UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 20, 2022

EA-22-107
EN 55817
NMED No. 220164 (Closed)

Benjamin Hunter, Associate Vice President
and Superintendent of Public Safety
Indiana University-IUPUI/IU Medical Center Campus
1120 W. Michigan St.
Radiation Safety Room 159
Indianapolis, IN 46202-5111

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001609/2022001(DRSS) AND 03009792/2022001(DRSS) - INDIANA UNIVERSITY-IUPUI/IU MEDICAL CENTER CAMPUS

Dear Benjamin Hunter:

On May 2-6, 2022, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Indianapolis, Indiana, medical centers with continued in-office review through November 29, 2022. The inspection included a review of the circumstances surrounding a lost dose of radium-223 that occurred on March 31, 2022; your staff reported this incident to the NRC on April 1, 2022. The in-office review included a review of your written report and proposed corrective actions taken in response to the reported lost dose as well as a review of the training and experience of multiple authorized individuals. The results of this inspection were discussed with your staff in a telephonic exit meeting on November 29, 2022.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Enclosure 3 contains Sensitive Unclassified Non-Safeguards Information. When separated from the Enclosures, this transmittal letter is decontrolled.

Based on the results of this inspection, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included 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 and include violations associated with the loss of control of a patient dose containing 126 microcuries radium-223 that was reported to the NRC on April 1, 2022. The dose was inadvertently disposed of in the normal hospital waste. The nuclear medicine staff failed to perform an adequate survey of the packaging and the waste receptacle prior to emptying the hot lab waste receptacle, failing to identify that the dose was within the original shipping package. The violations associated with loss of control are being cited in the Notice to emphasize the importance of performing adequate radiological surveys to ensure the security and control of licensed material. The additional violations are being cited because the NRC identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

Signed by Edwards, Rhex
on 12/20/22

Rhex A. Edwards, Branch Chief
Division of Radiological Safety and Security

Docket Numbers: 030-01609, 030-09792
License Numbers: 13-02752-03, 13-02752-08

Enclosures:
1. Notice of Violation (public)
2. Inspection Report Numbers 03001609/2022001(DRSS)
   AND 03009792/2022001(DRSS) (public)
3. Security Addendum (non-public)

cc w/encl: Christopher P. Harvey, MS, MHP, RSO
Rachel Schmidt
Kathryn Manteussel
State of Indiana

Letter to B. Hunter from R. Edwards dated December 20, 2022.

SUBJECT: NRC ROUTINE INSPECTION REPORT NUMBERS 03001609/2022001(DRSS) AND 03009792/2022001(DRSS) - INDIANA UNIVERSITY-IUPUI/IU MEDICAL CENTER CAMPUS

DISTRIBUTION w/encl:
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OFFICE	RIII-DRSS	RIII-DRSS	OE-HQ	NMSS-HQ	RIII-EICS
NAME	DPiskura	ETindle-Engelmann	LSreenivas	RSun	DBetancourt-Roldan
DATE	12/1/22	12/2/22	12/16/22	12/6/22	12/19/22

OFFICE	RIII-DRSS				
NAME	REdwards				
DATE	12/20/22				

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Indiana University-IUPUI/IU Medical Center Campus
Indianapolis, Indiana

License No. 13-02752-03
Docket No. 030-01609
EA-22-107

During a U.S. Nuclear Regulatory Commission inspection conducted onsite on May 2 through May 6, 2022, with continued in-office review through November 29, 2022, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, controlled area means an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and an unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

   Contrary to the above, on March 31, 2022, the licensee failed to secure from unauthorized removal or limit access to a unit dose containing approximately 126 microcuries of radium-223 that was stored in a controlled area. Specifically, the failure to secure the unit dose resulted in the dose being disposed in the normal hospital trash and then disposed of in a municipal waste landfill.

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

B. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

   Contrary to the above, on March 31, 2022, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a), which describes the authorized means of disposing of licensed material. Specifically, the licensee did not perform an adequate survey before disposing of a unit dose, containing 126 microcuries of radium-223, as normal, non-radioactive waste.

