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

January 30, 2020

EA-19-132

Jim Gillhouse
Chief Operating Officer
St. Joseph Regional Medical Center, Inc.
504 Sixth Street
Lewiston, Idaho 83501

SUBJECT: NRC INSPECTION REPORT 030-32211/2019-001

Dear Mr. Gillhouse:

This letter refers to the unannounced routine inspection conducted on July 8-9, 2019, and October 21, 2019, at your facility in Lewiston, Idaho, with in-office review through December 26, 2019. The purpose of the inspection was to examine activities conducted under your license as they relate to safety and 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 Ms. Denice Smith, Director - Imaging Services & Radiation Oncology, and Dr. Douglas Heidorn, Radiation Safety Officer, on July 8, 2019, and again on October 21, 2019. A final exit briefing was conducted telephonically with you and members of your staff on January 21, 2020.

Based on the results of this inspection, five 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) prepare written directives that were dated and signed by an Authorized User before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material; (2) ensure that written directives contained all required information; (3) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (4) appoint a Radiation Safety Officer, who agrees in writing, to be responsible for implementing the radiation protection program; and (5) conduct the program in accordance with the statements, representations, and procedures referenced in the license. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during the telephonic exit meeting on January 21, 2020.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a predecisional enforcement conference (PEC) or (2) 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 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 an enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: http://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the 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 A. Silva of my staff at 817-200-1455.

Sincerely,

/RA/

Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket No.: 030-32211
License No.: 11-27371-01

Enclosure:
NRC Inspection Report 030-32211/2019-001

cc w/enc.:
Mark Dietrich
Radiation Control Program Director
Idaho Department of Environmental Quality
1410 North Hilton Drive
Boise, ID 83706

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-32211
License No.:	11-27371-01
Inspection Report No.:	2019-001
EA No.:	EA-19-132
Licensee:	St. Joseph Regional Medical Center, Inc.
Location Inspected:	415 Sixth Street Lewiston, Idaho
Inspection Dates:	Onsite: July 8-9, 2019, and October 21, 2019 In-office review: through December 26, 2019
Exit Meeting Date:	January 21, 2020
Inspector:	Janine F. Katanic, PhD, CHP, Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety
Approved By:	Patricia A. Silva, Chief Materials Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

St. Joseph Regional Medical Center, Inc. (SJRMC)
NRC Inspection Report 030-32211/2019-001

On July 8-9, 2019, and October 21, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an unannounced routine inspection at the licensee's facility in Lewiston, Idaho, with in-office review through December 26, 2019. The purpose of the inspection was to examine activities conducted under the license as they relate to safety and compliance with the NRC's rules and regulations and with the conditions of the license. The inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The Inspection Report describes the findings of the inspection.

Program Overview

St. Joseph Regional Medical Center, Inc., was authorized under its NRC license to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facility in Lewiston, Idaho. (Section 1)

Background

On January 31, 2019, the NRC issued a Non-Cited Violation for the licensee's failure to ensure that licensed materials only be used by or under the supervision of Authorized Users as indicated on the license. This violation was related to three incidents where an Authorized User prescribed and administered quantities of iodine-131 sodium iodide that were greater than what the Authorized User was authorized in the license. (Section 2)

Inspection Observations and Findings

The inspection identified five apparent violations that involved the licensee's failure to: (1) prepare written directives that were dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material; (2) ensure that written directives contained all required information; (3) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (4) appoint a Radiation Safety Officer, who agrees in writing, to be responsible for implementing the radiation protection program; and (5) conduct the program in accordance with the statements, representations, and procedures referenced in the license. (Section 3)

Corrective Actions

On July 9, 2019, the licensee committed to develop revisions to its procedures for administrations requiring a written directive, committed to perform a causal analysis related to the identified deficiencies, and decided to put a portion of its program on hold until it could develop and implement appropriate corrective actions. On October 21, 2019, the inspector returned to the facility and found that the licensee had not finalized any procedure revisions, nor had the causal analysis been performed, but the licensee had resumed activities. An additional example of an improperly prepared written directive was identified. (Section 4)

REPORT DETAILS

1. Program Overview (Inspection Procedures 87131 and 87132)

1.1. Program Scope

St. Joseph Regional Medical Center, Inc., (SJRMC) was authorized under its U.S. Nuclear Regulatory Commission (NRC) Materials License 11-27371-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facility in Lewiston, Idaho.

