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

September 25, 2019

Mr. Robert Diaz
Regional Director
Kaiser Foundation Hospital
Diagnostic Imaging Department
3288 Moanalua Road
Honolulu, HI 96819

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-03546/2019-001

Dear Mr. Diaz:

This letter refers to the unannounced U.S. Nuclear Regulatory Commission's (NRC's) inspection conducted on June 12 and 13, 2019, at your facility located in Honolulu, Hawaii, with in-office review of a materials spill through August 13, 2019. The purpose of this inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the NRC's regulations and conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation surveys, and interviews with personnel. Preliminary inspection findings were discussed with you and your staff at the conclusion of the onsite inspection. A final exit meeting was conducted with you and your staff on August 29, 2019.

Based on the results of this inspection, the NRC has determined that six Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy, located on the NRC's website at: http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) because the NRC identified the violations during the inspection.

The violations involve failures to: a) notify the radiation safety officer immediately of a major spill of licensed material; b) make surveys of areas where the material was spilled and was reasonable under the circumstances to evaluate; c) provide instructions, commensurate with assigned duties, to nursing and housekeeping staff assigned to the spill of licensed materials; d) instruct nuclear medicine technologists in your radiation protection procedures; e) monitor packages labeled as containing radioactive materials for removable contamination; and f) implement written procedures for area surveys.

You are required to respond to this letter. 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. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. Information regarding (1) the reason for the violation, (2) the corrective actions already taken and (3) those planned to correct the violation and prevent recurrence, and (4) the date when full

compliance will be (was) achieved must be addressed in your response. 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 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).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access Management System (ADAMS), accessible from the NRC Website at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions regarding this letter or the enclosed Notice, please contact Jason C. Dykert at 817-200-1427 or the undersigned at 817-200-1455.

Sincerely,

/RA/

Patricia A. Silva, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No.: 030-03546
License No.: 53-05379-01

Enclosure:
1. Notice of Violation
2. NRC Inspection Report 2019-001

cc w/Enclosures:
Jeffrey Eckerd, Manager
State of Hawaii Radiation Control Program

NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-03546/2019-001 DATED SEPTEMBER 25, 2019

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NOTICE OF VIOLATION

Kaiser Foundation Hospital
Diagnostic Imaging Department

Docket No.: 030-03546
License No.: 53-05379-01

An NRC inspection conducted on June 12 - 13, 2019, identified six violations of NRC requirements. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. License condition 17A of License 53-05379-01, Amendment 79, dated June 18, 2018, requires, in part, that the licensee conduct its program in accordance with the procedures contained in the license application. In the license application, dated December 10, 2014, the licensee committed to follow their procedure, "Safely Managing Radioactive Materials," 1452-RS-5, revised on January 28, 2009. Section 4.5, "Radioactive Spills," requires that the radiation safety officer (RSO) be notified immediately and supervise the cleanup of major spills.

   Contrary to the above, on January 22, 2019, the licensee failed to ensure that the RSO was notified immediately and supervise the cleanup of a major spill. Specifically, after a spill of iodine-131 occurred licensee staff failed to immediately notify the RSO. As a result, the RSO was not able to supervise the cleanup of the major spill.

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

B. 10 CFR 20.1501 requires, in part, that the licensee shall make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected.

   Contrary to the above, on January 22, 2019, the licensee failed to make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected. Specifically, following a major spill involving iodine-131, surveys to evaluate the magnitude and extent of radiation levels in the contaminated area were not performed prior to personnel entry and work in that area.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

C. 10 CFR 35.310 requires, in part, that a licensee shall provide radiation safety instruction to personnel caring for patients who cannot be released under 10 CFR 35.75, commensurate with the duties of the personnel, including the subjects of contamination control and waste control.

