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

November 2, 2018

EA-18-133

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

SUBJECT: NRC SPECIAL INSPECTION REPORT 030-13426/2018-002

Dear Ms. Goss:

This letter refers to the announced special inspection conducted on August 13-16, 2018, at your facilities in Anchorage, Alaska. The purpose of the special inspection was to review potential overexposures of occupational workers at Providence Alaska Medical Center. The inspection was conducted in response to concerns identified during the June 25 and 26, 2018, routine inspection and escalated enforcement follow-up. These concerns included apparent failures: (1) of occupational workers to wear dosimetry; (2) for management to investigate abnormal dosimetry results; and (3) to assess outside employment in determining the total occupational exposure of applicable staff. Based on these concerns, the NRC determined that a special inspection was the appropriate level of regulatory response to obtain additional information to fully assess the significance of the licensee's apparent deficiencies.

The objectives of the special inspection were to: 1) review the facts and circumstances surrounding these apparent deficiencies; 2) evaluate your dose estimates, and perform an independent dose reconstruction; 3) assess your compliance with license conditions and other applicable regulatory requirements related to the occupational dosimetry program; 4) perform an independent causal analysis of the apparent deficiencies; 5) evaluate the adequacy of your root cause analysis; and 6) evaluate your immediate and planned long term corrective actions to prevent recurrence.

The special inspection consisted of interviews of staff and review of procedures, policies, training records, and the radiation safety program documents. Preliminary inspection findings were discussed with you and members of your staff during the on-site portion of the special inspection on August 16, 2018. In the interim, additional inspection activities were performed by the NRC regarding the dose reconstruction for the affected individuals.

Based on the preliminary results of the NRC's Special Inspection and our independent assessment of your calculations, we determined that none of the reviewed individuals received occupational exposures in excess of the regulatory limits in calendar years 2016, 2017, or year-to-date 2018, either from Providence Alaska Medical Center alone or in aggregate with other third-party facilities. Nevertheless, the NRC determined that because of the programmatic

failures associated with the dosimetry program, individuals had a substantial potential to exceed NRC occupational exposure limits. The NRC also acknowledges that a complete reconstruction of exposure histories is ongoing and a potential for overexposures in prior years exists.

The NRC has determined that four apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is on the NRC's website at: https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failures to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation and account for external employment for purposes of occupational dose; (2) provide adequate instructions to workers associated with exposure to radiation; (3) provide reports to workers regarding personnel exposure information; and (4) implement certain elements of the radiation protection program. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit meeting on October 29, 2018.

Since the NRC has not made a final determination in this matter, no Notice of Violation is 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.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a predecisional enforcement conference (PEC) or (2) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. If you decide to participate in a PEC or pursue ADR, please contact Mr. James Thompson at 817-200-1538 within 10 days of the date of this letter. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision.

The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, 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, and is on the NRC Web site at http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a 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 ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html, as well as NRC brochure NUREG/BR-0317, "Enforcement Alternative Dispute Resolution Program" Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession ML18122A101). 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 these issues through ADR.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's 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. James Thompson of my staff at 817-200-1538.

Sincerely,

Troy W. Pruett, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. NRC Special Inspection Report 030-13426/2018-002
2. Special Inspection Charter dated August 7, 2018
3. Management Directive 8.3 Evaluation for Providence Alaska Medical Center

cc w/Enclosures:
Dr. Bernard Jilly, State Lab Director
State of Alaska Radiation Program

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-13426
License:	50-17838-01
Report:	2018-002
EA No:	18-133
Licensee:	Providence Alaska Medical Center
Location Inspected:	Providence Alaska Medical Center 3200 Providence Drive, Anchorage, Alaska
Inspection Dates:	Onsite August 13-16, 2018 In-office review through October 17, 2018
Exit Meeting Date:	October 29, 2018
Inspectors:	Jason vonEhr, Senior Health Physicist Materials Licensing and Inspection Branch Division of Nuclear Materials Safety, Region IV Penny Lanzisera, Senior Health Physicist Medical and Licensing Assistant Branch Division of Nuclear Materials Safety, Region I
Accompanied By:	Michael C. Hay, Former Chief Materials Licensing and Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved By:	James L. Thompson, Chief Materials Licensing and Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Providence Alaska Medical Center
NRC Special Inspection Report 030-13426/2018-002

Between August 13-16, 2018, the U.S. Nuclear Regulatory Commission performed an announced special inspection at Providence Alaska Medical Center at its facilities in Anchorage, Alaska, with in-office reviews through October 17, 2018. The scope of the inspection was to perform a review of the radiation safety program with a focus on the occupational exposure monitoring program (see Enclosure 2: Inspection Charter to Evaluate Potential Radiation Overexposures at Providence Alaska Medical Center in Anchorage, Alaska). 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 at its facilities in Anchorage, Alaska. (Section 1)

Inspection Findings

During an announced special inspection, four apparent violations were identified which involved the licensee's failure to: (1) monitor occupational exposure of workers from licensed and unlicensed sources of radiation and account for external employment for purposes of occupational dose; (2) provide adequate instructions to workers associated with exposure to radiation; (3) provide reports to workers regarding personnel exposure information; and (4) implement elements of the radiation protection program. (Section 3)

Dose Assessment

The licensee conducted an occupational dose reconstruction and determined a whole body deep dose equivalent of three authorized users. (Section 5)

	Estimated Occupational Exposures in Select Years (millirem)			
Physician	YTD2018 (thru July)	CY2017	CY2016	CY2015
Authorized User 1	1,154	3,433	3,153	3,846
Authorized User 2	673	2,774	2,700	2,752
Authorized User 3	333	1,662	2,258	2,658

Corrective Actions

The licensee conducted an initial assessment of the authorized users' occupational exposures in calendar year 2015 through year-to-date 2018. In addition, the licensee initiated the drafting of a Personal Radiation Dosimetry Badge policy to correct several issues identified by the NRC. (Section 7)

REPORT DETAILS

1. Program Overview (87103)

1.1. Program Scope

Providence Alaska Medical Center (PAMC) is authorized under the U.S. Nuclear Regulatory Commission (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 at its facilities in Anchorage, Alaska.

