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

August 25, 2021

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

SUBJECT: NRC INSPECTION REPORT 030-39216/2021-001-AVERA MCKENNAN

Dear Mr. Flicek:

This letter refers to the announced, reactive inspection conducted beginning January 11, 2021, with in-office review through August 3, 2021. The inspection was conducted in response to a medical event that occurred at your facility on December 15, 2020, and that was reported to the U.S. Nuclear Regulatory Commission (NRC) on December 23, 2020. The inspection was an examination of activities conducted under your license as they relate to radiation safety and compliance with the Commission's rules and regulations, as well as the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records relevant to the medical event, as well as interviews with personnel. A final exit briefing was conducted telephonically with you and members of your staff on August 3, 2021. The enclosed report presents the results of this inspection.

Based on the results of this inspection, there were no violations of NRC requirements identified. Although specific violations of NRC requirements were not identified, there were numerous deficiencies identified in your radiation safety program with respect to the receipt, documentation, and transmission of physician requests for patient treatment requiring a written directive. These deficiencies were at least partially responsible for the medical event that occurred at your facility on December 15, 2020. The details of these inspection findings that did not result in cited violations are described in detail in the subject inspection report.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosure 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.

If you have any questions concerning this matter, please contact James Thompson of my staff at 817-200-1538.

Sincerely,


Signed by Roldan-Otero, Lizette
on 08/25/21

Lizette Roldan-Otero, PhD, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-39216
License No. 40-16571-02

Enclosure:
NRC Inspection Report 030-39216/2021-001

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

NRC INSPECTION REPORT 030-39216/2021-001 - DATED AUGUST 25, 2021

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.	030-39216
License No.	40-16571-02
Report:	2021-001
EN No.:	55045
Licensee:	Avera McKennan Nuclear Medicine
Location Inspected:	1325 South Cliff Avenue (Remote Inspection) Sioux Falls, South Dakota
Inspection Date:	January 11, 2021 through August 3, 2021
Inspectors:	James L. Thompson, Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety
Approved By:	Lizette Roldan-Otero, PhD., Chief Materials Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Avera McKennan Nuclear Medicine
NRC Inspection Report 030-39216/2021-001

This was an announced, special inspection beginning on January 11, 2021, that was performed in response to a medical event at Avera McKennan Nuclear Medicine (Avera) located in Sioux Falls, South Dakota, that was reported to the NRC on December 23, 2020. The medical event involved the erroneous administration of a therapeutic dose of iodine-131 instead of the intended diagnostic dose of iodine-123. Even though this administration was in accordance with the written directive, the NRC determined that a medical event did in fact occur in this case because the dose administered was the wrong radioactive drug with respect to the patient's physician's intent and original request. This report describes the findings of the special inspection.

Program Overview

Avera is authorized under the U.S. Nuclear Regulatory Commission's (NRC) Materials License 40-16571-02 to possess and use both sealed and unsealed byproduct materials for diagnostic and therapeutic medical uses at various locations in South Dakota. (Section 1)

Medical Event Causal Analysis

There were multiple contributing causes of this event, including the failure of the administering authorized user to review the patient's clinical situation prior to the administration, the failure of the authorized user that prepared the written directive to review the patient's clinical situation prior to creating the written directive, and the failure to provide the patient's physician's original order to the nuclear medicine department for review so that the written directive could be prepared in accordance with this original order. The root cause of this event was determined to be the absence of a standardized workflow methodology between Avera Centralized Scheduling and Avera's nuclear medicine department, combined with the absence of a description of duties and responsibilities for each worker within centralized scheduling and within the nuclear medicine department. (Section 4)

Inspection Findings

There were no violations identified as a result of this medical event, even though the intent of the prescribing physician for the treatment of the patient was not met. The intent of the prescribing physician was for the patient to receive a diagnostic dose of iodine-123 for a thyroid uptake scan because the patient had abnormal labs indicative of hyperthyroidism; however, due to a misunderstanding of the physician's order, the Avera authorized user created the written directive documenting that a therapeutic dose of iodine-131 was to be administered. Since the administration was in fact performed in accordance with the written directive, and since this procedure did not require that a treatment plan be created, no violation of 10 CFR 35.41(b)(2) existed. (Section 5.1)

Corrective Actions

- The licensee performed a detailed review of all iodine-131 administrations that occurred over the 6 months preceding the medical event reported on December 23, 2020, to determine if this event was isolated in nature. The results of this detailed review demonstrated that this medical event appeared to be isolated in nature. (Section 5.2)

- The licensee revised its written procedures to require that, prior to creating a written directive, the authorized user physically verify the prescribing physician's order for the treatment and also review the patient's electronic medical record, instead of solely relying on the electronic order sent from Avera Centralized Scheduling to the Avera Nuclear Medicine Department. (Section 5.2)

