INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

June 15, 2022

ATTN: Director, Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Resource@nrc.gov

RE: Response to the Apparent Violations in the Inspection Report No. 030-01609/2020002(DNMS); EA-21-167

Dear Sir/Madam:

Attached please find Indiana University's response to the apparent violations as noted in the aforementioned report. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Benjamin Hunter
Associate Vice President; Superintendent
Indiana University Public Safety

cc: Michael Martin, PhD, CHP – IUMC/IUPUI Radiation Safety Officer
Mark Payne, MD, FAAP, FACC – Chairman, Radionuclide Radiation Safety Committee
Dwayne Pinkney, PhD, Executive Vice President, IU Office of Finance & Administration

1120 W. Michigan St. – Gatch Hall, Rm. 159 Indianapolis, IN 46202 Phone (317) 274-4797 Fax (317) 274-2332 RADSAFE@IU.edu

RESPONSE TO THE APPARENT VIOLATIONS
Inspection Report No. 030-01609/2020002(DNMS); EA-21-167

Apparent Violation #1 – Control the annual occupational dose or total effective dose equivalent to an individual to 5 Rem as required by 10 CFR 20.1201(a)(1)(i)

1) Reason for Apparent Violation

The failure to control the annual occupational dose was the result of the actions of the first physician, Interventional Radiologist one (IR1), who did not consistently wear assigned dosimetry badges. For physicians and other employees using Y-90 radiation, dosimetry badges are required to be exchanged monthly; however, there were several months when IR1 did not return dosimetry badges or returned them unused. Attempts to collect unreturned badges or provide dose estimates for unused badges, at the time of occurrence, were unsuccessful. This allowed an elevated exposure to occur for IR1 for the total effective dose equivalent for the years of 2012 and 2013.

2) Corrective Steps That Have Been Taken

Although IUPUI-Radiation Safety is not able to change the outcome of the occupational dose for IR1 for the years of 2012 and 2013, several steps have been taken to address the issue, including the following:

- A mandatory compliance acknowledgement was created for all physicians performing Y-90 procedures. This document outlines proper dosimetry wear, return badge procedures, and institutes consequences for non-compliance. Briefly stated, the consequences for non-compliance are as follows: one instance of non-compliance results in a warning letter. Two instances result in suspension from Y-90 procedures for three months and requires completion of a radiation safety review course. Three instances result in total removal from Y-90 procedures. This compliance piece was included in the follow up response to the NRC dated December 11, 2020.

- The IUPUI-Radiation Safety presented to the Hospital System-wide Radiology Leadership Council on December 3, 2020, to provide dosimetry training and emphasize importance of proper dosimeter wear and gain leadership support and assistance (e.g., checking physicians for badge wear) at departmental levels. The details and PowerPoint slides for this discussion were also included in the follow-up response to the NRC dated December 11, 2020.

- A letter of reprimand was issued to IR1 for violation of existing radiation safety policies, hospital policies, and federal and state regulations (see Attachment 1).

- A comprehensive review of all unused and unreturned badges was implemented as a part of the ALARA (as low as reasonably achievable) program. The review includes a follow-up questionnaire to participants who do not return a badge or return an unused badge for a particular period. Additionally, a review of badges that receive minimum exposure for groups where greater-than-minimum doses are expected to occur is conducted. Dose estimates are performed, as needed, and updated dosimetry information is provided to the

badging vendor. While IUPUI-Radiation Safety has always had a process for unreturned badges, a more comprehensive review has become standard practice since the October 20, 2020, investigation (see Attachment 2 for an example of the email notification, missing badge form, FAQs and dose estimate form).

- As required under 10 CFR 20.2203(a)(2)(i), a letter of Notification of Overexposure was submitted to the NRC on April 23, 2021, which included dose estimates, levels of radiation or radioactive material, cause of the elevated exposure, and corrective actions taken. The physician receiving the overexposure was also notified on April 23, 2021.

- As was explained during an on-site investigation on October 20, 2020, IUPUI-Radiation Safety has been monitoring the physician's compliance with wearing dosimetry. All Y-90 physicians are complying with the requirements to date. Additionally, the dose history of the two physicians in questions are being monitored carefully.

3) Corrective Actions Taken to Avoid Further Violations

Previously, the university's institutional ALARA program flagged or reviewed exposures above certain thresholds. As mentioned above, while IUPUI-Radiation Safety has always had a process for unreturned badges, the ALARA program was revised to include a comprehensive review of unused or unreturned badges, along with greater attempts to collect these badges or to provide dose estimates at the time of occurrence, in order to avoid exposure issues before they become a problem. Additionally, the program was revised to include a review of badges that receive minimum exposure for groups where greater-than-minimum exposures are expected to occur. IUPUI-Radiation Safety will monitor the compliance with wearing dosimetry during every Y-90 procedure. Lastly, greater support has been received by leadership to control and prevent overexposure by implementing a compliance acknowledgement with proposed corrective actions, including but not limited to, removal of authorized user status of Y-90 procedures.

4) Date When Full Compliance Was Achieved

Full compliance was achieved as of the date of the follow up response to the NRC on December 11, 2020.

Apparent Violation #2 – Monitor exposure from licensed and unlicensed radiation sources as required by 10 CFR 20.1502(a)

1) Reason for the Apparent Violation

Although a personnel monitoring program has long-existed and been implemented by IUPUI-Radiation Safety, the failure of IUPUI-Radiation Safety staff to identify deficiencies in the personnel monitoring program allowed for unused and unreturned badges, and subsequently potential exposures, to go unresolved for IR1 and a second physician, IR2. These deficiencies were primarily caused by the failure of the physicians to wear their dosimetry badges as required, and whose failure was compounded by ineffective compliance monitoring policies and practices that have now been corrected.