   Contrary to the above, on January 22, 2019, the licensee did not provide radiation safety instruction to personnel caring for patients who cannot be released under 10 CFR 35.75, commensurate with the duties of the personnel, including the subjects of contamination control and waste control. Specifically, nursing and housekeeping staff who were caring for a patient not released under 10 CFR 35.75, did not receive radiation safety instructions commensurate with their duties, which included controlling entry into the

contaminated area and controlling the radioactive waste through surveys prior to removing it from the room and storing it in a dedicated area.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

D. 10 CFR 35.27 requires, in part, that the licensee instruct supervised individuals in their written radiation protection procedures.

Contrary to the above, prior to June 12, 2019, the licensee failed to instruct supervised individuals in their written radiation protection procedures. Specifically, two supervised individuals working as nuclear medicine technologists stated that they had not been instructed in the licensee's written radiation protection procedures prior to handling and using licensed byproduct materials.

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

E. 10 CFR 20.1906 requires, in part, that each licensee shall monitor the external surfaces of a labeled package for radioactive contamination.

Contrary to the above, on June 12, 2019, the licensee did not monitor the external surfaces of a labeled package for radioactive contamination. Specifically, the licensee failed to perform a test for removable contamination on a labeled package until after the package's contents were removed and it was labeled as empty.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d.4).

License condition 17 A of License No. 53-05379-01, Amendment 79, dated June 18, 2018, and License condition 18 A of License No. 53-05379-01, Amendments 78 and 77, dated September 17, 2015, and June 23, 2015, respectively, requires, in part, that the licensee conduct its program in accordance with the statements contained in the license application. The license application dated December 10, 2014, in Attachment 5 under Item # 10 requires that the licensee will implement and maintain written procedures for area surveys in accordance with CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. The area survey procedure, "Area Survey for Radiation Reading or Contamination, Policy Number 1452-N24, revision date July 2007, step 4.2.1 requires that wipe tests for removable contamination, when thallium or gallium is administered, be obtained at the end of each day of use.

Contrary to the above, since July 2015 on the days when thallium or gallium was administered, approximately 5-10 times per year, the licensee failed to implement step 4.2.1 of area survey procedure, "Area Survey for Radiation Reading or Contamination, Policy Number 1452-N24, revision date July 2007. Specifically, wipe tests for removable contamination, when thallium or gallium was administered, weren't obtained at the end of each day of use.

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

Pursuant to the provisions of 10 CFR 2.201, Kaiser Foundation Hospital Diagnostic Imaging Department 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 for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, 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 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 day of September 2019

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report 030-03546/2019-001

Docket:	030-03546
License:	53-05379-01
Report:	2019-001
Licensee:	Kaiser Foundation Hospital Diagnostic Imaging Department
Location Inspected	3288 Moanalua Road Honolulu, Hawaii
Inspection Dates:	June 12 and 13, 2019
Exit Meeting Date:	July 16, 2019
Inspector:	Jason Dykert, Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety
Approved by:	Patricia A. Silva, Chief Materials Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

NRC Inspection Report 030-03546/2019-001
Kaiser Foundation Hospital Diagnostic Imaging Department

Program Overview (Section 1)

Kaiser Foundation Hospital Diagnostic Imaging Department (Kaiser) was authorized by NRC license 53-05379-01 for medical possession and use of byproduct material as described in 10 CFR 35.100, .200, .300, and .1000. Licensed activities were authorized at the facility located at 3288 Moanalua Road in Honolulu, Hawaii.

Inspection Findings (Section 2)

The routine inspection performed on June 12 and 13, 2019, reviewed diagnostic and therapeutic nuclear medicine and TheraSphere permanent brachytherapy activities performed under the Kaiser license since the previous inspection on February 8, 2016.

Six violations were identified during the routine inspection. Two nuclear medicine technologists stated they did not receive instructions in any of the licensee's specific radiation protection procedures. A technologist failed to perform a wipe test for removable contamination on labeled packages containing radioactive materials. Written procedures for area surveys weren't followed when thallium or gallium was administered, which requires a daily wipe test.

Three of the violations were related to a non-reportable materials spill that occurred on January 22, 2019 and were identified by the NRC. The event involved a toilet that overflowed, while it contained radioactive material, in a dedicated iodine-131 in-patient room. The overflow created a contaminated area with measured radiation levels ranging from 0.06 - 1.03 millirem per hour in the restricted room.