1.2. Inspection Scope

On July 8-9, 2019, the NRC performed an unannounced, routine inspection at the licensee's facility in Lewiston, Idaho. In an effort to gather additional information regarding the preliminary inspection findings and the licensee's corrective actions, the NRC continued its unannounced, routine inspection on October 21, 2019, at the licensee's facility in Lewiston, Idaho. The NRC performed in-office reviews through December 26, 2019.

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

The inspection also reviewed an incident that was described by SJRMC to the NRC in November 2018 regarding an Authorized User (AU) administering a quantity of radioactive byproduct material that exceeded the quantity that the AU was authorized on the NRC license.

2. Background (Inspection Procedures 87131 and 87132)

2.1. Licensee's November 29, 2018 Amendment Request

On November 29, 2018, SJRMC submitted a license amendment request to the NRC requesting that two AUs be removed from the SJRMC NRC license. The amendment request described an incident that occurred at SJRMC when an AU listed on the NRC license prescribed and administered 150 millicuries of iodine-131 sodium iodide, but the AU was only authorized on the NRC license to prescribe 33 millicuries or less of iodine-131 sodium iodide. The amendment request letter described that the incident occurred on July 7, 2018, but the Radiation Safety Officer (RSO) only became aware of the incident during a tumor board meeting on November 8, 2018. After the incident was discussed at the licensee's Radiation Safety Committee (RSC) meeting on November 29, 2018, the licensee decided that as a corrective action, it would submit a license amendment request to the NRC to remove two AUs from the license. The licensee believed that a similar incident could be prevented by amending the license to remove two AUs who no longer worked at the SJRMC facility. The licensee's amendment request described that a copy of the amended license would be provided to its vendors who provide radioactive byproduct materials for medical use.

2.2. NRC's Evaluation of Licensee's November 29, 2018 Amendment Request

The NRC performed a contemporaneous in-office review of the information provided by the licensee in its November 29, 2018, license amendment request. The NRC inquired whether a review had been performed of other administrations of iodine-131 sodium iodide, in order to establish whether this incident was an isolated occurrence. On January 10, 2019, the licensee's RSO responded that iodine-131 sodium iodide cases were reviewed and found that there were two additional cases where an AU listed on the NRC license prescribed and administered 50 millicuries of iodine-131 sodium iodide, but the AU was only authorized on the NRC license to prescribe 33 millicuries or less of iodine-131 sodium iodide. It was noted that one case occurred on May 8, 2018, and the other on May 30, 2018. The RSO noted that each of the three cases (May 8, 2018, May 30, 2018, and July 7, 2018) involved the same AU.

On January 24, 2019, the RSO provided additional information to the NRC describing the licensee's review and indicated that there was an additional case identified from December 27, 2017, where a patient was administered 159 millicuries of iodine-131 sodium iodide but at the time there was an AU listed on the SJRMC NRC license who was authorized to administer this quantity.

As corrective actions, the RSO noted that he spoke with the nuclear medicine technologists, the Radiology Director, and the Radiologist (AU) and established an understanding that there would be no more iodine-131 sodium iodide cases for administrations greater than 33 millicuries. Cases above 33 millicuries would be referred to another authorized NRC or Agreement State licensee.

Based on the NRC's contemporaneous review of the information provided by the licensee, on January 31, 2019, the NRC issued a Non-Cited Violation (NCV) for the licensee's failure to follow License Condition (LC) 12 of NRC Byproduct Materials License 11-27371-01, which required, in part, that licensed materials only be used by or under the supervision of AUs as indicated on the license (NRC Agencywide Documents Access and Management System (ADAMS) Accession No. ML19060A190). (030-32211/2018-001-01).

The NCV identified three occasions in May and July 2018 where licensed materials were used by or under the supervision of an AU differently than indicated on the license. In the NCV, the licensee's corrective actions were noted as: (1) providing training to the AU; (2) requesting a license amendment to remove authorization for quantities of iodine-131 sodium iodide for greater than 33 millicuries for any AU; and (3) referring administrations greater than 33 millicuries to other licensed facilities. This was identified by the NRC as an NCV because it met the criteria in the NRC's Enforcement Policy, Section 2.3.2, in that the licensee identified the violation, the licensee corrected or committed to correct the violation within a reasonable time period by specific corrective action, the violation was not repetitive, and the violation was not willful.

3. Inspection Observations and Findings (Inspection Procedures 87131 and 87132)

The July 8-9, 2019, and October 21, 2019, unannounced routine inspection identified five apparent violations that involved the licensee's failure to: (1) prepare written directives that were dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed

byproduct material or any therapeutic dose of radiation from byproduct material; (2) ensure that written directives contained all required information; (3) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (4) appoint a Radiation Safety Officer, who agrees in writing, to be responsible for implementing the radiation protection program; and (5) conduct the program in accordance with the statements, representations, and procedures referenced in the license.

