Description of document:	Selected Nuclear Regulatory Commission (NRC) Office of Inspector General (OIG) Investigation Reports, 2022-2024
Requested date:	21-July-2025
Release date:	04-September-2025
Posted date:	29-September-2025
Source of document:	FOIA Request NRC Freedom of Information Act Officer U.S. Nuclear Regulatory Commission Inspector General Mail Stop TWFN-6 A60M Washington, DC 20555-0001 Email: FOIA.resource@nrc.gov FOIA.gov

NRC FORM 464 Part I (OIG) (01-26-2023)

U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

FOIA or Reference Number	Response Number
FOIA-2025-000642	1

Response Type: ☐ Interim ☑ Final

Requester:

Date: 09/04/2025

Description of Requested Records:

The final report, report of investigation (ROI), closing memo, referral memo/letter, and any other final documentation regarding the following closed NRC OIG investigations: i2100162, i2100176, i2400032, i2303311, i2200187, i2200191, i2303305, i2303349, i2400062, and P2400191.

PART I. -- INFORMATION RELEASED

☑ The NRC has made some, or all, of the requested records publicly available through one or more of the following means: (1) https://www.nrc.gov ; (2) public ADAMS, https://www.nrc.gov/reading-rm/adams.html; (3) microfiche available in the NRC Public Document Room; or the NRC Public Access Link (PAL), at https://foia.nrc-gateway.gov/app/Home.aspx.

☑ Agency records subject to the request are enclosed.

☐ Records subject to the request that contain information originated by or of interest to another Federal agency have been referred to that agency (See Part I.D -- Comments) for a disclosure determination and direct response to you.

☐ We are continuing to process your request.

☑ See Part I.D -- Comments.

PART I.A -- FEES

AMOUNT

☐ You will be billed by NRC for the amount indicated.

☐ You will receive a refund for the amount indicated.

☐ Fees waived.

☑ Since the minimum fee threshold was not met, you will not be charged fees.

☐ Due to our delayed response, you will not be charged search and/or duplication fees that would otherwise be applicable to your request.

PART I.B -- INFORMATION NOT LOCATED OR WITHHELD FROM DISCLOSURE

☐ We did not locate any agency records responsive to your request. *Note*: Agencies may treat three discrete categories of law enforcement and national security records as not subject to the FOIA ("exclusions"). See 5 U.S.C. 552(c). This is a standard notification given to all requesters; it should not be taken to mean that any excluded records do, or do not, exist.

☑ We have withheld certain information pursuant to the FOIA exemptions described, and for the reasons stated, in Part II.

☐ Because this is an interim response to your request, you may not appeal at this time. We will notify you of your right to appeal any of the responses we have issued in response to your request when we issue our final determination.

☑ You may appeal this final determination within 90 calendar days of the date of this response. If you submit an appeal by mail, address it to the FOIA Officer, at U.S. Nuclear Regulatory Commission, Mail Stop T-6 A60M, Washington, D.C. 20555-0001. You may submit an appeal by email to FOIA.resource@nrc.gov. You may fax an appeal to (301) 415-5130. Please be sure to include on your submission that it is a "FOIA Appeal." You may file an appeal through the NRC Public Access Link (PAL) at https://foia.nrc-gateway.gov/app/Home.aspx.

PART I.C -- REFERENCES AND POINTS OF CONTACT

You have the right to seek assistance from the NRC's FOIA Public Liaison by submitting your inquiry at https://www.nrc.gov/reading-rm/foia/contact-foia.html, or by calling the FOIA Public Liaison at (301) 415-0717.

If we have denied your request, you have the right to seek dispute resolution services from the NRC's Public Liaison or the Office of Government Information Services (OGIS). To seek dispute resolution services from OGIS, you may e-mail OGIS at ogis@nara.gov, send a fax to (202) 741-5789, or send a letter to: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740-6001. For additional information about OGIS, please visit the OGIS website at https://www.archives.gov/ogis.

NRC FORM 464 Part I (OIG)
(01-26-2023)

U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

FOIA or Reference Number	Response Number
FOIA-2025-000642	1

Response Type: ☐ Interim ☑ Final

PART I.D -- COMMENTS

The FOIA Office received your request on July 21, 2025, and tasked this office to search for, and provide disclosure determinations with respect to, the Report of Investigation, or other closing documentation, for each of the requested Office of the Inspector General (OIG) investigations.