The licensee staff's initial response to the overflow did not utilize the emergency spill response procedures which require an immediate notification to the radiation safety officer (RSO). Only one survey of the contaminated area was performed, and it did not capture any of the elevated dose rates which were identified in the trash used to clean the spill. The one survey was likely performed after maintenance personnel had entered the area to fix the toilet. The nursing and housekeeping staff were not instructed, commensurate with their assigned duties, in contamination control or waste control for response to a major spill.

Corrective Actions (Section 3)

After the overflow event the licensee began updating written procedures and nuclear medicine technologists were re-trained on the spill response procedure. After the inspection, nursing staff and technologists were provided in-person specific training from the RSO in areas of controlling access to dedicated in-patient iodine rooms, contamination areas, and in waste control protocols for items in or removed from the room. All the nuclear medicine technologists have a current read and sign statement verifying they have received instructions in the licensee's procedures. Additional corrective actions planned or taken are forthcoming in the licensee's written response to this inspection report and Notice of Violation.

REPORT DETAILS

1. Program Overview (Inspection Procedure 87131)

1.1. Program Scope

Kaiser's nuclear medicine department utilized four Siemens Symbia gamma cameras and employed two full time nuclear medicine technologists and two traveling temporary, or locum tenens, technologists at the time of this inspection. The department performed diagnostic imaging primarily with technecium-99m provided in unit dose form by Cardinal Health radiopharmacy. The department also utilized various unsealed isotopes as prescribed by authorized users for imaging and therapy, some of which require a written directive, including iodine-131.

The licensee is authorized for use of yttrium-90 TheraSpheres for permanent brachytherapy in the interventional radiology department, but at the time of inspection only one treatment had been performed. The licensee's RSO is typically onsite at the hospital one day a week. The technologists report directly to the Clinical Manager who reports to the Regional Director of Diagnostic Imaging.

1.2. Observations

The inspector observed one technologist open the nuclear medicine department around 6:30 a.m. and perform daily calibrations of the cameras, well counters, dose calibrators, survey instrumentation, and other related equipment. The unit doses are usually brought into the department by the radiopharmacy escorted by security. The hot lab is secured by an automatic locking door that requires a programmed keycard and unique pin number to access the lab. The previous inspection identified a violation of Title 10 *Code of Federal Regulations* (CFR) 20.1801 for failure to control access to the hot lab. The licensee's corrective actions were reviewed by the inspector and found to be adequate to prevent recurrence of this violation.

The inspector observed unit dose package receipt and opening, dose measurement, preparation and administration, daily surveys, and labeling of unit doses. The inspector questioned how the technologists tracked what patient received what dose and how that information is recorded into the licensee's computer software systems. The inspector reviewed selected written directives since the previous inspection; physical inventory lists; leak test records; records of the daily surveys and weekly wipe tests; dose calibrator calibrations of constancy, accuracy, and linearity; and material receipt and disposal records. One Severity Level IV (SL-IV) violation was identified from the items listed above, involving the requirement of 10 CFR 20.1906 for contamination surveys of radioactive packages during package receipt and opening as described in Section 2.2.

The inspector reviewed the licensee's procedures for safe use of radioactive materials, spill response, area surveys, and waste disposal of licensed materials. The inspector interviewed both locum tenens technologists about their training on the written radiation protection procedures listed above. Both temporary technologists stated that they had not been trained in the licensee's specific written procedures. One SL-IV violation of 10 CFR 35.27 which requires the technologists to be trained in those specific written procedures was identified. Additionally, one SL-IV violation of License Condition 17A,

involving developing procedures for area survey procedures was identified. Both violations are described in Section 2.2.

The radiation safety committee meetings minutes, annual audits, and personnel dosimetry records were reviewed. No high doses to workers were recorded. The RSO followed the licensee's procedural steps for when an individual reached a pre-set administrative dose limit at ALARA I. No ALARA II levels were reached by the nuclear medicine department materials users.