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

C. License Condition 27 of License No. 13-02752-03 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 25, 2013.

Enclosure 1

Item 7 of Section 2 of the application dated March 25, 2013, requires, in part, that physicians applying for authorization as an Authorized Nuclear Medicine Physician (ANMP) meet the training and experience requirements specified in the appropriate section of 10 CFR Part 35 and Radionuclide Radiation Safety Committee (RRSC) members evaluate the past training and experience evidence to determine if the individual met the minimum requirements to be authorized for 10 CFR 35.300 uses.

Contrary to the above, in August of 2021, one ANMP was approved by the Radiation Safety Officer and RRSC for 10 CFR 35.300 uses without evidence of adequate training and experience. Specifically, the ANMP was approved with 100 hours of classroom and laboratory training while 200 hours of classroom and laboratory training was needed.

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

D. License Condition 27 of License No. 13-02752-03 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 25, 2013.

Item 10 of Section 2 of the application dated March 25, 2013, states that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material. The licensee developed a written procedure, item 11 within their Radiation Safety Manual, entitled “Contamination Control.” Item A. i. f. of the procedure requires, in part, that disposal gloves are worn when handling any radioactive material.

Contrary to the above, on May 2 and May 4, 2022, two individuals were observed to be handling radioactive material while not wearing disposal gloves. Specifically, on May 2, a nuclear medicine technologist was observed handling a container of radioactive waste without gloves and on May 4, a researcher was observed handling a container of residual radioactive material without gloves.

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

E. 10 CFR 35.633(a) states, in part, that a licensee authorized to use a high dose rate remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source.

10 CFR 35.633(b) states, in part, that to satisfy the requirements of paragraph (a) of this section full calibration measurements must include determination of length of the source transfer tubes and length of the applicator.

Contrary to the above, prior to May 2, 2022, the licensee was authorized to use a high dose rate remote afterloader unit for medical use and did not perform full calibration measurements on the unit. Specifically, the licensee failed to determine the length of the source transfer tubes and the length of the applicators as part of their full calibration measurements.

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

Pursuant to the provisions of 10 CFR 2.201, Indiana University-IUPUI/IU Medical Center Campus 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 III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violations, or, if contested, the basis for disputing the violations or their 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 previously 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 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.

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

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 20 day of December 2022.

U.S. Nuclear Regulatory Commission
Region III

Docket Nos.	030-01609 030-09792
License Nos.	13-02752-03 13-02752-08
Report Nos.	030-01609/2022001(DRSS) AND 030-09792/2022001(DRSS)
NMED No.	220164
Licensee:	Indiana University-IUPUI/IU Medical Center Campus
Address:	1120 W. Michigan St. Indianapolis, IN 46202-5111
Locations Inspected:	IU Health Methodist Hospital IUPUI Medical Center Campus IUH North Schwarz Cancer Center
Inspection Dates:	May 2-6, 2022, with continued in-office review through November 29, 2022
Exit Meeting Date:	November 29, 2022
Inspectors:	Elizabeth D. Tindle-Engelmann Health Physicist Deborah A. Piskura Senior Health Physicist
Approved By:	Rhex A. Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure 2

EXECUTIVE SUMMARY

Indiana University-IUPUI/IU Medical Center Campus
NRC Inspection Reports 03001609/2022001(DRSS) AND 03009792/2022001(DRSS)

This was an announced routine inspection of a multi-site broad scope medical institution with facilities located in central Indiana. Indiana University-IUPUI/IU Medical Center Campus (IUPUI) was authorized under NRC License Numbers 13-02752-03 and 13-02752-08 to possess and use diagnostic and therapeutic radiopharmaceuticals as well as various sealed sources and devices for brachytherapy and gamma stereotactic radiosurgery (GSR) for uses permitted by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 and research and development.

The NRC conducted an announced routine inspection on May 2-6, 2022. The scope of the inspection was to examine the activities conducted under the licenses and to confirm compliance with the NRC rules, regulations, and the conditions of the licenses. The inspection assessed the adequacy of the university's NRC-licensed operations authorized under two NRC licenses: the medical/academic and research broad scope license and the GSR license. The inspection also included a review of the circumstances surrounding the inadvertent disposal of a 126-microcurie dose of radium-223 (Ra-223) that occurred on March 31, 2022.

