFR 35.400 brachytherapy program had no licensed activity in several years. The activity remains authorized on the NRC license for use or storage at the Avera McKennan Hospital in Sioux Falls. The most recent cases were: (1) for iodine-125; a prostate implant on December 21, 2016; and (2) for palladium-103; a prostate implant on April 29, 2014. With no activities conducted more recently than the date of the last NRC inspection in June 2018, no further reviews were conducted with regards to this program. The inspectors encouraged the licensee to consider either providing booster or refresher training to applicable personnel should it decide to restart this long-idled program or removing this authorization from the NRC license.

3.5. Remote Afterloader Brachytherapy

The licensee was authorized as of Amendment 74, issued on October 6, 2018, for the medical use of a new Flexitron remote afterloader brachytherapy unit. This unit was authorized as of the date of the inspection under Amendment 79 for use at the Avera Radiation Oncology unit of the Avera Cancer Center Institute, Prairie Center, in Sioux Falls. The inspectors conducted a review of this high dose rate (HDR) remote afterloader unit's operations, including the observation of a medical treatment while onsite.

The HDR remote afterloader was used to primarily provide brachytherapy treatments for gynecological cancers, and occasionally endobronchial, endobiliary and skin cancers. Approximately 20 patients were treated quarterly with the unit by a staff including two AUs and two authorized medical physicists (AMP). As of the date of the inspection, the gynecological treatments were using vaginal cylinders for three to five fractions and tandem and ovoids for five fractions. Starting in December 2019, a new applicator, Venezia, was scheduled to be used. The staff established a multidisciplinary committee to develop written procedures to comprehensively address aspects of its implementation. The applicator was anticipated to provide more flexibility to treat cancers in multiple areas at once and with a variety of shapes.

Regarding security, the HDR remote afterloader was locked in a cabinet in the treatment vault when not in use. The licensee's keys to the cabinet were restricted to the AMPs. The console was password protected and likewise restricted to the AMPs.

One of the inspectors observed a vaginal cylinder treatment. The AMP performed the required spot check prior to the treatment and placed the emergency equipment in the room next to the HDR remote afterloader. The inspector observed the AMP prepare the treatment plan using the treatment software. Once the AMP completed the plan, the oncologist AU reviewed and verified the plan prior to treatment. The AMP, AU, and a nurse were present for the entire treatment. The patient was surveyed at the end of the treatment prior to leaving the treatment vault to verify the absence of radioactive material. No issues were identified.

The inspector reviewed written directives, incidents, full calibration records, training, spot checks, emergency procedures and postings, security, and dosimetry as they related to the HDR remote afterloader. Full calibrations, performed at source exchange, were discussed with the AMPs. The inspector noted that the linearity for the unit was being evaluated for up to 90 seconds, which covered the longest individual dwell time;

however, the treatments could range for 5-10 minutes. The AMP stated that the evaluation of linearity would be increased to cover the total treatment time.

In addition, during the full calibration, the length of the source transfer tubes, length of applicators, and function of the source transfer tubes, applicators and interfaces (10 CFR 35.633(b)) were not being performed. The AMP explained that this was done annually and at the time of each treatment, and therefore more frequent than the corresponding NRC regulation required. The AMP agreed to document this in accordance with 10 CFR 35.2632 to satisfy the documentation requirement regarding full calibrations. This was determined to be a minor violation consistent with NRC Enforcement Policy Section 2.3.1. Independent radiation surveys of the HDR remote afterloader suite confirmed licensee postings and were within regulatory limits. No issues of greater-than-minor significance were identified.

3.6. Licensee Nuclear Medicine Oversight and Miscellaneous

The inspectors reviewed several program items of note, including Radiation Safety Committee (RSC) meeting minutes, audits conducted by the licensee, audits conducted by an independent third party, and discussed program changes anticipated by the licensee at the time of the inspection.

The licensee utilized the services of a consultant to provide quarterly and annual audits of both the Nuclear Medicine and Radiation Oncology departments. The consultant's quarterly and annual reports documented the review of, but not limited to: staff training, ALARA reviews of exposure records, scanning and dosing equipment quality control and assurance, radiation survey equipment calibration, sealed source leak tests and inventory, postings, records review of surveys, waste management, dose receipt and return shipments. The consultant reports were submitted to applicable licensee supervisors and reviewed by the licensee's RSCs. The inspectors reviewed the reports and found them to be reasonably thorough and comprehensive.

The inspectors reviewed the 'variance' or incident file. The inspectors noted that the incident file was well maintained, in that the licensee was consistently documenting issues such as minor spills, errors in dosing, security infractions, losses of dosimetry, personnel exposure to x-ray radiation while conducting operating room surveys, and needlesticks. The inspectors determined that the incidents were identified and documented in a timely manner by licensee staff or supervisors but failed to follow-through with the opportunity to identify root causes or document corrective actions. When interviewed about the incidents, the supervisors stated that they did perform follow-up, but that it was rarely documented.