1.2. Background - June 2018 NRC Inspection

During a routine unannounced inspection on June 25-26, 2018, with follow-up to escalated enforcement (see EA-17-182 and NRC Inspection Report 030-13426/2017-001 and Notice of Violation, ADAMS Accession ML18033B654), the NRC identified several issues. These issues included apparent failures: (1) of occupational workers to wear dosimetry; (2) for management to investigate abnormal dosimetry results; and (3) to assess outside employment in determining the total occupational exposure of certain workers under the license. As a result, the NRC initiated a special inspection on August 13, 2018, under an Inspection Charter dated August 7, 2018 (see Enclosure 2: Inspection Charter to Evaluate Potential Radiation Overexposures at Providence Alaska Medical Center in Anchorage, Alaska).

1.3. Inspection Scope

On August 13-16, 2018, the NRC performed an announced special inspection of PAMC at its facilities in Anchorage, Alaska, with in-office reviews through October 17, 2018. The scope of the inspection was to perform a review of the radiation safety program with a focus on the occupational exposure monitoring program.

2. Background

2.1. June 2018 Inspection

During the inspection on June 25-26, 2018, the NRC identified several issues related to the licensee's occupational exposure monitoring program.

The licensee historically had an occupational monitoring program with a monthly exchange of a two-dosimeter system for users inside the catheterization laboratory. With two dosimeters for each individual, one would be worn outside a personal lead apron in the collar area, while the second would be worn beneath the lead apron near the waist. In April 2018, the licensee transitioned to a single-dosimeter system exchanged quarterly, where the dosimeter would be worn outside the lead apron in the collar-area.

The first issue related to the observation of an authorized user, henceforth referred to in this report as Authorized User 1, who was interviewed by the NRC inspector. During Authorized User 1's interview, the inspector observed the individual wearing three dosimeters. The three dosimeters included one assigned to Authorized User 1 for the

current wearing period (calendar quarter April through June 2018), one for Authorized User 1 from the monitoring period of September 2017, and one with Authorized User 1's name written on tape overtop of a former PAMC employee's name.

The second issue related to the consistent and correct use of dosimetry. The inspector's identified this during the review of the 2018 Radiation Safety Committee (RSC) meeting minutes. These minutes included several discussions related to staff or physicians not wearing dosimetry, or not wearing dosimetry correctly. These discussions included direct observations by the radiation safety officer (RSO) of Authorized User 3, concerns submitted by PAMC staff, and repeated observations by the staff of a third-party consultant documented in the consultant's reports to PAMC.

The third issue related to the reporting of individuals' occupational exposure. The inspectors identified this during the review of the dosimetry results for PAMC staff and physicians who conduct NRC licensed activities at PAMC. Exposure results on dosimetry records from June 2016 through March 2018 indicated several unusual findings. These included: (1) several months with numerous staff having no data (indicating that the dosimeter processing company had not been provided a dosimeter for the corresponding month, and therefore provided no exposure reading); and (2) three authorized users with limited recorded dose. Out of 60 occupational dosimetry reports provided by PAMC for Authorized Users 1, 2, and 3 between June 2016 and March 2018, 48 reported 'M' or "below minimum measurable quantity." Based on interviews with Authorized User 1 and Authorized User 2, discussions with supervisors, managers, and the licensee's RSO, and understanding the type and frequency of work these authorized users conduct, the inspector had anticipated exposures exceeding 100 mrem/month.

The final issue related to the management knowledge of and action for the deficiencies in the occupational exposure program. During the inspection, the inspector had several interactions with the RSO regarding the conduct of Authorized Users 1, 2, and 3 with respect to wearing dosimetry. The RSO's explanation for the limited recorded results was that the authorized users likely were not wearing their dosimeters. The RSO had been in his position since August 2017. In his time as RSO, he stated that he had directly observed physicians, including Authorized User 3, not wearing required dosimetry. The observation of Authorized User 3 was during the RSO's observation of a yttrium-90 microsphere procedure. Just prior to the initiation of the procedure, the RSO questioned why Authorized User 3 was not using any dosimeters. The procedure was delayed until the appropriate dosimeters were located and worn by the authorized user.

2.2. Fluoroscopy and Dosimetry

The type of work Authorized Users 1, 2, and 3 performed included frequent use of fluoroscopes, which is an X-ray generating machine that is capable of outputting significant quantities of radiation with the purpose of imaging patients during different types of procedures, such as cardiology and interventional radiology. Most of the generated radiation is directed along a primary beam from the X-ray generating tubes and deposited either in the patient or in the imaging intensifier, where the image is generated (see Figure 1). The authorized users' radiation exposure is predominantly a result of radiation scatter from the beam's interactions with the patient and table.