The inspection identified five safety-related violations regarding the licensee's failure to: (1) secure from unauthorized removal or limit access to a unit dose containing approximately 126 microcuries of Ra-223 in accordance with 10 CFR 20.1801; (2) perform an adequate survey before disposing of a unit dose, containing 126 microcuries of Ra-223, as normal, non-radioactive waste in accordance with 10 CFR 20.1501; (3) conduct the approval of authorized users in accordance with the statements, representations, and procedures contained in their NRC License; (4) wear disposable gloves while handling radioactive material in accordance with the statements, representations, and procedures contained in their NRC License; and (5) perform full calibration measurements on the high-dose remote afterloader (HDR) unit that included determination of length of the source transfer tubes and length of the applicators in accordance with 10 CFR 35.633.

The inspection did not identify any security-related violations; the security inspection is discussed in the non-public Security Addendum to this IR.

REPORT DETAILS

1 Program Overview and Inspection History

The IUPUI was a large medical institution that conducted licensed activities at six locations in the Indianapolis, Indiana, metropolitan area. Under NRC License Number 13-02752-03, the licensee operated a Type A medical broad scope program with authorization to use licensed material with atomic numbers 3-83, and yttrium-90 (Y-90) microspheres. The licensee was authorized to conduct research including both animal and human studies under the oversight of the licensee's Institutional Review Board. Laboratory research and development activities were conducted under the supervision of approximately 30 individuals designated as principal investigators who were approved by the university's Radionuclide Radiation Safety Committee (RRSC). NRC License Number 13-02752-08 authorized the licensee's Gamma Stereotactic Radiosurgery (GSR) program. The licensee staffed its program with authorized gamma knife physicists and authorized users who were approved by the university's RRSC.

The NRC conducted annual routine inspections on June 3-7, 2019, and May 21-25, 2018, as part of the Regional Office's "broad scope initiative"; no violations of NRC requirements were identified during these inspections. The NRC conducted a reactive inspection on September 27-28, 2018, to review the circumstances, causes, and licensee corrective actions relative to a medical event that occurred on August 31, 2018; no violations were identified during this inspection.

The NRC issued an escalated enforcement action (EA-21-167) on September 1, 2022, for violations identified during an inspection conducted on October 19-20, 2020. The inspection was conducted to review the licensee's October 13, 2020, report of a medical event involving a Y-90 TheraSpheres® treatment. No violations of NRC requirements were identified related to the medical event; however, the inspector identified two interventional radiologists, approved for the use of Y-90, who failed to wear their assigned personnel monitoring for several years. The inspection identified four violations involving the licensee's failure to: (1) control the annual occupational dose or total effective dose equivalent to an individual to 5 rem in accordance with 10 CFR 20.1201(a)(1)(i); (2) monitor individuals' exposure from licensed and unlicensed radiation sources in accordance with 10 CFR 20.1502; (3) implement certain elements of the radiation protection program in accordance with 10 CFR 20.1101(a); and (4) provide instruction to individuals who were likely to receive in a year, an occupational dose in excess of 100 millirem in accordance with 10 CFR 19.12(a)(3). The licensee's corrective actions taken for these violations were not reviewed during the current inspection and will be reviewed during a future inspection.

2 Management Oversight

2.1 Inspection Scope

The inspectors reviewed the licensee's organization and management controls for the radiation protection program, including the organizational structure, management, and RRSC involvement and oversight, radiation safety office staffing, and the effectiveness of procedures and management practices in implementing the program.

2.2 Observations and Findings

The inspectors reviewed selected RRSC meeting minutes and documentation of training for physicians approved as authorized medical physicist and authorized users for various medical uses of licensed material. The RRSC established a quorum for its meetings that were held at least quarterly to review events, program audit results, and approve uses, facilities, and users. Protocols for human studies were reviewed by the licensee's Institutional Review Board and results were discussed at the RRSC meetings.

The radiation safety office was staffed with a full-time radiation safety officer (RSO) supported by four health physicists designated as Assistant RSOs, two administrative support persons, and one part time student intern who worked during the summer. In May 2022, the named RSO departed from the medical center and the position was assumed by one of the senior members of the health physics staff. The licensee filed an amendment request to change its RSO on May 10, 2022; on August 5, 2022, the NRC approved the licensee's amendment request to change its RSO for both NRC licenses.

