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

February 2, 2018

EA-17-182

Robert Honeycutt
Chief Operating Officer
Providence Alaska Medical Center
3200 Providence Drive
P.O. Box 196604
Anchorage, AK 99519-6604

SUBJECT: NRC INSPECTION REPORT 030-13426/2017-001 AND NOTICE OF VIOLATION

Dear Mr. Honeycutt:

This letter refers to the special inspection conducted June 27-30, 2017, at your facility in Anchorage, Alaska. The inspection was conducted in response to a medical event that occurred on June 14, 2017, and was reported to the U.S. Nuclear Regulatory Commission (NRC) Operations Center (Event Notification 52807) on June 15, 2017. The enclosed report presents the results of this inspection. The inspectors discussed the preliminary inspection findings with you and members of your staff on June 30, 2017, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and members of your staff on January 3, 2018.

The medical event involved the administration of yttrium-90 (Y-90) TheraSphere® glass microspheres for radioembolization of blood vessels in the liver. The right lobe of the patient's liver received 54,000 centigray (rad) instead of the intended prescribed dose of 11,000 centigray (rad). We initiated a special inspection to review the circumstances surrounding the event, including: (1) developing a sequence of events associated with the medical event; (2) evaluating your staff's investigation and causal analysis; (3) reviewing other Y-90 procedures to determine if there were previous unidentified medical events; (4) reviewing your facility's Y-90 administration procedures; (5) reviewing and assessing your corrective actions; (5) reviewing the radiation dose to the patient's liver and other potentially exposed organs or tissues; and (6) clarifying the difference between the intended and actual dose delivered.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The circumstances surrounding these apparent violations, the significance of the associated issues, and the need for lasting and effective corrective action were discussed with you at the conclusion of the onsite inspection and during the final telephonic exit briefing.

Before the NRC makes its enforcement decision, we are providing you with an opportunity to: (1) request a predecisional enforcement conference (PEC) or (2) request alternative dispute

resolution (ADR). Please contact Mr. Michael C. Hay at 817-200-1455 within 10 days of the date of this letter to notify the NRC of your intended response.

If you choose to request a PEC, it will be open for public observation and the NRC will issue a meeting notice to announce the time and date of the conference. 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. 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. You can find the Information Notice on the NRC Web site at http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. A PEC should be held within 30 days of the date of this letter.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. ADR sessions are not conducted with public observation though the outcome of the ADR agreement is made public.

Since the NRC has not made a final determination in this matter, a Notice of Violation (Notice) is not being issued for these inspection findings at this time. 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.

Additionally, based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. This violation was evaluated in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed Notice. The violation is being cited in the enclosed Notice because it was identified by the NRC during the special inspection. The violation involved the failure of your Radiation Safety Committee to meet at least once each calendar quarter.

You are required to respond to the Notice in Enclosure 1 and should follow the instructions specified in the Notice when preparing your response. As previously discussed, 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. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 Mr. Michael C. Hay of my staff, at 817-200-1455.

Sincerely,

/RA/

Scott A. Morris
Deputy Regional Administrator

License No. 50-17838-01
Docket No. 030-13426

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-13426/2017-001

cc w/Enclosures:
Dr. Bernd Jilly, State of Alaska Radiation Control Program Director

NOTICE OF VIOLATION

Providence Alaska Medical Center
Anchorage, Alaska

Docket No. 030-13426
License No. 50-17838-01
EA-17-182

During an NRC inspection conducted June 27-30, 2017, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> License Condition 18 of NRC License Number 50-17838-01, Amendments 67-69, require, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in License Condition 18.
>
> License Condition 18, documents received on May 1, 2015, provides the licensee's Radiation Safety Program Manual, dated May 9, 2014. The Radiation Safety Program Manual section titled "Radiation Safety Committee" requires, in part, that the Radiation Safety Committee shall meet at least once in each calendar quarter.
>
> Contrary to the above, from February 1 to March 31, 2016, and from July 1 to September 30, 2016, the licensee failed to assure that the Radiation Safety Committee met at least once in each calendar quarter. Specifically, the licensee's Radiation Safety Committee did not did not meet in the first quarter and in the third quarter of 2016.

This is a Severity Level IV violation. (NRC Enforcement Policy Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, Providence Alaska Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-17-182" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 2nd day of February 2018

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.	030-13426
License No.	50-17838-01
Report No.	030-13426/2017-001
EA No.	EA-17-182
Licensee:	Providence Alaska Medical Center
Facility:	3200 Providence Drive Anchorage, Alaska
Inspection Dates:	Onsite June 27-30, 2017 In-office review through January 3, 2018
Exit Meeting Date:	January 3, 2018
Inspectors:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Licensing and Inspection Branch Division of Nuclear Materials Safety, Region IV Pete J. Hernandez Health Physicist Materials Licensing and Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved by:	Michael C. Hay Chief, Materials Licensing and Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Providence Alaska Medical Center (PAMC)
NRC Inspection Report 030-13426/2017-001

During June 27-30, 2017, the NRC conducted a special inspection at the licensee's facility in Anchorage, Alaska. In-office review was conducted through January 3, 2018. The inspection was conducted in response to a medical event that occurred on June 14, 2017, and was reported to the NRC Operations Center on June 15, 2017. The medical event involved the administration of yttrium-90 (Y-90) TheraSphere® glass microspheres for radioembolization of blood vessels in the liver. The licensee reported to the NRC that the right lobe of the patient's liver received 54,000 centigray (rad) instead of the Authorized User's (AU's) intended prescribed dose of 11,000 centigray (rad).

Program Overview

Providence Alaska Medical Center is authorized under NRC Materials License Number 50-17838-01, to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulations* (10 CFR) Part 35. One of the authorized licensed activities is the use of Y-90 TheraSphere® glass microspheres under the provisions of 10 CFR 35.1000.

Causal Analysis

The licensee's preliminary causal analysis concluded that the following contributed to the occurrence of the medical event: ordering the dose with the wrong calibration date; and the written directive not being prepared and signed by an AU prior to the administration. In addition, the licensee indicated that the measurements of the vial of Y-90 by the Nuclear Medicine Supervisor "did not rouse attention by comparison to the calculated data."

The inspectors determined that the direct cause of the medical event was the administration of an incorrect activity of Y-90 TheraSphere® microspheres to the right lobe of the patient's liver. The inspectors identified that contributing causes of the medical event were: training inadequacies; deficiencies in policies and procedures; and the lack of a properly prepared, dated, and signed written directive. The inspectors determined that the root cause of the medical event can be attributed to the failure on the part of PAMC management, the PAMC Radiation Safety Committee, and the PAMC Radiation Safety Officer to adequately oversee and manage the risks associated with the PAMC Y-90 TheraSphere® program.

Inspection Findings

Three apparent violations were identified regarding the licensee's failure to: (1) have written directives dated and signed by an AU before the administration of therapeutic doses of radiation from byproduct material; (2) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; and (3) provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. One Severity Level IV violation was identified regarding the licensee's failure to assure that its Radiation Safety Committee met at least once in each calendar quarter.