We have completed our review of the responsive records; they are enclosed. Please refer to Part II for the exemptions claimed. In addition, two of the requested records are already publicly available:

• ML2372A039, which is the report for OIG case I2100162. It may be found here: https://www.nrc.gov/docs/ML2327/ML23272A039.pdf; and,

• ML24089A252, which is the report for OIG case I2200187. It may be found here: https://www.nrc.gov/docs/ML2408/ML24089A252.pdf.

This completes our processing of your request.

Signature - Assistant Inspector General for Investigations or Designee

MALION BARTLEY

Digitally signed by MALION BARTLEY
Date: 2025.09.04 19:10:39 -04'00'

NRC FORM 464 Part II (OIG)
(04-30-2024)

U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

FOIA or Reference Number: FOIA-2025-000642

PART II.A -- APPLICABLE EXEMPTIONS

Records subject to the request are being withheld in their entirety or in part under the FOIA exemption(s) as indicated below (5 U.S.C. 552(b)), after taking into consideration the foreseeable harm standard when reviewing records and applying these FOIA exemptions.

- ☐ Exemption 1: The withheld information is properly classified pursuant to an Executive Order protecting national security information.
- ☐ Exemption 2: The withheld information relates solely to the internal personnel rules and practices of NRC.
- ☐ Exemption 3: The withheld information is specifically exempted from public disclosure by the statute indicated.
  - ☐ Sections 141-145 of the Atomic Energy Act, which prohibits the disclosure of Restricted Data or Formerly Restricted Data (42 U.S.C. 2161-2165).
  - ☐ Section 147 of the Atomic Energy Act, which prohibits the disclosure of Unclassified Safeguards Information (42 U.S.C. 2167).
  - ☐ 41 U.S.C. 4702(b), which prohibits the disclosure of contractor proposals, except when incorporated into the contract between the agency and the submitter of the proposal.
  - ☐ Other:
- ☑ Exemption 4: The withheld information is a trade secret or confidential commercial or financial information that is being withheld for the reason(s) indicated.
  - ☐ The information is considered to be proprietary because it concerns a licensee's or applicant's physical protection or material control and accounting program for special nuclear material pursuant to 10 CFR 2.390(d)(1).
  - ☑ The information is considered to be another type of confidential business (proprietary) information.
  - ☐ The information was submitted by a foreign source and received in confidence pursuant to 10 CFR 2.390(d)(2).
- ☑ Exemption 5: The withheld information consists of interagency or intraagency records that are normally privileged in civil litigation.
  - ☑ None of the information being withheld under Exemption 5/Deliberative Process Privilege is appropriate for discretionary disclosure.
  - ☐ Attorney work product privilege.
  - ☐ Attorney-client privilege.
- ☐ Exemption 6: The withheld information from a personnel, medical, or similar file, is exempted from public disclosure because its disclosure would result in a clearly unwarranted invasion of personal privacy.
- ☑ Exemption 7: The withheld information consists of records compiled for law enforcement purposes and is being withheld for the reason(s) indicated.
  - ☐ (A) Disclosure could reasonably be expected to interfere with an open enforcement proceeding.
  - ☑ (C) Disclosure could reasonably be expected to constitute an unwarranted invasion of personal privacy.
  - ☐ (D) The information consists of names and other information the disclosure of which could reasonably be expected to reveal identities of confidential sources.
  - ☑ (E) Disclosure would reveal techniques and procedures for law enforcement investigations or prosecutions, or guidelines that could reasonably be expected to risk circumvention of the law.
  - ☐ (F) Disclosure could reasonably be expected to endanger the life or physical safety of an individual.
- ☐ Other

PART II.B -- DENYING OFFICIAL

In accordance with 10 CFR 9.25(g)(1) of the U.S. Nuclear Regulatory Commission regulations, the official listed below has made the determination to withhold certain information, described below, responsive to your request.