3.1. Licensed Activities requiring a Written Directive

The license authorized several activities requiring a written directive. Specifically, the license authorized activities under 10 CFR Part 35, Subpart E, Unsealed Byproduct Material – Written Directive Required, referred to as 10 CFR 35.300, and the license also authorized activities under 10 CFR Part 35, Subpart F, Manual Brachytherapy, referred to as 10 CFR 35.400.

Under the licensee's 10 CFR 35.300 authorization, the licensee used unsealed byproduct material that required a written directive for administrations of iodine-131, sodium iodide, radium-223 dichloride, and samarium-153 administrations. Since the previous NRC routine inspection on June 1, 2016, the licensee performed 35 administrations of iodine-131 sodium iodide; 27 administrations of unsealed byproduct material in the form of radium-223 dichloride; and one administration of unsealed byproduct material in the form of samarium-153 that required a written directive.

Under the licensee's 10 CFR 35.400 authorization, the licensee used sealed sources containing palladium-103 for the treatment of prostate cancer using permanent implant manual brachytherapy. Since the previous NRC routine inspection on June 1, 2016, the licensee performed 16 therapeutic doses of radiation from byproduct material from palladium-103 for permanent implant manual brachytherapy. The licensee's permanent implant manual brachytherapy program was in abeyance since February 2018. This was due to the fact that since February 2018 there were no AUs working at the licensee to perform this activity, and since February 2019 there were no longer any AUs listed on the license that were authorized for this activity. The last permanent implant manual brachytherapy procedure was performed at the facility on June 16, 2017.

3.2. Authorized Users for Procedures Requiring a Written Directive

Since the previous NRC routine inspection on June 1, 2016, several changes have occurred with regard to the licensee's AUs. For the purposes of this Inspection Report, the AUs will be referred to as AU1, AU2, AU3, and AU4.

The four AUs had been authorized on the SJRMC NRC license for the following licensed activities requiring written directives:

AU1: Oral administration of sodium iodide in quantities less than or equal to 33 millicuries
AU2: 10 CFR 35.300, 10 CFR 35.400
AU3: 10 CFR 35.300, 10 CFR 35.400
AU4: Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV

The following presents a timeline regarding AU activities and authorizations on the SJRMC NRC license:

August 2017	AU2 leaves the licensee's employment, but the license is not amended to remove AU2.
February 2018	AU3 leaves the licensee's employment, but the license is not amended to remove AU3. AU3's departure results in no AU working at the SJRMC facility who can sign written directives for: (1) iodine-131 sodium iodide in quantities greater than 33 millicuries, and (2) manual brachytherapy.
November 29, 2018	Licensee amendment request notifies the NRC of the July 7, 2018, incident.
February 28, 2019	License Amendment No. 15 issued, removing AU2 and AU3 from the license. This leaves the following AUs listed on the license for procedures requiring a written directive as: (1) AU1 for oral administration of iodine-131 sodium iodide in quantities less than or equal to 33 millicuries, and (2) AU4 for parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV (i.e. radium-223 dichloride and samarium-153).

3.3. Apparent Violations

3.3.1. Apparent Violation 1

During the inspection conducted on July 8-9, 2019, the inspector performed a 100 percent review of all written directives that were prepared since the last routine inspection on June 1, 2016. This consisted of 63 written directives for administrations under 10 CFR 35.300 and 16 written directives for administrations under 10 CFR 35.400. The review also included a focused evaluation of the May 8, 2018, May 30, 2018, and July 7, 2018, administrations of iodine-131 sodium iodide that were the subject of the NCV issued by the NRC on January 31, 2019.

The initial case that the NRC was notified about was for a written directive prepared, dated, and signed by AU1 on June 15, 2018, for the administration of 150 millicuries of iodine-131 sodium iodide. In this case, the measured activity delivered to the patient was 153 millicuries on July 7, 2018.

The second case was for a written directive prepared, dated, and signed by AU1 on May 1, 2018, for the administration of 50 millicuries of iodine-131 sodium iodide. In this case, the measured activity delivered to the patient was 53 millicuries on May 8, 2018.

The third case was for a written directive prepared, dated, and signed by AU1 on May 25, 2018, for the administration of 50 millicuries of iodine-131 sodium iodide. In this case, the measured activity delivered to the patient was 53 millicuries on May 30, 2018.