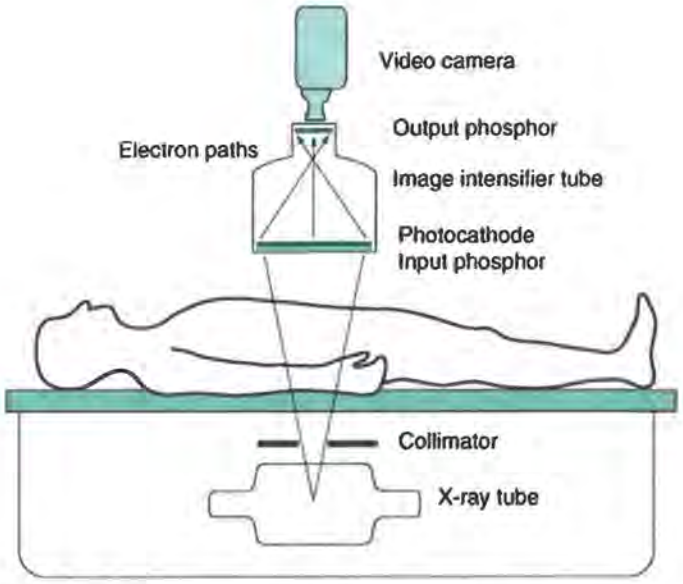

Figure 1 - Basic diagram of a fluoroscope.
Source; Chen MYM, Pope TL, Ott DJ: *Basic Radiology, 2nd Edition:* http://www.accessmedicine.com

When Authorized Users 1, 2, and 3 did have exposures recorded on their dosimeters, some results were unusually high, or inconsistent with the use of a collar/waist dosimeter with a lead apron. For example, for the February 2016 monitoring period Authorized User 3 had a waist and collar reading of 1,215 millirem and 1,249 millirem, respectively. Based on the penetrating energies involved, the anticipated attenuation from the lead apron, and literature on fluoroscopy procedures, the inspector expected a factor of approximately 10 to 25 difference between the shielded waist dosimeter and the exposed collar dosimeter. In the example above, the waist dosimeter was apparently exposed to more radiation than the collar dosimeter, which is implausible if the dosimeters were worn correctly. When Authorized User 1's dosimeter that was being worn during the June 2018 inspection was processed, it reported a radiation exposure of 2,405 millirem. While the dosimeter was observed on Authorized User 1's collar, it was assigned to the waist. In addition, Authorized User 1's cumulative dose according to licensee records from August 2016 through March 2018 was only 13 millirem, without including the 2,405 millirem result referenced above.

2.3. Special Inspection

Following the on-site inspection on June 25-26, 2018, and during the in-office review, the licensee continued to submit requested documents and records. The NRC began evaluating the known and suspected information against the criteria for a focused, reactive inspection of the licensee. The result was the Management Directive 8.3 Evaluation for Providence Alaska Medical Center, finalized on August 7, 2018 (see Enclosure 3).

3. Observations and Findings - August 2018 Special Inspection

The August 13-16, 2018, Special Inspection was focused on the licensee's oversight and implementation of its occupational exposure monitoring program. Four apparent

violations were identified involving the licensee's failure to: (1) account for radiation exposures received during external employment and the failure to monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (2) provide adequate instructions to workers associated with exposure to radiation; (3) provide reports to workers regarding personnel exposure information; and (4) implement certain elements of the radiation protection program.

3.1. Apparent Violation 1 - 10 CFR 20.1502(a)(1) and 20.1201(f)

Title 10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

10 CFR 20.1201(f) requires the licensee to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Prior to August 2018, PAMC failed to ensure that personnel who conduct operations under the authority of the NRC license were adequately monitored for exposure to radiation and radioactive material to ensure compliance with the occupational dose limits of 10 CFR Part 20. The licensee conducted a dose reconstruction of three authorized users on the NRC license for a period from January 2016 to July 2018, and determined that the dosimetry records on file for these individuals were grossly inaccurate. The NRC conducted an independent dose reconstruction and confirmed this assertion.

In addition, the licensee failed to take into account the authorized users' occupational exposures that were received as a result of occupational duties at facilities other than PAMC, and therefore failed to reduce the authorized users' allowable occupational dose to be received prior to the end of the calendar year.

The licensee's failure to adequately monitor exposure to radiation and radioactive material from exposures received at PAMC and the failure to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person was identified as an apparent violation of 10 CFR 20.1502(a)(1) and 10 CFR 20.1201(f). (030-13426/2018-002-01)

3.2. Apparent Violation 2 - 10 CFR 19.12(a)(3)

Title 10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 millirem shall be instructed in, and required to observe, to the extent within the workers control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Prior to August 2018, PAMC failed to provide instruction to individuals who in the course of employment are likely to receive an occupational dose in excess of 100 millirem in a year on applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, PAMC failed to provide adequate instructions regarding radiation safety

involving the proper use of dosimeters to at least three contract occupational workers resulting in their failure to properly wear dosimetry to monitor their exposure to occupational radiation.

Based on the results of the licensee's and the NRC's occupational dose reconstruction, three authorized users were identified who experienced an occupational dose in excess of 100 millirem. These authorized users were contracted through a physicians group to PAMC, and were not direct employees of the hospital. As a result of interviews with the three authorized users and others in PAMC operations and management, and a review of records and applicable documents, the NRC determined that the licensee failed to provide any instruction to the three authorized users, either at the beginning of the authorized users' work with licensed activities at PAMC or any type of refresher training since. The licensee assumed that the contract physicians' extensive educational background was sufficient and therefore the doctors required no training or instruction specific to PAMC.

The NRC determined that direct employees of PAMC who work in the catheterization laboratories received initial and annual refresher training and were required to demonstrate competency in related subjects applicable to 10 CFR Part 19; however, these same instructions were not provided to the authorized users, because they were not seen as employees of PAMC, and therefore not mandated to undergo the same training activities.

The failure to provide adequate instructions regarding radiation safety involving the proper use of dosimeters to three occupational contract workers resulting in their failure to properly wear dosimetry to monitor their exposure to occupational radiation was identified as an apparent violation of 10 CFR 19.12(a)(3). (030-13426/2018-002-02)

3.3. Apparent Violation 3 - 10 CFR 19.13(b)(1)

Title 10 CFR 19.13(b)(1) requires, in part, that the licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if the individual's occupational dose exceeds 100 mrem total effective dose equivalent.

Prior to August 2018, PAMC failed to provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year when the individual's occupational dose exceeded 100 mrem total effective dose equivalent. Specifically, PAMC failed to provide radiation exposure data to the contract occupational workers and staff in the course of their employment.