Corrective Actions

The licensee's proposed corrective actions included: providing additional radiation safety training to the Nuclear Medicine Supervisor and the Director of Radiology; providing additional TheraSphere® training to the other nuclear medicine technologists; developing process improvements to ordering TheraSphere® microspheres; developing process improvements regarding the signing and reviewing of written directives by AUs, and confirming the dose to be administered prior to the start of the procedure; implementing the use of time-outs in the interventional radiology suite prior to the procedure; hiring an additional medical physicist; conducting a Radiation Safety Committee meeting; and continuing to perform medical follow-up of the patient.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87103, 87132)

1.1 Program Scope

Providence Alaska Medical Center (PAMC) is authorized under NRC Materials License Number 50-17838-01, to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulations* (10 CFR) Part 35. One of the authorized licensed activities is the use of yttrium-90 (Y-90) under the provisions of 10 CFR 35.1000. Licensed activities are authorized to be performed at the licensee's facility located in Anchorage, Alaska. At the time of the inspection, the licensee's Radiation Safety Officer (RSO) was also the PAMC Chief Medical Physicist.

1.2 Inspection Scope

This inspection report is limited to observations and findings related to the licensee's use of Y-90 TheraSphere® glass microspheres under the provisions of 10 CFR 35.1000. The inspectors observed licensed activities at the licensee's facilities, reviewed records, procedures, and documents maintained by the licensee, and interviewed licensee personnel. The inspectors also obtained and reviewed additional documents provided by the licensee following the inspection. Collectively, the activities observed, interviews conducted, and documents reviewed described the licensee's implementation of its program for the medical use of Y-90.

2 Background (IP 87103, 87132)

2.1 Inspection Scope

The inspectors reviewed records, procedures, documents maintained by the licensee, and interviewed licensee personnel. The inspectors also reviewed literature and training materials regarding Y-90 TheraSphere® glass microspheres.

2.2 Observation and Findings

During June 27-30, 2017, a special inspection was performed to review the circumstances surrounding a medical event that occurred on June 14, 2017. The medical event involved the administration of Y-90 TheraSphere® glass microspheres for radioembolization of blood vessels in the liver. TheraSphere® is a type of brachytherapy device that consists of insoluble glass microspheres in which Y-90, a beta particle emitter, is an integral constituent of the glass. TheraSphere® procedures are performed for radioembolization of blood vessels in the liver. The microspheres become embolized within the tumor vasculature and are retained within the tumor. The procedure can be performed as a palliative therapy or as a means to downstage tumors as a pathway to other therapeutic procedures.

Various clinical factors, such as the amount of extrahepatic lung shunting, are evaluated by medical professionals prior to selecting TheraSphere® as the desired therapeutic protocol. As part of the treatment planning, technetium-99m macroaggregated albumin (Tc-99m MAA) is used to identify and evaluate the percentage of shunting of

microspheres to the lungs. If in the AU's medical opinion this lung shunt fraction is too high, Y-90 microsphere therapy may not be selected because it may cause undue radiation dose to the lungs. If the clinical factors indicate, in the AU's medical opinion, that Y-90 TheraSphere® microsphere therapy is appropriate, the AU must determine the appropriate activity of Y-90 to be administered to the patient to deliver the desired radiation dose.

TheraSphere® microspheres are supplied by the manufacturer in six standard activity vials or are available as a custom activity vial. The "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" is an electronic form that is provided by the manufacturer as a treatment planning tool and can be used to assist in selecting the appropriate activity vial of Y-90 to be ordered, based on the desired radiation dose, timing of the administration (e.g. time zone, date, and time of day), lung shunt fraction, dose to the lungs and anticipated residual waste. After this information is entered into the electronic form, the form auto-populates and displays various treatment options in a matrix according to the six standard available vial sizes and planned treatment week. Treatment options are displayed for the first and second week after the manufacturer's activity calibration. The vial activities are calibrated by the manufacturer for Sundays at noon Eastern Time. Radiation dose values that fall within the "treatment window" of +/- 20 percent of the desired radiation dose are displayed in bold font on the matrix, for ease of selecting an appropriate activity vial and desired treatment week and day. Vials of different activities of Y-90 have different numbers of microspheres per vial. Generally, to deliver the same radiation dose, a vial of Y-90 used during the second week after the manufacturer's activity calibration has decayed further, resulting in more microspheres delivered than a vial of Y-90 used the first week after the manufacturer's activity calibration. As a result, AUs may have a preference to perform the administration during the first or second week depending on patient specific considerations.

After the vials are ordered, they are delivered to the facility. The microspheres are supplied in a 1.0 milliliter V-bottom vial, within a clear acrylic vial shield, that has a label that indicates the date of calibration, activity, and other information. This vial is further contained in a lead shield that also has a label that indicates the date of calibration, activity, and other information. This lead shield is then shipped to the facility within appropriate packaging that is marked and labeled for transportation.

When the package arrives at the facility, it should be received in accordance with licensee-established procedures. The patient vial is supposed to be ordered so that it is the appropriate activity at the date and time of administration; therefore, no manipulation of the contents of the vial is necessary. The facility should follow its established protocols or license conditions to prepare the vial for administration, such as measuring the vial in a dose calibrator to verify the activity prior to administration. Additionally, a written directive should be properly prepared, dated, and signed by an AU prior to the procedure.

TheraSphere® microspheres are delivered to the patient via an infusion through catheterization of an artery that leads to the tumor site. The procedure is therefore normally performed in an interventional radiology suite. After the patient has been catheterized and is ready for the procedure, the vial of Y-90 is placed into an acrylic box that has been equipped with a single-use administration set. The administration set

consists of a series of one-way valves, tubing, and an injector assembly that is deployed by an AU to administer the Y-90 to the patient.

The TheraSphere® administration kit comes with an electronic dosimeter that can be monitored by the AU during the Y-90 infusion process. The readings on the electronic dosimeter provide an indication of the contents of the vial and can be used as an indication that the Y-90 has been flushed from the vial and tubing and has been infused to the patient.

At the completion of the infusion procedure, the administration kit is disassembled, radiation surveys are performed, and any waste is collected for final measurement and disposal.

3 Event Chronology (IP 87103)

3.1 Inspection Scope

The inspectors reviewed records, procedures, and documents maintained by the licensee and interviewed licensee personnel. Following the onsite inspection, the inspectors reviewed additional records, procedures, and documents that were provided by the licensee.

3.2 Observation and Findings

On August 7, 2013, NRC License 50-17838-01, Amendment No. 62 was issued to PAMC, authorizing the use of Y-90 TheraSphere® glass microspheres under the provisions of 10 CFR 35.1000. The PAMC license authorizes four AUs for the medical use of Y-90 TheraSphere® glass microspheres. Two AUs were involved with the medical event: AU1 was approved for the use of Y-90 TheraSphere® glass microspheres in Amendment No. 62, issued on August 7, 2013 and AU2 was approved for the use of Y-90 TheraSphere® glass microspheres in Amendment No. 66, issued on November 7, 2015.

On February 7, 2017, the patient had a Y-90 TheraSphere® procedure performed at PAMC. Prior to the procedure, the patient's lung shunt fraction was determined to be 6.20 percent. The right lobe and left lobe of the patient's liver were treated. The AU's prescribed dose to the right lobe of the patient's liver was 11,000 centigray (rad) and the licensee determined that the Y-90 administration resulted in the delivery of 9,770 centigray (rad). The AU's prescribed dose to the left lobe of the patient's liver was 11,000 centigray (rad) and the licensee determined that the Y-90 administration resulted in the delivery of 10,900 centigray (rad). Both administrations were within an acceptable range of the prescribed dose. The licensee determined that the administrations resulted in the patient's lungs receiving 873 centigray (rad). This information is taken into consideration when planning further Y-90 procedures on the patient.