The inspector also reviewed the fourth case that was identified but later dismissed by the licensee. In this case, the RSO concluded that there was a written directive that had

been prepared, dated and signed by an AU that was not authorized for the quantity administered, but that there was an AU working at the facility that was authorized for this activity, so the case did not need to be included. Based on a review of the records provided by the licensee, the inspector determined that the RSO's conclusion was unsound. The inspector found that in this case, AU1 prepared, dated, and signed a written directive on December 18, 2017, for the administration of 150 millicuries of iodine-131 sodium iodide. The measured activity delivered to the patient was 159 millicuries on December 22, 2017. The RSO had dismissed this case because AU3 was still employed at the facility and was authorized for this activity. The inspector's review of the patient file for this case found no evidence that AU3 had any involvement in the case. The RSO erroneously inferred that AU3's employment at the facility excused the fact that AU1 had prepared, dated, and signed a written directive for an activity for which AU1 was not authorized. The RSO stated that AU1 may have been working under the supervision of AU3, but the RSO acknowledged that there were no records to indicate that, and that if it were to have been the case, the written directive would have needed to have been prepared, dated, and signed by AU3 as opposed to AU1.

During the inspector's review of the licensee's written directives, the inspector also identified three cases where there was no written directive prepared, dated, or signed by an AU. The cases were as follows: (1) 32.9 millicuries of iodine-131 sodium iodide administered on April 23, 2019; (2) 16.0 millicuries of iodine-131 sodium iodide administered on May 6, 2019; and (3) 21.3 millicuries of iodine-131 sodium iodide administered on May 16, 2019. In each of the patient files, there was a patient referral for the procedures from a physician, such as an endocrinologist, who were not AUs listed on the SJRMC NRC license. The patient referrals described the clinical indications that necessitated the administration of iodine-131 sodium iodide. None of the three cases had written directives that were dated and signed by an AU. However, each of the three cases had written annotations in the margin that stated "I agree (with) dose" that were dated May 31, 2019, and signed by AU1. The inspector interviewed AU1 regarding these annotations. In response, AU1 stated that he was unable to provide any reason as to why there were no written directives prepared, signed, or dated prior to these administrations. During the interview, AU1 remembered that the case files were brought to him after the fact, on May 31, 2019, and that he reviewed them and concluded that since it was after the fact and the administrations occurred, he could not prepare, date and sign written directives being as this would not be consistent with the regulatory requirements. However, he stated that he made the annotations because he felt that had he been asked to prior to the administrations, he would have "agreed with" the dose to be administered based on the clinical information in the patient referrals.

At the conclusion of the inspection on July 9, 2019, the inspector discussed the above matters with licensee representatives. As a result, the licensee decided that they would put iodine-131 sodium iodide administrations that required a written directive on hold until they could develop and implement appropriate corrective actions. When the inspector returned to the licensee facility on October 21, 2019, the inspector was informed that the iodine-131 sodium iodide administrations that required a written directive had recently resumed. Only one such administration had been performed since the program had been taken off hold. The inspector reviewed the written directive, which was for the administration of 15 millicuries of iodine-131 sodium iodide. The written directive was prepared and signed by AU1 but was not dated as required. In

this case, the measured activity delivered to the patient was 16.3 millicuries on September 26, 2019.

The licensee's manual brachytherapy program was no longer active at the time of the inspection, but the inspector reviewed the case files for the 16 cases that had been performed since the previous NRC inspection. For these administrations, the licensee was not using a standard or specific written directive form. Rather, there were records, such as a needle loading report, that were generated prior to the procedures, that were reviewed by the AU prior to the administration. In some of those cases, the documents were signed and dated by the AU prior to the administration. However, it was identified that 12 therapeutic doses of radiation from byproduct material from palladium-103 had written directives that were signed, but not dated by an AU.

The apparent violation is provided below:

> 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.
>
> Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to prepare written directives that were dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.
>
> Specifically,
>
> (1) On December 18, 2017, May 1, 2018, May 25, 2018, and June 15, 2018, written directives for administrations of iodine-131 sodium iodide greater than 33 millicuries were dated and signed by an individual that was not authorized under NRC License No. 11-27371-01 as an AU for 10 CFR 35.300 or for oral administration of iodine-131 sodium iodide in quantities greater than 33 millicuries.
>
> (2) On April 23, 2019, May 6, 2019, and May 16, 2019, the licensee administered iodine-131 sodium iodide greater than 30 microcuries and the licensee failed to prepare written directives for these administrations.
>
> (3) On September 26, 2019, the licensee administered iodine-131 sodium iodide greater than 30 microcuries and the written directive was not dated by an AU.
>
> (4) Between June 1, 2016, and October 21, 2019, the licensee administered 12 therapeutic doses of radiation from byproduct material from palladium-103 and the written directives were not dated by an AU.