As a result of interviews with the three authorized users and others in PAMC operations and management, and a review of records and applicable documents, the NRC determined that the licensee failed to provide radiation exposure data to the authorized users and PAMC staff in the course of their employment at PAMC. Of the PAMC staff and physicians, both contract and PAMC employees, interviewed by NRC inspectors, none recalled receiving or being provided with occupational exposure information unless it involved a notification of an abnormally high exposure.

Although PAMC was able to produce NRC Form 5s, "Occupational Dose Record for a Monitoring Period," for all requested employees, it does not appear that an effective

process was in place or implemented to ensure that all applicable workers under the NRC license received their NRC Form 5.

The failure to ensure that radiation exposure data, and the results of any measurements or analyses were provided to occupational workers was identified as an apparent violation of 10 CFR 19.13(b)(1). (030-13426/2018-002-03)

3.4. Apparent Violation 4 - 10 CFR 20.1101(a)

Title 10 CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

Prior to August 2018, the license failed to implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically, the licensee failed to implement elements of its radiation protection program to review and evaluate abnormal radiation exposure reports, investigate exposure reports with results over certain licensee-set administrative limits, and develop recommendations to management on any required corrective action.

One example of this failure involved the three authorized users' unusually low, repeated months of no exposure detected over extended periods of time despite being among the most at-risk individuals at the hospital to chronic high radiation exposures. In addition, there were several indicators that suggested that dosimetry was not being worn, or worn correctly that included direct observations by the RSO, anonymous concerns submitted by hospital employees, and repeated reports made by a third-party consultant contracted since August 2017. The RSO and RSC were obligated to review occupational exposures by the PAMC Radiation Safety Program, Sections 1, 2, and 7; RSO Delegation, Radiation Safety Committee, and ALARA Program, respectively. The RSO and RSC failed to take effective actions commensurate with the significance and scale of the apparent deficiencies.

A second example was the RSO's and RSC's failure to evaluate or investigate reported doses that exceeded licensee-set administrative action levels in accordance with the PAMC Radiation Safety Program, Section 7 on the ALARA Program. These action levels were put in place to monitor exposures as the year progresses, and thus demonstrate compliance with requirements in 10 CFR Part 20. The licensee exceeded investigatory levels in 14 instances by the three authorized users in the 2015-2018 period. The licensee could produce only four records of ALARA investigations, hospital wide, over the same period. Of these four ALARA records, all four were reviewed by the NRC and deemed inadequate, were signed and completed on the same day, and only one of these four were for one of the three authorized users. None of the four ALARA investigations were effective in achieving their stated purpose to determining the cause of an employee's or authorized user's abnormally high occupational exposure.

The licensee's failure to effectively implement portions of its radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20 was identified as an apparent violation of 10 CFR 20.1101(a). (030-13426/2018-002-04)

4. Licensee Oversight of the Occupational Dosimetry Program

At PAMC, the RSC has overall responsibility for and oversight of the Radiation Safety Program. The RSC is required to meet at least once each calendar quarter, and by PAMC policy reviews a number of aspects of the Radiation Safety Program, including the occupational dosimetry program.

In the 2018 Special Inspection, the inspectors reviewed records for RSC meetings back to 2009. There were several meetings where dosimetry-related issues were discussed. For example, in April 2011, the RSC had discussions among its staff about the accuracy of the dose reports, and whether PAMC physicians and employees were wearing dosimeters appropriately. A draft badge wearing policy was created and discussed as a result of concerns that certain physicians, including the authorized users the NRC identified in 2018, were not wearing dosimeters correctly and that the PAMC RSC believed it was a "serious concern" that required a "proactive stance" by the hospital. In the meeting minutes, the RSC specifically names two of the three authorized users the NRC identified in 2018: "Issue regarding MDs [Medical Doctor] - not wearing badges, over-exposure reports regarding MDs."

Communications leading up to the April 2011 RSC meeting included: an RSC member's wish to "talk about ways to protect PAMC from [physicians'] nonconformance with dosimeter wearing requirements," ideas regarding training and drafting short presentations to physicians and staff regarding the criteria for wearing the dosimeters and logistics for returning and exchanging dosimeters at the end of the month, and the then-RSO stating "My impression is even if we took routine procedures and had this issue discussed with stress in the meetings, but things [would still be] getting worse. It is all our responsibilities for this [dosimetry] issue, and this issue could end up with very unpleasant results..." The draft Badge Wearing Policy resurfaced again in RSC meetings in 2015, when it was again discussed with respect to physician compliance with wearing dosimeters, again without an apparent conclusion.

While these are specific examples, other RSC meetings between 2009 and 2013 continue to discuss the general issue of physician compliance with wearing of dosimeters. In the NRC's Special Inspection, the inspectors' requested copies of any policy that might demonstrate that the draft Badge Wearing Policy might have been finalized and put into effect, or revised and issued in some other form. However no policy or program of the same name or nature could be discovered in the licensee's systems, nor recollection made of the members on the RSC still at PAMC that this draft document was finalized.

In early 2018, during the February RSC meeting, the RSC discussed several indicators suggesting that dosimeters were not being worn or not worn correctly. In particular, staff concerns were raised regarding the lack of physician compliance with dosimeter wearing, observations made directly by RSC members of lack of compliance with dosimeter wearing, and a compliance issue was raised through the licensee's "Physician Action Line." Through a review of the RSC records, interviews with RSC members, and review of licensee communications regarding the RSC meetings, it does not appear that any effective action or actions were taken commensurate to the significance of the risk of non-compliance.

5. Dose Reconstruction

As a result of the deficiencies identified in PAMC's occupational dosimetry program, the NRC determined that it was necessary to reconstruct the three authorized users' occupational exposure history. The NRC chose to focus on the period from the beginning of 2016 through year-to-date 2018.