The licensee staff, nuclear medicine supervisor, and radiation safety officer (RSO) stated that they reviewed the incidents for trends and reported them to the RSC. The inspectors noted that many incidents were repetitive, for example spills caused by leaking intravenous connections. The inspectors impressed upon the licensee that the value in identifying incidents was to provide an opportunity to determine root causes and address them to prevent recurrences. The licensee representatives indicated that they would revise the form to include a section to record follow-up activities, such as training sessions that are conducted to address identified root causes. The representatives further stated that they would include an evaluation of the corrective actions in their trend analysis to determine if implemented corrective actions were successful.

The licensee's RSO and inspectors discussed the licensee's anticipation of submitting a license amendment to allow the start of lutetium-177 Dotatate administrations in the near future. The licensee was in the process of identifying a satisfactory location to perform the administration. The inspectors discussed with the RSO that a license amendment would be needed for the NRC to review and approve the waste procedures for the longer-lived lutetium-177m contaminate (with a 161-day half-life, this contaminant's half-life is greater than the 120-day half-life authorized to be decayed-in-storage by the licensee under the provisions of 10 CFR 35.92) known to be present in small quantities.

3.7. Yttrium-90 Microspheres

The NRC inspectors conducted a review of the licensee's yttrium-90 microsphere administrations, authorized under License Condition 6/7/8/9 G (SIR-Spheres) and H (TheraSpheres) for use or storage at the Avera McKennan Hospital in Sioux Falls (as of Amendment 79). The licensee had conducted 85 administrations of either SIR-Spheres or TheraSphere yttrium-90 microspheres since the beginning of calendar year 2018, 49 of which were conducted year-to-date 2019 through November 22, 2019. On Friday, November 22, 2019, one of the inspectors observed portions of a yttrium-90 TheraSphere administration.

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 (ADAMS Accession ML15350A099) concerning the use of microspheres, as committed to by the licensee in the October 17, 2018, amendment request (issued as part of Amendment 75), currently listed under License Condition 15.S.

Nuclear medicine personnel were involved with the yttrium-90 microsphere administrations. The technologists participated in the ordering and measuring of the yttrium-90 dose (and manipulation of the Y-90 microsphere activity for SIR-sphere administrations), radiological monitoring of personnel entrances and exits from the catheterization lab (cath lab) during the administration and taking contamination wipes following the administration. The nuclear medicine personnel did not take part in the manipulation/administration of the dose in the cath lab, and therefore, were not required to use leaded aprons or dual dosimeters, as the fluoroscope would not be operating when the nuclear medicine personnel were in the room.

3.8. Dosimetry Program

The inspector reviewed the licensee's dosimetry program with special attention to the juncture between cath lab and nuclear medicine operations. As briefly described above in Section 2.3, cath lab personnel involved with yttrium-90 microsphere procedures were involved with NRC-licensed activities, and therefore their radiation exposures must be monitored in accordance with the NRC's regulations in 10 CFR Part 20.

Cath lab technologists and the principal responsible AUs wore dedicated lead aprons with two radiation dosimeters. Cath lab nurses likewise wore lead aprons, but only wore one dosimeter. The dual dosimeters would include one dosimeter worn above the lead-shielded apron at the collar and one worn below the lead apron at the waist, and these would be exchanged on a monthly basis. The single dosimeter would be worn above the lead apron at the collar level, and likewise exchanged on a monthly basis. For

personnel using the two-dosimeter system, 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)*

For personnel using a single-dosimeter system, the dosimetry vendor used a lead correction formula tailored to a simpler approximation, "EDE2," to determine the whole-body exposure, shown below:

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

However, in the inspectors' review, the lead correction factors were inconsistently applied to the AUs', cath lab techs' and nurses' dosimeter results. This was likely in part due to the inconsistent return of dosimeters to the dosimetry vendor and, in part, due to the common issue of the return of dosimeters 'unused' to the dosimetry vendor. When lead correction factors were not applied, the whole-body exposure was assigned directly from the collar or waist dosimeter, if returned, without any lead correction factor applied. This necessarily overestimated the radiation exposure to the employees, as it discounted the substantial shielding provided by the lead apron.

In the inspectors' review of the cath lab personnel's occupational radiation exposures, the inspector observed that two of the three principal yttrium-90 AUs had exceeded NRC regulatory requirements in year-to-date 2019, with a total occupational radiation exposure of 10,114 mrem and 8,181 mrem assigned. These two AUs' (hereafter AU 1, AU 2, and their colleague, AU 3) exposures were unevenly distributed across the year and across the two dosimeters assigned to each AU.

For AU 1, the AU participated in or lead NRC-licensed activities (yttrium-90 microsphere administrations) in 2016-2019. The individual had a majority of dosimeters either returned to the dosimetry vendor as 'unused,' with no recorded exposures, or were unaccounted for (never returned to the dosimetry vendor). As a result of the lack of lead corrections being applied to AU 1 and the gaps in AU 1's occupational exposure record, the whole-body radiation exposure assigned to this individual at the time of the inspection was 10,114 mrem for calendar year 2019 through the October monitoring period, 2,390 mrem for calendar year 2018, 1,388 mrem for calendar year 2017, and zero occupational exposure for calendar year 2016.

Authorized user 2's exposure record was very similar to AU 1's: numerous unused dosimeters, unreturned dosimeters, or minimal radiation exposures recorded. As a result of the lack of lead corrections being applied to AU 2 and the gaps in AU 2's occupational exposure record, the whole-body radiation exposure assigned to this individual was 8,181 mrem for calendar year 2019 through the October monitoring period.