The licensee's failure to prepare written directives that were dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material was identified as an apparent violation of 10 CFR 35.40(a). (030-32211/2019-001-01)

3.3.2. Apparent Violation 2

The inspector's review of the written directives prepared by the licensee also included a review of the content that is required to be provided in written directives. Of the 27 written directives reviewed for administrations of radium-223 dichloride, it was found that sixteen written directives did not contain the route of administration. While it is widely known that the radioactive drug radium-223 dichloride, known commercially as Xofigo, is administered via intravenous injection, the regulations nevertheless require that the route of administration be documented on the written directive. There were also two written directives that had a numerical value for the activity to be administered (i.e. 127.3) but did not contain the unit of activity (i.e. microcuries) and therefore the written directives did not contain the dosage as required. Again, although it is widely known that the radioactive drug radium-223 dichloride, known commercially as Xofigo, is administered in microcurie quantities, the regulations require that the dosage be documented on the written directive.

The apparent violation is provided below:

> 10 CFR 35.40(b)(2) requires, in part, that the written directive must contain for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration.
>
> Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to ensure that written directives contained, for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration.
>
> Specifically, for therapeutic dosages of unsealed radium-223:
>
> (1) Sixteen written directives did not contain the route of administration.
>
> (2) Two written directives did not contain the dosage (did not contain the units of activity to specify the dosage).

The licensee's failure to ensure that written directives contained the information required by regulation was identified as an apparent violation of 10 CFR 35.40(b)(2). (030-32211/2019-001-02)

3.3.3. Apparent Violation 3

The licensee had written procedures for administrations requiring written directives. These procedures were reviewed during the inspection.

For iodine-131 sodium iodide administrations, the licensee had a procedure titled, "Radiopharmaceutical Quality Management Program – Iodine-131," revised on March 25, 2013, and reviewed by the licensee on January 9, 2017. In this procedure, it is noted that on a quarterly basis, the RSC will review all patients who have received iodine-131 during the quarter. This review by the RSC was not occurring and no one appeared to be tasked with this quarterly review of all patients who had received iodine-131 during the quarter.

For manual brachytherapy procedures, the licensee had a procedure titled "Brachytherapy Quality Management Program – Permanent Prostate Seed Implants," revised on February 21, 2011, and reviewed by the licensee on January 9, 2017. In this procedure it is noted that following the completion of each brachytherapy implant there will be a complete audit by the physicist and/or dosimetrist of the implant. Although the final doses delivered to the target organ and adjacent tissue were being evaluated, there was no evaluation or audit of the case file to review whether a properly prepared written directive had been prepared, dated, and signed by an AU prior to the administration.

For administrations of radium-223 dichloride, the licensee had a procedure titled "Radiopharmaceutical Quality Management Program – Xofigo," issued on July 29, 2013. This procedure incorrectly listed the prescribing information to be 1.35 millicuries per kilogram of body weight, whereas the vendor's prescribing information is 1.49 microcuries per kilogram of body weight. In the procedure, it is noted that the RSC will review all patients who have received a Xofigo injection during the previous quarter. This review by the RSC was not occurring and no one appeared to be tasked with this quarterly review of all patients who had received a Xofigo injection during the previous quarter.

The apparent violation is provided below:

> 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Specifically,
>
> (1) Regarding the licensee's procedure "Radiopharmaceutical Quality Management Program – Iodine-131," revised on March 25, 2013, and reviewed by the licensee on January 9, 2017, the licensee failed to implement the "Audit Program" of the procedure, which states, in part, that "the Radiation Safety Committee will review all patients who have received iodine-131 during the quarter."
>
> (2) Regarding the licensee's procedure "Brachytherapy Quality Management Program – Permanent Prostate Seed Implants," revised on February 21, 2011, and reviewed by the licensee on January 9, 2017, the licensee failed to implement the "Audit Program" of the procedure, which states, in part, that "Following the completion of each brachytherapy implant there will be a complete audit by the physicist and/or dosimetrist of the implant."
>
> (3) Regarding the licensee's Procedure, "Radiopharmaceutical Quality Management Program – Xofigo," issued on July 29, 2013, the licensee failed to: (a) correctly specify the activity of radium-223 to be administered per kilogram body weight; and (b) implement the "Audit Program" of the procedure, which states, in part, that "the Radiation Safety Committee will review all patients who have received a Xofigo injection during the previous quarter."

The licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive was identified as an apparent violation of 10 CFR 35.41(a)(2). (030-32211/2019-001-03)

3.3.4. Apparent Violation 4

The NRC's regulations require that a licensee's management shall appoint an RSO, who agrees in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Based on the inspector's observations of the licensee's procedures requiring a written directive, the inspector inquired as to the RSO's oversight of the license's radiation safety program and whether there was a documented delegation of authority to the RSO.

During the onsite inspection on July 8, 2019, the inspector requested to review the delegation of authority memo, but the licensee was unable to locate one. Although the individual was the appointed SJRMC RSO for many years, it did not appear that a delegation of authority memo was ever signed where the RSO accepted this responsibility in writing. As a corrective action, on July 9, 2019, the Director - Imaging Services & Radiation Oncology provided the inspector with a new delegation of authority memo that had been prepared for the RSO. It was signed by the Chief Financial Officer on July 8, 2019, and by the RSO on July 9, 2019. The inspector reviewed the delegation of authority memo and noted that it stated that the RSO was free to raise issues with the California Department of Public Health, Radiologic Health Branch. The inspector pointed out that this should have instead said that the RSO was free to raise issues with the U.S. NRC, since the licensee's facility was located in Idaho, an NRC state, and was not located in California. The licensee was asked by the inspector to revise the memo and to provide a copy to the inspector following the inspection. A revised memo was not provided to the inspector.

When the inspector returned to the facility on October 21, 2019, and inquired as to the status of the revised memo, the licensee provided a blank template delegation of authority memo indicating that issues could be reported to the U.S. Nuclear Regulatory Commission. However, this template was not completed by the licensee in that there was no RSO name, and it was not signed or dated by licensee management or the RSO.

The licensee provided a Position Description & Analysis document for the position of Medical Physicist being as the RSO is also a medical physicist at the licensee facility. The document noted that an essential duty is to perform the duties as the RSO. This document is a position description and not a delegation of authority.

The apparent violation is provided below:

> 10 CFR 35.24(b) requires, in part, that a licensee's management shall appoint an RSO, who agrees in writing, to be responsible for implementing the radiation protection program.
>
> Contrary to the above, from June 1, 2016, to October 21, 2019, the licensee's management failed to appoint an RSO, who agreed in writing, to be responsible for implementing the radiation protection program.

The licensee's failure to appoint an RSO, who agreed in writing, to be responsible for implementing the radiation protection program, was identified as an apparent violation of 10 CFR 35.24(b). (030-32211/2019-001-04)

3.3.5. Apparent Violation 5

During the July 8-9, 2019, inspection, the inspector reviewed the licensee's program documents to verify the commitments made by the licensee in accordance with the statements, representations, and procedures contained in the documents listed in the license, often referred to as "tie-down" documents. One of the tie-down documents, Email with attachments dated March 18, 2013, contains a statement that was checked "Yes" by the licensee to indicate: "We have developed and will implement and maintain written procedures for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

During the inspection, the inspector asked to review the referenced procedure. The licensee could not produce the procedure and there was a lack of familiarity with the license commitment. The licensee provided the inspector with a procedure for the use of sealed sources, as opposed to unsealed byproduct material, however even that procedure was noted as being a draft procedure which had not been finalized. The inspector afforded the licensee the opportunity to search its records to find a written procedure for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301. When the inspector returned to the facility to continue the inspection on October 21, 2019, the licensee had not been able to locate a written procedure for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301, and had not developed a procedure that would meet the license commitment.

The apparent violation is provided below:

> NRC License 11-27371-01, Amendment Numbers 11 - 15, require, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in Emails with attachments dated March 18, 2013. Email with attachments dated March 18, 2013, contains a statement that was checked "Yes" by the licensee to indicate "We have developed and will implement and maintain written procedures for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."
>
> Contrary to the above, from December 3, 2014, to October 21, 2019, the licensee failed to conduct its program in accordance with Emails with attachments dated March 18, 2013. Specifically, the licensee failed to develop, implement, and maintain written procedures for the safe use of unsealed byproduct material that met the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

The licensee's failure to conduct its program in accordance with the statements, representations, and procedures contained in the license, was identified as an apparent violation of NRC license 11-27371-01, Amendment Numbers 11 - 15. (030-32211/2019-001-05)

3.4. Causal Factors

The causal factors that contributed to the apparent violations include: (1) lack of RSO oversight of the licensee's program for administrations requiring a written directive; (2) lack of AU understanding of license authorization quantities; (3) deficiencies in licensee administrative processes; and (4) inadequate procedures for administrations written directives.