The inspector observed two different waste storage areas and found the decay-in-storage sharps, linens, I.V. tubing, etc. containers to be properly labeled, taped closed in bags, and secured. Independent surveys performed by the NRC with a RadEye G survey meter (Serial Number 0376, calibration due November 9, 2019) demonstrated that the licensee's postings of radiation areas were adequate and indicated dose rates, during normal operations, would be within regulatory limits.

2. Inspection Findings

2.1. Event Assessment

On January 22, 2019, a non-reportable spill event occurred involving a patient that had been administered 102.8 mCi of iodine-131. The patient was in a private room where the plumbing was not working correctly. The toilet was known to have overflowed in the past, and the issue was not corrected prior to the patient's stay. Approximately an hour and a half after the radiopharmaceutical administration, the toilet overflowed. The bodily clearance rate of iodine-131 is typically highest in the first urination after administration. It is likely that a large fraction of the iodine-131 administered was voided during the patient's first urination. The liquid mixture that overflowed out of the toilet created a contamination area in the room. It is unknown how much of the liquid in the toilet initially went down the drain pipe and how much of it spilled back out onto the floor.

Between 4:30 and 5 p.m. the toilet overflowed, and a charge nurse called the lead nuclear medicine technologist requesting that a maintenance worker be allowed to enter the room to un-clog the toilet. The lead technologist did not immediately stop all work activity near the patient's room or call the RSO. Instead, she gave instructions to the nursing staff, via the telephone, that it was okay for maintenance to go in the room.

All the licensee's employees are given a training course regarding the hazards of ionizing radiation. The licensee has x-ray producing machines and licensed radioactive materials, but most licensee employees are not exposed to these sources during their normal job duties. The licensee considers all employees radiation workers who might receive, during their assigned duties, a very low occupational dose. Most employees are not expected to receive annual doses anywhere near 100 mrem and are not provided training that meets the criteria found in 10 CFR 19.12. Although the dose that the licensee employees received from this event are unknown, they were likely less than 1 mrem. This is estimated by the NRC based upon the range of dose rates recorded by different individuals and the time that licensee employees spent near the material that had overflowed back onto the floor.

The toilet in this room had overflowed in the recent past and was a known issue to maintenance personnel. The licensee had the opportunity prior to placing the patient in

the room to identify and correct the malfunctioning toilet. Also, the lead technologist had the opportunity to immediately prevent personnel entry into the contaminated area. When maintenance was allowed to enter the room, via telephone, they had not received specific instructions involving area contamination controls.

Around 5 p.m. the supervisor over nursing staff called the lead technologist to request assistance with the overflow. When the lead technologist arrived in the room, they placed linens and chucks (absorbent mats) around the toilet area.

The lead technologist documented one pre-clean up survey result of 0.08 mrem per hour on a “Radioactive Spill Contamination Survey” form. However, the test for removable contamination in the general toilet area was identified as being less than 0.01 nanocurie, which doesn’t correlate to the 0.08 mrem per hour dose rate in the area. No specific time was documented for the survey or the contamination wipe, a map of the spill area wasn’t created for staff going into the room, and information related to where the one survey was taken, relative to the spilled water, wasn’t provided. The one pre-clean up survey was inadequate because it didn’t identify the that the absorbent chucks used to clean the spill had dose rates greater than 1 mrem per hour at about one foot away, and due to the unreconciled conflicting results between the area survey and wipe test result.

Around 5:15 p.m., housekeeping staff was paged over the hospital intercom system to clean the in-patient room. When the housekeeper arrived at the room, the supervising nurse instructed them to stop, not enter the area and stop work due to the contamination. Unfortunately, after the housekeeper stopped to leave, the intercom page persisted so the individual believed that being asked to stop and leave was a mistake, and they returned to the room and began cleaning. The lead technologist was not in the area to prevent entry into the room. The housekeeper had not received radioactive waste control training but handled the radioactive linens and chucks with disposable gloves, cleaned and mopped the toilet area, and left the room. The housekeeper placed the trash bag near other regular trash without performing a survey or holding the trash for decay-in-storage.