The raw data was gathered primarily from the authorized users work with fluoroscopy machines. At PAMC and a second NRC licensed facility, the fluoroscopy machines themselves captured information on how long the beam was on, penetrating power of the produced beam, and the machine-calculated patient exposure. At a third NRC licensed facility and a non-NRC licensed facility, the fluoroscopy machines captured beam time, and at times the procedures' beam times were rounded or estimated after the fact. In total, this raw data represented over 4,000 fluoroscopy procedures at four medical facilities in the Anchorage area.

5.1. Licensee Reconstruction

The licensee also sought to reconstruct the three authorized users' occupational exposure history. The licensee hired a third-party consultant to lead the reconstruction efforts on behalf of PAMC.

The licensee's consultant conducted physical radiation surveys with a phantom (patient-equivalent device used to simulate radiation scatter, normally for calibration purposes) and used several personal dosimeters to monitor radiation exposure on an authorized user during three real procedures involving the fluoroscopy machine in PAMC Cath Lab 6.

Through a series of calculations and conservative assumptions regarding shielding and authorized user positioning relative to the fluoroscopy machine and the patient, the licensee's consultant determined a 'scatter ratio,' which in turn could be used to calculate the authorized users' occupational exposure using the aggregated raw data on procedures from PAMC and the other involved medical facilities.

The consultant produced a series of reports to describe and document their efforts and methodologies, as well as to produce the initial and later revised estimates for the authorized users' occupational exposure for the initial calendar years 2016 to present. These reports are dated August 21, 2018 (ADAMS Accession ML18290A73), August 29, 2018 (ADAMS Accession ML18290A570), September 15, 2018 (ADAMS Accession ML18290A571), and September 26, 2018 (ADAMS Accession ML18290A572).

5.2. Licensee Results

The licensee's consultant reports, referenced above in Section 5.1, utilized two different dosimetry methodologies to back calculate the authorized users' exposure histories. The first, used in the report dated August 21 and 26, 2018, was to calculate the exposure that a single dosimeter placed on the collar of the authorized user would have been exposed to. The one-dosimeter methodology was what the licensee changed its dosimetry program to in April 2018.

The resulting exposure on the collar badge was inputted into the Webster Equation. The Webster Equation in general calculates the Total Effective Dose Equivalent to the human body by compartmentalizing the body into sections, and aggregating the resulting exposure by weighting each section of the body, with the additional knowledge that a personal lead apron will cut down on the exposure to the shielded portions of the body.

The results of the revised (August 26, 2018) report are listed below.

Physician	YTD2018 (thru July)	CY2017	CY2016
AU 1	1,461	4,337	4,290
AU 2	853	3,506	3,488
AU 3	426	2,112	3,683

Table 1 - Estimated occupational exposures for select years (in millirem) for the three Authorized Users using a one-dosimeter methodology

The licensee's second dosimetry methodology was to simulate the use of a two-dosimeter system, like the one in place prior to the April 2018 change in the PAMC dosimetry program. The two dosimeter methodology also weights the human body by compartmentalization, and then uses a dosimeter at the collar (the highest exposed portion of the body) and a dosimeter under the lead apron at the waist (the highest 'weighted' section of the human body). A weighting of the two resulting dosimeter results is referred to as the Modified Webster Equation.

The results of the two-dosimeter methodology report (September 15, 2018) are listed below:

	Estimated Occupational Exposures in Select Years (millirem)			
Physician	YTD2018 (thru July)	CY2017	CY2016	CY2015
AU 1	1,154	3,433	3,153	3,846
AU 2	673	2,774	2,700	2,752
AU 3	333	1,662	2,258	2,658

Table 2 - Estimated occupational exposures for select years (in millirem) for the three Authorized Users using a two-dosimeter methodology

While the NRC's independent evaluation was conducted using non-machine or facility-specific information such as the licensee's calculated or measured scatter ratio, the NRC's evaluation was in general agreement with the results of the evaluation conducted by the licensee's consultant.

As of the date of this report, PAMC has not yet assigned an exposure estimate to the Authorized Users' official dosimetry records.

6. Causal Analysis of the Licensee's Program Failures

6.1. Root Cause Evaluation

The NRC's determination of the most likely root cause of the licensee's failure to effectively monitor radiation workers' occupational exposures and general dosimetry

program breakdown was the failure on the part of the PAMC management to provide oversight for the Radiation Safety Program. This determination is based on a review of contemporary and historical records, especially records of RSC meetings, as well as interviews with PAMC staff, physicians, and members of PAMC management and executive management teams.

The failure of PAMC management to provide oversight is best exemplified by the content and background to the RSC meetings. From 2009 through 2012, a series of discussions were captured, ideas proposed, and draft policies and procedures developed in an attempt to address the issue of physician noncompliance with NRC occupational dosimetry requirements. No corrective actions were implemented that corrected the licensee-identified deficiencies, and no lasting program of greater oversight, scrutiny, or verification was enacted as a result of these meetings and discussions. As a direct result, physicians did not have a clear understanding of certain PAMC policies and procedures, PAMC expectations or delegation of responsibilities with regards to occupational dosimetry monitoring, or their own occupational exposures.

6.2. Direct Cause

The most likely direct cause of the licensee's failure to monitor radiation workers' occupational radiation exposures was the failure to wear, or wear correctly, the assigned radiation dosimetry. This failure in turn resulted in the official dosimetry results diverging from the actual radiation exposures experienced by the physicians, or not being available at all.

This cause was best exemplified by the June 2018 inspection when Authorized User 1 was interviewed by the NRC inspector while wearing multiple radiation dosimetry badges, one of which was assigned to another individual (who had left employment at PAMC) and another which was assigned to a different area of the body for a different monitoring period.

6.3. Contributing Causes

The licensee's failure to effectively monitor radiation workers' occupational radiation exposures had several likely contributing causes. The most significant contributing causes included: (1) the licensee's failure to provide basic training on the subject of occupational monitoring to all applicable individuals; (2) the failure to evaluate and follow-up with abnormal dosimetry results; and (3) the failure to provide adequate resources to support the oversight of the Radiation Safety Program.