The RSO, who is also a medical physicist at the facility, is rather busy with radiation oncology duties and did not have time for much involvement with or oversight of nuclear medicine activities, such as those involving administrations of iodine-131 sodium iodide or radium-223 dichloride requiring a written directive. The RSO relied on the experience level and high competence of the nuclear medicine technologists and quarterly reviews performed by a consultant. However, even when the consultant identified issues with written directives, the licensee failed to perform adequate corrective actions. For example, a review performed by the consultant on May 22, 2019, identified instances of administrations with no written directives. No attempt was made by the licensee to understand why there were no written directives as required. The licensee simply attempted to correct the record by AU1 making annotations in the margin of the patient files after the fact. These annotations indicated that the administrations were clinically acceptable.

The RSO was directly involved in the permanent implant manual brachytherapy program, as this was directly related to radiation oncology duties. However, the RSO relied on informal communication methods with the AU and did not insist on strict adherence to regulatory requirements, such as those for written directives. For example, the RSO stated that the AU's review of the manual brachytherapy treatment plan would suffice as meeting the requirements for written directives and that most of the patients received a standard dose which was known prior to preparing a treatment plan. In order to provide high confidence that administrations will be in accordance with written directives, therapeutic procedures should be performed based on a written directive that is reviewed, signed, and dated by the AU prior to the administration.

For many years there were three AUs on the SJRMC NRC license for iodine-131 administrations requiring a written directive. As noted in Section 3.2, one AU could authorize 33 millicuries or less, and the other two AUs could authorize any amount requiring a written directive. For the AUs that could authorize any amount requiring a written directive, one left the facility in August 2017 and the other in February 2018, although the license was not amended at that time to make the corrections. During interviews with AU1, who is authorized for the administration of 33 millicuries or less of iodine-131 sodium iodide, he stated that he believed that he could authorize the administration of greater than 33 millicuries. In this regard, AU1 believed that he had authorized such quantities in the past at another licensed facility. However, neither AU1 nor the RSO have been able to produce any documentation or records to support this statement. Accordingly, the licensee has not requested an amendment to the SJRMC NRC license to amend AU1's authorization.

Deficiencies in licensee administrative practices were also a contributing factor. The SJRMC nuclear medicine department was staffed by three nuclear medicine technologists who worked alternating schedules. Although the licensee had three nuclear medicine technologists, only one was responsible for all nuclear medicine

procedures requiring a written directive. This was based on a SJRMC administrative practices decision to restrict involvement in these types of procedures to one specific nuclear medicine technologist. This nuclear medicine technologist had administrative control of all nuclear medicine procedures requiring a written directive and did not utilize peer checks or reviews by the other two nuclear medicine technologists. The use of peer checks or secondary reviews by the other nuclear medicine technologists might have identified the deficiencies with the written directives in some cases, or the lack of written directives in other cases.

As another example of a deficiency in administrative practices, the SJRMC NRC license was not amended in a timely manner when the two AUs that were authorized for the administration of any amount requiring a written directive left the facility. Therefore, the vendor radiopharmacy was unaware of any staffing changes. As a result, when doses greater than 33 millicuries of iodine-131 sodium iodide were ordered by SJRMC, the vendor radiopharmacy continued to send those doses. After the July 7, 2018 incident was identified by the licensee, a license amendment request was submitted to the NRC on November 29, 2018, to remove the two AUs who left the facility from the license. In the license amendment request, the RSO noted, "I will send the amended license to our vendors so that they will be able to verify that we do not have anyone listed for 10 CFR 35.300." However, during the inspection, the vendor radiopharmacy was contacted and stated that the most current version of the SJRMC license that it was provided by SJRMC was Amendment No. 10, dated March 27, 2013. Meaning, the vendor radiopharmacy still did not have the revision to the SJRMC NRC license reflecting that SJRMC was only authorized for the administration of 33 millicuries or less of iodine-131 sodium iodide. Therefore, the vendor radiopharmacy could have continued to provide greater quantities if they had been ordered by SJRMC. During the inspection performed on July 8-9, 2019, after NRC prompting, Amendment No. 15, dated February 28, 2019, was provided by the licensee to the vendor radiopharmacy.

Finally, although the licensee had procedures for the various types of administrations requiring a written directive, the procedures were inadequate and were not being fully implemented by the licensee. As a result, the procedures did not provide high confidence that each administration would be in accordance with the written directive.

3.5. Conclusions

Five apparent violations of NRC requirements were identified involving the licensee's failures to: (1) prepare written directives that were dated and signed by an Authorized User before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material; (2) ensure that written directives contained all required information; (3) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (4) appoint a Radiation Safety Officer, who agrees in writing, to be responsible for implementing the radiation protection program; and (5) conduct the program in accordance with the statements, representations, and procedures referenced in the license.