Authorized user 3 in contrast had relatively consistent results and with all dosimeters turned in, with one exception. With the exception of August 2019, every month had both dosimeters returned to the dosimetry vendor with radiation exposures recorded and had the EDE1 lead correction factor applied. Since the August 2019 waist dosimeter was returned to the dosimetry vendor as 'unused,' that month's whole-body exposure was assigned straight from the collar dosimeter, which invariably overestimated AU 3's occupational radiation exposure for the month. Authorized user 3's whole-body radiation

exposure assignment for calendar year 2019 through the October monitoring period was 2,171 mrem.

In accordance with the brief discussion in Section 2.3, the NRC's regulatory oversight into the persons performing or participating in interventional radiology only extends to when that individual is involved in an NRC-licensed activity. Since AUs 2 and 3 only participated in NRC-licensed activities (yttrium-90 microsphere administrations) in 2019, the inspectors limited their review of these AU's occupational exposures to 2019.

Based on interviews with the AU 3, who was onsite during the inspection and leading the TheraSphere administration observed by the inspector on November 22, 2019, AU 3 believed that the July 2019 waist dosimeter was worn for 2 months, thereby providing a potential explanation for the unused August 2019 waist dosimeter. This explanation also reasonably agreed with the licensee's later reconstruction (see Section 4.1 and 4.2) of AU 3's occupational exposure for July and August. The reconstruction calculated an estimated exposure of 192 mrem for July and August for AU 3, which was in near-agreement to the 207 mrem that was calculated if the July and August dosimeter results were combined and corrected for lead with the 'EDE1' formula.

In a single, apparently isolated instance, the licensee's physicist sent a letter dated June 26, 2019 to AU 1 regarding AU 1's calendar year 2019, Quarter 1 (January through March) exposure. The letter stated that AU 1's dosimeter reported a quarterly total of 2,989 mrem. The letter further stated that the physicist estimated AU 1's effective dose equivalent to be 897 mrem for the first 3 months of 2019, using the EDE2 lead correction factor. Finally, the letter emphasized the importance of wearing both assigned dosimeters and the State of South Dakota's rules for x-ray exposure limits.

However, this isolated response to the elevated doses recorded was inadequate in that it failed to recognize that the March dosimeters had zero recorded exposures, which was highly improbable given the frequency and type of work AU 1 conducted. Following the on-site inspection, the licensee could not identify any further instances where written communication was provided to the three subject AUs.

The licensee's RSC that had authority over matters concerning x-ray modalities recorded in its meeting minutes, dated April 11, 2018, a discussion on occupational exposure. The minutes stated:

> *The question of why the new interventional radiologist, [AU 3], had higher levels of exposure than his [peers] was discussed. The primary reason was low compliance of the other radiologists to wear their badges. [Physician-Management Representative] will discuss the issue with his colleagues encouraging greater compliance.*

The inspectors further noted that in other meetings, such as the October 5, 2016, meeting by the x-ray RSC, failed to identify that AU 1 had no radiation exposure recorded in calendar year 2016. In the inspector's interviews with AU 1 and 2, neither recollected the physician-management representative speaking with them, nor were they aware of the physician-management representative speaking to any of their peers in radiology who did not conduct work under the NRC license.

A summary of the three AUs' collar dosimeters, chest dosimeters, and assigned whole-body exposures as they appeared at the time of the inspection is provided in Attachment 1 to this enclosure.

Of the remaining cath lab personnel reviewed, no other employees were observed to have exceeded NRC regulatory requirements for occupational dose limits.

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

The licensee failed to adequately monitor the AUs' occupational exposure. During months when the AUs received minimal radiation exposures, the licensee should have recognized the implausibility of these results compared with the AU's known type and frequency of work involving radiation. Furthermore, when the AU received elevated exposure results, had no dosimeter turned in, or had unused dosimeter reported by dosimetry vendor, the licensee was obligated 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 at least 2016 to November 22, 2019, the licensee failed to adequately monitor individuals' occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, at least two individuals whose occupational exposure exceeded 10 percent of the limits in 10 CFR 20.1201(a) were not monitored over the course of at least 3 years.

The licensee's failure from at least 2016 to November 22, 2019, to adequately monitor exposure to radiation and radioactive material from exposures received at Avera McKennan was identified as an apparent violation of 10 CFR 20.1502(a). (030-11252/2019-002-01)

3.8.2. Apparent Violation 2 – 10 CFR 20.2203(a)(2)(i)

The licensee was required to provide 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 two AUs' cumulative calendar year 2019 occupational radiation exposure exceeded the NRC's annual limit with the receipt of the July 2019 monitoring period's dosimeter's exposure report. The July 2019 dosimeter report was provided by the dosimetry vendor to the licensee on August 27, 2019. Furthermore, the dosimetry vendor highlighted the exposure of the AU 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

September 27, 2019. No such report was provided to the NRC between initial discovery on August 27, 2019 to the date of the inspection on November 18-22, 2019.