The radiation safety office conducted an annual review of the radiation safety program. The results of the annual review were provided to the RRSC in a written report. The report served as an overall status report to senior management on the state of the radiation safety program

The RRSC approved all users and uses of licensed material and provided program direction and oversight through the establishment of procedures and administrative controls. RRSC membership and meeting minutes for 2020 through quarter 1 of 2022 were reviewed by the inspectors. The inspectors found that the RRSC had an active role in approving users and uses of licensed material. However, the inspectors identified one violation regarding the RRSC's criteria used for approving users for certain medical uses. Specifically, in August of 2021, one Authorized Nuclear Medicine Physician (ANMP) was approved by the RSO and RRSC for 10 CFR 35.300 uses without evidence of adequate training and experience. The ANMP was approved with 100 hours of classroom and laboratory training while 200 hours of classroom and laboratory training was needed. This is a violation of License Condition 27 of License No. 13-02752-03 which requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 25, 2013. Item 7 of Section 2 of this application requires, in part, that physicians applying for authorization as an ANMP meet the training and experience requirements specified in the appropriate section of 10 CFR 35 and RRSC members evaluate the past training and experience evidence to determine if the individual met the minimum requirements to be authorized for 10 CFR 35.300 uses. During the inspection, it was determined that the ANMP had the required training. However, the RRSC did not consider the required training when they approved the individual as an authorized user.

2.3 Conclusions

The inspectors determined that the licensee had adequate management oversight of the activities conducted under the licenses. However, the inspectors identified one violation relative to the licensee's failure to conduct the approval of authorized users in accordance with the statements, representations, and procedures contained in their NRC License.

3 Inadvertent Disposal of Ra-223

3.1 Inspection Scope

This inspection included a review of the sequence of events that resulted in the loss of a unit dose of Ra-223. The inspection included a tour of the licensee's nuclear medicine department at the University Hospital where the dose was received and stored. The inspectors interviewed selected licensee personnel. The inspectors assessed the licensee's efforts to locate and recover the lost dose, the licensee's root cause determination, and the licensee's proposed corrective actions to prevent similar events. The inspectors reviewed the licensee's April 29, 2022, written report of the lost dose.

3.2 Observations and Findings

On April 1, 2022, the licensee reported the loss of a unit dose syringe containing approximately 126 microcuries of Ra-223. Two clinical doses of Ra-223 had been delivered to the licensee's nuclear medicine department at University Hospital on March 31, 2022. At approximately 10:00 AM EDT, the licensee received the package containing the two doses. Patient 1 received their intended dose on March 31, 2022. Patient 2 was scheduled to receive their dose on April 1, 2022, at 1:00 PM EDT. However, at the time of the scheduled administration, the licensee's staff could not locate the dose within the hot lab.

The licensee concluded that the second dose was accidentally disposed of in the original box in which both doses were received. The licensee's investigation determined that a nuclear medicine technologist threw the box away in the normal trash without recognizing that the second dose remained inside. The licensee provided that for its site, it was rare for two doses to be delivered in a single package. The licensee's end of the day surveys of the trash can did not detect the second dose remaining within the shipping box. The licensee did confirm that the first spent dose was disposed of in the radioactive "sharps" container. Although the hospital's central waste facility was equipped with a portal monitor, the unused dose was not detected by that equipment.

The licensee notified the NRC Operations Center of the lost Ra-223 dose (Event Number 55817) on April 1 by telephone and provided its written report of the lost dose to the NRC in a letter dated April 29, 2022 (ADAMS Accession No. ML22175A199). The report included the information required by 10 CFR 20.2201(b).

Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801 requires that the licensee secure from unauthorized removal licensed materials that are stored in controlled or unrestricted areas. Title 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and an unrestricted area means an area, access to which is neither limited nor controlled by the licensee. The licensee's failure to secure from unauthorized removal or limit access to a unit dose containing approximately

126 microcuries of Ra-223 was stored in either a controlled or uncontrolled area is a violation of 10 CFR 20.1801.

Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. The inspectors determined that on March 31, 2022, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a), which describes the authorized means of disposing of licensed material. The licensee's failure to perform an adequate survey before disposing of a unit dose, containing 126 microcuries of Ra-223, as normal, non-radioactive waste is a violation of 10 CFR 20.1501.