The licensee's failures with regards to: (1) providing basic training to applicable individuals and (2) evaluation and follow-up with abnormal dosimetry results were described in detail in Section 3.2 and Section 3.4.

Lastly, the licensee failed to provide adequate resources to support the oversight of the Radiation Safety Program. The individual who held the role of RSO (up to August 2017) performed the roles of both RSO and the Chief Medical Physicist. The current RSO has also split his time between his oversight role as RSO and again as Chief Medical Physicist, while attempting to navigate the licensee through the NRC's enforcement process as a result of the 2017 yttrium-90 medical event. Although there were some efforts made under the new RSO to address the long-standing issue of physician

noncompliance in radiation dosimetry, the actions were not effective or inadequately implemented to correct the problem. Additional time and resources were not made available to the RSO or RSC to combat the noncompliance or oversee the effectiveness and longevity of the corrective actions.

The oversight of the program was hampered by the various levels of autonomy provided to different groups or departments inside of PAMC. Certain responsibilities for implementation of the program were delegated, or assumed to be delegated, to different group supervisors or department heads, but the licensee failed to provide oversight for these delegations, and did not effectively communicate responsibilities or expectations for delegated activities.

6.4. Conclusions Regarding Causal Analysis

The licensee experienced a general programmatic breakdown in the area of occupational radiation monitoring. A lack of resources, ineffective implementation, failures in communication, failures to delegate or failures to provide oversight of delegated responsibilities all were identified by the NRC during the Special Inspection as direct and contributing causes.

7. Corrective Actions

In the weeks that followed the NRC's June 2018 inspection, the licensee had not initiated any means of evaluating or calculating the affected physician's occupational exposures either for 2018 or prior years. Following the Special Inspection initiated on August 13, 2018, the licensee initiated its dose reconstruction efforts through a third-party contractor. The first contractor report was dated August 21, 2018.

Following this initial report, the licensee has conducted an initial assessment of the authorized users' occupational exposures in calendar year 2015 through year-to-date 2018. In addition, the licensee began drafting a Personal Radiation Dosimetry Badge policy to correct several programmatic issues the NRC identified.

8. Exit Meeting Summary

On August 16, 2018, the NRC inspectors provided the preliminary inspection findings at the conclusion of the on-site portion of the Special Inspection. Providence Alaska Medical Center was represented at the preliminary exit meeting by:

- Ella Goss - Chief Executive Officer
- Michael Acarregui, M.D. - Chief Medical Officer
- Robert Honeycutt - Chief Operating Officer
- Deborah Hansen - Chief Nursing Officer
- Ross Newcombe - Chief Financial Officer
- Scott Hazelbaker, RSC Chair and Director of the Radiology Service Line
- Jennifer Baker - Director of the Cardiovascular Service Line
- Betsy Baldwin - Interim Director of the Oncology Service Line
- Joe Stratman - Director of Risk/Legal Claims
- Tara Bird - Program Manager of Regulatory Compliance
- Noelle Brassard - Manager, Cath Lab

- Stephanie Tasker - Program Manager, Compliance/Privacy
- Donald (Jay) Vogel - Manager, Accreditation Support for Providence St. Joseph
- Brenda O'Neal - Supervisor, Radiology
- Theresa Posini - Coordinator, Regulatory Compliance
- Mark Winslow, Ph.D., RSO and Senior Chief Medical Physicist

The licensee was also represented by legal counsel provided by Mr. Dunnington Babb of Cashion Gilmore, LLC.

On October 29, 2018, the NRC and PAMC conducted a final telephonic exit briefing. Providence Alaska Medical Center was represented by:

- Ella Goss - Chief Executive Officer
- Robert Honeycutt - Chief Operating Officer
- Scott Hazelbaker, RSC Chair and Director of the Radiology Service Line
- Jennifer Baker - Director of the Cardiovascular Service Line
- Mark Winslow, Ph.D., RSO and Senior Chief Medical Physicist

The licensee was also represented by legal counsel provided by Mr. Chester Gilmore and Mr. Dunnington Babb of Cashion Gilmore, LLC. The licensee acknowledged the inspection findings and did not dispute any of the details presented during the call.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Ella Goss - Chief Executive Officer
Michael Acarregui, M.D. - Chief Medical Officer
Robert Honeycutt - Chief Operating Officer
Deborah Hansen - Chief Nursing Officer
Ross Newcombe - Chief Financial Officer
Scott Hazelbaker, RSC Chair and Director of the Radiology Service Line
Jennifer Baker - Director of the Cardiovascular Service Line
Betsy Baldwin - Interim Director of the Oncology Service Line
Joe Stratman - Director of Risk/Legal Claims
Andre G. Neptune, PAMC, Director of Pharmacy
Tara Bird - Program Manager of Regulatory Compliance
Noelle Brassard - Manager, Cath Lab
Stephanie Tasker - Program Manager, Compliance/Privacy
Donald J. Vogel - Manager, Accreditation Support for Providence St. Joseph
Brenda O'Neal - Supervisor, Radiology
Theresa Posini - Coordinator, Regulatory Compliance
Mark Winslow, Ph.D., RSO and Senior Chief Medical Physicist

Legal Counsel:
Chester Gilmore and Dunnington Babb of Cashion Gilmore LLC

INSPECTION PROCEDURES USED

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

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-13426/2018-002-01	APV	Failure to monitor exposure to radiation and radioactive material from exposures received at PAMC and the failure to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. (10 CFR 20.1502(a)(1) and 20.1201(f))
030-13426/2018-002-02	APV	Failure to provide adequate instructions regarding radiation safety involving the proper use of dosimeters to radiation workers resulting in their failure to properly wear dosimetry to monitor their exposure to occupational radiation. (10 CFR 19.12(a)(3))
030-13426/2018-002-03	APV	Failure to ensure that radiation exposure data, and the results of any measurements or analyses are provided to occupational workers. (10 CFR 19.13(b)(1))