The licensee physicist had been conducting quarterly 'badge reviews' of AU 1, 2, and 3's dosimetry data and generating new estimates, which were documented but not shared beyond the physicist (i.e., a 'note-to-self'). These estimates were inadequate in that they were not based on interviews with the effected AU, a review of fluoroscopy machine data or usage, or patient data, and did not account for missing or non-exposed dosimeters, and on at least one occasion could not be reproduced to demonstrate any methodology. In addition, the corrections were not tracked through the calendar year, nor sent to the dosimetry vendor for correction of the employee's estimate. Since the physicist was the only individual to receive the dosimeter report on AU 1, 2, and 3, and he had already created what he viewed as corrections to the effected individuals, he did not take any additional action when he received the dosimeter reports, and dismissed the contents.

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 more contemporaneous setting. The apparent violation is listed below:

> 10 CFR 20.2203(a)(2)(i) 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 September 27, 2019, to December 6, 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 its dosimetry vendor on August 27, 2019, of two exposures exceeding the NRC's annual dose limits for an individual and failed to provide any notification to the NRC within 30 days. A reconstruction of the subject authorized users was competed demonstrating the authorized users' dose under the 10 CFR 20.1201 occupational dose limits for adults and submitted to the NRC on December 6, 2019.

The licensee's failure from September 27 through November 22, 2019, to submit a written report within 30 days of the discovery of two AU overexposures was identified as an apparent violation of 10 CFR 20.2203(a). (030-11252/2019-002-02)

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

The licensee had a written radiation protection program to ensure compliance with the provision of 10 CFR Part 20. This program was captured in a series of protocols, procedures, and policies. These documents included but were not limited to: RS-100 "Program for Maintaining Occupational Radiation Exposures ALARA," RS-101 "Duties and Responsibilities of the Radiation Safety Officer," and S02 "Program for Maintaining Occupational Radiation Exposures ALARA in Diagnostic and Interventional Imaging." The licensee had numerous responsibilities, authorities, and obligations under its written radiation protection program that provided the tools and methods that should have provided preventative actions against, identification of, and responsive or corrective actions to potential occupational radiation overexposures of staff.

When AUs 1, 2, and 3 received elevated exposure results the licensee was obligated under its own written program, Policy Number S02, to have investigated these anomalies and, based on the results of those investigations, corrected the employee's occupational dose record. The licensee's investigation levels for radiology staff, including those involved in fluoroscopy, was 300 mrem/quarter and 400 mrem/quarter, or 150 mrem/month and 200 mrem/month, for "Level I" and "Level II," respectively. At these investigation levels, the licensee should have conducted Level II investigations on 25 occasions (using the 'monthly' trigger) for the three AUs since 2018, and for at least two additional occasions for other NRC-permitted AUs (whose recorded dosimetry results are not, at this time, being questioned for their authenticity).

The inspectors found limited inquiries were made into other staff and AU dosimetry, however the interventionalists were not identified as an issue by the x-ray RSC, with the licensee's meeting minutes noting "All values are typical for busy interventional radiology" or similar. As already noted in Section 3.8, in a single isolated instance, the radiology physicist provided a letter to AU 1 regarding the AU's dose of record and providing a new 'estimated' EDE.

The NRC identified several lapses where the licensee did not meet the obligations and requirements of its radiation protection program. From these, the NRC identified the four most significant deficiencies that most impacted the issues in the dosimetry program, and from these four drafted the apparent violation below:

> 10 CFR 20.1101(a) requires, in part, that each licensee 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 developed policies S02, "Program for Maintaining Occupational Radiation Exposures ALARA in Diagnostic and Interventional Imaging" and RS-101, "Duties and Responsibilities of the Radiation Safety Officer (RSO)," in part, to 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.
>
> Policy S02 requires, in part, that the RSO will: (1) review at least quarterly the external radiation exposures of AUs and workers (Step 3.a.2); (2) investigate all known instances of deviation from good ALARA practice and, if possible, to determine the causes, and when the cause is known will require changes in the program to maintain exposures to ALARA (Step 3.d.1); and (3) investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II (400 mrem/quarter or 200 mrem/month) and, if warranted will take action (Step 5.b.3);
>
> Policy RS-101 requires, in part, that the RSO will ensure that if violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented (Step 13).
>
> Contrary to the above, from April 11, 2018 to November 22, 2019, the license failed to 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: (1) perform quarterly reviews of

external radiation exposures of AUs and workers; (2) investigate all known instances of deviation from good ALARA practice; (3) investigate in a timely manner the cause of all personnel exposures equaling or exceeding Investigational Level II (400 mrem/quarter or 200 mrem/month); and (4) develop, implement, and document corrective actions for violations of regulations, license conditions, or program weaknesses that are identified.

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). (030-11252/2019-002-03)

3.8.4. Apparent Violation 4 – 10 CFR 19.12(a)(3)

In the inspectors' review of the licensee's training provided to staff and physicians, including AUs, the inspectors determined that the licensee failed to provide any radiation safety instruction to AUs 1, 2, and 3. No instruction or other training was provided to the AUs with regards to the expectations or logistics involving their interaction with the dosimetry program, such as what dosimeters to wear, where to wear them, or how often and how to exchange them. In addition, AUs 1, 2, and 3 were occupationally exposed to or reasonably expected to be occupationally exposed to at least 100 mrem each calendar year. The apparent violation is listed below:

> 10 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 the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.
>
> Contrary to the above, from at least 2016 to November 18, 2019, the licensee failed to provide instruction to individuals, who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instructions regarding radiation safety involving the proper use of dosimeters to three occupational workers who were likely to receive an occupational dose in excess of 100 mrem in a year, which resulted in their failure to properly wear dosimetry to monitor their exposure to occupational radiation.