DENYING OFFICIAL	TITLE/OFFICE	INFORMATION DENIED	APPELLATE OFFICIAL
Malion A. Bartley	Assistant Inspector General for Investigations	third party PII; investigative techniques; predecisional, proprietary, and deliberative information	Inspector General

MEMORANDUM

DATE: September 8, 2022

TO: Daniel H. Dorman
Executive Director for Operations

FROM: Malion A. Bartley
Assistant Inspector General for Investigations

Malion A. Bartley

Digitally signed by Malion A. Bartley
Date: 2022.09.08 12:22:09 -04'00'

SUBJECT: ALLEGATION THAT REGION II MANAGEMENT KNOWINGLY ALLOWED UNAUTHORIZED TELEWORK (OIG Case No. 21-020)

Attached is an Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), Report of Investigation (ROI) pertaining to unauthorized telework and travel-related issues. We found an NRC employee conducted unauthorized telework on 11 dates during 2021, but did not find management complicit. We also found that between January 2018 and July 2021, the employee violated federal and NRC policy by traveling indirectly on 17 occasions, claiming an improper TDY location with higher per diem rates on 3 occasions, and overcharging the government for multiple modes of travel once, which resulted in a loss of $1701.24. Lastly, we found payment of per diem meals and incidental expenses (M&IE) for non-workdays on nine of the employee's travel vouchers between January 2018 and February 2020, totaling an overpayment of $3,867—a grand total of $5,568.24. We recommend the agency recover the overpayment.

This report is furnished for whatever action you deem appropriate. Please notify this office by January 30, 2023, of what action you take based on the results of this investigation, and if you require further assistance.

The distribution of this report should be limited to those NRC managers required for evaluation of this matter. Neither the ROI nor its exhibits may be placed in ADAMS without the OIG's express written permission.

Attachments: ROI with exhibits

cc: Chairman Hanson, w/o exhibits
Commissioner Baran, w/o exhibits
Commissioner Wright, w/o exhibits
Commissioner Caputo, w/o exhibits
Commissioner Crowell, w/o exhibits
Christoph Heilig, PSB, w/o exhibits
Cathy Scott, OGC, w/ exhibits
Mary Lamary, CHCO, w/ exhibits
Cherish Johnson, CFO, w/o exhibits

CONTACT: (b)(7)(C)

REPORT OF INVESTIGATION

Allegation that Region II Management Knowingly Allowed Unauthorized Telework Case No. 21-020

(b)(7)(C) Special Agent		(b)(7)(C)		(b)(7)(C)	
(b)(7)(C)	Digitally signed by (b)(7)(C) (b)(7)(C) Date: 2022.09.08 12:35:49 -04'00'	(b)(7)(C)	Digitally signed by (b)(7)(C) Date: 2022.09.08 13:07:46 -04'00'	(b)(7)(C)	Digitally signed by (b)(7)(C) Date: 2022.09.08 13:54:18 -04'00'

THIS REPORT IS RELEASABLE ONLY BY THE U.S. NUCLEAR REGULATORY COMMISSION, OFFICE OF THE INSPECTOR GENERAL.

THIS REPORT AND ITS EXHIBITS MAY NOT BE PLACED IN ADAMS WITHOUT WRITTEN PERMISSION OF THE NRC OIG.

EXEMPT FROM RELEASE UNDER FREEDOM OF INFORMATION ACT EXEMPTIONS (5), (6), OR (7) AND PRIVACY ACT EXEMPTIONS (j)(2) OR (k)(1).

TABLE OF CONTENTS

STATUTES, REGULATIONS, AND POLICY

TELEWORK ENHANCEMENT ACT

The terms "telework" and "teleworking" refer to a work flexibility arrangement under which an employee performs the duties and responsibilities of such employee's position, and other authorized activities, from an approved worksite other than the location from which the employee would otherwise work. § 6502—Executive agencies telework requirement (a) establish a policy under which eligible employees of the agency may be authorized to telework, (b) determine the eligibility for all employees of the agency to participate in telework, and (c) notify all employees of the agency of their eligibility to telework.

5 U.S.C. § 6502, EXECUTIVE AGENCIES TELEWORK REQUIREMENT

(a)(2) LIMITATION: An employee may not telework under a policy established under this section if (b) the employee has been officially disciplined for violations of subpart G of the Standards of Ethical Conduct for Employees of the Executive Branch for viewing, downloading, or exchanging pornography, including child pornography, on a federal government computer or while performing official federal government duties.

18 U.S.C. § 1001, STATEMENTS OR ENTRIES GENERALLY

(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the government of the United States, knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under this title, imprisoned not more than 5 years or both.

