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

September 25, 2018

Ella Goss
Chief Executive Officer
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, Alaska 99519-6604

SUBJECT: NRC INSPECTION REPORT 030-13426/2018-001 AND NOTICE OF VIOLATION

Dear Ms. Goss:

This letter refers to the unannounced inspection conducted on June 25 and 26, 2018, at your facilities in Anchorage, Alaska. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, 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, and interviews with personnel. The preliminary inspection findings were discussed with your staff at the conclusion of the onsite portion of the inspection on June 26, 2018. A final exit briefing was conducted telephonically with Mr. Scott Hazelbaker, Radiation Safety Committee Chairman, Mr. Robert Honeycutt, Chief Operating Officer, Ms. Jennifer Baker, Director of Cardiovascular Services, Dr. Mark Winslow, Radiation Safety Officer and Authorized Medical Physicist, and your legal counsel representative Mr. Dunnington Babb on September 10, 2018.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited and described in the enclosed Notice of Violation (Notice).

The violations involved the failure to: (1) have written directives dated by an authorized user before the administration of therapeutic doses of radiation from byproduct material, and (2) equip each entrance to the remote afterloader unit treatment room with an electrical interlock system that will prevent operation under required circumstances. The enclosed report presents the results of the NRC's inspection, as well as the NRC's understanding of your actions since the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. 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://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. Information regarding the reason for the violations, the corrective actions taken and planned to correct the

violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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, 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 information, 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 Title 10 of the *Code of Federal Regulations* (CFR) 2.390(b) to support a request for withholding confidential commercial or financial information).

During the June 25 and 26, 2018 inspection and the in-office review that followed, the NRC identified concerns involving apparent failures to properly monitor personnel exposures, apparent failures to evaluate abnormal dosimetry results, and an apparent failure to assess outside employment in determining the total occupational exposure of applicable staff. As a result, the NRC conducted a Special Inspection on August 13-16, 2018 in accordance with the Inspection Charter dated August 7, 2018 (ADAMS Accession ML18220A991). The results of the NRC's Special Inspection will be issued in a separate correspondence.

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, will be made available electronically for public inspection in the NRC Public Document Room or 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.

Should you have any questions regarding this letter or the enclosed Notice, please contact Jason vonEhr at 817-200-1186, or the undersigned at 817-200-1455.

Sincerely,

/RA/

Michael C. Hay, Chief
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

Docket: 030-13426
License: 50-17838-01

Enclosures:
1. Notice of Violation (Notice)
2. NRC Inspection
   Report 030-13426/2018-001

cc:
Dr. Jilly, State Lab Director
State of Alaska Radiation Program

Mark Winslow, Ph.D., DABR
Sr. Chief Medical Physicist
Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, Alaska 99519-6604

NRC INSPECTION REPORT 030-13426/2018-001 - DATED September 25, 2018

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By: JEV	☒ Yes ☐ No	☒ Publicly Available	☐ Sensitive	NRC-002

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NOTICE OF VIOLATION

Providence Alaska Medical Center
Anchorage, AK

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

During an NRC inspection conducted on June 25-26, 2018, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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

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.

Providence Alaska Medical Center's written procedures contained in the Radiation Protection Program for Iodine-131 Therapy requires, in part, that an authorized user date and sign a written directive prior to the administration that includes the information in 10 CFR 35.40(b), including the patient or human research subject's name.

Contrary to the above, from at least January 1, 2016 through June 25, 2018, the licensee failed to have written directives dated and signed by an authorized user before the administration of therapeutic doses of radiation from byproduct material. Specifically, the licensee failed to have written directives dated by an authorized user for administrations of therapeutic doses of radiation from iodine-131 in quantities greater than 30 microcuries, which was required by NRC regulation and the applicable Providence Alaska Medical Center written procedure.

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

B) 10 CFR 35.615(b) requires that a licensee equip each entrance to the treatment room with an electrical interlock system that will: (1) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; (2) cause the source(s) to be shielded when an entrance door is opened; and (3) prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

License Condition 17 of NRC License 50-17838-01, Amendment 72, dated November 22, 2017, 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 17.

