UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 20, 2022

IA-22-006

Dr. Maximilian Pyko
[NOTE: HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

SUBJECT: NRC INVESTIGATION REPORT 3-2021-002

Dear Dr. Pyko:

This letter refers to the investigation completed on November 10, 2021, by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations at the site of the Indiana - IUPUI/IU Medical Center Campus(IUPUI, the licensee) in Indianapolis, Indiana. The investigation was conducted, in part, to determine whether you, an interventional radiologist working for IUPUI, willfully failed to wear dosimetry assigned to you by IUPUI. A factual summary of the investigation, as it pertains to your actions, is provided as Enclosure 1.

Based on the information acquired during the investigation, an apparent violation was identified and is being considered for escalated enforcement action 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 apparent violation, as documented in Enclosure 2, pertains to your failure to comply with 10 CFR 30.10(a)(1), which requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule or regulation issued by the Commission. Your actions appear to have caused IUPUI, the licensee, to be in violation of 10 CFR 20.1502(a)(1) as described in Enclosure 3.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violation in Enclosure 2 of this letter within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request Alternative Dispute Resolution (ADR) mediation. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however the PEC will be closed to public observation since information related to an Office of Investigations report will be discussed and the report has not been made public. **If you decide to participate in a PEC or pursue ADR, please contact Michael Kunowski, Chief, Materials Inspection Branch, Division of Nuclear Materials Safety, at 630-829-9618 or via email at Michael.Kunowski@nrc.gov. within 10 days of the date of this letter.** A PEC should be held within 30 days and an ADR mediation within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violation, NRC Investigation Report 3-2021-002; IA-22-006" and should include for the apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that you have taken and the results achieved; and (3) the corrective steps that you will take. Your response should be sent to the Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region III,

2442 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and emailed to RIIIEICS_ADMIN Resource@nrc.gov. If an adequate response is not received within 30 days of the date of this letter or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In lieu of a PEC, you may request ADR 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 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 about the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.**

In addition, please be advised that the number and characterization of the apparent violation described in Enclosure 2 may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

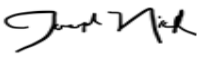
Because this letter references and encloses information addressing NRC's review of an apparent enforcement action against an individual, this letter and its enclosures will be maintained by the Office of Enforcement in an NRC Privacy Act System of Records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from our Web site at http://www.nrc.gov/reading-rm/foia/privacy-systems.html, then select Republication of Systems of Records Notices, September 20, 2010 (75 FR 57334).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," if the NRC concludes that enforcement action should be issued to you, this letter will be made publicly available either electronically for public inspection in the NRC Public Document Room or from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC's website at https://www.nrc.gov/readingrm/adams.html. In addition, you should be aware that all final NRC documents, including the final Office of Investigations report, are official agency records and may be made available to the public under the Freedom of Information Act and subject to redaction of certain information in accordance with the Freedom of Information Act. To the extent possible, any response which you provide should not include

any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions regarding this matter, you may contact Michael Kunowski, Chief, Materials Inspection Branch, Division of Nuclear Materials Safety, at 630-829-9618 or via email at Michael.Kunowski@nrc.gov.

Sincerely,



Nick, Joseph signing on behalf
of Brock, Kathryn
on 05/20/22

Kathryn M. Brock
Division of Nuclear Materials Safety

Enclosures:
1. Factual Summary
2. Apparent Violation
3. Applicable regulations

FACTUAL SUMMARY OF
OFFICE OF INVESTIGATIONS REPORT 3-2021-002

On November 12, 2020, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), initiated an investigation to determine, in part, whether you, an interventional radiologist working for Indiana University-IUPUI/IU Medical Center Campus (IUPUI, the licensee) in Indianapolis, Indiana, willfully failed to wear dosimetry assigned to you by IUPUI. The investigation was completed on November 10, 2021.

The OI investigation showed that you worked with yttrium-90 (Y-90) administrations (licensed activities) and x-ray fluoroscopy procedures (non-licensed activities) at IUPUI since 2016. As a radiologist working at IUPUI, your dosimetry consisted of whole body and ring dosimeters assigned to you by IUPUI. Based on the investigator's interviews with IUPUI radiation safety staff, new dosimetry badges are distributed and collected monthly for forwarding to a third party, Landauer Incorporated, for processing. Only high doses were flagged by the vendor. If a badge was marked as unused or missing, IUPUI would send a survey asking the respective badge wearer about their exposures in the past month. IUPUI dosimetry records reflect that you did not wear your dosimetry on multiple occasions.