The following is a sequence of events that preceded and immediately followed the medical event referenced in this report:

May 5, 2017

- The patient's referring physician ordered Y-90 radioembolization and non-radioactive chemoembolization for liver lesions resulting from secondary malignant neoplasm of the liver.

Between May 5-June 2, 2017

- The PAMC Nurse Scheduling Coordinator reviewed the medical information, including the results of the patient's lung shunt fraction determination, prior radiation dose to the lungs, and the results of the patient's previous Y-90 TheraSphere® procedure. The Nurse Scheduling Coordinator took into account the dates and times of AU and patient availability and prepared several "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" forms for the procedure.

- AU1 reviewed the treatment planning forms along with the patient's information and selected a vial activity size and a treatment date by circling values on the forms. One form was completed for the planned treatment to the right lobe of the patient's liver; a second form was completed for the planned treatment to the left lobe of the patient's liver.

- AU1 spoke with AU2 about the planned Y-90 procedure because although AU1 planned the treatment, due to scheduling, AU2 was going to administer the Y-90 to the patient.

June 2, 2017

- The two "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" forms, one for the left lobe of the liver and one for the right lobe of the liver, were placed in the Nuclear Medicine Supervisor's chair in the nuclear medicine department.

- Based on the values circled by AU1 on the forms, the Nuclear Medicine Supervisor ordered two vials of Y-90 TheraSphere® microspheres using the TheraSphere® online ordering form. Based on the Nuclear Medicine Supervisor's interpretation of AU1's circled values on the TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator forms, the following vials were ordered:

    - Y-90; 20 GigaBecquerel (GBq) vial; calibrated for June 11, 2017; for June 14, 2017 treatment date.

    - Y-90; 8 GBq vial; calibrated for June 11, 2017; for June 14, 2017 treatment date.

    - This order indicated that both vials were to be used for treatment during the first week after calibration, as opposed to the second week after calibration.

- The Nuclear Medicine Supervisor received an email from the vendor that confirmed the information for the two vials ordered.

June 12, 2017

- Two packages, each containing one vial of Y-90, arrived in the Nuclear Medicine Department and were checked in by the Nuclear Medicine Supervisor. The packages were surveyed and checked for removable contamination on the outside and inside of the box. The manufacturer-provided Calibration Data Sheets contained in the packages matched the quantities and calibration date for the two ordered vials.

June 14, 2017

- In the interventional radiology suite, the patient was prepped for the procedure and a time out was performed to verify the patient's identity, that the correct procedure was going to be performed, and patient known allergy check. The interventional radiology staff set up and primed the TheraSphere® administration kit in preparation for the procedure.

- Concurrently, in the nuclear medicine department, the Nuclear Medicine Supervisor performed actions to prepare for the procedure. The actions were documented on a "Therasphere Checklist" (Checklist) that was an enclosure to PAMC Departmental Policy 198.536, "Theraspheres Therapy." The Nuclear Medicine Supervisor measured the vials of Y-90 in the dose calibrator. The vial for the right lobe of the liver was measured in the dose calibrator and recorded on the Checklist as 8.55 GBq. The manufacturer's activity at the time of calibration was decay corrected by the Nuclear Medicine Supervisor and documented as 8.52 GBq. The dose rate at 11 inches from the vial was measured and documented as 8.1 millirem/hour.

- Back in the interventional radiology suite, during the catheterization process, AU2 performed chemoembolization (non-radioactive) of selected vessels in the liver. AU2 found that the vascularity of the left hepatic artery appeared decreased and elected to not perform Y-90 radioembolization of the left lobe of the liver.

- AU2 proceeded to catheterize the right hepatic artery of the patient's liver. When the catheter was in position and AU2 was ready, the Nuclear Medicine Department was called to bring the Y-90 to the interventional radiology suite.

- The Nuclear Medicine Supervisor placed the two shielded vials of Y-90 on a cart, along with a survey meter, and brought them to the interventional radiology suite. Upon arrival, the Nuclear Medicine Supervisor was informed by AU2 that only the right lobe of the patient's liver was going to be treated.

- The Nuclear Medicine Supervisor placed the vial of Y-90 into the administration kit. AU2 asked the Nuclear Medicine Supervisor "Is that the right/correct dose?" which the Nuclear Medicine Supervisor interpreted to mean "Is this the dose for the right lobe of the liver?" The Nuclear Medicine Supervisor confirmed that the vial of Y-90 was indeed the one intended for the right lobe of the liver.

- When the vial of Y-90 and tubing were in position, a member of the interventional radiology team read aloud the value of 27.6 millirem/hour that was displayed on the electronic dosimeter that was attached to the administration kit. The Nuclear Medicine Supervisor recorded the value on the Checklist.

- The interventional radiology team performed the final assembly of the administration kit and AU2 flushed the infusion catheter to assure satisfactory flow.

- At 14:40 local time, AU2 commenced the administration of Y-90 TheraSphere® microspheres to the right lobe of the liver. After three flushes of the administration kit, the electronic dosimeter was read and recorded as zero (0) millirem/hour. At 14:43, the administration was documented as complete.

- The catheter was withdrawn from the patient, the administration kit was disassembled, and the components were placed into a waste container. The Nuclear Medicine Supervisor recorded the radiation levels from the patient on the Checklist and returned to the Nuclear Medicine Department with the cart, the waste container, and the unused Y-90 vial for the left lobe of the liver. The patient was moved to a recovery area and AU2 went to a work area to prepare for another procedure.

- Following the steps in the Checklist, the Nuclear Medicine Supervisor entered the data into the written directive. The written directive is a spreadsheet-based form that contains blank spaces for relevant data. When the data is entered into the written directive form, certain values, such as the radiation dose to the liver, are populated into the form. When the data was entered into the written directive, and the calculated results were populated onto the form, the Nuclear Medicine Supervisor realized that an error occurred. One indicator of an error was that the radiation dose to the liver was determined to be 54,000 centigray (rad) instead of the AU's intended prescribed dose of 11,000 centigray (rad). Additionally, the overall percent delivery of the dose to the right lobe of the liver is targeted to be 100 percent, but in this case it was determined to be 491 percent, in other words, a difference of 391 percent, indicating a radiation dose to the liver that was significantly higher than intended.

- Approximately 30-45 minutes after the conclusion of the administration, the Nuclear Medicine Supervisor informed AU2 that an error had occurred. Subsequently, the RSO and PAMC administration were notified of the error.

- AU2 notified the patient and the patient's spouse of the delivery of a higher than anticipated dose of Y-90 and left a message for the referring physician regarding the delivery of a higher than anticipated dose of Y-90 to the patient.

- AU2 signed but did not date the written directive that had been completed by the Nuclear Medicine Supervisor following the procedure.

4 Notifications and Reports to the NRC (IP 87103)

4.1 Inspection Scope

The inspectors reviewed reports submitted by the licensee, and interviewed licensee personnel. Following the onsite inspection, the inspectors reviewed additional records and documents that were provided by the licensee.

4.2 Observation and Findings

On June 15, 2017, the licensee contacted the NRC's Operations Center to report a medical event in accordance with 10 CFR 35.3045(a)(1) (Event Number 52807). 10 CFR 35.3045(a)(1) requires, in part, that a licensee report any event in which the administration of byproduct material results in a dose that differs from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue, and the total dose delivered differs from the prescribed dosage by 20 percent or more. For the purposes of this report 1 rem = 1 rad. The licensee determined that the right lobe of the patient's liver received 54,000 centigray (rad) instead of the AU's intended prescribed dose of 11,000 centigray (rad), a difference of greater than 0.5 Sv (50 rem) to an organ, and that differed from the intended prescribed dosage by 391 percent.