License Condition 17.A, in documents received May 1, 2015, provides the licensee's Radiation Safety Manual, dated May 9, 2014. The Radiation Safety Program section titled "8.19: Other Equipment and Facilities" requires, in part, that the maze door be closed during treatment.

Contrary to the above, from approximately August 2006 through June 25, 2018, the licensee failed to equip each entrance to the treatment room with an electrical interlock system to provide the required functionalities, and failed to ensure that the treatment

room door be closed during treatment. Specifically, the licensee installed and used a laser curtain, rather than the treatment room door, to accomplish the functionalities required by 10 CFR 35.615(b). During patient treatments the licensee would normally leave the treatment door open.

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

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" and should include: (1) the reason for the violations, 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 2 working days of receipt.

Dated this 25th, September 2018

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-13426
License:	50-17838-01
Report:	2018-001
EA No:	N/A
Licensee:	Providence Alaska Medical Center
Location Inspected:	Providence Alaska Medical Center 3200 Providence Drive, Anchorage, Alaska Providence Cancer Center, Radiation Oncology 3851 Piper Street, Tower "U" Suite LL002, Anchorage, Alaska Providence Professional Building 3300 Providence Drive, Suite 114, Anchorage, Alaska
Inspection Dates:	Onsite June 25-26, 2018 In-office review through August 21, 2018
Exit Meeting Date:	September 10, 2018
Inspector:	Jason vonEhr, Health Physicist Materials Licensing and Inspection Branch Division of Nuclear Materials Safety
Accompanied By:	Troy Pruett, Director Division of Nuclear Materials Safety
Approved By:	Michael C. Hay, Chief Materials Licensing and Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Providence Alaska Medical Center
NRC Inspection Report 030-13426/2018-001

On June 25 and 26, 2018, the U.S. Nuclear Regulatory Commission (NRC) performed an unannounced routine inspection, including escalated enforcement follow-up at Providence Alaska Medical Center at its facilities in Anchorage, Alaska, with in-office reviews through August 21, 2018. The scope of the inspection included the direct observation of licensed activities, discussions with licensee personnel concerning radiation safety, compliance with the Commission's rules and regulations, and the conditions of the license.

The inspection also included a review of representative records, interviews with the Providence Alaska Medical Center radiation safety officer, and other personnel to assess the adequacy of corrective actions planned and implemented to address the deficiencies that resulted in a medical event on June 14, 2017. These deficiencies were the subject of escalated enforcement action issued on February 2, 2018, located at NRC Agencywide Documents Access and Management System Accession ML18033B654. This report describes the findings of the inspection.

Program Overview

Providence Alaska Medical Center is authorized under NRC Materials License 50-17838-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulations* Part 35.

Inspection Findings

During a routine, unannounced inspection conducted on June 25 and 26, 2018, with continued reviews through August 21, 2018, two Severity Level IV violations of NRC requirements were identified involving the licensee's failure to: (1) have written directives dated by an authorized user before the administration of therapeutic doses of radiation from byproduct material, and (2) equip each entrance to the remote afterloader unit treatment room with an electrical interlock system that will prevent operation under required circumstances.

Corrective Actions

The licensee has changed the written directive forms in use for iodine-131 and Xofigo radium-223 treatments to ensure that the Authorized User captures the date of their approval. In addition, the licensee has requested a license amendment and regulatory exemption from certain requirements in 10 CFR Part 35 regarding the interlock system for the high dose rate afterloader.

REPORT DETAILS

1. Program Overview (Inspection Procedure (IP) 87131 and 87132)

1.1. Program Scope

Providence Alaska Medical Center (PAMC) is authorized under NRC Materials License 50-17838-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 *Code of Federal Regulation* (10 CFR) Part 35. Licensed activities are authorized to be performed at the licensee's facilities located in Anchorage, Alaska.

1.2. Inspection Scope

An unannounced inspection was conducted on June 25 and 26, 2018, at the licensee's facilities in Anchorage, Alaska. The inspection had two overall objectives: (1) evaluate the adequacy of the licensee's corrective actions planned and implemented to address the deficiencies that resulted in a medical event on June 14, 2017, and (2) assess the overall adequacy and performance of the licensee's radiation safety program as part of a routine NRC safety inspection.