2) Corrective Steps That Have Been Taken

Several of the corrective steps that have been taken to resolve Apparent Violation #1 are applicable this apparent violation too. These include the following:

- The mandatory compliance acknowledgment that was created for all physicians performing Y-90 procedures. The acknowledgment outlines proper dosimetry wear and return badge procedures.

- The IUPUI-Radiation Safety presentation to the Hospital System-wide Radiology Leadership Council to provide dosimetry training and emphasize proper dosimeter wear as well as to gain leadership support and assistance at department levels.

- A comprehensive review of all unused and unreturned badges was implemented as a part of the ALARA program. Dose estimates were performed, as needed, and updated dosimetry information is provided to the badging vendor.

- The IUPUI-Radiation Safety has monitored the physician's compliance with wearing dosimetry. All Y-90 physicians have been complying with the requirements to date.

3) Corrective Actions Taken to Avoid Further Violations

The follow actions are being taken to avoid further violations:

- The mandatory compliance acknowledgment will be reviewed and signed by all physicians who perform Y-90 procedures on an annual basis. Corrective actions will be taken for any of the physicians who do not comply as indicated on the document.

- The IUPUI-Radiation Safety will monitor physician compliance with wearing dosimetry. Radiation Safety staff will monitor compliance so that all physicians are wearing their dosimetry prior to performing any Y-90 procedures.

- The comprehensive review of all unused and unreturned badges will continue to be implemented. This process has been added to standard operating procedures and the Radiation Safety Procedures Manual was updated to highlight this practice.

- The IUPUI-Radiation Safety application for personnel monitoring was updated in June of 2014 to include the following statement: "I agree to wear all badges issued to me correctly each time I work with radioactive materials/radiation-producing machines. I also agree to wear all prescribed protective devices each time I work with radioactive material/radiation-producing machines. If my work conditions change or if there is a problem with my badges, I will notify the RSO immediately." This statement was signed by IR2 when completing the application (see Attachment 4). However, this update did not occur prior to IR1 completing a personnel monitoring application. IUPUI-Radiation Safety will continue to require the acknowledgement of this statement on all applications for personnel monitoring.

4) Date When Full Compliance Was Achieved

Full compliance was achieved as of the date of this letter.

Apparent Violation #3 – Implement certain elements of your radiation protection program as required by 10 CFR 20.1101(a)

1) Reason for Apparent Violation

The failure to implement certain elements of the radiation protection program as required by 10 CFR 20.1101(a) was due to ineffective policies and practices preventing IUPUI-Radiation Safety to identify, monitor, and address dosimeter use and to discover unexpectedly low dosimeter readings.

2) Corrective Steps That Have Been Taken

The corrective steps that have been taken include:

- The IUPUI-Radiation Safety's standard operating procedures were updated to illustrate the steps for identifying a lack of dosimeter use or lower than anticipated exposure results. Also, the Radiation Safety Procedures Manual was updated to mention this change (see yellow highlighted sections of Attachment 3).

- The procedure for notifying employees of unreturned badges was enhanced to include a more efficient electronic (online) form, instead of a paper form. The procedure includes an email sent directly to the employee with a link to the online electronic form. Responses to the online form are then sent directly to IUPUI-Radiation Safety. Radiation Safety staff will perform dose estimates and update dose reports, as necessary, based on the response received on the forms. This process will allow IUPUI-Radiation Safety to better track unused dosimeters. This procedure was implemented with our comprehensive review of unused and unreturned badges, which became standard practice on October 20, 2020.

- A review of badges that received minimum exposure for groups where greater-than-minimum exposure are expected to occur was conducted. This review includes all IR physicians who are involved in Y-90 procedures. Dose estimates are performed, as needed, and updated dosimetry information is provided to the badging vendor. This has also become standard practice since October 20, 2020.

- As mentioned above, the IUPUI-Radiation Safety has committed to monitor compliance in wearing dosimetry for persons involved in Y-90 procedures, including the two physicians in question, during every Y-90 procedure.

3) Corrective Actions Taken to Avoid Further Violations

All corrective steps mentioned above continue to be used to avoid non-compliance.

4) Date When Full Compliance Was Achieved

Full compliance was achieved as of the date of this letter.

Apparent Violation #4 – Provide instruction to individuals who were likely to receive in a year, an occupational dose more than 100 millirem as required by 10 CFR 19.12(a)(3)

1) Reason for Apparent Violation

The reason for the apparent violation is because instruction regarding the proper use of personnel dosimeters prior to the NRC investigation was not adequately tracked and documented prior to November 10, 2020.

2) Corrective Steps That Have Been Taken

While IUPUI-Radiation Safety is not able to demonstrate that IR1 and IR2 received instruction at the time they were provided with dosimeters and started using radioactive material, IUPUI-Radiation Safety believes both physicians were informed on how to wear their dosimeters and given instructions on dose reduction techniques the same as any other user as a matter of standard practice. This information is outlined in the Radiation Safety Procedures Manual (see Attachment 3) and IU Health policies. Additionally, proper badge wear and dose reduction techniques are mentioned in all radiation safety training for both academic and clinical areas.

It is IUPUI-Radiation Safety's practice that when an employee completes an application for personnel dosimetry, the employee is provided with a document that outlines the proper badge wear (see Attachment 5). This document is sent to the employee along with temporary badges, if needed, via campus mail after the application has been processed. Additionally, this information is also sent to any employee who receives an ALARA notification. Both physicians in question had received an ALARA notification with proper badge wear attachment prior to this investigation.

As mentioned above, a mandatory compliance acknowledgement was created for all physicians performing Y-90 procedures. This document outlines proper dosimetry wear, return badge procedures, and institutes consequences for non-compliance. This compliance piece was included in the follow up response to the NRC dated December 11, 2020.