030-13426/2018-002-04	APV	Failure to effectively implement portions of the Radiation Protection Program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20 (10 CFR 20.1101(a))

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALARA	As-Low-As-Reasonably-Achievable
APV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
MD	Medical Doctor
NRC	Nuclear Regulatory Commission
PAMC	Providence Alaska Medical Center
PEC	Pre-decisional Enforcement Conference
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer

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

August 7, 2018

MEMORANDUM TO: Jason E. vonEhr, Senior Health Physicist
Materials Licensing and Inspection Branch
Division of Nuclear Materials Safety

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

FROM: Troy W. Pruett, Director
Division of Nuclear Materials Safety

SUBJECT: INSPECTION CHARTER TO EVALUATE POTENTIAL RADIATION OVEREXPOSURES AT PROVIDENCE ALASKA MEDICAL CENTER IN ANCHORAGE, ALASKA

A special inspection has been chartered to review potential overexposures of occupational workers at Providence Alaska Medical Center (licensee) facility in Anchorage, Alaska (License: 50-17838-01, Docket: 030-13426).

A. Background and Basis

On June 15, 2017, a significant medical event occurred at the Providence Alaska Medical Center (PAMC) involving yttrium-90 (Y-90) TheraSphere® glass microspheres. The event involved a programmatic failure in processes and implementation of procedures to identify that the wrong dosage of Y-90 microspheres had been ordered from the vendor, despite several opportunities prior to administration of the byproduct material to the patient. The NRC conducted a special inspection on June 27-30, 2017, as a result of the notification on June 15, 2017, from PAMC of the medical event, which resulted in escalated enforcement.

This enforcement action included a Severity Level II problem, and a civil penalty of $11,600, involving 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 (Title 10 of the *Code of Federal Regulations* (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)); and (3) provide training in the licensee's procedures to all individuals involved in the Y-90 microsphere program, commensurate with the individual's duties and responsibilities (License Condition 18.C), as well as a Severity Level IV violation for failure of the Radiation Safety Committee to meet quarterly, as required (License Condition 18.C).

On June 25 and 26, 2018, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection and escalated enforcement follow-up at the PAMC facilities in Anchorage, Alaska. During the inspection, the NRC identified concerns related to the licensee's dosimetry program, including apparent failures of multiple occupational workers to wear dosimetry, apparent failures for management to investigate abnormal dosimetry results, and an apparent failure to assess outside employment in determining the total occupational exposure of applicable staff. Based on the limited information available to the NRC as a result of these deficiencies, at least three individuals employed at the licensee's facilities potentially exceeded occupational dose limits.

Since the inspection, the licensee has not completed a dose reconstruction for staff with suspect exposure monitoring records.

The NRC is chartering this special inspection pursuant to NRC Manual Chapter 1301, "Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Response Plan," and Management Directive 8.3, "NRC Incident Investigation Program."

B. Scope

The inspection should seek to address the following items at a minimum:

1. Identify and review all pertinent records, documents, and procedural guidance related to the licensee's dosimetry program, including but not limited to: dosimetry results, as-low-as reasonably achievable investigations, Radiation Safety Committee meeting minutes, audit results, anonymous concerns by licensee staff, and actions taken or communications to the staff by management related to personnel monitoring. Interview, as appropriate, members of licensee staff and management.

2. If performed, review and evaluate the licensee's dose assessment for missing or suspected monitoring periods for employee occupational exposure, including dose reconstruction, if appropriate.

3. Perform independent dose estimates by means of calculations, re-enactments, and time-motion studies, in conjunction with independent reviews of licensee personnel to estimate radiation doses to individuals from licensed and unlicensed sources of ionizing radiation, including any outside NRC-licensed employers. Note: if non-NRC-licensed facilities are needed to complete the independent dose estimate, assistance from PAMC and/or the State of Alaska may be needed.

4. Assess the licensee's compliance with license conditions and other applicable regulatory requirements related to personnel monitoring and occupational dose limits.

5. Based on the above, perform an independent causal factor analysis.

6. Develop a timeline for determining when staff failed to be adequately monitored for radiation exposure and when corrective actions were implemented.

7. Determine if the inspection should be elevated to an augmented inspection team.

C. Team Members

Jason vonEhr, Team Leader
Penny Lanzisera, Team Member

D. Guidance

The NRC is chartering this special inspection pursuant to Management Directive 8.3, "NRC Incident Investigation Program," and NRC Manual Chapter 1301, "Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Response Plan." Manual Chapter 1301 identifies Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing," for specific use in reviewing events. The planned dates of the onsite inspection are August 13-17, 2018.

This inspection should emphasize fact-finding in its review of the circumstances surrounding the use of dosimetry and exposure monitoring of staff. Safety concerns identified that are not directly related to these areas should be reported to NRC management for appropriate action.

Daily briefings with NRC management should occur to discuss the team's progress and preliminary observations.

In accordance with Manual Chapter 0610, "Nuclear Material Safety and Safeguards Inspection Reports," a report documenting the results of the inspection should be issued within 45 days of the completion of the inspection.

This Charter may be modified should the team develop significant new information that warrants review. Should you have any questions concerning this charter, please contact Michael C. Hay at 817-200-1455.