Title 10 CFR 35.3045(c) requires that the licensee notify the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee discovered the medical event on June 14, 2017 and reported it to the NRC Operations Center on June 15, 2017, no later than the next calendar day after discovery.

During the NRC's June 27-30, 2017 inspection, the inspectors observed that the medical event was also required to be reported to the NRC under 10 CFR 35.3045(a)(3). 10 CFR 35.3045(a)(3) requires, in part, that a licensee report any event in which the administration of byproduct material results in a dose to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent of more than the dose expected from the administration. The inspectors identified that the dose to the patient's lungs met this criteria and was required to be reported to the NRC operations center in accordance with 10 CFR 35.3045(c). Based on AU1's treatment planning, the administration of Y-90 to the right lobe of the liver was expected to result in 524 centigray (rad) to the lungs. However, the administration resulted in the patient's lungs receiving 2,576 centigray (rad). Therefore the patient's lungs, an organ other than the treatment site, received a dose that exceeded the expected dose by 0.5 Sv (50 rem) and was 392 percent more than the dose expected from the administration. On June 28, 2017, the licensee contacted the NRC's Operations Center and updated Event Number 52807, to reflect the additional reporting criteria.

The licensee documented the TheraSphere® medical event in written reports to the NRC on June 22 and 28, 2017. In addition, the licensee provided a final written report for the medical event to the NRC Region IV Office on June 30, 2017 (ADAMS Accession ML17186A312).

4.3 Conclusions

In accordance with NRC regulations, the licensee notified the NRC of a medical event that met the criteria in 10 CFR 35.3045(a)(1) and 10 CFR 35.3045(a)(3) and subsequently provided the NRC with a written report regarding the medical event.

5 Dose Determination and Potential Medical Consequences (IP 87103)

5.1 Inspection Scope

The inspectors reviewed information and documents provided by the licensee related to the patient's medical status following the medical event. The inspectors reviewed the information provided by the NRC's physician and medical physics consultants that reviewed the circumstances of the medical event. The inspectors also reviewed information related to the event to be further considered by the NRC for potential inclusion in its Abnormal Occurrence Report.

5.2 Observation and Findings

The licensee determined that the right lobe of the patient's liver received 54,000 centigray (rad) instead of the AU's intended prescribed dose of 11,000 centigray (rad). The licensee also determined that the patient's lungs received 2,576 centigray (rad) instead of 524 centigray (rad) that was expected to be delivered to the lungs based on the licensee-determined lung shunt fraction. The lung shunt fraction value used by the licensee was 6.20 percent, and was based on a determination made by the licensee prior to the patient's February 7, 2017, Y-90 TheraSphere® procedure. The cumulative dose to the patient's lungs from the February 7, 2017, procedure and the June 14, 2017, procedure was determined to be 3,449 centigray (rad) instead of 1,397 centigray (rad) that was expected to be delivered to the lungs.

After the licensee identified the medical event, the licensee committed to perform medical follow up of the patient. The day after the medical event, on June 15, 2017, the patient returned to PAMC for follow up SPECT imaging of the liver. The patient was seen by the referring physician on June 20, and again on June 27, 2017, for follow up and liver function tests.

On September 17, 2017, AU2 provided the inspectors with an overview of the patient's medical status. The patient was having frequent oncology office visits with laboratory tests performed. It was also noted that the patient was clinically stable with no new symptoms or complications from the medical event. Liver function tests appeared to be stabilized and there was no anticipated lung function decline. Additional assessment was projected to be performed at 6-months post-medical event.

On October 19, 2017, AU2 provided an update of the patient's status based on a Computed Tomography examination. It was noted that the regions of tumor within the liver showed good response to the Y-90 with little change in the appearance of the normal liver tissue. On December 8, 2017, AU2 reported that the patient is doing well without significant symptomatic complications related to the medical event.

The NRC contracted with a physician consultant and a medical physics consultant to assist the NRC's inspection activities related to the medical event. The NRC's medical physics consultant opined that radiation dose to the liver could not be estimated without additional information that was not available. Additionally, because the patient had a prior Y-90 procedure performed, microsphere distribution would differ on a microscopic scale, making dose estimation more complex. Regarding radiation dose to the lungs, the NRC's medical physics consultant opined that radiation dose could not be determined with any accuracy because: the pre-procedure lung shunt fraction imaging may not accurately predict the distribution of microspheres in the lungs; the patient did not have another lung shunt fraction determination after the first Y-90 procedure; and the distribution of microspheres in the lungs may not be uniform. The NRC's physician consultant opined that there was too much uncertainty in the dosimetric variables and other factors that resulted in the inability to speculate on any likely or probable medical effects to the patient as a result of the dose to the liver and lungs. It was noted that any estimates of radiation dose to the liver and lungs would have an enormous range of error.

Section 208 of the Energy Reorganization Act of 1974, as amended, defines an AO as an unscheduled incident or event which the Commission considers significant from the standpoint of public health or safety. The NRC is required to report AOs to Congress annually. The AO criterion, which was in effect at the time of the event, was published in the *Federal Register* on October 12, 2006 (71 FR 60198). For medical licensees, Criterion III.C.1.b and III.C.2.a provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 gray (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

5.3 Conclusions

The licensee determined that the right lobe of the patient's liver received 54,000 centigray (rad) instead of the intended prescribed dose of 11,000 centigray (rad), and that the patient's lungs received 2,576 centigray (rad) instead of the intended value of 524 centigray (rad). Medical follow up was performed of the patient following the medical event. The licensee's assessment was that there was no anticipated significant liver or lung function decline. The NRC's medical physics and physician consultants were unable to comment on the accuracy of the licensee's dose determination and expected medical outcome due to uncertainty related to dosimetric variables and other factors. Based on the information provided by the licensee, the medical event meets the criterion that the NRC uses for evaluating whether or not an event will be reported as an Abnormal Occurrence to Congress.

6 Causal Analysis (IP 87103)

6.1 PAMC Causal Analysis

The licensee stated that a complete review of the medical event and internal investigation was going to be performed. The licensee has not shared the results of its full evaluation with the NRC. However, in its written report to NRC for the medical event, PAMC noted that a series of mistakes contributed to the medical event. The mistakes

included: ordering the dose with the wrong calibration date; and the written directive not being prepared and signed by an AU prior to the administration. The licensee furthermore stated that the measurements of the vial of Y-90 by the Nuclear Medicine Supervisor "did not rouse attention by comparison to the calculated data."

6.2 NRC Causal Analysis

The NRC conducted an independent causal analysis using various methods to review the causal factors associated with the medical event.

6.2.1 Direct Cause

The direct cause of the medical event is what led to the incident without any intervening action. The inspectors determined that the direct cause of the medical event was the administration of an incorrect activity of Y-90 TheraSphere® microspheres to the right lobe of the patient's liver.

6.2.2 Contributing Causes

Contributing causes are those that did not lead to the incident, but made the medical event more probable. The inspectors identified that the contributing causes were: training inadequacies; deficiencies in policies and procedures; and the lack of a properly prepared, dated, and signed written directive.