The root cause of the loss of control and inadvertent disposal of the Ra-223 dose was attributed to poor survey techniques of the waste receptacle which failed to identify the presence of the dose. Contributing factors leading to the loss of the dose included the infrequency of receiving multiple doses in one package and the staff who initially handled the package were not the same staff who collect empty packages and who conducted the final lab waste collection at the end of the day.

The licensee implemented immediate corrective actions to address the direct cause of the lost dose to preclude similar events. The licensee revised its nuclear medicine procedures and processes to immediately place all therapeutic doses received from the vendor in a dosing rack within the hot lab. Prior to the incident, doses were only placed in the rack on the intended day of use. Now, doses are placed in the rack upon receipt and stay in the rack until use or proper disposal. The rack system holds doses within their shields.

3.3 Conclusions

The licensee made all the notifications and reports for the lost dose as required by 10 CFR 20.2201(a)(1) and 10 CFR 20.2201(b) within the specified time period. The licensee's written report for the lost material included all the required information. The inspectors concluded that the licensee's determination of the root cause of the lost dose was adequate and that initial corrective actions appear to be sufficient. The inspectors identified a violation for the licensee's failure to secure from unauthorized removal or limit access to a unit dose containing approximately 126 microcuries of Ra-223 in accordance with 10 CFR 20.1801 and a violation for the licensee's failure perform an adequate survey before disposing of a unit dose, containing 126 microcuries of Ra-223, as normal, non-radioactive waste in accordance with 10 CFR 20.1501.

4 Personnel Monitoring Program

4.1 Inspection Scope

This inspection included a review of the licensee's personnel program with focus on the interventional radiologists. The inspectors reviewed the licensee's bioassay program for select isotopes used for research and development. The inspectors reviewed records, procedures, and documents maintained by the licensee, observed licensed activities,

and interviewed selected licensee personnel. The inspectors reviewed personnel monitoring reports.

4.2 Observations and Findings

The licensee implemented a personnel monitoring program for monitoring external and internal occupational dose as required by 10 CFR 20.1502. The licensee provided whole body and extremity monitoring devices to those individuals who routinely handled specified quantities of beta/gamma emitting material in the department of radiation oncology nuclear medicine and radiation safety researchers who used quantities of byproduct material also received whole body and extremity monitoring devices. The licensee monitored radiation exposure to nuclear medicine technologists using whole body and extremity personnel dosimeters provided by an accredited laboratory. The dosimeters were exchanged monthly. All technologists were advised of their exposure data at least annually, as were other users who might exceed 100 mrem in a year or who requested a report of their exposure. The inspectors reviewed a sampling of dosimetry reports and determined that all monitoring results were below Part 20 occupational exposure limits.

The licensee implemented programs for informing staff of Declared Pregnant Worker (DPW) policies and procedures for monitoring and recording the fetal dose. DPWs were provided separate fetal dose monitors. The licensee individually tracked and monitored the fetal dose as required by 10 CFR 20.1208.

The licensee implemented a bioassay program to monitor potential intake of radioactive material such as routine thyroid monitoring which was conducted on workers who handled radioiodine above specified thresholds. For these researchers, the radiation safety office logged all material purchases and tracked the use of these materials which warranted a worker bioassay.

4.3 Conclusions

The licensee's personnel monitoring program met the regulatory requirements.

5 Facility Tours and Observations

5.1 Inspection Scope

The inspectors observed licensed activities, interviewed licensee personnel, and reviewed selected records concerning use and security of licensed materials, and other aspects of the radiation safety program. The inspectors observed the use of byproduct material, including the administration of several doses for various nuclear medicine studies. The inspectors toured research labs and other medical use facilities and observed the licensee’s staff handling radioactive materials and the safety protocols they used while handling radioactive materials

5.2 Observations and Findings

The inspectors reviewed other aspects of the licensee’s radiation protection program, which included, security of licensed material, personnel monitoring, training, labeling of containers, and postings.

The inspectors observed licensee personnel prepare, assay, and administer two Y-90 microspheres doses for patient treatments. The inspectors interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers, and reviewed selected records.