The inspector reviewed the licensee's storage and control of licensed material, performance of the radiation safety program, dosimetry program, radiation surveys and instrumentation, staff training and experience, and overall management oversight. The inspection included direct observations of licensed activities, and a review of a selection of representative records which included, but was not limited to: contamination surveys, patient release criteria, Radiation Safety Committee (RSC) meeting minutes, written directives for administration of therapeutic doses of radiation from byproduct material, training records, and occupational exposure reports. The inspectors interviewed licensee personnel including nuclear medicine technologists, nurses involved in the inpatient care following therapeutic administrations of unsealed byproduct material, the Radiation Safety Officer (RSO), and authorized users involved in different therapeutic modalities at PAMC.

2. Background

2.1. June 15, 2017 Medical Event

On June 15, 2017, a medical event occurred involving yittrium-90 TheraSphere® glass microspheres, a procedure that involves radioembolization of blood vessels in the liver. In response the NRC conducted a Special Inspection on June 27-30, 2017.

The NRC Special Inspection identified violations of NRC requirements that lead to the medical event. These violations involved the failures to: (1) have written directives dated and signed by an authorized user prior to the administration of therapeutic doses of radiation from byproduct material (10 CFR 35.40(a)), (2) develop, implement, and maintain procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41(a)), (3) provide training in the licensee's procedures to all individuals involved in the yttrium-90 microsphere program, commensurate with the individual's duties and responsibilities (License Condition 18.A), and (4) ensure the RSC met at least once each calendar quarter.

The NRC's findings were detailed in NRC Inspection Report 030-13426/2017 and Notice of Violation, dated February 2, 2018 (ADAMS Accession ML18033B654).

Providence Alaska Medical Center provided a detailed response to the NRC in a letter dated May 18, 2018 (ADAMS Accession ML18163A128). The letter detailed corrective actions that PAMC had taken or were in the process of taking, which included: (1) the performance of a series of audits to identify any further deficiencies, (2) revising the process for the preparation and review of written directives, ordering of yttrium-90 doses, and verification of activity against the written directive; (3) revising the written procedures which guide the above processes; (4) adding additional resources and staff; (5) retraining all staff involved in the yttrium-90 microsphere program; (6) provide additional oversight of the yttrium-90 microsphere program; and (7) engage the yttrium-90 vendor to incorporate lessons learned from the event into the ordering process.

3. Inspection Findings - Follow-Up Inspection

3.1. Review of Providence Alaska Medical Center's Implementation of Corrective Actions

The adequacy of PAMC's planned and implemented corrective actions were reviewed as part of the June 25 and 26, 2018 inspection, with the objective of determining whether the corrective actions for the four violations previously identified addressed the causes and appeared lasting and effective. The four violations reviewed included:

- 10 CFR 35.40(a)
- 10 CFR 35.41(a)
- NRC License Condition 18.C (Training)
- NRC License Condition 18.A (RSC Meetings)

Violation of 10 CFR 35.40(a) & 10 CFR 35.41(a)

Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material. The NRC Inspection Report 030-13426/2017-001 identified that at least 40 written directives between January 1, 2015, and June 27, 2017 were not signed and dated by an authorized user prior to the administration of yttrium-90 microspheres.

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. The NRC Inspection Report 030-13426/2017-001 concluded that PAMC failed to implement portions of its written procedures for prerequisites for ThereSphere® therapies.

The inspector interviewed two of the three interventional radiologists that are authorized users under NRC Materials License 50-17838-01 to administer yttrium-90 Sir-Spheres® and TheraSphere® microspheres. The nuclear medicine technologist and other staff involved with ordering and measuring microsphere doses, as well as the current and former RSO were interviewed to understand current practices as they existed on the day of the inspection and contrast those with the past practices in place during the June 2017 medical event.