The licensee's failure to provide minimum instruction to radiation workers who exceed or are expected to exceed an occupational dose of 100 mrem in a calendar year was identified as an apparent violation of 10 CFR 19.12(a)(3). (030-11252/2019-002-04)

3.8.5. Apparent Violation 5 – 10 CFR 19.13(b)(1)

The inspectors interviewed AUs 1, 2, and 3, in addition to numerous cath lab nurses and technical staff, nuclear medicine staff, and other licensee AU, in addition to reviewing documentation related to the licensee's methodology and frequency of reporting occupational exposures to individuals working under the NRC license. The inspectors determined that the licensee was adequately communicating occupational exposure to most of the radiation workers who were occupationally exposed under the NRC license,

although the method for communication varied by which Department was responsible for subject individual. However, in the case of AUs 1, 2, and 3, no such communications were identified.

Licensee supervisors and managers could not provide any proof of communication, nor did they claim that there had been communication of occupational exposure to the three AUs. The sole exception to this was the June 26, 2019, letter discussed in Section 3.8 of this report, which was provided without further discussion, context, or review with AU 1. In all three interviews conducted with AUs 1, 2, and 3, none of the AUs recalled ever having received a communication, written or otherwise, stating their occupational exposure under the NRC license. This apparent violation is listed below:

> 10 CFR 19.13(b)(1) requires, in part, that the licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if the individual's occupational dose exceeds 100 mrem total effective dose equivalent.
>
> Contrary to the above, from at least 2016 to November 18, 2019, the licensee failed to provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year when the individual's occupational dose exceeded 100 mrem total effective dose equivalent. Specifically, the licensee failed to provide radiation exposure data to three occupational workers in the course of their employment, who had exceeded 100 mrem total effective dose equivalent.

The licensee's failure to provide communication to the three AUs, who were occupationally exposed to or reasonably expected to be occupationally exposed to an excess of 100 mrem in a calendar year, regarding their occupational exposure received while working under the NRC license was identified as an apparent violation of 10 CFR 19.13(b)(1). (030-11252/2019-002-05)

3.8.6. Apparent Violation 6 – 10 CFR 35.24(f)

During the inspectors' review of the licensee's management oversight of licensed activities, the inspectors reviewed minutes for the licensee's two RSCs. Of note was the fact that the licensee cleaved the formerly singular RSC into two oversight committees in April 2018, with one principally serving the machine-generated (state-regulated) x-ray community at Avera McKennan, and one serving the RAM-using (NRC-regulated) community at Avera McKennan. There was a disconnect in that, in practice, the *administrations* of Y-90 microspheres came under the RAM committee, but the AUs fell under the x-ray committee (e.g., their dosimetry). The x-ray committee failed to understand the significance of the dosimetry results and took no meaningful corrective action when the high radiation exposures were discussed.

In the review of these minutes for both the radioactive materials RSC and the x-ray RSC, the inspectors identified a failure to represent the interventional staff on either committee. In particular, the licensee is required under 10 CFR 35.24(f) to establish an RSC to oversee all uses of byproduct material with, at a minimum, an AU of each type of use permitted under the NRC license. By not including any of the three AUs for the yttrium-90 microsphere program, the licensee lost the opportunity to bring their additional and unique expertise to the RSC, and additionally lost the input from an AU qualified in and actively practicing in the subject modality. The apparent violation is listed below:

10 CFR 35.24(f) requires, in part, that licensees shall establish a RSC to oversee all uses of byproduct material permitted by the license. The committee must include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO.

Contrary to the above, from January 25, 2018, through October 9, 2019, the licensee's RSC failed to include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Specifically, during the eight quarterly committee meetings between the above dates, there was not an authorized user on the licensee's committee to represent the 10 CFR 35.1000 yttrium-90 microsphere use.

The licensee's failure to establish an RSC to oversee all uses of byproduct material permitted by the license and include an AU of each type of use permitted by the license was identified as an apparent violation of 10 CFR 35.24(f). (030-11252/2019-002-06)

In addition, the inspectors noted that the 10 CFR 35.400 (brachytherapy), 35.600 (HDR), and 35.1000 (gamma knife) modalities, which were permitted under the NRC license, had an AU who was nominally assigned to the radioactive materials committee. However, there was no evidence that the user ever attended or contributed to the committee over the course of nearly 2 years. Following this, the AU departed from the hospital and two other AU's of similar qualification were assigned to the committee, but again did not appear to have ever attended or contributed to the committee. Furthermore, the nursing representative was either not assigned or not present for two of the four quarterly meetings in 2018. With the exception of the 10 CFR 35.400 brachytherapy (inactive since the end of 2016), each of the above quoted modalities were active in the use of radioactive material for medical practice.