The inspectors determined that the medical event occurred, in part, due to inadequate training of personnel involved with the PAMC Theraphere® program. Specifically, PAMC nuclear medicine staff who were responsible for ordering Y-90 Theraphere® doses from the vendor did not have training commensurate with the duties to be performed, which included ordering Y-90 TheraSphere® from the vendor. Training that was provided to the nuclear medicine staff was informal or did not cover topics that were relevant to the nuclear medicine staff's assigned duties, such as ordering Y-90 from the vendor. The inspectors reviewed prior TheraSphere® cases and interviewed PAMC personnel and became aware of additional Y-90 ordering issues that demonstrated a lack of familiarity of the nuclear medicine staff with the ordering process. For example, in one case a vial of Y-90 was ordered with a calibration date of Saturday but the vendor only calibrates vials for Sunday. In this case, the Y-90 order was rejected by the vendor.

The nuclear medicine staff also had inadequate training regarding the "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" form that was used to order vials of Y-90 TheraSphere®. The Nuclear Medicine Supervisor who was responsible for ordering Y-90 TheraSphere® vials was not aware that radiation dose values that fall within +/- 20 percent of the radiation desired dose are displayed in bold font on the matrix form. Accordingly, if a non-bold font value was circled by an AU, it should be questioned because it would be outside the desired radiation dose window. In the case of the medical event, for the right lobe of the patient's liver, AU1 circled two areas on the form, one with a bold font number and one with a non-bold font number. The Nuclear Medicine Supervisor failed to recognize the out-of-bounds values and proceeded to place the Y-90 TheraSphere® order using data from the non-bold font number, which fell outside of the desired radiation dose window. The Nuclear Medicine staff did not understand the need to compare the measured activity of Y-90 from the dose calibrator

(8.55 GBq) to the activity of Y-90 required at administration as documented on the "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" form (1.71 GBq). The inspectors determined that these training inadequacies contributed to the medical event occurring.

Deficiencies in PAMC policies and procedures related to the Y-90 TheraSphere® administration program also contributed to the occurrence of the medical event. Licensees are required to develop, implement, and maintain written procedures to provide high confidence that administrations are performed in accordance with properly prepared written directives that are dated and signed by an AU prior to the administration. The licensee's Departmental Policy Number 198.536, "Providence Alaska Medical Center Departmental Policy-Therasphere Therapy," dated November 11, 2013, states that a properly prepared, dated, and signed written directive is a prerequisite to performing a TheraSphere® procedure. However, the Checklist that is enclosed with the procedure, used by the nuclear medicine staff for performing TheraSphere® procedures, did not include any steps to verify that the PAMC prerequisites for Y-90 TheraSphere® had been completed prior to the procedure. Specifically, the licensee's Checklist described dose calibrator measurement, administration set priming, vial preparation, final assembly, administration, disassembly, waste disposal, but did not mention written directives until the last step of the last section of the Checklist, which stated "sign and forward the completed written directive to the AU and to the Medical Physicist for review and signature."

The dose calibrator measurement section of Checklist included verifying the activity of the vial of Y-90 in the dose calibrator and comparing it with the manufacturer's decay-corrected calibrated activity from the calibration data sheet. In the case of the medical event, those two numbers very closely matched (8.55 GBq measured activity vs. 8.52 GBq calibrated activity) because the vendor sent PAMC the activity vial that was ordered. However, the Checklist did not include a step to compare the measured activity of Y-90 from the dose calibrator to the activity of Y-90 required at administration to deliver the desired radiation dose to the liver (8.55 GBq measured activity vs. 1.71 GBq required activity). Accordingly, the Checklist did not contain adequate prompts to assure that a vial containing the correct activity of Y-90 was prepared for administration to the patient. Furthermore, the PAMC procedures did not contain steps or a Checklist for ordering vials of Y-90 from the vendor. Instead, staff relied on passed-down information or tribal knowledge for navigating the vendor's Y-90 ordering tools.

In the absence of a properly prepared, signed, and dated written directive from an AU, the nuclear medicine staff placed orders for Y-90 TheraSphere® vials based on an AU's circled values on the "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" form. The inspectors observed that the general practice was for an AU to place a circle around the number that represented that activity vial (GBq) of Y-90 that was desired and to place a second circle around a number that represented the desired radiation dose (Gy) on a given treatment week (first or second week after calibration), desired treatment day (day of the week the administration was planned to be performed), and desired treatment time (approximate time of day of the planned administration). The practice of the PAMC AUs was to circle the numbers on the form and subsequently provide the form to the Nuclear Medicine staff to place the order for the vial(s) of Y-90 TheraSphere® necessary for the administration to the patient.

In the case of the medical event, AU1 placed a circle around the desired activity vial (20 GBq), but this circle was large and encompassed a desired treatment week (first week after calibration), desired treatment day (first Wednesday), and desired treatment time (8:00 a.m.), as opposed to just placing the circle around the desired activity vial (20 GBq). A second circle was also placed by AU1 on the form on a different treatment week (second week after calibration), different desired treatment day (second Wednesday), and encompassed at least two different desired treatment times (12:00 p.m. and 4:00 p.m.).

The inspectors reviewed other "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" forms to determine whether ambiguous circles were only used in this one case but found numerous examples of ambiguous circles on the form that was being used by the AUs to communicate desired ordering information to the Nuclear Medicine staff. In one prior case, three circles were indicated on a "TheraSphere® Y-90 Glass Microsphere Treatment Window Illustrator" form. One circle indicated a 7 GBq vial to be administered the second Wednesday after calibration, at 12:00 p.m.; a second circle indicated a 7 GBq vial to be administered the second Thursday after calibration, with three different times of day: 8:00 a.m., 12:00 p.m., and 4:00 p.m.; and a third circle that had an X though it indicated a 4 GBq vial to be administered the second Monday after calibration at 8:00 a.m. This practice of ambiguously circling values on a form resulted in a lack of clarity that set conditions in place to make a Y-90 TheraSphere® ordering error more likely.

The NRC's regulations require a written directive for Y-90 TheraSphere® procedures so that the AU's directions are clear and unambiguous prior to the administration of the Y-90 to patients. However, the inspectors noted that AUs were not preparing, signing, or dating written directives prior to the administration of the Y-90 TheraSphere®. One AU stated that he was not comfortable preparing, signing, and dating written directives prior to Y-90 procedures because although he performed the treatment planning, a different AU was often the one that was going to administer the Y-90 TheraSphere® to the patient. Both AU1 and AU2 stated that the long-standing practice was to perform the administration, and that typically within one hour of the administration, the Nuclear Medicine staff would return with the completed written directive, which the AU would sign and date.

As described in this report, work processes and procedures for the Y-90 program were not well thought out and were inconsistent with NRC regulatory requirements. Management, AUs, and staff had developed a complacency regarding the Y-90 program because of perceived success in administering the program. The inspectors were informed by an AU that it never occurred to him that the Nuclear Medicine staff could give him an incorrect activity vial of Y-90 and that he trusted that the Nuclear Medicine Supervisor would always give him the correct activity vial of Y-90. The inspectors noted this reflected the lack of a questioning attitude. Although there was at least one prior case of an incorrect activity vial of Y-90 being ordered, which is described later in this report, the licensee did not fully evaluate the circumstances of the ordering error or implement any corrective actions. The inspectors observed that PAMC had an active safety communication program with tools to be used by staff, such as "STAR: Stop-Think-Act-Review" and "CUSS: Concerned, Uncomfortable, need to Stop, this is a Safety issue" and "Validate & Verify." However, the safety communication outreach did not encompass all areas of the PAMC Radiology Department, including the Nuclear

Medicine Department. These and other tools were available to PAMC staff to improve safety culture but were not effective in preventing the medical event from occurring.