3) Corrective Actions Taken to Avoid Further Violations

In addition to the mandatory compliance acknowledgment mentioned above, IUPUI-Radiation Safety staff are providing all physicians who perform Y-90 procedures instructions for proper badge wear and dose reduction techniques (see Attachment 6). IUPUI-Radiation Safety will provide this document to the physicians on an annual basis (as a refresher).

4) Date When Full Compliance Was Achieved

Full compliance was achieved as of the date of this letter.

INDIANA UNIVERSITY
SCHOOL OF MEDICINE
Department of Radiology and Imaging Sciences

June 2, 2021

[redacted]

RE: Letter of Reprimand – Radiation Safety

Dr. [redacted],

This letter is to inform you that you are hereby officially reprimanded for violation of IU School of Medicine (Radiation Safety Procedures Manual) and IU Health (Radiation Safety: Personnel Monitoring) policies. These policies are enacted to provide for your health and safety, as well as to comply with state and federal regulations and hospital accreditation. Specifically, from 2012 through October of 2020, you neglected to correctly or consistently wear your assigned personnel radiation monitoring device ("dosimeter"). Failure to appropriately wear your dosimeter has not only resulted in inadvertently exceeding annual radiation exposure limits in 2012 and 2013, but has also caused a violation of state and federal regulations.

In the future, you are required to correctly and consistently wear your assigned dosimeter during all occupational exposures to ionizing radiation at IU and IU Health facilities. The dosimeter shall be worn at or near the collar, outside of the lead. Dosimeters should be promptly exchanged at the beginning of the month. If a new dosimeter is unavailable due to work location or other issues, continue to wear your existing dosimeter until you can exchange devices.

This disciplinary notice shall serve to warn you that any recurrence of the same or similar violation will be considered just cause for more severe disciplinary action. Failure to comply with the referenced policies not only puts yourself at risk but may also incite regulatory consequences for the institution. If you have any questions regarding this letter, you may contact myself or Academic Affairs.

Sincerely,

Himanshu Shah, M.D.

Himanshu Shah, MD, FACR, FSIR
Chair, Department of Radiology & Imaging Sciences
Eugene C. Klatte Scholar in Radiology
Associate Professor of Clinical Radiology and Imaging Sciences

Acknowledged by:

[redacted]

cc: [redacted]
Mary Dankoski, PhD, IUSM Faculty Affairs
Emily Jerman-Brown, IU Health Physicians Human Resources

From: RADSAFE
Sent: Monday, June 6, 2022 7:03 AM
To:
Subject: Missing Badge Notification for Jun 2021

From: RADSAFE <radsafe@iupui.edu>
Sent: Thursday, October 14, 2021 10:42 AM
To: [redacted]
Subject: Missing Badge Notification for Jun 2021

Good Afternoon,

For the period indicated in the subject line, your radiation monitoring badge(s) has not been returned to Landauer.

Please **CLICK HERE** to complete a brief survey regarding your radiation use during this time period. The survey must be completed within **two weeks**.

Wearing your radiation monitoring badge is not optional. It is required by the Nuclear Regulatory Commission, Indiana state law, and hospital policy when you are working with radiation. If you don't believe you meet the requirements to need a badge, contact your Badge Coordinator or the Radiation Safety Office.

You may reply to this e-mail with questions. Thank you,

IUPUI Radiation Safety Office

Following up on unused/unreturned badges is a new process that came about in response to a recent inspection. Users who may not have worn their badge when required will receive similar notices in the future.
<< This message was generated automatically. >>

Missing Badge Form

If your badge is marked as "unreturned," then it never made it back to Landauer for processing. (It could be delayed; if you did return your badge, indicate this below.) Even if your badge was not used, it still must be returned to Landauer.

When usual dosimeter data is unavailable, it is important that we gather as much information on your radiation use as possible in order to have the most accurate estimate of your radiation exposure.

RESPOND WITHIN 2 WEEKS OF RECEIVING THIS SURVEY. Contact radsafe@iupui.edu with any questions.

Name; Participant Number; Account Number; Series Code *

[redacted]

Badge(s) & Wear Date *

COLLAR for JUL 2021

Was this badge(s) used at all? *

- ○ Yes
- ◉ No
- ○ Other:

If your badge(s) was not used, why? *

No procedures

Is this badge lost, or will it be returned? *

- (●) My badge was already returned.
- ( ) Yes, I will return this badge with the next outgoing group.
- ( ) No, my badge is lost.
- ( ) Other: _____

Was your workload during this time considered "typical" for you? *

- ( ) Yes
- (●) No
- ( ) Other: _____

Please describe your workload in detail. This could include number and types of cases, fluoroscopy "on" time, proximity to a highly radioactive source and time exposed, etc. *

Surgical ICU

Do you require any changes to your badging account? (Name, location, etc.)

IUPUI
OFFICE OF THE EXECUTIVE VICE PRESIDENT
FOR UNIVERSITY ACADEMIC AFFAIRS
University Environmental Health and Safety
Radiation Safety

FREQUENTLY ASKED QUESTIONS

The Radiation Safety Office has recently begun to follow up on unused and missing radiation monitoring badges. Please see the below answers to some common concerns.

Why am I receiving this survey?

The Radiation Safety Office does not have your exposure data for the time period indicated in the survey. This is because your badge was not received by Landauer at the time the survey was generated (usually indicating that the badge is about two months late). If you did not perform any work involving radiation during this time, please indicate so on the survey for our records.

I returned my badge to my badge coordinator for this time period, but the survey says my badge was not returned. Why am I receiving this survey?