5 C.F.R. 735, EMPLOYEE RESPONSIBILITES AND CONDUCT

§ 735.203—An employee shall not engage in criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct, or other conduct prejudicial to the government.

5 C.F.R. 2635, STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH,

Subpart G—Misuse of Position—§ 2635.704—Use of Government Property: (a) Standard. An employee has a duty to protect and conserve government property and shall not use such property, or allow its use, for other than authorized purposes.

§ 2635.705—Use of Official Time: (a) Use of an employee's own time. Unless authorized in accordance with law or regulations to use such time for other purposes, an employee shall use official time in an honest effort to perform official duties.

41 C.F.R. 301, FEDERAL TRAVEL REGULATION, TEMPORARY DUTY (TDY) TRAVEL ALLOWANCES

§ 301-2.2—Your agency may pay only those expenses essential to the transaction of official business, which include (a) transportation expenses as provided in part 301-10 of this chapter, and (b) per diem expenses as provided in part 301-11 of this chapter.

§ 301-10.5—What are the presumptions as to the most advantageous method of transportation by order of precedence?

(a) Common carrier—Travel by common carrier is presumed to be the most advantageous method of transportation and must be used when reasonably available.
(b) Government automobile—When your agency determines that your travel must be performed by automobile, a government-furnished automobile is presumed to be the most advantageous method of transportation.
(c) Rental car—If no government-furnished automobile is available, but your agency has determined that travel must be performed by automobile, then a rental car should be authorized.
(d) Privately Owned Vehicle (POV)—POVs should be determined to be the most advantageous method of transportation only after your agency evaluates the use of a common carrier, a government-furnished automobile, and a rental car.

§ 301-10.7—You must travel to your destination by the usually traveled route unless your agency authorizes or approves a different route as officially necessary.

§ 301-10.8—Your reimbursement will be limited to the cost of travel by a direct route or on an uninterrupted basis. You will be responsible for any additional costs.

§ 301-11.1—Eligibility for an allowance (per diem or actual expense): when (a) you perform official travel away from your official station or other areas defined by your agency, (b) you incur per diem expenses while performing official travel, and (c) you are in a travel status for more than 12 hours.

NRC MANAGEMENT DIRECTIVE (MD) 14.1, OFFICIAL TEMPORARY DUTY TRAVEL

It is the policy of the NRC to adhere to the statutory and regulatory principles of 41 C.F.R. 301–304 (Federal Travel Regulation), associated executive orders, comptroller general decisions, and decisions of the General Services Administration Board of Contract Appeals related to official government travel.

IV(H)(1)(a)—Authority to Use POV: The NRC may authorize use of a POV for official travel if it is advantageous to the government. In making that determination, the NRC will consider the following:

(i) Cost;
(ii) Availability of common carrier transportation, government contract car rental, or government-owned vehicles; and,
(iii) The most expeditious transaction of the public business.

IV(H)(1)(d)(i) —Indirect Routing: If a traveler uses a circuitous route for personal reasons, he or she shall report mileage for the entire distance traveled but shall only claim mileage for the direct route.

VI(A)(5)(a) —Interruption of Per Diem Entitlement: Leave and Non-workdays:

(i) If an employee takes a leave of absence for more than one-half of the prescribed daily working hours, other than for emergency travel (see Section VIII.G, "Emergency Travel," of this handbook), no per diem will be allowed for that day;

(ii) Federal holidays, weekends, or other scheduled non-workdays are considered non-workdays. An employee is in a per diem status on non-workdays unless:

- The employee returns to the official station or home; or,
- The employee takes more than one-half day of leave immediately before and after the non-workday.

(iii) Per diem will not be paid for more than 2 non-workdays when leave is taken for all the working hours between the non-workdays.

VI(A)(5)(c) —Indirect Route or Interrupted Travel: If there is an interruption of travel or deviation from the direct route because of an employee's personal preference, convenience, or through the taking of leave, the per diem allowed will not exceed that which would have been allowed on uninterrupted travel by a direct or usually traveled route.

NRC MD 10.43, TIME AND LABOR REPORTING

It is NRC policy that recorded time be detailed as necessary for preparing payroll, salaries, and expenses; assessing NRC fees and reimbursements; supporting budget formulation and execution; interacting with the core accounting system; and supporting managerial and financial cost accounting reporting.