6.2.3 Root Cause

The inspectors determined that the root cause of the medical event can be attributed to the failure on the part of PAMC management, the PAMC Radiation Safety Committee (RSC), and the PAMC RSO to adequately oversee and manage the risks associated with the PAMC Y-90 TheraSphere® program.

When PAMC began performing Y-90 procedures under the provisions of 10 CFR 35.1000, direct oversight was provided by the RSO and the Y-90 procedures were performed as part of the PAMC Cancer Center activities. After a period of successful Y-90 procedures, the RSO discontinued direct oversight of the Y-90 TheraSphere® program. Additionally, the Y-90 program was transferred from the PAMC Cancer Center to the PAMC Nuclear Medicine Department. After the transfer, the RSO, who was PAMC's Chief Medical Physicist, spent the majority of his time on medical physics issues and had little direct interaction with, or oversight of, the PAMC Nuclear Medicine Department.

The RSO's decision to transfer oversight of the Y-90 TheraSphere® program to the PAMC Nuclear Medicine Department was not adequately reviewed by PAMC management or the PAMC RSC. Specifically, PAMC management and the RSC did not evaluate and manage the risks associated with Y-90 procedures and did not take steps to assure that the Nuclear Medicine Department had appropriate procedures, systems, and training in place to both implement and oversee the Y-90 program. After the hand-off, adequate follow up was not performed by the RSO, RSC, or PAMC management to determine if the change resulted in any unintended consequences or if the Y-90 TheraSphere® program was being effectively implemented in accordance with the NRC's regulatory requirements and the terms and conditions of the PAMC NRC license.

Instead of PAMC management, RSC, and RSO oversight of the Y-90 TheraSphere® program, both implementation and oversight of the program fell onto the shoulders of one individual, the Nuclear Medicine Supervisor. With no defense in depth, it became more likely that an error would occur. When one individual is responsible for both implementing and overseeing a program, there is no independent verification and the likelihood for identifying and correcting errors is decreased.

The inspectors also reviewed available records for TheraSphere® procedures that were performed by PAMC for the two years preceding the medical event and found that there were prior instances of issues and errors when ordering Y-90 TheraSphere® vials. These issues did not trigger any additional RSO or PAMC management oversight or result in any retraining, revisions to procedures, process improvements, or corrective actions. The RSC also demonstrated ineffective oversight when reviewing cases with Y-90 ordering errors.

In one case, the second quarter 2016 RSC meeting minutes noted: TheraSphere® mistake; patient order for TheraSphere® was caught (ordered incorrectly), postponed, good oversight. The inspectors pursued this issue but the licensee did not have records

available that were specifically related to the ordering error. Individuals that were interviewed by the inspectors could only recollect that a Y-90 TheraSphere® ordering error was made and caught by the former Nuclear Medicine Supervisor before the administration to the patient. However, no one that was interviewed could recollect how the ordering error was made or how it was identified.

Based on interviews with the available staff and a review of the limited documentation available, the inspectors were able to determine that the subject treatment plan called for a 15 GBq vial of Y-90 to be ordered for administration to a patient on a Tuesday, but a 20 GBq vial of Y-90 was erroneously ordered, and the administration was postponed to Wednesday, to allow the activity to decay to more closely achieve the desired radiation dose to the liver. It could not be determined how this error was identified, but it appeared that a former Nuclear Medicine Supervisor discovered the error prior to administration to the patient.

Although this could be considered a near-miss, the PAMC RSO, RSC, and management did not take adequate steps to identify the cause of the ordering error or initiate corrective actions to prevent recurrence. The only action documented as taken by the RSC was to recognize "good oversight" rather than to more fully understand the circumstances of the error and take corrective actions as appropriate. Furthermore the ordering error did not prompt the RSO to review the Y-90 program to determine if there had been any additional Y-90 ordering errors or if process improvements or additional oversight of the Y-90 TheraSphere® program were necessary. For this specific Y-90 ordering error case, the inspectors determined that the ordering error did not result in a medical event. However the Y-90 ordering error and lack of corrective actions is illustrative of the failure on the part of PAMC management, the PAMC RSC, and the PAMC RSO to adequately oversee and manage the risks associated with the PAMC Y-90 TheraSphere® program.

6.3 Conclusions

The licensee's preliminary causal analysis concluded that mistakes were made that included: ordering the dose with the wrong calibration date; the written directive not being prepared and signed by an AU prior to the administration; and that the measurements of the vial of Y-90 by the Nuclear Medicine Supervisor "did not rouse attention by comparison to the calculated data."

The inspectors determined that the direct cause of the medical event was the administration of an incorrect activity of Y-90 TheraSphere® microspheres to the right lobe of the patient's liver. The inspectors identified that contributing causes of the medical event were: training inadequacies; deficiencies in policies and procedures; and the lack of a properly prepared, dated, and signed written directive. The inspectors determined that the root cause of the medical event can be attributed to the failure on the part of PAMC management, the PAMC RSC, and the PAMC RSO to adequately oversee and manage the risks associated with the PAMC Y-90 TheraSphere® program.

The inspectors determined that the medical event was not the result of the occurrence of a one-time error or circumstance. Although there were no other medical events identified involving Y-90, all of the same conditions that led to the occurrence of the medical event existed for some time. These same latent conditions were present in the

PAMC Y-90 TheraSphere® administration program (i.e. training inadequacies, deficiencies in policies and procedures, lack of properly prepared, signed, and dated written directives, and inadequate oversight) and went unnoticed and undetected by the licensee until an unexpected response, a medical event, occurred.

7 Inspection Findings (IP 87103, 87132)

7.1 Inspection Scope

The inspectors observed licensed activities, reviewed records, procedures, and documents maintained by the licensee, and interviewed licensee personnel. Following the onsite inspection, the inspectors reviewed additional records, procedures, and documents that were requested and obtained from PAMC. The inspectors also reviewed information maintained by the NRC as part of approved licensing actions and license amendment requests.

7.2 Observation and Findings

The inspectors determined that for the administration of Y-90 TheraSphere® microspheres to the patient on June 14, 2017, written directives were not prepared for the planned administrations to either the right lobe or the left lobe of the patient's liver. For medical reasons, the procedure for the left lobe of the liver was not performed. The inspectors examined whether the lack of properly prepared, dated and signed written directives was isolated to this patient's procedure or whether the issue was programmatic in nature.

The licensee's procedure for the performance of Y-90 TheraSphere® procedures was described in its Departmental Policy Number 198.536, "Providence Alaska Medical Center Departmental Policy-Therasphere Therapy," dated November 11, 2013. The section of the policy "Prerequisites for Therasphere Therapy" specifies that once a planned activity for delivery has been calculated, a written directive is prepared. This section does not specify that the written directive be dated and signed by an AU, but instead that the written directive and calculation sheet be forwarded to the nuclear medicine staff and the Medical Physicist for review. After the Medical Physicist has reviewed the information, the nuclear medicine personnel can order the material. The following section, "Therasphere Delivery," states that "the signed written directive" be obtained before delivery of the TheraSphere® to the patient.

The "Therasphere Checklist" that is an enclosure to the PAMC procedure does not mention having a prepared, dated, and signed written directive prior to the administration. However, the section, "Final Documentation of Therasphere Delivery," has as the last step of the Checklist: "forward the completed written directive to the AU and Medical Physicist for review and signature."