Representative records were reviewed, including ordering forms, written directives, training attendance, and PAMC policies and procedures, which together describe the licensee's radiation protection program as it applies to the yttrium-90 microsphere program. After a suspension of the yttrium-90 program following the June 2017 medical event, PAMC restarted the program with an administration on August 9, 2017. In total, nine administrations of yttrium-90 microspheres, all TheraSphere®, were performed between August 9, 2017 and the date of the inspection, with the most recent administration performed on May 31, 2018.

For the yttrium-90 microsphere program, PAMC significantly revised and developed its existing written procedures. As described above, the inspector reviewed these procedures, as well as their implementation since the June 2017 medical event. Of the nine administrations reviewed, eight were determined to be signed and dated by an authorized user prior to administration. Although the new processes for the authorized user to clearly document the intended treatment, the ordering of the dose, and several quality checks/time-outs were implemented, a single instance on April 16, 2018 was identified by PAMC prior to the 2018 inspection where the written directive was signed, but not dated, by the authorized user prior to the administration. This was determined to be a single minor and self-identified exception, as the licensee had demonstrated that they had corrected the deficiencies previously identified by the NRC as they applied to the yttrium-90 microsphere program.

The written directive requirement found in 10 CFR 35.40(a) also applies to several other modalities that are authorized by the PAMC's NRC Materials License, including 10 CFR 35.300 use of unsealed byproduct material in certain types and quantities, 10 CFR 35.400 use of byproduct material for brachytherapy, and 10 CFR 35.600 use of a sealed source of byproduct material for a high dose rate (HDR) remote afterloader unit.

The licensee's activities under 10 CFR 35.300 were reviewed through November 2015, the date of the last NRC routine inspection. During this period, PAMC had one patient who was administered two fractions of Xofigo radium-223, in April and May of 2016, prior to the June 2017 medical event. Providence Alaska Medical Center also performed numerous iodine-131 administrations greater than 30 microcuries requiring a written directive, including 14 administrations since the June 2017 medical event. All of the written directives reviewed for the above administrations were signed by an authorized user, however the authorized user never accompanied their signature by a date. A date of the procedure was clearly listed, however by PAMC's written procedures this date is not meant to represent the authorized user's dated signature. The failure to date and sign a written directive by an authorized user was identified as a violation of 10 CFR 35.40(a).

In the administrations reviewed, there were other data points available to the inspector to infer that the authorized user's signature predated the administration of byproduct material, which allowed the inspector to conclude that adequate levels of review of the prescription itself occurred prior to the administration of the licensed material.

The licensee's written procedures for the unsealed materials program did not appear to have been changed since July 2007. The written procedure states, in Section 8.34 "Procedures for Administrations when a Written Directive is Required:"

> Have an authorized user date and sign a written directive prior to the administration that includes the information in 10 CFR 35.40(b), including the patient or human research subject's name;
>
> For the administration of quantities greater than 1.11 MBq (30 micro Ci) of sodium iodine-131, the only other requirement of 10 CFR 35.40(b) to be contained in the written directive is the dosage and the radioisotope. . .[and] include date and time of administration.

Providence Alaska Medical Center's written directive forms for both Xofigo radium-223 and iodine-131 administrations direct the authorized user to sign the form, and for the PAMC staff to include the date of the procedure, however there is no clear space for the authorized user to date the signature, and no authorized user appeared to have dated the signature.

The licensee's activities under 10 CFR 35.400 were reviewed through November 2015. Historically, PAMC conducted two types of administrations under this authorization: temporary implant brachytherapy using cesium-137 seeds, and permanent implant brachytherapy primarily using iodine-125 seeds. Both of these programs were discontinued prior to the November 2015 inspection: the temporary seed program's last administration was on November 12, 2015, and the permanent seed program's was on May 14, 2012. As a result, both program's licensed activities fell outside the scope of the 2018 inspection.

Under 10 CFR 35.600, PAMC conducted administrations using a Varian Medical VariSource iX HDR remote afterloading device. Each patient, depending on the type of treatment, may receive anywhere between three and six treatment fractions with the HDR device. More than a dozen administrations were conducted in the two months leading up to the 2018 inspection. A sample of cases were reviewed by the inspector and each was determined to be appropriately signed and dated by an authorized user prior to the administration.