The licensee's failures related to procedures requiring a written directive were programmatic in nature. The identified deficiencies existed for various types of administrations performed under 10 CFR 35.300 as well as administrations performed

under 10 CFR 35.400. Deficiencies in properly prepared written directives were not limited to an isolated occurrence but rather were associated with multiple occurrences. Although the licensee had procedures for activities requiring written directives, these procedures were not being fully implemented and failed to provide high confidence that administrations would be in accordance with written directives.

4. Corrective Actions (Inspection Procedures 87131 and 87132)

The NCV that was issued by the NRC on January 31, 2019, was predicated, in part, on the corrective actions taken by or committed to be taken by the licensee to correct the violation within a reasonable time period. Although the licensee took corrective actions to provide informal training to AU1, request a license amendment to remove the authorization for quantities of iodine-131 sodium iodide for greater than 33 millicuries, and refer administrations greater than 33 millicuries to other licensed facilities, these corrective actions were inadequate to fully address the programmatic nature of the deficiencies. The licensee did not promptly notify the vendor radiopharmacy of the amended license and did not take actions to review and revise its procedures for administrations requiring a written directive. As a result, additional deficiencies occurred in this program area.

Each of the identified issues described in the apparent violations were discussed with the RSO and licensee management on July 9, 2019. The inspector emphasized the need for prompt and comprehensive actions that would correct the identified issues and prevent recurrence of the issues. The licensee committed to develop revisions to its procedures for administrations requiring a written directive. During the inspection, AU1 and the RSO could not provide a rationale for why there were no written directives for three procedures, and the nuclear medicine technologist responsible for these types of procedures was not available to be interviewed. The licensee agreed to review the matter and to perform a causal analysis related to why there were some procedures that required written directives but were performed with no written directives. At the conclusion of the inspection on July 9, 2019, the licensee decided that they would put iodine-131 sodium iodide administrations that required a written directive on hold until they could develop and implement appropriate corrective actions.

On October 21, 2019, the inspector returned to the facility and found that the licensee had not finalized any procedure revisions, nor could it provide an explanation as to why there were three administrations with no written directives, but the licensee had resumed activities. The inspector identified that after the licensee resumed activities, there was one administration of iodine-131 sodium iodide that had occurred, and this was an additional example of an improperly prepared written directive. There had been seven administrations of radium-223 dichloride since July 9, 2019. In these cases, AU4 had modified the written directive form as a corrective action, and in all cases, for this type of administration, there were no further instances of written directives that did not contain the required information.

5. Exit Meeting Summary

The preliminary inspection findings were discussed with Ms. Denice Smith, Director, Imaging Services & Radiation Oncology, and Dr. Douglas Heidorn, Radiation Safety Officer, on July 8, 2019, and again on October 21, 2019.

A final telephonic exit meeting was conducted on January 21, 2020. The licensee was represented by Mr. Jim Gillhouse, Chief Operating Officer, Ms. Denise Smith, Director, Imaging Services & Radiation Oncology, and Dr. Doug Heidorn, Radiation Safety Officer.

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

Supplemental Inspection Information

LIST OF PERSONS CONTACTED

Denice Smith, Director, Imaging Services & Radiation Oncology
Douglas Heidorn, PhD, Radiation Safety Officer
Paul Sanchirico, MD, Authorized User
Terry Morton, Nuclear Medicine Technologist
Dominic Fiorino, Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

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

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-32211/2019-001-01	AV	Failure to prepare written directives that were dated and signed by an AU before the administration of iodine-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. (10 CFR 35.40(a))
030-32211/2019-001-02	AV	Failure to ensure that written directives contained the information required by regulation. (10 CFR 35.40(b)(2))
030-32211/2019-001-03	AV	Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. (10 CFR 35.41(a)(2))
030-32211/2019-001-04	AV	Failure to appoint an RSO, who agrees in writing, to be responsible for implementing the radiation protection program. (10 CFR 35.24(b))
030-32211/2019-001-05	AV	Failure to conduct its program in accordance with the statements, representations, and procedures contained in the license. (NRC license 11-27371-01, Amendment Numbers 11 – 15)

Closed

None

Discussed

030-32211/2018-001-01	NCV	Failure to ensure that licensed materials were only used by or under the supervision of authorized users as indicated on the license. (LC 12, Amendment No. 15, dated February 28, 2019)

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
LC	License Condition
NCV	Non-Cited Violation
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SJRMC	St. Joseph Regional Medical Center

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

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