4. Dose Reconstruction

As a result of the deficiencies identified in Avera McKennan's occupational dosimetry program, the NRC determined that it was necessary to reconstruct the subject AUs' occupational exposure history. Since AU 1 began conducting work under the NRC license in January 2016, the NRC determined that the reconstruction needed to include calendar year 2016 forward. AU 2 and 3 began conducting NRC-licensed activities in November and May, respectively, of 2019, and therefore their reconstructions needed to include only calendar year 2019.

The licensee aggregated the reconstruction's raw data primarily from the AUs' work with fluoroscopy and other x-ray generating machines. At Avera McKennan, 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 mathematical modeling.

4.1 Licensee Reconstruction

The licensee reconstructed the three AU's occupational exposure history. For AU 1, this effort included a period from 2016 forward, AUs 2 and 3 for calendar year 2019. The licensee utilized a physicist within Avera's corporate organization 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 fluoroscope machines that the AUs would have utilized during the subject period. 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 AUs' 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 AU's occupational exposure using the aggregated raw data on procedures from Avera McKennan. These calculations were conducted for interventional procedures and CT procedures, as these were the two routes for the subject AUs to receive occupational exposure.

The physicist produced and submitted for NRC review an initial report for each AU on December 6, 2019. Following revisions made to these documents, a final report was created and submitted for AUs 2 and 3 on December 9, 2019, and AU 1 on December 16, 2019 (publicly available copy available at the NRC's ADAMS Accessions ML19346E382 and ML19353C878 for AU 1, and ML19346E379 and ML19346E380 for AUs 2 and 3, respectively). These reports collectively describe and document the licensee's physicist's efforts and methodologies, as well the final estimates for the subject AUs' occupational exposure for the applicable calendar years.

The licensee's reports referenced above utilized a dosimetry methodology to back calculate the AU's occupational exposure histories. The methodology was to calculate the occupational radiation exposure that a physician would experience at the collar level (above the leaded apron/thyroid shield) and at the waist level (below the leaded apron), corresponding to the placement of the dosimeters in the EDE2 dosimetry vendor calculation (discussed in Section 3.8).

The licensee then used a modified EDE2 equation to generate an estimated whole-body effective dose equivalent using the machine-generated date for the dose area product or DAP. This calculation was conducted twice for each subject time period to generate a conservative, or upper-bound estimate for the AU's exposure, and a lower estimate the licensee deemed more realistic. This second estimate removed certain conservative measures, such as the decreasing the estimated distance from the midline of the patient to the AU, which would result in less scatter radiation in accordance with the inverse square law, or the increased frequency of use of an overhead shield available to the AUs. The licensee's removal of certain conservative estimates dropped the resulting exposures by approximately 45 percent for interventional radiology exposures, and 38 percent for CT-related exposures.

The realistic estimate was corroborated by comparing the results to AU 3's pre-inspection recorded dosimetry results, as AU 3 appeared to be consistent in the wearing of the assigned dosimeters (with the noted exception of August 2019's dosimeter). As was briefly mentioned in Section 3.8, this comparison allowed the licensee to demonstrate that AU 3 most likely wore the assigned July waist dosimeter for 2 months; a calculation using only the pre-inspection dosimetry data using this assumption and the EDE2 equation yields a total whole-body exposure of 207 mrem for the combined July and August 2019 period, while the licensee's recalculation methodology yields a total of between 173 mrem ("realistic" methodology) and 296 mrem (conservative methodology).

4.2 Licensee Results

The licensee's final results for calendar years 2016 through 2018 and calendar year 2019 (through the end of November) for AU 1 were a conservative estimate of 1,406 mrem, 2,650 mrem, 3,104 mrem, and 2,637 mrem, respectively. For AU 2, the conservative estimate for calendar year 2019 through the end of November was 2,128 mrem. For AU 3, the calculated conservative correction related to July and August 2019's dosimetry results concluded with 296 mrem for the combined two-month period.

The licensee also produced an estimate that took into account additional details that the licensee judged reasonable to assume but impractical or challenging to prove in practice. This more refined estimate is what the licensee deemed "realistic" and was used to correct the AUs' official occupational exposure record. This "realistic" estimate concluded a total for calendar years 2016 through 2018 and calendar year 2019 (through the end of November) for AU 1 were an estimate of 809 mrem, 1,516 mrem, 1,771 mrem, and 1,518 mrem, respectively. For AU 2, the conservative estimate for calendar year 2019 through the end of November was 1,237 mrem. For AU 3, the correction related to July and August 2019's dosimetry results concluded with a total of 207 mrem, which the licensee elected to correct by assigning 43 mrem for the month of August, such that the combined July and August 2019 totals matched the reconstruction value. This correction resulted in a corrected calendar year total of 901 mrem for 2019.

The inspector conducted an independent review of the licensee's methodology, assumptions, and mathematical results, with no significant deficiencies identified. The inspector concluded that the licensee's upper-estimate was reasonable given the data at hand, the results of interviews conducted with the AUs and involved staff, and review of the radiation producing equipment and shielding available at the facility. Therefore, it was reasonable to assume none of the subject AUs were occupationally exposed in excess of NRC regulatory limits in the applicable calendar years.