Violation of License Condition 18.C

License Condition 18.C of NRC License Number 50-17838-01, Amendment 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," Revision 9, issued February 12, 2016. In doing so, the licensee committed to provide training in the licensee's procedures to all individuals involved in yttrium-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 yttrium-90 microspheres. The NRC Inspection Report 030-13426/2017-001 concluded that PAMC failed to provide the requisite level of training, commensurate with the duties and responsibilities of the applicable individuals, to the nuclear medicine and radiology staff.

Following the June 2017 medical event, PAMC arranged for the vendor (BTG International) to provide training on TheraSphere® microspheres on July 25, 2017. Twenty-three PAMC employees attended the training, and a record was produced showing the attendees, training provider, location, and date of the training. However following the July 25, 2017, training, PAMC significantly modified its yttrium-90 microsphere program, including the processes and procedures that the staff and physicians would be implementing.

For example, changes were made to the processes to order the yttrium-90 microspheres, verification of ordered activity, and timeouts prior to administration to confirm patient name, prescribed radiation dose or activity, and other medically important criteria. Following these significant program changes the PAMC RSO conducted informal, undocumented training on a one-on-one basis with employees to update those employees on the revisions to the program, and how those revisions effected the staff's duties and responsibilities.

Based on interviews of staff during the on-site inspection, the staff were competent and knowledgeable about their roles and responsibilities. Based on these interviews, this violation is closed. However, the inspector stressed to licensee management and the RSO that the long-term success and compliance of the microsphere program, as well as the consistency and the comprehensiveness of staff and physician training would be greatly assisted by more formality and documentation, such as documenting who was trained in what role, when, and with what content.

Violation of License Condition 18.A

License Condition 18.A of NRC License Number 50-17838-01, Amendment 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.A, documents received on May 1, 2015, provides the licensee's Radiation Safety Program Manual, dated May 9, 2014. The Radiation Safety Program section titled "Radiation Safety Committee" requires, in part, that the RSC shall meet at least once in each calendar quarter. NRC Inspection Report 030-13426/2017-001 identified that the RSC did not meet in the first or third quarter of 2016, and therefore diminished the effectiveness of the licensee's oversight of NRC licensed activities.

The inspector discussed RSC meetings with different staff at PAMC. Meeting minutes were reasonably well documented, and readily available for the inspector to review. At times, errors, such as mistakes made in recording the attendance at the RSC meetings, inhibited a fuller review of the RSC's oversight of the radiation safety program. However, the inspector concluded that the RSC met at least once each calendar quarter since the June 2017 medical event, and appeared to have sufficient mechanisms in place to prevent recurrence of the violation, and therefore the 2017 violation is closed.

3.2. Conclusions

The licensee failed to assess the full scope of the radiation safety program at PAMC to identify where other modalities such as iodine-131 or Xofigo radium-223 administrations

were subject to the same requirements, and were potentially vulnerable to the same failures as were identified by the NRC during the 2017 Special Inspection for the yttrium-90 microsphere program. The NRC identified a violation involving the failure of authorized users to sign and date written directives for iodine-131 and Xofigo radium-223 administrations.

The licensee corrected the two other violations cited in NRC Inspection Report 030-13426/2017-001, which involved the failure to provide training to individuals in the yttrium-90 microsphere program commensurate to their duties and responsibilities, as well as the failure of the RSC to meet at least once each calendar quarter.

3.3. Corrective Actions

The licensee revised its forms for Xofigo radium-223 and iodine-131 administrations that require a written directive. The revised forms provide space and clearly call for the authorized user to sign and date their approval of the form's contents, in accordance with the licensee's existing respective written procedures.

4. Inspection Findings - Routine Inspection

4.1. Observations and Findings

The inspector identified one violation of NRC requirements. The violation involved the failure to control access to the HDR treatment room with a shield door, and related failures for the required interlocks on the door. In addition, during the inspection and the in-office review that followed, the inspector identified concerns involving apparent failures to properly monitor personnel exposures, apparent failures to evaluate abnormal dosimetry results, and apparent failures to assess outside employment in determining the total occupational exposure of applicable staff. As a result, the NRC conducted a Special Inspection on August 13-16, 2018 in accordance with the Inspection Charter dated August 7, 2018 (ADAMS Accession ML18220A991). The results of the NRC's Special Inspection will be issued in a separate correspondence. (See Section 4.2.2).