When the on-call locum tenens technologist arrived at the hospital to assist, they asked if the RSO had been called. The RSO had not been called about the spill. The locum tenens was tasked with cleaning the room by the lead technologist. When the locum tenens arrived at the in-patient’s room, they found that the room had already been cleaned by housekeeping. The locum tenens performed surveys of the room, the pc suit, and immediately asked where the linens and chucks had been taken. They then went and performed surveys of the trash bag containing those items, detected radioactivity, labeled it and placed it into a dedicated decay-in-storage room.

The locum tenens went and found the housekeeper who had cleaned the room, performed surveys of their clothing, hands and body and recorded those measurements appropriately. The dose rates were recorded as 0.02 – 0.03 mrem/h which is approximately the background dose rate measured at the hospital. No surveys of the maintenance worker were recorded. The dose rates documented for the spill did not exceed regulatory limits. The area was restricted to workers and the patient, and the overflow did not require reporting to the NRC.

2.2. Observations and Findings

Severity Level IV Violation of License Condition 17 A.

The licensee's spill procedure from the license application, in Section 4.5, "Radioactive Spills," requires that the "RSO be notified immediately and supervise the cleanup of major spills." The spill procedures did not address who, how and when a response to an event like an overflow should proceed. The licensee considered the overflow event a major spill, a technologist who was on-call was telephoned to come in and help with the clean-up, but the RSO wasn't called. The RSO wasn't notified of the spill or cleanup until after it was completed, and other staff members had supervised the response.

Severity Level IV Violation of 10 CFR 20.1501

When an iodine-131 patient's toilet is clogged and overflowing, it is reasonable to perform surveys and contamination wipe tests before clean-up work begins in the area. It isn't clear from the event documentation when the one survey was taken, but it was likely performed after the two phone calls from nursing to the lead technologist. The lead nuclear medicine technologist could not remember exactly when the surveys were performed, and she authorized entry into the room over the phone.

There were conflicting results between the area survey and the contamination wipe test which weren't reconciled. Survey results greater than 1 mrem per hour of the absorbent chucks, obtained more than an hour after they were removed from the room, demonstrated that the surveys and contamination wipes weren't adequate to identify dose rates in all areas of the room.

Severity Level IV Violation of 10 CFR 35.310

A dedicated in-patient room for iodine therapy is a room that requires specific controls, and the staff who implement those controls are required to have training commensurate with their duties. The licensee provides basic radiation awareness training to all their employees, including maintenance and housekeeping staff. The nursing staff caring for the in-patient iodine therapies have had radiation safety training to administer that care.

However, the training provided to the nurse, who permitted maintenance and housekeeping staff to enter the room, was not commensurate with the duties regarding contamination control. Additionally, the housekeeping staff was not provided training commensurate with their duties regarding waste control for properly removing radioactive chucks and linens from the room. Surveys should have been performed on the items prior to removal from the room, and they should have been segregated from the regular trash area.

Severity Level IV Violation of 10 CFR 35.27

The inspector interviewed two nuclear medicine technologists during the onsite inspection. Both technologists stated that they had not been instructed in, nor had they seen where the licensee's written radiation protection procedures were located prior to handling and using licensed byproduct materials. The lead technologist stated that the printed procedures had not been readily available in the department prior to the event in January 2019.

The inspector noted that the licensee only employed technologists who were highly educated and trained individuals, with many years of experience working as nuclear medicine technologists. The technologists had hands on job training at Kaiser and had the expertise to perform normal duties appropriately. The technologists understood the verbal expectations of the authorized users on the license. For the most part, they implemented tasks in the nuclear medicine department appropriately, but instruction in Kaiser's written procedures had not been accomplished.

Severity Level IV Violation of 10 CFR 20.1906

The inspector observed a technologist receive and open a labeled package containing radioactive materials. To check in the package, the technologist turned the survey meter on about a meter away, ensured that it was working and read the meter, then surveyed the surface of the package. The technologist did not wipe test the package to monitor for removable contamination.