It was reported to the inspectors that when PAMC first began performing Y-90 procedures, every treatment planning form and written directive was reviewed by the RSO prior to the ordering of any Y-90. The RSO stated that the written directives that were forwarded to him during that time frame were already signed and dated by an AU. During interviews with various individuals, it was reported that after a period of success in performing Y-90 procedures, the practice of the RSO reviewing all treatment planning

forms and written directives was discontinued and the RSO no longer reviewed any information pertaining to Y-90 procedures prior to administration. It was around this time frame that written directives ceased being prepared prior to the administration of Y-90. The inspectors could not establish an exact date at which point it occurred, but based on interviews performed and records reviewed, the practice of having prepared, dated, and signed written directives for Y-90 administrations was discontinued around January 1, 2015. Although an exact number of cases could not be identified, between January 1, 2015 and June 27, 2017, at least 40 administrations of Y-90 TheraSphere® were performed without properly prepared, dated, and signed written directives prior to the procedures. Accordingly, the licensee's failure in this regard is considered to be a programmatic issue.

Apparent violation of 10 CFR 35.40(a)

Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an AU before the administration of any therapeutic dose of radiation from byproduct material.

From January 1, 2015, to June 27, 2017, the licensee failed to have written directives dated and signed by an AU before the administration of therapeutic doses of radiation from byproduct material. Specifically, the licensee failed to have written directives dated and signed by an AU before the administration of at least 40 therapeutic doses of radiation from byproduct material from Y-90 TheraSphere® microspheres.

The licensee's failure to have written directives dated and signed by an AU before the administration of therapeutic doses of radiation from byproduct material was identified as an apparent violation of 10 CFR 35.40(a). (030-13426/2017-001-01)

Apparent violation of 10 CFR 35.41(a)

Licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's Departmental Policy Number 198.536, "Providence Alaska Medical Center Departmental Policy-Therasphere Therapy," dated November 11, 2013, is the procedure that was developed by the licensee to provide high confidence that each administration is in accordance with the written directive. As noted above, the licensee did not implement portions of its procedure, specifically the prerequisites for therapy that included the requirement for a signed written directive. Since at least January 1, 2015, the Medical Physicist, then the PAMC RSO, had ceased following the PAMC procedure that stated that the Medical Physicist would perform a review of the prerequisite information prior to the Y-90 being ordered. Additionally, the PAMC Departmental Policy failed to include criteria for the periodic review of Y-90 administrations to provide high confidence that the administrations were performed appropriately, or that any issues with processes were identified and promptly corrected.

Title 10 CFR 35.41(a) 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.

On November 11, 2013, the licensee established “Providence Alaska Medical Center Departmental Policy-Therasphere Therapy.” The policy specifies procedures and contains prerequisites for TheraSphere® administrations, including but not limited to: preparation of a written directive including authorized user signature; review of the written directive and dose calculation sheet by the Medical Physicist ; and direction/confirmation from the Medical Physicist to the nuclear medicine staff that the material can be ordered.

From January 1, 2015, to June 27, 2017, 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, 2017, the licensee failed to implement portions of its procedure for prerequisites for TheraSphere® therapy, including the failure to prepare a written directive with authorized user signature, the Medical Physicist’s failure to perform a review of the written directive and dose calculation sheet, and the failure of the Medical Physicist to provide direction to the nuclear medicine staff that the material can be ordered. Additionally, the licensee’s Theraphere® procedure did not describe methods to verify the ordered and received doses against the planned dose.

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). (030-13426/2017-001-02)

Apparent violation of License Condition 18

The inspectors determined that the medical event occurred, in part, due to inadequate training of personnel involved with the PAMC Theraphere® program. A deficiency in training was particularly evident for the nuclear medicine staff who were responsible for ordering Y-90 Theraphere® doses from the vendor. The PAMC license commits the licensee to provide training in its procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual’s duties to be performed, and that the training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres. Although the nuclear medicine staff were responsible to order Y-90 Theraphere® doses, the staff at the time of the medical event had received no formal training in this process and did not demonstrate adequate knowledge of the process.

Although the training records maintained by PAMC were incomplete, it appeared that the former Nuclear Medicine Supervisor received some training regarding Y-90 TheraSphere®, but it was limited to the assembly of the administration set and did not include instruction on properly ordering doses.

License Condition 18 of NRC License Number 50-17838-01, Amendment No. 70, dated October 28, 2016, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in License Condition 18.

License Condition 18, letter dated April 4, 2016, requires, in part, that the licensee implement the NRC’s licensing guidance, “Yttrium-90 Microsphere Brachytherapy Sources and Devices Theraphere® and SIR-Sphere® Licensing Guidance, revised February 12, 2016, Revision 9.” In doing so, the licensee committed to provide training

in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed and that the training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

From October 28, 2016, to June 27, 2017, the licensee failed to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. Specifically, the licensee failed to provide its nuclear medicine staff with training in the licensee's TheraSphere® procedures that was commensurate with the duties to be performed, including, but not limited to ordering, preparing, and measuring Y-90 microspheres.

The licensee's failure to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed was identified as an apparent violation of License Condition 18. (030-13426/2017-001-03)

Violation of License Condition 18

The inspectors reviewed PAMC's oversight of its Y-90 TheraSphere® program, including the oversight of the PAMC RSC. The PAMC Radiation Safety Program Manual, dated May 9, 2014, states that the RSO oversees the use of radiation and radioactive material and ensures that radioactive material is used safely and in accordance with applicable federal, state, and local regulations. The PAMC Radiation Safety Program Manual states that the RSC shall meet at least once in each calendar quarter. It was identified that the RSC failed to meet during two calendar quarters in calendar year 2016.

License Condition 18 of NRC License Number 50-17838-01, Amendments 67-69, require, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in License Condition 18.

License Condition 18, documents received on May 1, 2015, provides the licensee's Radiation Safety Program Manual, dated May 9, 2014. The Radiation Safety Program Manual section titled "Radiation Safety Committee" requires, in part, that the Radiation Safety Committee shall meet at least once in each calendar quarter.

Contrary to the above, from February 1 to March 31, 2016, and from July 1 to September 30, 2016, the licensee failed to assure that the Radiation Safety Committee met at least once in each calendar quarter. Specifically, the licensee's Radiation Safety Committee did not did not meet in the first quarter and in the third quarter of 2016.

The licensee's failure to assure that the RSC met at least once in each calendar quarter was identified as a Severity Level IV violation of License Condition 18. (030-13426/2017-001-04)

7.3 Conclusions

Three apparent violations were identified regarding the licensees failure to: (1) have written directives dated and signed by an AU before the administration of therapeutic doses of radiation from byproduct material; (2) develop, implement, and maintain written

procedures to provide high confidence that each administration is in accordance with the written directive; and (3) provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. One Severity Level IV violation was identified regarding the licensee's failure to assure that the RSC met at least once in each calendar quarter.

8 Corrective Actions

On June 28, 2017, PAMC provided the inspectors with a corrective action plan (ADAMS Accession No. ML17186A313). The corrective action plan noted that PAMC determined that the current Y-90 procedures in place guarantees the correctness of source order and dose delivery, but that the importance of step-by-step implementation of the procedure would be stressed. The inspectors met with the PAMC administration and RSO and stressed that the PAMC Y-90 procedures in place did not guarantee the correctness of source order and dose delivery, as evidenced by the occurrence of a medical event, and that the licensee needed to develop a more appropriate and robust corrective action plan. The licensee voluntarily temporarily suspended the performance of Y-90 TheraSphere® procedures until it better understood the circumstances of the medical event and could initiate more comprehensive corrective actions.