"Missing" indicates that Landauer has not yet received the badge. Your badge coordinator may have returned the badges late, or the Radiation Safety Office may have received the badges late. Please indicate whether that time period was considered a typical workload regarding radiation use, so that the Radiation Safety Office can perform a dose estimate if needed.

I did not know I was assigned a radiation monitoring badge. Why am I receiving this survey?

If you work with radiation, it's possible that a badge was requested for you without your knowledge. The Radiation Safety Office can tell you who your badge coordinator is, but we usually don't know where they keep your badges for pickup and return; you'll have to ask them that.

I do not work with radiation. Why am I receiving this survey?

You may have worked with radiation in the past and your badge was never requested to be deactivated. It's also possible that someone else requested a badge for you without your knowledge. Or, we may have contacted the wrong person! Please respond in the survey with your concern.

Your badges must be worn when you are working with radiation-producing equipment or material. Remove the tab from the top of your badge to ensure it is read correctly. When you are not wearing your badges, store them away from all radiation sources. Please remember to exchange badges at the beginning of each cycle and return your old badges to your badge coordinator; failure to do so could result in erroneous exposure reporting. Ask us if you don't know who your badge coordinator is. If you have any questions, contact the Radiation Safety Office at (317) 274-4797.

IUPUI Radiation Safety Office

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FOR UNIVERSITY ACADEMIC AFFAIRS
University Environmental Health and Safety
Radiation Safety

FREQUENTLY ASKED QUESTIONS

The Radiation Safety Office has recently begun to follow up on unused radiation monitoring badges. Please see the below answers to some common concerns.

Why am I receiving this survey?

The Radiation Safety Office does not have your exposure data for the time period indicated in the survey. This is because your badge was coded as "unused," meaning that the tab at the top was not removed. If you did not perform any work involving radiation during this time, please indicate so on the survey for our records.

I used my badge during this time period, but the survey says my badge is unused. Why am I receiving this survey?

"Unused" indicates that the tab at the top of your badge was not removed. Please tell the Radiation Safety Office if you did not remove the tab during a time period when you did use your badge. We can ask Landauer to add that badge reading to your dose report.

My badge was correctly marked "unused" for this time period. Why am I receiving this survey?

Because a large number of users erroneously leave the tabs on their badge or don't return their badge at all, the Radiation Safety Office is required to follow up on these badges to ensure that dose records are accurate. Tell us in the survey if your badge was not used because you did not use radiation during that time period.

I did not know I was assigned a radiation monitoring badge. Why am I receiving this survey?

If you work with radiation, it's possible that a badge was requested for you without your knowledge. The Radiation Safety Office can tell you who your badge coordinator is, but we usually don't know where they keep your badges for pickup and return; you'll have to ask them that.

I do not work with radiation. Why am I receiving this survey?

You may have worked with radiation in the past and your badge was never requested to be deactivated. It's also possible that someone else requested a badge for you without your knowledge. Or, we may have contacted the wrong person! Please respond in the survey with your concern.

Your badges must be worn when you are working with radiation-producing equipment or material. Remove the tab from the top of your badge to ensure it is read correctly. When you are not wearing your badges, store them away from all radiation sources. Please remember to exchange badges at the beginning of each cycle and return your old badges to your badge coordinator; failure to do so could result in erroneous exposure reporting. Ask us if you don't know who your badge coordinator is. If you have any questions, contact the Radiation Safety Office at (317) 274-4797.

IUPUI Radiation Safety Office

INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY – INDIANAPOLIS

Dose Estimate Due to Absence of Personnel Monitoring

_____

Name:_____ Badge: _____-_____

According to our records, our office did not receive the following dosimeter(s) by the established due date:

_____ assigned from _____ to _____

As a reminder, it is a requirement of the Nuclear Regulatory Commission and the Indiana State Department of Health that you be monitored for radiation exposure. All old badges should be returned when new badges are issued. In order to remain compliant, an estimate of your exposure for the indicated wear date must be made. Please complete the **entire** form, providing as much **detail** as possible, and return it to our office. The estimate will be added to your permanent exposure history. If the badge(s) indicated is still in your possession, please return it along with this form as soon as possible so that it may be processed.

1. List any non-routine activities (i.e., more frequent use).

   _____

   _____

   _____

2. If working with x-ray producing machines, was any work performed while holding patients in fluorographic rooms or for any portable units? If yes, approximate how many during this period.

   _____

   _____

   _____

3. You would expect your exposure to be _____ usual.

Signature: _____ *Date:* _____

RADIATION SAFETY OFFICE USE ONLY

Estimated Exposure:_____ mrem Date Entered:_____

541 Clinical Drive – Room 159 Indianapolis, IN 46202-5111 (317) 274-4797 Fax (317) 274-2332

7. Maximum Permissible Radiation Dose Limits

A. Annual Occupational Dose Limits

i. Occupational radiation dose limits have been established by the NRC to (1) prevent deterministic effects and (2) limit the risk of stochastic effects. These limits are shown below and can also be found in 10 CFR 20.

TABLE 7-1: MAXIMUM PERMISSIBLE DOSE LIMITS

	ADULT (≥18 YRS)	MINOR (<18 YRS)
WHOLE BODY/TEDE	5,000 mrem/yr	500 mrem/yr
LENS OF EYE	15,000 mrem/yr	1,500 mrem/yr
EXTREMITIES	50,000 mrem/yr	5,000 mrem/yr
SKIN	50,000 mrem/yr	5,000 mrem/yr
ORGAN	50,000 mrem/yr	5,000 mrem/yr

TEDE = Total Effective Dose Equivalent

ii. For the purpose of external exposure, whole body includes the head and trunk area (i.e., arms above the elbows, legs above the knee, and the gonads). Extremities include the hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

iii. The whole body/TEDE limit requires that internal and external exposures be summed. External exposure is determined by the use of personnel monitoring devices. Internal exposure may be determined by calculation and/or by the performance of bioassays.

iv. Compliance with NRC regulations is determined by comparing the amount of radioactivity in the body to the appropriate Annual Limit on Intake (ALI) in 10 CFR 20, Appendix B. The limits for individuals under 18 years of age are 10% of the adult limits.