The package was opened, the unit doses were removed, and the placard on the package was flipped over without a survey to indicate that it was empty. The inspector questioned the technologist if they were supposed to perform a wipe test, and the technologist stated that they had forgot. A wipe test was then performed for removable contamination, and none was found.

Severity Level IV Violation of License Condition 17 A.

In the license application a commitment was made to implement and maintain procedures for area surveys. During a document review, the inspector requested to review the procedure that specifically addressed area surveys. None of the licensee's staff could locate a procedure for area surveys, and the RSO stated that one did not exist. The RSO also stated that the locations of where surveys should be performed and the records of those surveys were kept electronically, and those tasks were performed without a procedure.

However, after the exit meeting concluded, the RSO stated that they had found the procedure developed for area surveys. The procedure, "Area Survey for Radiation Reading or Contamination, Policy Number 1452-N24, rev date July 2007, hadn't been looked at by licensee staff since approximately July 2015.

The procedure directed that daily area surveys and weekly wipe tests for removable contamination be performed, and when administering thallium or gallium, wipe tests be taken daily. Daily wipe tests, when administering thallium or gallium, were not performed. However, proper surveys at the end of each day and weekly wipe tests were performed when unit doses of Technicium-99m were administered.

The inspector noted that the procedure did not specify the types of surveys to perform under emergency situations, such as spill response, be performed by the RSO or that wipe tests and area surveys be performed. Information about what instrument was appropriate for use or maps with locations to survey was not included in the procedure. The inspector questioned the RSO whether the licensee wanted these topics in the procedure, and the RSO stated that they were considering these topics for the revision planned for the area surveys procedure.

3. Corrective Actions

The inspector observed that the licensee updated many of the written procedures after the overflow event. Also, the nuclear medicine technologists were re-trained specifically on the licensee's spill response procedure and the problems associated with iodine contamination from in-patient care. After the inspection, nursing staff responsible for iodine-131 in-patient care received in-person specific training from the RSO in areas of controlling access to the dedicated rooms and contamination areas if a spill occurs, and in waste control protocols for the items in the room.

4. Exit Meeting Summary

On August 29, 2019, a final telephonic exit meeting was conducted with the Regional Director and the Clinical Manager of Diagnostic Imaging, the RSO, and the lead nuclear medicine technologist. The NRC inspector described the Severity Level-IV violations and discussed the timeline for a response to the Notice of Violation in writing. The RSO acknowledged that a written response was required and understood the timeline required for the response.

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Robert Diaz, Regional Director of Diagnostic Imaging
Larry Ham, Clinical Manager of Diagnostic Imaging
Harry Palmer, Radiation Safety Officer
Cora Sagucio, Lead Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

87131 Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03546/2019-001-01	VIO	Failure to notify RSO immediately of spill (License Condition 17A.)
030-03546/2019-001-02	VIO	Failure to make surveys that were reasonable under the circumstances (10 CFR 20.1501)
030-03546/2019-001-03	VIO	Failure to provide instruction commensurate with duties for I-131 inpatient care (10 CFR 35.310)
030-03546/2019-001-04	VIO	Failure to instruct supervised individuals in licensee specific radiation protection procedures (10 CFR 35.27)
030-03546/2019-001-05	VIO	Failure to monitor labeled package for removable contamination (10 CFR 20.1906)
030-03546/2019-001-06	VIO	Failure to develop procedures for area surveys (License Condition 17 A.)

Closed

030-03546/2016-001-01	VIO	Failure to control access to the hot lab (10 CFR 20.1801)

Discussed

None

ACRONYMS

ADAMS - Agencywide Documents Access Management System
ALARA - As Low As Is Reasonably Achievable
CFR - Code of Federal Regulations
mCi - milliCurie
mrem/h - millirem per hour
NRC - U.S. Nuclear Regulatory Commission
RSO - Radiation Safety Officer
SL-IV - Severity Level IV