- The licensee also revised its procedure for ordering doses for therapeutic administrations to include the requirement for an assigned nuclear medicine worker to collect information regarding the order; this assigned worker will create a hard-copy folder to include this information and provide it to the authorized user. The authorized user will then use this information to verify that the written directive will be created in accordance with the original physician's order. (Section 5.2)

REPORT DETAILS

1 Program Overview (87131)

1.1 Inspection Scope

Beginning January 11, 2021, the NRC performed a remote, reactive, announced inspection of Avera McKennan Nuclear Medicine (Avera), with in-office reviews through August 3, 2021. The scope of the inspection was to perform a review of the licensee's radiation safety program with respect to a medical event that occurred on December 15, 2020, involving a patient receiving a therapeutic dose of iodine-131 instead of the intended diagnostic dose of iodine-123.

Within these areas, the inspection included an examination of activities conducted under the Avera license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the Avera license. The inspection consisted of a selected examination of procedures and representative records and interviews with personnel either directly or indirectly involved in the medical event.

1.2 Observations and Findings

Avera is authorized under U.S. Nuclear Regulatory Commission's (NRC's) Materials License 40-16571-02 to use byproduct material to perform both diagnostic and therapeutic medical administrations. The license authorizes Avera to perform nuclear medicine studies, to include medical therapies, out of 10 locations in South Dakota.

Avera is a large hospital complex with 10 storage and use locations in Sioux Falls, Mitchell, and Parkston, South Dakota. Therapeutic administrations in the nuclear medicine department include the use of yttrium-90 and iodine-131, as well as diagnostic administrations performed at either fixed facilities or in mobile medical applications at temporary job sites. Avera has an active radiation safety committee that meets quarterly.

2 Overview of the Medical Event (87103)

The following represents a brief overview of the timeline associated with the reported medical event that occurred at Avera on December 15, 2020, to include post-event actions taken by both the prescribing physician and Avera licensee personnel:

December 2, 2020:

- Patient had abnormal labs indicative of hyperthyroidism performed by an outside provider.
- Outside provider ordered a radioactive iodine uptake from Avera to determine a possible etiology for the hyperthyroidism.

- Outside provider met with the patient to discuss abnormal lab results and the plan for the radioactive iodine uptake scan to determine a possible cause of the patient's symptoms. A referral for endocrinology was submitted on that day.

December 7, 2020:

- Outside provider documented this order in their electronic medical system and sent a fax to Avera Centralized Scheduling. The fax sent from the outside provider stated, "Outside Provider – radioactive iodine uptake (RAIU) test", and also stated, "new diagnosis hyperthyroidism."

- Avera Centralized Scheduling then took the fax from the outside provider and created an electronic order that stated, "Test Name: NM I-131 Therapy Thyr Ablation," and also stated, "Reason for Visit: New Diagnosis Hyperthyroidism."

NOTE: Avera Centralized Scheduling made a phone call to Avera Nuclear Medicine Scheduling to better understand what "RAIU" meant. The question was misunderstood, and the answer provided was that it was for a low dose, 15-millicurie iodine-131 dose.

- The electronic order was then sent to nuclear medicine, and the original fax from the outside provider was never sent to nuclear medicine or scanned into the patient's electronic medical record.

December 8, 2020:

- The authorized user on duty (AU1) created a written directive from the electronic order provided by Avera Centralized Scheduling for precisely what the electronic order stated: iodine-131, Sodium Iodide Capsule, 15 millicuries; it was then signed and dated by AU1.

NOTE: AU1 did not review the patient's hard-copy chart/folder because one did not exist, as it was never created; further, AU1 did not check the patient's electronic medical record prior to creating the written directive.

December 11, 2020:

- Patient met with an Avera endocrinologist via telehealth encounter and spoke to the outside provider after the encounter on the same day and agreed with the plan for the radioactive iodine uptake scan (using iodine-123) to be performed. His encounter note specified, "Once iodine scan completed start methimazole 20 mg daily." Having the patient meet with the endocrinology doctor was to establish a specialized treatment plan.

December 15, 2020:

- On the day of the patient administration, a different authorized user (AU2) was on duty. AU2 and the other nuclear medicine staff present for the treatment followed Avera's written procedures by performing a "time-out." This time-out is performed to ensure that the administration that is about to be performed is in accordance with the written directive.

NOTE: AU2 did not review the patient's hard-copy chart/folder because one did not exist; further, AU2 did not check the patient's electronic medical record prior to administering the iodine-131 sodium iodide capsule.

- When all agree that the dosage is the same as what the written directive states, the "time-out" is documented and signed/dated, and the patient is administered 15.8 millicuries of encapsulated iodine-131 sodium iodide.