B. Dose Limits for Declared Pregnant Workers

i. A number of studies indicate that the risks associated with radiation exposure to the embryo/fetus are greater than those to adults (see NRC Regulatory Guide 8.13).

ii. In keeping with this information, the NRC has established a regulatory limit of 500 mrem to the embryo/fetus of a declared pregnant woman for the entire gestation period. In addition, this dose should be distributed evenly throughout the gestation period (approximately 50 mrem per month).

iii. Pregnant women who are occupationally exposed to radiation have the option to declare their pregnancy by completing the Form A-7: *Notice of Pregnancy*.

iv. When pregnancy is declared, the RSO will review any previous exposures the employee may have received as well as the potential for future exposures during the pregnancy. Based upon the review, the RSO will provide specific recommendations and/or implement any additional precautions.

v. If the pregnant employee does not declare pregnancy, the occupational exposure limits remain.

C. ALARA Program

i. The RSO evaluates radiation exposures for adherence to the radiation safety program for maintaining exposures **As Low As Reasonably Achievable** (ALARA). The ALARA program is implemented to ensure that exposures to ionizing radiation are as low as practical by utilizing safe work practices, such as time, distance, and shielding. Any excessive exposures and/or deviations from the ALARA program are investigated by the RSO and reported to the RRSC.

ii. ALARA investigational levels are set at 10% and 30% of the quarterly occupational exposure limit. The investigation levels and the basic procedures for maintaining the ALARA program are as follows:

TABLE 7-2: QUARTERLY ALARA LEVELS (MREM)

	Year Limit	Quarter Limit	Level I (10%)	Level II (30%)
Whole Body	5,000	1,250	125	375
Lens of Eye	15,000	3,750	375	1,250
Extremity	50,000	12,500	1,250	3,750
Skin	50,000	12,500	1,250	3,750
Organ	50,000	12,500	1,250	3,750

iii. When a participant exceeds one of the ALARA investigational levels, an ALARA notification is sent to the participant to ensure they are aware of their dose. The notification includes questions for the participant to complete regarding their exposure and provides an opportunity for any necessary dose corrections. Individuals who consistently receive higher doses each month will receive year-to-date ALARA notifications instead of quarterly ALARA notifications. Once an individual receives a year-to-date ALARA notification, they will receive monthly updates of their exposure for the remainder of the calendar year.

iv. Exposure(s) < Level I

a. In most cases, no further action will be required when an individual's exposure is less than those listed under Level I.

b. Investigation of exposure will be required if the individual's duties and dose history suggest an underexposure for the period, especially for groups where a greater occupational dose is anticipated.

v. For cases in which exposures are expected to routinely exceed an ALARA investigational level, a new, higher level may be established if it is consistent with good ALARA practices for that individual or group. Justification for a new ALARA level will be documented.

vi. Level I < Exposure(s) < Level II

a. Individuals exceeding ALARA Level I in a given quarter will receive a non-disciplinary ALARA notification.

b. The ALARA form must be completed by the individual and returned to the RSO so that corrections can be made as needed, or a record maintained that the individual acknowledged their dose. Radiation doses are a legal record, and a dose cannot be corrected without the consent of the participant.

c. The RSO will report the results of this review at the first RRSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Level

II, no action related specifically to the exposure is required unless deemed appropriate by the RSO and/or RRSC.

d. The RRSC will consider each exposure in comparison with those of others performing similar procedures as an indication of the ALARA program quality and will record the review in the RRSC minutes.

vii. Exposure(s) > Level II

a. Individuals exceeding ALARA Level II in a given quarter will receive a non-disciplinary ALARA notification with the badge coordinator on copy.

b. The RSO will investigate in a timely manner the cause(s) of exposures equaling or exceeding Level II and, if warranted, take action. Further investigation may be conducted such as shadowing an experiment or procedure to determine the cause of the elevated exposure.

c. The RRSC will be presented with this data at the first quarterly meeting following completion of the investigation.

d. The details of the investigation will also be made available to NRC inspectors for review at the time of inspection.

viii. Individuals whose exposure(s) exceed the year limit will be instructed to stop work immediately. The RSO will investigate these exposures and will notify the NRC and/or state as applicable. Work may restart if the overexposure is determined to be an error.

8. Personnel Monitoring

A. Monitoring Requirements

i. Radiation monitoring devices are provided by the Radiation Safety Office (RSO) to measure an individual's occupational radiation exposure from working with radiation-producing equipment or radioactive sources.

ii. Personnel are required to be monitored for radiation exposure if they are likely to receive at least 500 millirem in a year (10% of the annual occupational whole-body dose limit).

iii. If the necessity for personnel monitoring is unclear, the RSO may require personnel monitoring on a trial basis for a finite period of time. The result of this trial monitoring will be the basis for determining the need for continued personnel monitoring.

iv. In general, the radiation levels within a given area are controlled in such a way as to limit exposures to others within those areas to insignificant levels. The following criteria is used by the RSO to determine whether an individual requires monitoring for radiation exposure:

TABLE 8-1. PERSONNEL MONITORING REQUIREMENTS FOR RADIOACTIVE MATERIAL USERS

Radiation Type/Energy	Nuclide(s)	Activity/Experiment	Frequency/Type
Beta-emitters < 300 keV	^{14}C, ^{35}S, ^{3}H, ^{45}Ca	Any	None
Beta-emitters > 300 keV	^{32}P, ^{36}Cl, ^{131}I	< 1 mCi	None
		> 1 mCi and < 20 mCi	Quarterly body & ring
		> 20 mCi	Monthly body & ring
X-ray/Gamma-emitters < 500 keV	^{125}I, ^{51}Cr, ^{111}In, ^{99m}Tc	< 5 mCi	None
		> 5 mCi and < 10 mCi	Quarterly body & ring
		> 10 mCi	Monthly body & ring
X-ray/Gamma-emitters > 500 keV	^{22}Na, ^{64}Cu, ^{60}Co	< 0.5 mCi	None
		> 0.5 mCi and < 5 mCi	Quarterly body & ring
		> 5 mCi	Monthly body & ring

v. Depending on the radionuclide, the above limits may be lowered by a factor of 10 for minors and declared pregnant workers.

vi. Individuals who declare their pregnancy with the RSO will be given special instructions for personnel monitoring.

vii. RSO recommendations may vary on a case-by-case basis.

B. Initiating Personnel Monitoring

i. Before the initial monitoring devices can be ordered for a PH, an account number must be submitted to the RSO. The cost of routine personnel monitoring will be the responsibility of the PH. The RSO can be contacted for current pricing information.

ii. All individuals who meet the radiation monitoring requirements must complete the Form A-5: *Request for Personnel Monitoring Service*. This form must be fully completed before a badge will be issued.

iii. A new Form A-5 should be completed anytime an individual begins working for another PH that requires monitoring.

iv. Personnel monitoring badges are provided by the vendor with the individual's name printed directly on the badge.

v. There may be a one month delay between the time the Form A-5 is received by the RSO and the actual receipt of the individual's badge. A temporary badge will be provided by the RSO until the first reoccurring permanent badge is received.

C. Types of Personnel Monitoring

i. Whole-body badge: The whole-body badge is used to determine the whole-body deep dose and skin dose. Occupational radiation workers who are issued whole-body badges must wear their badges when working with radiation-producing equipment and/or radioactive material.

a. Chest Badge: If your whole-body badge has a pictogram of a black silhouette with a white dot in the center, you have been assigned a chest badge and it should be worn between your neck and torso (e.g. lapel pocket) with your name facing outward. If you wear a lead apron, it should always be worn underneath your lead apron.

b. Collar Badge: If your whole-body badge has a pictogram of a red silhouette with a white dot at the collar, you have been assigned a collar badge and it should be worn near your collar with your name facing outward. If you wear a lead apron, it should always be worn outside of your lead apron or thyroid shield.

ii. Ring badge: Individuals who handle radioactive material may be issued an additional ring badge to wear on the hand closest to the source of the radiation.

a. These badges are available in small, medium/large, or x-large to accommodate different finger sizes. Medium/large rings will be ordered unless specified otherwise by the badge coordinator.

b. Ring badges should be worn on one of the fingers of the dominant hand with the label of the ring badge facing towards the radiation source (generally towards your palm).

c. When handling radioactive material, ring badges should be worn under protective gloves to prevent contamination.

iii. Fetal badge: A fetal badge may be issued to individuals who declare their pregnancy by completing the Form A-7: *Notice of Pregnancy*.

a. Fetal badges are issued on a monthly basis and should be worn on the abdominal area underneath any lead apron.

D. Exchanging Personnel Monitoring Badges

i. Radiation monitoring badges are issued on a monthly or quarterly basis depending on potential for radiation exposure and frequency of radionuclide use.

ii. Whole-body badges are issued on a quarterly basis when the potential for significant individual exposure on a monthly basis is low and/or if personnel monitoring is required by a non-regulatory agency.

iii. When a ring badge is assigned in addition to a whole-body badge, they should be exchanged at the same frequency.

iv. Generally, one individual within a group or department is designated as a badge contact for that group of badge recipients. A few days prior to the exchange date (end wear-date), the contact person will receive and distribute the badges for their group. When the new badge is received, the used badge should be returned to the contact person who will mail it back to the RSO.

v. It is very important to exchange badges promptly. Failure to return used badges delays the badge readout process and, in some cases, results in an erroneous readout of the badge. If an individual does not receive a new badge at the appropriate time, they should notify the contact person and/or the RSO and continue wearing their old badge to ensure that there is no lapse in dose monitoring.

E. General Procedures for the Care and Use of Personnel Monitoring Devices. The following guidelines should be observed to achieve accurate data from radiation monitoring devices:

i. Badges shall only be worn by the individual whose name appears on the badge.

ii. Badges shall never be cut, torn, or opened. All badges should be returned to the RSO in the same condition they were received.

iii. When not in use, personnel monitoring devices should be stored well away from sources of radiation exposure.

iv. All personnel monitoring devices are issued for determining occupational exposure received at this institution only. Badges should not be taken home or otherwise removed from the premises; however, it is important to notify the RSO if you are occupationally exposed to radiation at another place of employment so that your annual Total Effective Dose Equivalent is accurate.

v. Upon termination of employment, all badges and holders should be returned to the RSO. The Form A-13: *Employee Status Change* shall be completed for each terminated employee and submitted to the RSO

vi. The RSO should be contacted immediately if any of the following events occur:

a. A badge is left near a radiation source.

b. A badge is contaminated with radioactive material.

c. A badge is exposed to excessive heat and/or humidity (e.g., placed in a washing machine or a dryer)

d. The film packet is cut/torn in such a way as to allow light to enter.

e. The badge is lost.