On June 30, 2017, PAMC provided the inspectors with a revised corrective action plan (ADAMS Accession No. ML17186A312). The revised corrective action plan differed from the initial plan by the addition of the licensee's plan to develop a method to measure the dose rate (millirem/hour) to compare with the calculated data to confirm the correct activity to be used.

The licensee also provided a copy of a revised TheraSphere® Checklist. The inspectors observed that the revised Checklist was a moderate improvement but still did not address the causal factors that contributed to the occurrence of the medical event. The inspectors expressed to PAMC administration and the RSO that the corrective action plan was still lacking and did not describe sufficient corrective actions to prevent recurrence of the circumstances that led to the medical event occurring. For example, the licensee's revised corrective action plan stated "while it was determined that the current procedure is still standing to guarantee the correctness of the source order and dose delivery…the following will be stressed and reiterated…" and went on to state that it would be reiterated that a written directive be filled out and signed prior to the administration. Simply stressing and reiterating an NRC regulatory requirement does not constitute appropriate corrective action to prevent recurrence.

Furthermore, the fact that a medical event occurred demonstrates that the licensee's current procedure did not "guarantee the correctness of the source order and dose delivery". Licensee management continued to express to the inspectors that the medical event was caused by an error on the part of one individual rather than taking a comprehensive approach to understanding the causes of the event to identify and correct the programmatic deficiencies that were present in the PAMC Y-90 TheraSphere® program.

On July 7, 2017, PAMC provided the NRC with a table that included more detailed additional corrective actions (ADAMS Accession No. ML17235A526). The additional corrective actions included: providing additional radiation safety training to the Nuclear Medicine Supervisor and the Director of Radiology; providing additional TheraSphere® training to the other nuclear medicine technologists; developing process improvements

to ordering TheraSphere® microspheres; developing process improvements regarding the signing and reviewing of written directives by AUs, and confirming the dose to be administered prior to the start of the procedure; implementing the use of time-outs in the interventional radiology suite prior to the procedure; performing a dry run of a TheraSphere® procedure prior to resuming the procedures; verifying the dose calibrator measurement settings for Y-90; hiring an additional medical physicist; conducting a RSC meeting; and continuing to perform medical follow-up of the patient.

On August 9, 2017, the licensee reported that it resumed the performance of Y-90 TheraSphere® administrations and that the first procedure was performed without incident.

As the licensee completes action items, it has been providing the NRC with periodic updates. The most recent revision of the corrective action plan was provided to the NRC on October 6, 2017 (ADAMS Accession No. ML17289B280).

9 Exit Meeting Summary

On January 3, 2018, a final telephonic exit meeting was conducted with Mr. Robert Honeycutt, Chief Operating Officer, and other licensee representatives to discuss the inspection findings. The NRC representatives described the NRC's enforcement process and the options for the licensee to request to attend a PEC or request ADR with the NRC.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Robert Honeycutt, Chief Operating Officer
Michael Acarregui, M.D., Chief Medical Officer
Yongli Ning, RSO, Chief Medical Physicist
Scott Hazelbaker, Director of Radiology
Chakri S, Inampudi, M.D., Authorized User 1
Erik Maurer, M.D., Authorized User
Christopher Kottra, M.D., Authorized User 2
Ella Goss, Director, Cancer Center
Betsy Baldwin, Manager, Radiation Oncology
Joe Stratman, Director of Risk Management
Erica Steeves, R.N., Director of Patient Safety
Debra Gwizdala, RT(N), CNMT, Nuclear Medicine Supervisor
Melissa Davis, R.N., Patient Safety Specialist
Jim Scott, Radiologic Technologist
Donald North, Radiologic Technologist
Lee Warnick, Cardiovascular Technologist
Kim Doncheck, R.N., Scheduling Coordinator
Shannon Baker, R.N., Nurse Practitioner
Edward B. Silberstein, M.D., NRC Medical Consultant
Bruce Thomadsen, Ph.D., NRC Medical Physics Consultant

INSPECTION PROCEDURES USED

87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-13426/2017-001-01	APV	Failure to have written directives dated and signed by an AU before the administration of therapeutic doses of radiation from byproduct material. (10 CFR 35.40(a)).
030-13426/2017-001-02	APV	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))
030-13426/2017-001-03	APV	Failure to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. (License Condition 18)
030-13426/2017-001-04	VIO	Failure to assure that the RSC met at least once in each calendar quarter. (License Condition 18)

Attachment

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AO	Abnormal Occurrence
APV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
IP	Inspection Procedure
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
VIO	Violation

NRC INSPECTION REPORT 030-13426/2017-001 AND NOTICE OF VIOLATION
PROVIDENCE ALASKA MEDICAL CENTER - DATED FEBRUARY 2, 2018

DISTRIBUTION:

KKennedy, RA
SMorris, DRA
MShaffer, DNMS
MHay, DNMS
RKellar, DNMS
RErickson, DNMS
BTharakan, DNMS
MVasquez, ORA
MHerrera, DRMA
JWeaver, ORA
R4DNMS_MLIB
LDimmick, NMSS
DBollock, NMSS
R4Enforcement Resource
RidsOeMailCenter Resource
RidsSecyMailCenter Resource
RidsEdoMailCenter Resource
BMaier, ORA
JKramer, ORA
CAlldredge, ORA
VDricks, ORA
SKirkwood, OGC
NColeman, OE
NHilton, OE
MBurgess, NMSS
SHoliday, NMSS
JBowen, OEDO
SCoker, NSIR
SDaibes, NMSS
RidsRgn1MailCenter Resource
RidsOpaMail Resource
RidsNmssOd Resource
RidsOcaMailCenter Resource
RidsOcfoMailCenter Resource
ABoland, OE
FPeduzzi, OE
SWoods, OE
LSreenivas, OE
KNorman, OE
EDO_Managers
JPeralta, OE
JWeil, CA
AMoreno, CA
MLayton, NSIR
RidsNsirOd Resource
RidsOIMailCenter Resource
OEWEB Resource
RidsRgn3MailCenter Resource
RidsOgcMailCenter Resource
RidsOigMailCenter Resource

ADAMS ACCESSION NUMBER: ML18033B654

☒ SUNSI Review By: **JFK** | ADAMS: ☒ Yes ☐ No | ☐ Non-Publicly Available ☒ Publicly Available | ☒ Non-Sensitive ☐ Sensitive | Keyword: EA-17-182

OFFICE	RIV:MLIB	RIV:MLIB	C:MLIB	ACES:TL	OGC/RC
NAME	JFKatanic	PJHernandez	MCHay	GMVasquez	SKirkwood
SIGNATURE	***/RA/***	***/RA/***	***/RA/***	***/RA JGK Acting For/***	***/RA by Email/***
DATE	01/08/18	01/09/18	01/05/18	01/18/18	02/02/18
OFFICE	OE	NMSS	D:DNMS	DRA	
NAME	FPeduzzi	RSun	MRShaffer	SAMorris	
SIGNATURE	***/RA by Email/***	***/RA by Email/***	***/RA by Email/***	***/RA/***	
DATE	01/29/18	0122/18	02/02/18	02/02/18	

OFFICIAL RECORD COPY