4.2. High Dose Rate Treatment Room Access

During the inspector's review of the licensee's program under its 35.600 authorization for the Varian HDR system, the inspector observed a 'light gate' or 'laser curtain' (see Figure 1 - HDR Treatment Room access with the laser curtain sensors in blue.) installed on the entrance to the licensee's combination HDR and Linear Accelerator Treatment Room. The RSO and Authorized Medical Physicists informed the inspector that patients often required anesthesia, and as a result PAMC elected to leave the treatment shield door open and utilize a laser curtain system to act as the interlock switch. According to the personnel interviewed, this was to allow PAMC staff quicker access to patients.

The laser curtain appeared to have all the functionality that 10 CFR 35.600 requires for the treatment room shield door. The treatment room shield door was still installed and functional at PAMC, however the functionalities required by regulation were instead installed with the laser curtain. The treatment room shield door is a compound door inset in a concrete wall at the end of a short one-leg maze. The regulatory purpose of the door is to minimize dose to operators and prevent inadvertent entry to the room during treatment.

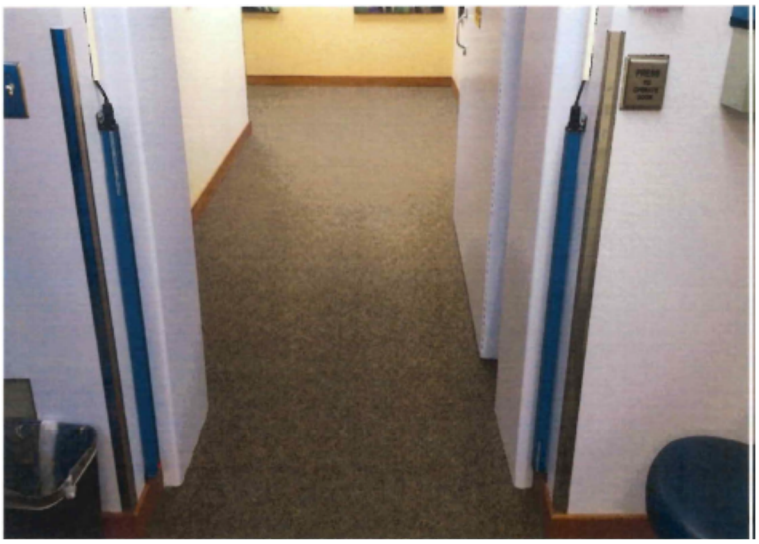

Figure 1 - HDR Treatment Room access with the laser curtain sensors in blue.

There are a number of NRC requirements in 10 CFR 35.600 and in the conditions of PAMC's NRC license that pertain to the functionality and use of the treatment room shield door. As a result of the licensee's failure to close the shield door during HDR treatments and the licensee's decision to use the laser curtain to accomplish certain functions, the following violation was identified:

10 CFR 35.615(b), which requires a licensee to equip each entrance to a treatment room with an electrical interlock system that will (1) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed, (2) cause the source(s) to be shielded when an entrance door is opened, and (3) prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

License Condition 17.A of NRC License 50-17838-01, Amendment No. 72, dated November 22, 2017, 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 17.A, documents received on May 1, 2015, provides the licensee's Radiation Safety Program Manual, dated May 9, 2014. The Radiation Safety Program section titled "8.19: Other Equipment and Facilities" requires, in part, that the maze door be closed during treatment.

As a direct result of the above non-compliance and the licensee's design change to shift the functionality of the door interlock system to the laser curtain, additional requirements were found to be in violation, including applicable sections of the Radiation Safety Program Manual, dated May 9, 2014, which were tied to the NRC license by License Condition 17.A. These sections include, but are not limited to:

- "Calibration Procedure for VariSource HDR Remote Afterloader," which requires as part of the quarterly check that (1) Delivery [of the source] will not initiate with door open; and (2) Delivery will not restart unless door interlock cleared, then correctly restarts. Associated calibration procedures include various other steps which also include insuring that the door interlock is operational.