December 17, 2020:

- Avera sent documentation of the ablation that was performed on December 15th to the patient's outside provider, and this is when the outside provider identified the mistake of administration of a therapeutic dose of iodine-131 instead of a diagnostic dose of iodine-123.

- The outside provider contacted the patient's endocrinologist after receiving documentation of the ablation, vice uptake study.

December 18, 2020:

- The outside provider contacted Avera's Medical Director to discuss an apparent error in the treatment that was requested for the patient; however, the outside provider was not sure if the error was made when their office placed the order for the scan with Avera or if it occurred afterwards.

December 18-23, 2020:

- Avera staff discussed the issues surrounding the reported error in patient treatment; confusion existed on what went wrong, due to the fact that the patient treatment matched the written directive. On December 22, 2020, Avera staff researched the endocrinologist physician's notes, and the intended order for an iodine-123 scan and uptake was located. The next day, Avera reported this misadministration as a medical event to the NRC.

December 28, 2020:

- The outside provider met with the patient to discuss the mistaken thyroid ablation and to update the treatment plan.

- The patient continues to be monitored remotely by the Avera endocrinologist. The patient's next telehealth encounter is scheduled in April 2021.

3 Extent of Condition Analysis

As a result of the medical event, and at the request of the NRC, Avera personnel performed an analysis of the possibility of previous events such as this one by reviewing all of the iodine-131 administrations that occurred within the 6 months preceding the medical event that occurred on December 15, 2020.

In all, 30 iodine-131 administrations were reviewed; this review analyzed comparisons between each administration and the clinical notes in the patient's chart and/or electronic medical record. Each entry noted the date of administration, indication of illness, clinical notes, activity to be administered on the written directive, and the actual administered activity in millicuries.

No instances of unidentified medical events were discovered during this analysis. All 30 of the iodine-131 administrations were administered in accordance with the written directives, and all 30 of the written directives were created in accordance with the prescribing physician's intent and clinical diagnosis.

4 Causal Evaluation of the Reported Medical Event (87103)

4.1 The Licensee's Causal Evaluation

The licensee performed a causal analysis and submitted it to the NRC as an attachment to their 15-day written report dated January 4, 2021. The licensee determined that the contributing cause of the medical event was that a miscommunication existed between Avera Centralized Scheduling and Avera Nuclear Medicine scheduling. When Avera Centralized Scheduling received the fax requesting an "RAIU" scan for a hyperthyroid diagnosis, they called Avera Nuclear Medicine to ask what "RAIU" meant. The nuclear medicine technologist replied that if it was for hyperthyroidism, then it would be a low-dose iodine-131 therapy. Avera Centralized Scheduling then used this information to create the electronic order for a 15 millicurie iodine-131 therapy treatment and sent the electronic order to nuclear medicine.

The licensee further stated that the probable root cause of the medical event was the failure of the authorized user to review the patient's clinical situation prior to creating the written directive. In this case, the authorized user that created the written directive relied on the information provided in the electronic order.

4.2 The NRC's Causal Evaluation

The NRC determined that there existed numerous factors that contributed to the medical event, including both personnel and processes in place at the time of the event, in multiple areas of operations within the Avera facility. The NRC also determined that a singular root cause was associated with the medical event, as described below.

4.2.1 Contributing Causes of the Medical Event

- The physician authorized user that administered the therapeutic dose of iodine-131 to the patient failed to review the patient's clinical situation beforehand and relied solely on the information provided in the written directive. This is an important aspect of this causal analysis because the authorized user that administered the dose of iodine-131 was different than the authorized user that created the written directive. Had the authorized user that administered the dose reviewed the patient's clinical situation prior to the administration, instead of assuming that the authorized user that created the written directive had done so, the medical event may have been avoided.

- The physician authorized user that created the written directive failed to review the patient's clinical situation beforehand and relied solely on the information provided in the electronic order sent to the nuclear medicine department from Avera Centralized Scheduling. This was a crucial omission because Avera Centralized Scheduling had created and sent to nuclear medicine an erroneous electronic order for a 15-millicurie iodine-131 treatment, instead of the physician's intended order for a diagnostic dose of iodine-123 for a thyroid uptake scan. Had the authorized user reviewed the patient's clinical situation prior to creating the written directive, instead of assuming that the nuclear medicine technologist had done so, the medical event may have been avoided.

- One of the nuclear medicine technologists on duty the day of the medical event misunderstood a question from Avera Centralized Scheduling and incorrectly answered the question, stating that the patient needed an iodine-131 low dose therapy instead of a thyroid uptake scan. This occurred due to a misunderstanding by Avera Centralized Scheduling of the meaning of the acronym "RAIU" in the original physician's order.

