



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

September 1, 2022

EA-21-167
NMED Nos. 200416 and 220174 (Closed)

Mr. Dwayne Pinkney, PhD
Executive Vice President for
Finance and Administration
Indiana University-IUPUI/IU Medical
Center Campus
1120 W. Michigan St.
Radiation Safety Room 159
Indianapolis, IN 46202-5111

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY
\$8,000, NRC REACTIVE INSPECTION REPORT NO. 030-01609/2020002(DNMS)
AND OFFICE OF INVESTIGATIONS REPORT NO. 3-2021-002 - INDIANA
UNIVERSITY-IUPUI/IU MEDICAL CENTER CAMPUS (IUPUI)

Dear Dr. Pinkney:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on October 19-20, 2020, at the Indiana University Methodist Hospital, with continued in-office review through April 14, 2022. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number [ML2212A205](#), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>. The purpose of the inspection was to review the circumstances surrounding a medical event that occurred on October 13, 2020. This letter also refers to an investigation completed by the NRC Office of Investigations (OI) on November 10, 2021, at the Indiana University-IUPUI/IU Medical Center Campus (IUPUI). The purpose of the investigation was to determine whether willful failures to comply with NRC regulations occurred regarding: (1) two interventional radiologists working for IUPUI who did not wear dosimetry assigned to them by IUPUI and (2) IUPUI requiring and monitoring the wearing of dosimetry.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by: (1) requesting alternative dispute mediation; (2) attending a predecisional enforcement conference or; (3) by providing a written response before we made our final enforcement decision. In a letter dated June 15, 2022, your staff provided a written response to the apparent violations.

Based on the information developed during the inspection and investigation, and the information provided in the response to the inspection report dated June 15, 2022, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding them are described in detail in the subject inspection report. The apparent violations are not related to the medical event, but rather are related to the implementation of your personnel dosimetry (individual monitoring) program. The apparent violations involve the failures to: (A) monitor exposure from

licensed and unlicensed radiation sources as required by 10 CFR 20.1502(a); (B) control the annual occupational dose or total effective dose equivalent to an individual to 5 rem as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1201(a)(1)(i); (C) implement certain elements of your radiation protection program as required by 10 CFR 20.1101(a); and (D) provide instruction to individuals who were likely to receive in a year, an occupational dose in excess of 100 millirem as required by 10 CFR 19.12(a)(3).

Based on the results of the OI investigation, two individuals were deliberately not wearing their assigned dosimetry as required by 10 CFR 20.1502(a). In accordance with the NRC Enforcement Policy (ADAMS Accession No. [ML21323A042](#)), willful violations are of particular concern because the NRC's regulatory program is based on licensees and their contractors and employees acting with integrity and communicating with candor. The Commission cannot tolerate willful violations. Therefore, violation A is categorized in accordance with the NRC Enforcement Policy at Severity Level III.

The failure of your radiation safety program: to ensure that individuals working with licensed and non-licensed materials are wearing their assigned dosimetry; to instruct workers on the requirement to wear dosimetry; and to take corrective actions to address deficiencies in the personnel monitoring program is a significant safety concern. The radiation safety program failures resulted in an individual receiving an annual occupational dose or total effective dose equivalent greater than 5 rem. Therefore, violations B, C, and D are categorized collectively as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8000 is considered for a Severity Level III violation or problem.

Because the failure to wear assigned dosimetry violation (Violation A) was deliberate, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Credit was not warranted for *Identification* because the NRC identified the violation during an inspection. Credit for *Corrective Action* was warranted. Corrective actions were described in your June 15, 2022, letter and included, but not limited to: (1) established a mandatory compliance acknowledgment document for all physicians performing yttrium-90 procedures that outlines proper dosimeter wearing, return badge procedure, and institutes consequences for non-compliance; (2) Radiation Safety presented to the Hospital System-wide Radiology Leadership Council on plans to provide dosimetry training and gain leadership support and assistance at department levels to check physicians for wearing dosimetry; (3) implemented a comprehensive review of all unused and unreturned badges, including a follow up questionnaire to participants who do not return a badge or return an unused badge, and estimating doses as needed; (4) monitoring all yttrium-90 physicians for compliance with wearing dosimetry; (5) updated Radiation Safety's standard operating procedures to illustrate the steps for identifying a lack of dosimeter use; and (6) enhanced the procedure for notifying employees to include a more efficient form for an employee to complete and return by email.

Since violations B, C, and D were not willful and your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit for *Corrective Action* was warranted. Credit for *Corrective Action* was warranted based on the corrective actions listed above as well as the following: (1) performed a comprehensive

review of all unused and unreturned badges; (2) updated radiation safety application for personnel monitoring to include a statement about agreeing to wear all badges issued while working with radioactive materials; (3) updated Radiation Safety's standard operating procedures to illustrate the steps for identifying a lack of dosimeter use or lower than expected exposure results; and (4) established a standard practice to review all badges that received minimum exposure for groups expected to receive greater-than-minimum exposure including all physicians involved with yttrium-90 procedures, provided dose estimates as needed and provided updated dosimetry information to the dosimetry vendor.