5. Corrective Actions

Upon identification by the NRC during the November 18-22, 2019, inspection, the licensee immediately arranged for an occupational exposure reconstruction for the subject AUs covering the applicable monitoring periods. 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 AUs' dose of record based on the results of the licensee's physicist's conclusions.

6. Exit Meeting Summary

From November 18-20, and November 22, 2019, the NRC inspector provided debriefs regarding the preliminary inspection findings at the conclusion of the on-site portion of the inspection each day. Avera McKennan was represented at the debriefs by:

- David Flicek – Chief Executive Officer and President of Avera McKennan
- Dr. Michael Elliott – Chief Medical Officer
- Keith Miller – Assistant Vice President of Imaging Services
- Rhonda Roesler – Chief Compliance Officer
- John Mathison – Vice President of Specialty Clinics
- Kris Gaster – Assistant Vice President of the Cancer Clinics
- Jared Hohn – Director of Radiation Oncology
- Dr. Christopher Gregory – M.D. and Physician's Director for Nuclear Medicine
- Traci Hollingshead – Radiation Safety Officer
- Michelle White – Assistant Radiation Safety Officer
- Shannon Gray – Nuclear Medicine and PET/CT Manager
- Kristin Olson – Interventional Radiology Manager
- Patty Larson – Clinical Manager 3
- Lee Kiessel – Diagnostic Physicist
- Robin Rayman – Nuclear Medicine Supervisor
- Ashley Hanson – Nuclear Medicine Mobile Coordinator
- Lynne Hagen – Human Resources Officer

On March 12, 2020, the NRC and Avera McKennan conducted a final telephonic exit briefing. Avera McKennan was represented by:

- Dr. Michael Elliott – Chief Medical Officer
- Rhonda Roesler – Chief Compliance Officer
- John Mathison – Vice President of Specialty Clinics
- Traci Nord – Director of Imaging Services
- Traci Hollingshead – Radiation Safety Officer (NRC License 40-16571-01)
- Michelle White – Radiation Safety Officer (NRC License 40-16571-02)
- Patty Larson – Clinic Manager
- Shannon Gray – PET/CT Manager
- Kristin Olson – Interventional Radiology Manager
- Ashley Hanson – Assistant RSO (NRC License 40-16571-02)
- Robin Rayman – Nuclear Medicine Supervisor

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

Authorized Users' Dosimeter Summaries

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2019			
November 2019	*current wear period		
October 2019	1,285	Unused	1,285
September 2019	1,293	Unused	1,293
August 2019	1,418	Unused	1,418
July 2019	1,645	Unused	1,645
June 2019	Unreturned	Unused	0
May 2019	Unreturned	Unused	0
April 2019	1,484	"M"	1,484
March 2019	Unused	"M"	0
February 2019	2,215	Unused	2,215
January 2019	774	Unused	774
CY2019 total	**10,114 mrem**	**0 mrem**	**10,114 mrem**

Table 1 – AU 1's 2019 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. None of the above dosimeters were processed with a lead correction factor applied.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2018	553	"M"	553
November 2018	Unused	Unused	0
October 2018	"M"	Unused	0
September 2018	Unreturned	"M"	0
August 2018	Unused	Unused	0
July 2018	Unused	Unused	0
June 2018	Unused	Unused	0
May 2018	Unused	Unused	0
April 2018	Unused	Unused	0
March 2018	1,837	Unused	1,837
February 2018	Unreturned	Unreturned	0
January 2018	Unused	Unreturned	0
CY2018 total	**2,390 mrem**	**0 mrem**	**2,390 mrem**

Table 2 – AU 1's 2018 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. None of the above dosimeters were processed with a lead correction factor applied.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2017	Unused	Unused	0
November 2017	Unused	Unused	0
October 2017	Unused	Unused	0
September 2017	Unused	Unused	0
August 2017	Unreturned	Unreturned	0
July 2017	Unused	No Waist Badge Assigned through July 2017	0
June 2017	Unused		0
May 2017	1,387		1,387
April 2017	Unused		0
March 2017	Unused		1
February 2017	1		0
January 2017	"M"		0
CY2017 total	**1,388 mrem**	**0 mrem**	**1,388 mrem**

Table 3 – AU 1's 2017 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. None of the above dosimeters were processed with a lead correction factor applied.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2016	Unused	No Waist Badge Assigned in 2016	0
November 2016	Unused		0
October 2016	"M"		0
September 2016	"M"		0
August 2016	Unused		0
July 2016	Unused		0
June 2016	Unused		0
May 2016	Unused		0
April 2016	Unused		0
March 2016	Unused		0
February 2016	Unused		0
January 2016	Unused		0
CY2016 total	**0 mrem**		**0 mrem**

Table 4 – AU 1's 2016 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. None of the above dosimeters were processed with a lead correction factor applied.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2019			
November 2019	*current wear period		
October 2019	1,593	"M"	1,593
September 2019	814	Unused	814
August 2019	397	Unused	397
July 2019	915	Unused	915
June 2019	"M"	106	106
May 2019	889	Unused	889
April 2019	"M"	Unused	0
March 2019	3,125	Unused	3,125
February 2019	342	"M"	342
January 2019	Unused	Unused	0
CY2019 total	**8,075 mrem**	**106 mrem**	**8,181 mrem**

Table 5 – AU 2's 2019 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. None of the above dosimeters were processed with a lead correction factor applied.