- The information in the original order received by Avera Centralized Scheduling from the patient's physician is never forwarded to the nuclear medicine department. Instead, this information, sometimes in the form of a facsimile, is entered into the patient's electronic medical record and in the electronic order that is sent to nuclear medicine; the original order is then oftentimes discarded. Had the physician's original order been maintained and forwarded to nuclear medicine, the authorized user that created the written directive may have identified the discrepancy, and the medical event may not have occurred.

During interviews with Avera staff members involved with the medical event, one overarching sentiment was observed; most stated that no one has the time to print out the electronic medical record and/or put together a hard copy file for each patient receiving a therapy procedure requiring a written directive, especially for the orders that come in to Avera from external physicians. Oftentimes, according to the interviewees, information involving the patient's clinical situation is not available for review in the electronic medical record or in a hard-copy file at the time of administration. It was suggested by some staff that if neither of these are available for the authorized users to review, then the administration should simply be postponed until the requisite information is available.

4.2.2 Root Cause of the Medical Event

The root cause of the medical event was determined by the NRC to be the lack of a standardized workflow methodology between Avera Centralized Scheduling and the nuclear medicine department, as well as within the nuclear medicine department itself. Additionally, there existed an absence of a description of duties and responsibilities for each worker within centralized scheduling and within the nuclear medicine department. This is important because, during interviews with staff, it became apparent that each staff member thought it to be the responsibility of other staff members to perform certain duties. For instance, each thought it to be the responsibility of another to print out information from the electronic medical record and/or electronic order and create a hard-copy file for each patient. Some believed that this action should be performed by Avera Centralized Scheduling, some believed that this action should be performed by the

nuclear medicine technologists, and some believed that this action should be performed by the authorized users that either created the written directive or that administered the dose. Had there existed a written expectation on the duties and responsibilities of each staff member, as well as a standardized workflow methodology describing what should be performed/documented at what point during the process of receiving and transmitting orders for patient treatments requiring a written directive, the medical event would likely not have occurred.

4.3 Conclusions Regarding the Causal Analyses

Although the NRC's causal analysis was in general agreement with Avera's causal analysis, there were differences in the determination of likely root causes of the medical event. Avera determined that the likely root cause of the medical event was the failure of the authorized user that created the written directive to check the patient's clinical situation prior to creating the written directive.

NRC believes that the true root cause of the medical event goes further than the creation of the written directive itself, because the authorized user had created the written directive based on erroneous information; this erroneous information was provided to the nuclear medicine department in the electronic order sent from Avera Centralized Scheduling. No hard copy of the original order was provided for the authorized user to reference, as there was no requirement or procedure/written process in place at Avera to maintain and forward this original physician's order.

In summary, the root cause of the medical event was not due to incorrect information present in the written directive (although it was certainly a contributing factor), but was due to the absence of a standardized workflow methodology between Avera Centralized Scheduling and Avera Nuclear Medicine that described the roles and responsibilities of each department, as well as those within each department, with regards to therapy procedures requiring a written directive.

5 Inspection Findings and Corrective Actions (87131)

5.1 Inspection Findings

There were no violations identified as a result of this medical event, even though the intent of the prescribing physician was not met. The intent of the prescribing physician was for the patient to receive a diagnostic dose of iodine-123 for a thyroid uptake scan because the patient had abnormal labs indicative of hyperthyroidism; however, due to a misunderstanding of the physician's order, the Avera authorized user created the written directive documenting that a therapeutic dose of iodine-131 was to be administered. Since the administration was in fact performed in accordance with the written directive, and since this procedure did not require that a treatment plan be created, no violation of 10 CFR 35.41(b)(2) existed.

5.2 Corrective Actions

The licensee revised their written procedures to require that, prior to creating a written directive, the authorized user verify that a therapeutic administration is what the prescribing physician intended by reviewing the physician's order and the patient's

electronic medical record. It was also discussed during the inspection that a thyroid uptake scan should also be present in the patient's file for review by the authorized user prior to the creation of a written directive authorizing the administration of a therapeutic dose of iodine-131.

6 Exit Meeting

On August 3, 2021, a final telephonic exit meeting was conducted with multiple members of Avera's staff, to include Avera's President and Chief Executive Officer. The licensee acknowledged the inspector's findings and results of the causal analysis and did not dispute any of the details presented during the exit call.

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

David Flicek, President and Chief Executive Officer
Michael Elliott, Avera Medical Director
Christopher Gregory, Avera Authorized User
Brad Paulson, Avera Authorized User
Kevin Casper, Avera Authorized User
Michelle White, Avera Radiation Safety Officer

INSPECTION PROCEDURES USED

87131	Nuclear Medicine Programs, Written Directive Required
87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

None

Closed

None

Discussed

03039216/21001-01	The reporting requirements found in 10 CFR 35.3045(a)

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
CFR	*Code of Federal Regulations*
NRC	Nuclear Regulatory Commission
Avera	Avera McKennan Nuclear Medicine
RAIU	Radioactive Iodine Uptake