During the OI interview, you identified that you knew wearing your dosimetry was a requirement of both the NRC and IUPUI. You also acknowledged to the OI investigator that you did not wear your assigned dosimetry and that no one instructed you not to wear it. Further, you acknowledged that you knew at the time that your decision to not wear dosimetry would place IUPUI in violation of NRC requirements.

Based on the evidence developed during the investigation, it appears that you violated 10 CFR 30.10(a)(1) by deliberately failing to wear the dosimetry assigned to you by IUPUI on multiple occasions over a period of four years. Your actions appear to have caused the licensee to be in violation of 10 CFR 20.1502(a)(1).

APPARENT VIOLATION

Based on the results of a United States Nuclear Regulatory Commission (NRC) investigation completed on November 10, 2021, an apparent violation of NRC requirements was identified. The apparent violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 30.10(a)(1) requires, in part, that an employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any regulation.

Title 10 CFR 30.10(c) defines "deliberate misconduct" as an intentional act or omission that a person knows would cause a licensee to be in violation of any rule, regulation, or order.

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

Between approximately February 2017 and October 20, 2020, while working as an interventional radiologist for Indiana University IUPUI/IU Medical Center Campus (IUPUI, the licensee), you violated 10 CFR 30.10(a)(1) by engaging in deliberate misconduct that caused the licensee to be in violation of NRC regulations. Specifically, while using licensed and unlicensed radiation sources under the control of IUPUI, you 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 therefore IUPUI was required to monitor your occupational exposure to radiation sources under its control. However, you intentionally failed to wear your assigned dosimetry, thereby preventing IUPUI from monitoring your occupational exposure to radiation, and causing IUPUI to be in violation of 10 CFR 20.1502(a).

Subpart C—Occupational Dose Limits

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of—

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998; 67 FR 16304, Apr. 5, 2002; 72 FR 68059, Dec. 4, 2007]

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a),

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to thebody, a deep dose equivalent in excess of 0.1 rem (1 mSv);[2] and

(4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor (see § 20.1204) the occupational intake of radioactive material by and assess thecommitted effective dose equivalent to—

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1,Columns 1 and 2, of appendix B to §§ 20.1001-20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective doseequivalent in excess of 0.1 rem (1 mSv).

[56 FR 23398, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

[2] All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

§ 30.10 Deliberate misconduct.

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate ofregistration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, certificate of registration holder, an applicant, or a licensee's,certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action inaccordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentionalact or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation,or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]

DISTRIBUTION: IA-22-005; IA-22-006
JGiessner, R-III
DDorman, OEDO/EDO
CHaney, OEDO/AO
MLombard, OE
TMartinezNavedo, OE
DLew, R-I
LDudes, R-II
SMorris, R-IV
MLemoncelli, OGC/GCHA/AGCMLE/NLO
JLubinski, NMSS
RLewis, NMSS
KWilliams, NMSS/MSST
RSun, NMSS/MSST/MSEB
RMcKinley, R-I/EAGLT
MKowal, R-II/ORA/EICS
JGroom, R-IV/ACES
MBurgess, NMSS/MSST/MSEB
MShuaibi, R-III
SLewman, R-III
KBrock, NSIR/DPR
HHarrington, OPA
THiggs, OI
PMeyer, OI/CFO
MBlair, OCFO/DOC/LAFBB
JQuichocho, NSIR/DPR/RLB
RWilliams, R-II/DFFI/PB1
ROrlikowski, R-III/DNMS/MLB
RChazell, SECY/RAS
JHeck, RIII/DNMS
JNick, R-I/DNMS
ABarker, R-III
DPiccirillo, R-III/DNMS
VMitlyng, OPA/OPA-RIII
PChandrathil, OPA/OPA-RIII
SBakhsh, R-III/EICS
DPiskura, R-III/DNMS/MIB

MKunowski, R-III/DNMS/MIB
SWoods, OE/EB
MSimon, OGC/GCHA/AGCMLE/NLO
JPeralta, OE/EB
KLambert, R-III/EICS

ADAMS ML22143A888

*** via email OE-001**

OFFICE	OCAA	R-III/DNMS/MIB	R-III/DNMS/MIB*	OE/EB*
NAME	SSpicer *SS*	DPiskura GWarren for *GW*	MKunowski GWarren for *GW*	JPeralta *JP*
DATE	May 19, 2022	May 19, 2022	May 19, 2022	May 19, 2022
OFFICE	OGC/GCHA /AGCMLE/NLO*	NMSS/MSST*	R-III	NSIR/DPR
NAME	MSimon *MS*	KWilliams *KW*	SLewman *SL*	KBrock JNick for *JN*
DATE	May 19, 2022	May 19, 2022	May 20, 2022	May 20, 2022

OFFICIAL RECORD COPY