	Collar Dosimeter (mrem)	Chest Dosimeter (mrem)	Whole-Body Assigned (mrem)
December 2019			
November 2019	*current wear period		
October 2019	1,523	41	122
September 2019	1,675	44	133
August 2019	1,058	Unused	1,058
July 2019	1,299	75	164
June 2019	1,584	34	114
May 2019	1,460	32	106
April 2019	1,711	43	133
March 2019	708	24	64
February 2019	2,102	72	192
January 2019	972	31	85
CY2019 total	**14,092 mrem**	**396 mrem**	**2,171 mrem**

Table 6 – AU 3's 2019 dosimeter results by dosimeter (collar and chest) and whole-body assigned exposure. All of the above dosimeters were processed with a lead correction factor "EDE1" applied, with the exception of August 2019.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

David Flicek – Chief Executive Officer and President of Avera McKennan
Dr. Michael Elliott – Chief Medical Officer
Keith Miller – Assistant Vice President of Imaging Services
Rhonda Roesler – Chief Compliance Officer
John Mathison – Vice President of Specialty Clinics
Kris Gaster – Assistant Vice President of the Cancer Clinics
Jared Hohn – Director of Radiation Oncology
Dr. Christopher Gregory – M.D. and Physician's Director for Nuclear Medicine
Traci Hollingshead – Radiation Safety Officer
Michelle White – Assistant Radiation Safety Officer (Later Radiation Safety Officer for NRC License 40-16571-02)
Shannon Gray – Nuclear Medicine and PET/CT Manager (Later Manager for only PET/CT)
Kristin Olson – Interventional Radiology Manager
Patty Larson – Clinic Manager
Lee Kiessel – Diagnostic Physicist
Robin Rayman – Nuclear Medicine Supervisor
Ashley Hanson – Nuclear Medicine Mobile Coordinator (Later Assistant Radiation Safety Officer for NRC License 40-16571-02)
Lynne Hagen – Human Resources Officer

INSPECTION PROCEDURES USED

87131 - Inspection of Nuclear Medicine Programs, Written Directive Required
87132 – Inspection of Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-11252/2019-002-01	AV	Failure to monitor occupational exposure to radiation and radioactive material from exposures received at Avera McKennan. (10 CFR 20.1502(a))
030-11252/2019-002-02	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))
030-11252/2019-002-03	AV	Failure to implement portions of the Avera McKennan's written radiation protection program. (10 CFR 20.1101(a))
030-11252/2019-002-04	AV	Failure to provide instructions regarding radiation safety, specifically involving the proper use of dosimeters, to certain radiation workers. (10 CFR 19.12(a)(3))
030-11252/2019-002-05	AV	Failure to provide occupational exposure reports to certain radiation workers. (10 CFR 19.13(b)(1))

030-11252/2019-002-06	AV	Failure to ensure that an authorized user of each type of use permitted by the license was represented on the Radiation Safety Committee. (10 CFR 35.24(f))

Closed

030-11252/2018-001-01	VIO	Failure to certify that hazardous Class 7 (radioactive) materials were offered for transport in accordance with applicable requirements. (10 CFR 71.5(a) / 49 CFR 172.204(a))
030-11252/2018-001-02	VIO	Failure to monitor packages containing Class 7 (radioactive) materials as soon as practical after receipt. (10 CFR 20.190b(c))
030-11252/2018-001-03	VIO	For mobile medical services, failure to obtain a letter signed by the management of each client that permits the use of byproduct material and clearly delineates the authority and responsibility of the licensee and the client. (10 CFR 35.80(a)(1))

Discussed

030-11252/2017-001-01	VIO	Failure to properly package shipments of radioactive material that were transported on public highways. (10 CFR 71.5(a) / 49 CFR 173.410(f))
030-11252/2017-001-02	VIO	Failure to describe the hazardous material on shipping Papers. (10 CFR 71.5(a) / 49 CFR 172.200(a))
030-11252/2017-001-03	VIO	Failure to mark each package containing hazardous material for shipment. (10 CFR 71.5(a) / 49 CFR 172.300(a))
030-11252/2017-001-04	VIO	Failure to label packages for shipment. (10 CFR 71.5(a) / 49 CFR 172.400(a) / 49 CFR 172.403(c))
030-11252/2017-001-05	VIO	Failure to secure packages containing radioactive material to prevent shifting during normal transportation conditions. (10 CFR 71.5(a) / 49 CFR 173.448(a))
030-11252/2017-001-06	VIO	Failure to monitor the external surfaces of labeled packages for radioactive contamination upon receipt. (10 CFR 20.190b(b)(1))

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALARA	As-Low-As-Reasonably-Achievable
AV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
CRCPD	Conference of Radiation Control Program Directors
CT	Computed Tomography
FDG	Fluorodeoxyglucose
HIDA	Hepatobiliary Iminodiacetic Acid
ICR	Institute on Conflict Resolution [at Cornell University]
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
PET	Positron-Emission Tomography
PRN	*Pro Re Nata*
RSC	Radiation Safety Committee
SCATR	Source Collection and Threat Reduction Program
VIO	Violation