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

August 7, 2018

MEMORANDUM TO: Kriss M. Kennedy, Regional Administrator

THRU: Troy W. Pruett, Director
Division of Nuclear Material Safety

FROM: Michael C. Hay, Chief
Materials Licensing and Inspection Branch

SUBJECT: MANAGEMENT DIRECTIVE 8.3 EVALUATION FOR PROVIDENCE ALASKA MEDICAL CENTER

Pursuant to Regional Office Policy Guide 0801.5, "Management Directive 8.3 And Inspection Manual Chapter 0309 Reactive Team Inspection Decisions, Implementation, and Documentation For Power Reactors"; Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility"; and Inspection Manual Chapter 1301, "Response To Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan," the enclosed table provides the evaluation for determining that a Special Inspection Team inspection will be conducted at the Providence Alaska Medical Center in response to concerns regarding occupational workers potentially exceeding yearly dose limits due to improper monitoring of personnel exposures.

Concur with Recommendation:
Kriss M. Kennedy
Regional Administrator

8/7/18
Date

CONTACT: Michael C. Hay, Chief
Materials Licensing and Inspection Branch
(817) 200-1455

Enclosure 3

MANAGEMENT DIRECTIVE 8.3

DECISION DOCUMENTATION FORM

(Deterministic and Risk Criteria Analyzed)

Materials Licensee	Providence Alaska Medical Center	**EVENT DATE:**	Ongoing Issue, thru at least 2016
RESPONSIBLE BRANCH CHIEF:	Michael C. Hay, MLIB/DNMS	**EVALUATION DATE:**	August 2, 2018

BRIEF DESCRIPTION OF THE SIGNIFICANT OPERATIONAL EVENT OR DEGRADED CONDITION:

During an on-site routine inspection on June 25 and 26, 2018, an NRC inspector reviewed dosimetry records and interviewed personnel regarding the licensee's dosimetry program. The inspector's review concluded that the licensee's occupational exposure records were unlikely to be accurate for three occupational workers because of the type and frequency of work and the inconsistent nature of the dosimetry records.

Three occupational workers collectively had 49 months out of 90 where exposures were recorded as "M" or minimal/below detectable, 5 months of missing records where no dosimeter was turned in for processing, and 10 months of "unused" dosimeters where dosimeters were turned in for processing with intact foils (indicating the individual never used the dosimeter). In addition, each individual had high exposures on other months ranging from approximately 400 to 1300 mrem. During interviews with licensee management, the three occupational workers' workloads were described as steady, and relatively even.

During an interview with one authorized user during the on-site inspection, the individual was observed wearing three dosimeters - one was the correct assigned dosimeter, one was the dosimeter from the previous year July, and one was a former employee's dosimeter with the individual's name taped over top.

Based on these factors, the inspector concluded that occupational exposure records were unlikely to be accurate, and that there existed a reasonable potential for one or more of the workers to have exceeded regulatory dose limits during the past 2 calendar years for which records were available and reviewed.

Based on the above information, NRC management determined that these concerns should be evaluated using the NRC's criteria for Special, Augmented, and Incident Inspection/Investigations. Listed below were the criteria used in evaluating the concerns.

(Continued on second page)

Enclosure

IIT (MD 8.3):

- Led to a significant occupational exposure or significant exposure to a member of the public. In both cases, "significant" is defined as five times the applicable regulatory limit (except for shallow-dose equivalent to the skin or extremities from discrete radioactive particles).

  NOT MET - at this time, the NRC suspects that up to three workers have potential exposures in excess of or in the region of 5 rems.

- Involved the medical use of byproduct, source, or special nuclear material and may have resulted in deterministic effects to a significant number of patients or individuals over a long period (months or years).

  NOT MET - no actual or suspected deterministic effects.

- Involved the medical, academic, or commercial use of byproduct, source, or special nuclear material and resulted in the potential exposure of a significant number of individuals above occupational or public dose limits.

  NOT MET - not a 'significant' number of individuals.

- Involved the deliberate misuse of byproduct, source, or special nuclear material from its intended or authorized use, which resulted in the exposure of a significant number of individuals.

  NOT MET - willfulness is not suspected in the use or misuse of licensed material.

- Involved circumstances sufficiently complex, unique, or not well enough understood, or involved safeguards concerns, or involved characteristics the investigation of which would best serve the needs and interests of the Commission.

  NOT MET - Issue is adequately narrow and reasonably well understood.

IIT (MD 8.10)

- An incident at a medical facility resulting in the potential exposure of a significant number of individuals above occupational or public dose limits.

  NOT MET - not a 'significant' number of individuals

- An event at a medical facility involving the medical use of byproduct, source, or special nuclear material that may result or may have resulted in deterministic effects to a significant number of patients or individuals over a long period (months or years).

  NOT MET - no actual or suspected deterministic effects.

AIT (MD 8.3):

- Involved the deliberate misuse of byproduct, source, or special nuclear material from its intended or authorized use and had the potential to cause an exposure of greater than 5 rem to an individual or 500 mrem to an embryo or fetus.

  NOT MET - willfulness is not suspected in the use or misuse of licensed material.

AIT (MD 8.10):

All criteria are related to medical events, and therefore, not applicable.

Special Inspections (IMC 1301)

- Single exposure of an occupational worker in excess of the dose limits in 10 CFR 20.1201.

  Criteria Met – Several licensee authorized users potentially exceeded occupational worker yearly dose limits due to improperly monitoring their exposures.

RESPONSE DECISION		
USING THE ABOVE INFORMATION AND OTHER KEY ELEMENTS OF CONSIDERATION AS APPROPRIATE, DOCUMENT THE RESPONSE DECISION TO THE EVENT OR CONDITION, AND THE BASIS FOR THAT DECISION		
DECISION AND DETAILS OF THE BASIS FOR THE DECISION: Recommended that a Special Inspection be conducted based on potential for occupational worker exposures in excess of the dose limits in 10 CFR 20.1201.		
BRANCH CHIEF REVIEW:	Michael Hay	DATE: 8/7/18
DIVISION DIRECTOR REVIEW:		DATE: 8/7/2018
ADAMS ACCESSION NUMBER: EVENT NOTIFICATION REPORT NUMBER (as applicable): E-mail to NRR_Reactive_Inspection@nrc.gov		