F. Exposure Reports and Dose Histories

i. The vendor-provided dosimetry report is initially received and reviewed by the RSO.

a. There is usually a two-to-four-week delay between the collection of badges and reporting of individual exposures due to processing. However, the vendor will immediately notify the RSO by telephone and email of any high exposures.

b. A copy of the dosimetry report is then forwarded to the badge contact person for each individual to review.

c. A copy of the report is retained and reviewed by the RSO.

ii. **If a badge is reported as "unused," or is not returned after 3 months, the individual will be contacted to obtain further information as to why the badge was not used or not returned. A dose investigation will be conducted if needed.**

iii. Individuals who have been issued personnel monitoring devices at other institutions shall provide the names and the addresses or other contact information of those institutions on the back of the Form A-5: *Request for Personnel Monitoring Service*. If an individual knows their exposure received at these institutions, it should be provided to the RSO.

iv. Radiation dosimetry records are available from the RSO.

a. An individual may request a copy of their exposure history at any time.

b. After leaving the University this may be accomplished by sending a written memorandum to the RSO providing their name, last 4 digits of social security number, department he/she worked in, and the dates of employment.

G. Bioassays

i. The necessity of bioassays, as well as the necessity of air monitoring, is determined by the RSO and/or the RRSC based upon the chemical form, the amount of the radioactive material being used, and the intended use.

ii. Bioassays may also be required if uptake of radioactive material is suspected.

iii. The following are two types of required bioassays:

a. Thyroid Bioassays

1. All individuals must have a baseline bioassay conducted before their initial use of unsealed (liquid) radioiodine.
2. Thyroid bioassays will be performed by the RSO between 24 and 72 hours after each iodination procedure.
3. The RSO should be contacted to set up a convenient time to perform the pre- and post-experiment bioassay.
4. The necessity and/or frequency of thyroid bioassays for other procedures will be at the discretion of the RSO.

b. Urine Bioassays

1. The RSO may require urine samples from individuals who handle quantities of radionuclides in excess of 20 mCi per experiment. This condition will be addressed in the PH's permit.
2. Unless otherwise instructed in the permit, these samples should be taken 24 hours after radionuclide use and delivered to the RSO for analysis.

ATTACHMENT 4 (PAGE 1 of 2)
Radiation Safety Form A.5
(Revised June 2015)

INDIANA UNIVERSITY

REQUEST FOR PERSONNEL MONITORING SERVICE

This form must be filled out in its entirety or badges will not be ordered.

Last Name: [redacted] First: [redacted] MI: ____ Sex: M ☒ F ☐

Department: Interventional Date of Birth: [redacted]

Bldg/Room: University Office Phone #: [redacted] Last Four Digits SSN #:XXX-XX-[redacted]

Permit Holder (if using radioactive material) or Badge Contact Person: Jewell Row

*NOTE: Submit this form and direct any questions to the Radiation Safety Office, CL-159, (P) 274-4797, (F) 274-2332.

Check the appropriate box:

☐ I will be working with these radiation-producing/radiation containing machines. (Please check all that apply.)

☐ Fixed X-Ray Unit	☒ Fixed X- Ray Fluoroscopy	☐ HDR
☐ Portable X-Ray Unit	☐ Portable X- Ray Fluoroscopy	☐ Gamma Knife
☐ CT	☐ PETCT	☐ ^{60}Co Teletherapy
☒ CT Fluoroscopy	☐ Accelerators	☐ Other (Please List): ____

If you checked fluoroscopy, how much time per week? ____ hours Dedicated IR physician
[If you are uncertain, ask your supervisor]

Will you be present in the exam room during any of these procedures? ☒ Yes ☐ No
If yes, please check below the protective devices that will be routinely utilized:
☒ Lead Apron ☒ Lead Glasses ☐ Thyroid Collar ☐ Other ____

☒ I will be working with radioactive material.
LIST RADIONUCLIDES AND MAXIMUM RADIOACTIVITY UTILIZED IN AN EXPERIMENT.
(You are also required to complete Radiation Safety Form A-3: *Authorization to Use Radioactive Materials.*)

Yttrium 90

THIS SECTION FOR ALL EMPLOYEES

I agree to wear all badges issued to me correctly each time I work with radioactive materials/radiation-producing machines. I also agree to wear all prescribed protective devices each time I work with radioactive materials/radiation-producing machines. If my work conditions change or if there is a problem with my badges, I will notify the RSO immediately.

Signature: [redacted] Date: 1/10/17

THIS SECTION FOR FEMALE EMPLOYEES ONLY

All female employees that are occupationally exposed to radiation are required to review the U.S. Nuclear Regulatory Commission *Regulatory Guide 8.13: Instruction Concerning Prenatal Exposure* in the Radiation Safety Procedures Manual. If you do not have access to a Radiation Safety Procedures Manual, you may request the regulatory guide from our office or view it from our website at http://researchadmin.iu.edu/Forms/radiation_safety/IUPUI/Reg_Guide%208.13.pdf. Specific questions regarding this topic should be directed to the Radiation Safety Office.

I acknowledge that I have received the instruction contained in the U.S Nuclear Regulatory Commission Regulatory Guide 8.13 concerning prenatal exposure, and I have been given an opportunity to ask questions.

Signature: ____ Date: ____

*****CONTINUED ON REVERSE SIDE*****

FOR OFFICE USE ONLY

Date ordered: 1-5-17

Participant #: 15484

Temp. Badge: chest - 9090965F
collar - 9090966F
ring - 9671595R

Series: DIR Dosimeter EDE1

Transferred ____ Reactivated ✓

ATTACHMENT 4 (PAGE 2 of 2)

PAST EXPOSURE INQUIRY

In compliance with 10 CFR Part 20.2104 of the U.S. Nuclear Regulatory Commission's *Rules and Regulations*, our office may be required to obtain your history of accumulated dose due to occupational exposure. Therefore, if you have previously been monitored (i.e. worn a film badge, etc.) for radiation exposure at any time, including work at Indiana University/Purdue University at Indianapolis and associated facilities, please provide *complete* information below. If you know your past exposure(s) received at your previous employment(s), please provide that information to the side along with your signature. Also, read and sign the release statement at the bottom of this application.