During facility tours and demonstrations of handling radioactive materials, the inspectors observed two individuals who failed to wear gloves while handling vials of radioactive material or spent radioactive doses. These vessels contained small or residual amounts of radioactive material. The inspectors pointed out the poor practice of handling radioactive material without proper protective equipment and the potential for skin contamination. This is a violation of License Condition 27 of License No. 13-02752-03 which requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 25, 2013. Item 10 of Section 2 of this application states that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material. The licensee developed a written procedure, item 11 within their Radiation Safety Manual, entitled "Contamination Control." Item A. i. f. of the procedure requires, in part, that disposable gloves are worn when handling any radioactive material.

The inspectors observed three HDR brachytherapy treatments. The inspectors reviewed the respective written directives and the treatment plans and interviewed selected individuals. The inspection included observations of quality assurance checks, safety checks, security of byproduct material, use of personnel monitoring, and patient surveys. The licensee's staff demonstrated elements from the HDR full calibration measurements. Based on a review of the full calibration records and the demonstration, the inspectors determined that the licensee did not perform full calibration measurements that included the determination of length of the source transfer tubes and length of the applicators. Specifically, the HDR source had been replaced approximately every 4 months, since the previous NRC inspection, and the licensee failed to determine the length of the source transfer tubes and the length of the applicators as part of their full calibration measurements which is a violation of 10 CFR 35.633. As a corrective action, the licensee performed a determination of length of the source transfer tubes and length of the applicators prior to the end of this inspection. The results were as expected. The inspector determined that there were no impacts to patient treatment or public health and safety.

5.3 Conclusions

The inspectors identified one violation for the licensee's failure to wear disposable gloves while handling radioactive material in accordance with the statements, representations, and procedures contained in their NRC License and one violation for the licensee's failure to perform full calibration measurements on the HDR unit that included determination of length of the source transfer tubes and length of the applicators in accordance with 10 CFR 35.633.

6 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facilities. The survey results were consistent with the licensee's postings, the licensee's survey results, and applicable regulatory limits.

Instrumentation: Model: RadEye G
Serial Number: 30650
Calibration Expiration: June 28, 2022

Instrumentation: Model: RadEye G
Serial Number: 30711
Calibration Expiration: 03/29/2023

7 Exit Meeting Summary

The NRC inspectors presented the preliminary inspection findings during an onsite inspection briefing following the onsite inspection on May 6, 2022. Upon completion of in-office review, a virtual exit meeting was held on November 29, 2022, with the licensee. On both occasions, the licensee acknowledged the findings. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary.

PARTIAL LIST OF PERSONNEL CONTACTED

Steve Adams, Sr. Director, Public Safety
Emily Choi, Assistant Radiation Safety Officer
Thomas Patrick Gannon, J.D., Senior Counsel
#*Christopher P. Harvey, MS, MHP, RSO
Benjamin Hunter, Associate Vice President, Public Safety
Tim David Kleyn, Assistant Radiation Safety Officer
#*Kathryn Manteuffel, University Director, Environmental Health and Safety
#T. Michael Martin, Ph.D., CHP, DABHP, Former RSO
Mark Payne, M.D., Chair RRSC & RDRC
#*Rachel Schmidt, M.S., Assistant Radiation Safety Officer

Several nuclear medicine, radiation oncology and research professionals were also contacted as part of this inspection

#Attended the inspection briefing on May 6, 2022
*Attended the virtual exit meeting on November 29, 2022

INSPECTION PROCEDURES USED

IP 87103, “Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing”
IP 87133, “Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs”
IP 87134, “Medical Broad Scope Programs”

LIST OF ACRONYMS AND ABBREVIATIONS USED

ANMP:	Authorized Nuclear Medicine Physician
DPW:	Declared Pregnant Worker
GSR:	Gamma Stereotactic Radiosurgery
HDR:	High Dose Rate remote afterloader
IUPUI:	Indiana University-IUPUI/IU Medical Center Campus
IR:	NRC Inspection Report
Ra-223:	radium-223
RRSC:	Radionuclide Radiation Safety Committee
RSO:	Radiation Safety Officer
Y-90:	yttrium-90
10 CFR:	Title 10 of the *Code of Federal Regulations*