IV(E)(b)—If employees are teleworking, they must select the appropriate telework box on their timesheet when entering time.

SUBJECT

(b)(7)(C) (GG-14)
(b)(7)(C)
Division of Reactor Safety (DRS) Region II
NRC

ALLEGATION

The OIG initiated this investigation after receiving an anonymous allegation claiming a staff member (later identified as (b)(7)(C)), who is ineligible for telework, could be circumventing the Telework Enhancement Act (TEA). The alleger stated Region II management may be complicit in the violation by allowing the staff member to telework and approving his time and attendance.

The OIG's review of the allegation did not identify evidence that Region II management was complicit in (b)(7)(C) circumventing the TEA; however, the investigation did substantiate (b)(7)(C)'s TEA violations and identified other travel-related misconduct as well as administrative issues.

FINDINGS

ISSUE #1. TELEWORK BY INELIGIBLE INDIVIDUAL

The OIG found evidence that (b)(7)(C) worked remotely on various dates in 2021 while ineligible for telework under the TEA. (b)(7)(C) failed to notify his supervisor that he was working from home, except during mandatory telework for the COVID-19 pandemic.

ISSUE #2. REGION II MANAGEMENT NOT COMPLICIT IN ALLOWING UNAUTHORIZED TELEWORK

The OIG did not substantiate that Region II management was complicit in allowing (b)(7)(C) unauthorized telework. Although Region II management expressed a desire to allow (b)(7)(C) to telework and discussed the matter with the Office of the Chief Human Capital Officer (OCHCO), NRC, the request was denied, and management directed (b)(7)(C) to return to in-person work at the Region II office. Additionally, (b)(7)(C) stated management was unaware he had worked from home and did not approve telework.

ISSUE #3. TRAVEL ROUTING AND RESERVATIONS VIOLATED POLICY

The OIG substantiated that between January 2018 and July 2021, (b)(7)(C) violated federal and NRC travel policy on 18 occasions: 17 by indirect routing and 1 additional incident of routing not advantageous to the government. On 17 occasions, (b)(7)(C) improperly booked flights into and out of airports near his residence in (b)(7)(C) instead of his official duty station (Atlanta, Georgia) or temporary duty (TDY) locations. (b)(7)(C) also overcharged the government for

multiple modes of travel for personal benefit. Lastly, the OIG found 3 of the 18 incidents also involved claiming an improper TDY location with higher per diem rates.

ISSUE #4. OVERPAYMENT OF TRAVEL VOUCHER EXPENSES

The OIG found payment of per diem meals and incidental expenses (M&IE) for non-workdays during interrupted travel on nine of (b)(7)(C) 's vouchers for travel between January 2018 and February 2020, totaling an overpayment of $3,867. Receipt of M&IE during interruption of travel is a violation of both federal and NRC travel policy. (b)(7)(C) denied intentionally requesting reimbursement for these expenses or knowledge that the funds were received. (b)(7)(C) stated he is willing and able to pay back the funds.

BASIS FOR FINDINGS

ISSUE #1. TELEWORK BY INELIGIBLE INDIVIDUAL

The OIG substantiated that (b)(7)(C) worked remotely on 11 dates during 2021, while ineligible for telework under the TEA.

The OIG substantiated that (b)(7)(C) is ineligible for telework under the TEA due to a prior suspension related to misuse of a government computer.

For further details, see Exhibit 1.

The OIG reviewed Human Resources Management System (HRMS) records, travel records, Region II security access logs, and Internet Protocol (IP) data to determine when (b)(7)(C) was working but not on travel and not in the Region II office. Potential instances of telework were identified in 2019, 2020, and 2021. Due to the unavailability of Region II access logs before June 2019 or IP data before January 2021, (b)(7)(C) 's absence or presence at the Region II office could not be confirmed. As such, the OIG did not consider dates before that time (see Table 1). The OIG identified 11 days in 2021 totaling 85 hours of suspected unauthorized telework.

For further details, see Exhibits 2–10.