Employer: [redacted]

Address: [redacted]

City/State/Zip: [redacted]

Department: Radiology

Period Monitored: From 7 / 10 To 6 / 14

If you know your exposure from this employer

Exposure: _____ mrem

Signature: _____

Employer: Indiana University

Address: 550 University BLVD

City/State/Zip: Indianapolis IN 46202

Department: Interventional Radiology - Fellow

Period Monitored: From 7 / 14 To 6 / 15

If you know your exposure from this employer

Exposure: _____ mrem

Signature: _____

Employer: [redacted]

Address: [redacted]

City/State/Zip: [redacted]

Department: Radiology

Period Monitored: From 7 / 15 To 10 / 16

If you know your exposure from this employer

Exposure: _____ mrem

Signature: _____

RADIATION EXPOSURE HISTORY RELEASE STATEMENT

TO WHOM IT MAY CONCERN:

You are hereby granted permission to make available to the Indiana University/Purdue University Indianapolis (IUPUI) Radiation Safety Office any and all information concerning my radiation exposure history. You are further authorized to include in your transmittal to said person any or all information regarding my radiation exposure history acquired by you from other persons, employers, or agencies if such records are in your possession.

[redacted]

Signature

[redacted]

Name (Type or Print legibly)

XXX–XX-[redacted]

Social Security Number (last 4 digits)

Date 1/10/17

PLEASE RETURN COMPLETED FORM TO:

Radiation Safety Office
Clinical Building – Room 159
541 Clinical Drive
Indianapolis, IN 46202
(P) 274-4797 (F) 274-2332
radsafe@iupui.edu

IUPUI
OFFICE OF THE EXECUTIVE VICE PRESIDENT
FOR UNIVERSITY ACADEMIC AFFAIRS
University Environmental Health and Safety
Radiation Safety

PROPER DOSIMETRY BADGE WEAR

Where you wear your badge(s) relative to your body and any leaded protection is dependent on the type – chest, collar, or ring. Because dose assessments are based on this, it is important to wear them correctly.

Chest Badge:
If you are assigned a chest badge, wear it on your body between your neck and your torso (e.g., lapel pocket) with your name facing outward. If you wear a lead apron, it should always be worn *underneath* the apron.

Collar Badge:
If you are assigned a collar badge, wear it near your collar with your name facing outward. This badge should always be worn *outside* of your lead apron or thyroid shield.

Ring Badge:
If you are assigned a ring badge, wear it on the hand closest to the source of radiation. The face of the ring badge should always be facing toward the source of radiation (generally towards your palm).

Two Body Badges:
If you are assigned both a collar badge and a chest badge, wear the chest badge *underneath* the apron and the collar badge *outside* of the apron. This is important to ensure your exposure is calculated correctly. Switching these badges, wearing both in the same location, or returning them at different times will greatly affect your calculated exposure.

Lead Protection:
How your dose is calculated is based on whether you wear a lead apron and protective glasses. If you are not wearing protection when required or as assumed, your dose will be underestimated.

If you have questions about badge wear or what assumptions are made in the calculation of your exposure, please contact me.

Your badges should always be worn when you are working with radiation-producing equipment or material. When you are not wearing your badges, store them away from all radiation sources. Please remember to exchange badges at the beginning of each cycle and return your old badges to your badge contact person; failure to do so could result in erroneous exposure reporting. If you have any questions, contact the Radiation Safety Office at (317) 274-4797.

Sincerely,

IUPUI/IUMC Radiation Safety Office

INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

PROPER DOSIMETRY BADGE WEAR

COLLAR BADGE

If you are assigned a collar badge, wear it near your collar with your name facing outward. This badge should always be worn *outside* of your lead apron or thyroid shield. This is required any time you are performing work with radiation.

RING BADGE

If you are assigned a ring badge, wear it on the hand closest to the source of radiation. The face of the ring badge should always be facing toward the source of radiation, generally towards your palm. This is required any time you are using radioactive materials (like Y-90).

REMOVE THE TAB

The "Remove" tab on top of your badge must be removed, even if your badge is not placed in a clip. Failure to remove this tab will result in the badge being labeled "unused," and the exposure not appearing on your record.

It is required that you wear your badge(s) when you are working with radiation-producing equipment or material. When you are not wearing your badges, store them away from all radiation sources. Please remember to exchange badges at the beginning of each cycle and return your old badges to your badge contact person. Failure to do so could result in erroneous exposure reporting.

RADIATION EXPOSURE REDUCTION

TIME

Less fluoroscopy time is directly related to less radiation exposure to both you, your staff, and the patient. Use tools like Last Image Hold and lower frame rates to reduce "on" time.

DISTANCE

Doubling your distance from the patient table will lower your radiation exposure by 75%. Step out of the room or far from the patient during high-radiation runs like DSA.

SHIELDING

Always wear your lead apron and thyroid shield. Lead glasses reduce dose to your eyes by over 80%. If your hands will be in the beam, leaded gloves are required. Leaded mobile shields in the room may also be used.

OTHER TECHNIQUES

Use tight collimation to the area of interest and magnify only as needed. Minimize the patient-to-detector distance and maximize tube-to-patient distance. Minimize use of high-output modes. Always be mindful of how your choices affect machine output.

1120 W. Michigan St. – Gatch Hall, Rm. 159 Indianapolis, IN 46202-5111 (317) 274-4797 Fax (317) 274-2332