- "Operating Procedures for Varian HDR Remote Afterloaders," which require a spot check (daily machine quality assurance) which includes verification of proper operation of interlock(s): "Door Interlock prevents treatment," and associated procedures which again requires steps associated with the opening, closing, and verification of various interlocks/status displays for the treatment door.

As of July 11, 2018, PAMC was pursuing an exemption to the regulatory requirement alongside an amendment to the NRC license to allow for the continued use of the laser curtain system (ADAMS Accession ML18254A037). Until the NRC has made a determination on this matter, the licensee has committed to ensuring the shield door is shut during all patient treatments.

4.3. Conclusions

A Severity Level IV violation was identified related to PAMC's use of a laser curtain in substitution for the treatment room shield door. The violation is the direct cause of several other non-compliances that relate to the use of or include language regarding the shield door. At the time of the inspection, the required functionalities that the NRC requires to be installed with the shield door appeared to have been in place but tied to the laser curtain instead.

4.4. Corrective Actions

Following the on-site inspection, the PAMC RSO submitted an amendment request on July 11, 2018 to pursue an exemption to the regulatory requirement alongside an amendment to the NRC license to allow for the continued use of the laser curtain system. This exemption and license amendment is in the process of being reviewed, and a final determination has not yet been made by the NRC. In the meantime, the licensee has committed to closing the treatment door to the HDR suite during each treatment. The functionalities required by 10 CFR 35.615 were still tied to the laser curtain, as the steps needed to move those functionalities to the treatment door would require a complete modification to the entire HDR treatment system.

5. Exit Meeting Summary

On September 10, 2018, a final telephonic exit meeting was conducted with PAMC management and radiation program representatives to discuss the inspection findings. On the call PAMC was represented by Mr. Scott Hazelbaker, RSC Chairman, Mr. Robert Honeycutt, Chief Operating Officer, Ms. Jennifer Baker, Director of Cardiovascular Services, Dr. Mark Winslow, RSO and Authorized Medical Physicist, and your legal counsel representative Mr. Dunnington Babb. The NRC representatives described the two Severity Level IV violations, and that the results of the special inspection conducted on August 13-16, 2018 would be issued in a separate inspection report. The licensee did not dispute the violations or the characterization of the findings.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Ella Goss, Chief Executive Officer
Robert Honeycutt, Chief Operations Officer
Michael Acarregui, Chief Medical Officer
Scott Hazelbaker, Director of Radiology
Erica Steeves, Director of Patient Safety and Regulatory Affairs
Jennifer Baker, Director of Cardiovascular Services
Mr. Yongli Ning, Authorized Medical Physicist and former RSO
Dr. Mark Winslow, Authorized Medical Physicist and current RSO
Melissa Davis, Patient Safety
Joe Stratman, Director of Risk Management
Kelly Ogden, Clinical Manager - 5 North
Victoria Phillips, Assistant Chief Nurse

INSPECTION PROCEDURES USED

87131 - Nuclear Medicine Programs, Written Directive Required
87132 - Brachytherapy Programs

ITEMS OPENED, CLOSED, and DISCUSSED

Opened

030-13426/2018-001-01	VIO	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)). Failure to implement written procedures to provide high confidence that each administration is in accordance with the written directive. (10 CFR 35.41(a)).
030-13426/2018-001-02	VIO	Failure to equip each entrance to the treatment room with an electrical interlock system that achieves certain functionalities. (10 CFR 35.615(b)).

Closed

030-13426/2017-001-03		Failure to provide training in the licensee's procedure to all individuals involved in yttrium-90 microsphere use, commensurate with the individual's duties to be performed (License Condition 18 (License Amendment 70)).
030-13426/2017-001-04		Failure to assure that the RSC met at least once in each calendar quarter (License Condition 18 (License Amendment 70)).

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
CFR	*Code of Federal Regulations*
HDR	High Dose Rate
IP	Inspection Procedure
NRC	Nuclear Regulatory Commission
PAMC	Providence Alaska Medical Center
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
VIO	Violation