Therefore, to emphasize the importance of wearing assigned dosimetry, compliance with dose limits and of prompt identification of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$8,000 for Violation A. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

You may choose to pay the proposed civil penalty by submitting your payment, with the invoice enclosed to this letter, to the following address:

Office of the Chief Financial Officer
US Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

In addition, you may pay the proposed civil penalty in accordance with [NUREG/BR-0254](#). When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the "enforcement action identifier" when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request alternative dispute resolution (ADR) mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral individual (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Diana Betancourt-Roldan at (630) 810-4373 within 10 days of the date of this letter. You may also contact both ICR and Ms. Betancourt-Roldan for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil penalty and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-01609/2020002(DNMS) and IUPUI's letter dated June 15, 2022. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or security-related 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). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

D. Pinkney

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If you have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement and Investigations Officer, at (630) 810-4373.

Sincerely,



Shuaibi, Mohammed signing on behalf
of Giessner, Jack
on 09/01/22

John B. Giessner
Regional Administrator

Docket No. 030-01609
License No. 13-02752-03

Enclosure:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Civil Penalty Invoice No. EA-21-167

cc: Michael Matin, Ph.D.
Radiation Safety Officer, IUPUI
Christopher P. Harvey, IUPUI
Kathryn Manteuffel, IUPUI
Benjamin Hunter, IUPUI
State of Indiana

Letter to D. Pinkney from John B. Giessner dated September 1, 2022

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

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

Docket No. 030-01609
License No. 13-02752-03
EA-21-167

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 19-20, 2020, with continued in-office review through April 14, 2021, and an NRC investigation completed on November 10, 2021, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

- A. 10 CFR 20.1502(a)(1) requires, in part, that each licensee monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from 2012 through October 20, 2020, Indiana University-IUPUI/IU Medical Center Campus (licensee) failed to monitor individuals' occupational exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. Specifically, from 2012 through 2020, for one interventional radiologist, and from 2017 through 2020, for a second interventional radiologist, the licensee failed to monitor their occupational exposure to radiation from licensed and unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by the interventional radiologists, who were likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a), and had a substantial potential to exceed the NRC's annual limit in 10 CFR 20.1201(a).

This is a Severity Level III violation (NRC Enforcement Policy Section 6.7)
Civil Penalty \$8,000 (EA-21-167).

II. Violations Not Assessed a Civil Penalty

- B. 10 CFR 20.1201(a)(1)(i) requires, with exceptions not applicable here, that the licensee control the occupational dose to individual adults to an annual limit of 5 rem total effective dose equivalent.

Contrary to the above, the licensee did not limit the annual occupational dose to an adult interventional radiologist to 5 rem, total effective dose equivalent. Specifically, the individual received 5.132 rem, total effective dose equivalent, for 2012, and 7.082 rem for 2013.

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

The licensee's policy, "Radiation Safety: Personnel Monitoring," effective date August 29, 2019 (ALARA – As Low As Reasonably Achievable)," Section III, Item A., states, in part, that for personnel dose less than the Investigational Level I: except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than the Table 1 values for ALARA Level I.

Contrary to the above, between 2012 and 2020, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee's policy, "Radiation Safety: Personnel Monitoring," effective date August 29, 2019 (ALARA - As Low As Reasonably Achievable)," failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

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

Contrary to the above, prior to October 20, 2020, the licensee failed to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instructions regarding the proper use of dosimeters to two interventional radiologists who were likely to receive in a year an occupational dose in excess of 100 mrem.

Violations B, C, and D are categorized collectively as a Severity Level III problem (NRC Enforcement Policy Sections 6.3 and 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-01609/2020002(DNMS) and IUPUI's letter dated June 15, 2022. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-21-167," and send it to the Director, Office of Enforcement, US Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and the Document Control Desk, Washington, DC 20555-0001.

The licensee may pay the civil penalty proposed above through one of the following two methods:

1. Submit the payment with the enclosed invoice for Civil Penalty EA-21-167 issued to Indiana University-IUPUI/IU Medical Center Campus to the following address:

Office of the Chief Financial Officer
US Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

OR

2. Submit the payment in accordance with NUREG/BR-0254.

The licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, US Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing civil penalty.

Upon failure to pay any civil penalty, which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Mark Lombard, Director, Office of Enforcement, US Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, US Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in NRC's Agencywide Documents Access and Management System (ADAMS). To the extent possible, your response should not include any personal privacy, proprietary, classified or safeguards information so that it can be made

available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this day of September 1, 2022