During his interview with the OIG, (b)(7)(C) confirmed he was notified of his ineligibility to telework in 2018, and initially denied working from home after 2018. After reviewing the dates shown in Table 1, (b)(7)(C) was unable to provide an explanation for them, and stated he should have been at the Region II office on those dates. (b)(7)(C) was informed the Region II access logs indicated he did not access the office on the dates in question. (b)(7)(C) then acknowledged it was possible he worked from home on the dates in question in June, August, October, and November. In addition, during subsequent contact with the OIG, (b)(7)(C) stated he teleworked for 2 hours on December 23, 2021.

For further details, see Exhibit 11.

Table 1: Dates identified as suspected telework and supporting evidence

Dates (2021)	Hours worked (per HRMS records)	In office (per Region II security logs)	Travel status (per travel records)	Connection to internal NRC network (per (b)(7)(C)'s laptop)
June 30	5 regular hours (REG)	No	Not traveling	No
August 16	10 REG	No	Not traveling	No
August 17	10 REG, including 2 hours training	No	Not traveling	No
August 18	10 REG	No	Not traveling	No
August 19	10 REG	No	Not traveling	No
October 12	8 REG	No	Not traveling	No, and IP data from (b)(7)(C)'s NRC laptop showed a connection to a secure sockets layer (SSL) virtual private network (VPN), indicating (b)(7)(C) remotely accessed the system.
October 13	8 REG	No	Not traveling	No, and with SSL VPN connection.
October 14	8 REG	No	Not traveling	No, and with SSL VPN connection.
October 15	8 REG	No	Not traveling	No, and with SSL VPN connection.
November 12	6 REG, including 2 hours training	No	Not traveling	No, and with SSL VPN connection.
December 23	2 REG 4 excused absences	No	Not traveling*	No, and with a connection to "R2 Turkey Point RISE Prod," and to an SSL VPN.

*Travel vouchers and HRMS logs indicated (b)(7)(C) traveled to Turkey Point on December 22; however, according to logs, this travel ended on December 22 and (b)(7)(C) was not in Turkey Point on December 23.

(Source: Exhibits 2–10)

ISSUE #2. REGION II MANAGEMENT NOT COMPLICIT IN ALLOWING UNAUTHORIZED TELEWORK

The OIG did not substantiate that Region II management was complicit in allowing (b)(7)(C) unauthorized telework.

(b)(7)(C), DRS, and two OCHCO personnel told the OIG that (b)(7)(C) participated in the telework program under previous DRS (b)(7)(C). On February 15, 2018, (b)(7)(C) was advised he was ineligible for telework based on the TEA. The OIG confirmed the termination of (b)(7)(C)'s telework as well as his 2013 suspension with relevant documents.

On March 18, 2020, Region II management determined that (b)(7)(C) would continue reporting to Region II and was not allowed to telework despite the COVID-19 pandemic; however, that decision was retracted when the Region II building closed, and mandatory telework was imposed on all employees on March 19, 2020. OCHCO personnel confirmed (b)(7)(C) could telework during mandatory telework (Phase 0) but would be required to return in person once the Region II office reopened under maximum telework (Phase 1), which was subsequently scheduled for June 21, 2020.

For further details, see Exhibits 12–15.

The OIG found Region II management allowed (b)(7)(C) to telework June 22–26, 2020, while management engaged in ongoing discussions with OCHCO related to a reasonable accommodation request from (b)(7)(C). Email communications revealed that on June 22, 2020, (b)(7)(C) requested a reasonable accommodation to allow continued telework, claiming he had (b)(7)(C) a risk factor for complications from COVID-19. Two days later, Region II Human Resources, on behalf of OCHCO, denied the request because (b)(7)(C) was prohibited from telework. Despite (b)(7)(C)'s argument against the decision, (b)(7)(C) was ultimately required to return to in-person work. No additional instances of Region II management allowing (b)(7)(C) to telework were identified.

Although (b)(7)(C) acknowledged possibly teleworking on several dates, he repeatedly denied to the OIG that (b)(7)(C) or Region II management was aware he did so. A review of email communications from (b)(7)(C), (b)(7)(C), and (b)(7)(C), Region II, NRC, failed to indicate such awareness. In addition, during the OIG's interview with (b)(7)(C), (b)(7)(C) denied knowledge of (b)(7)(C) teleworking.

For further details, see Exhibits 16–17.

ISSUE #3. TRAVEL ROUTING AND RESERVATIONS VIOLATED POLICY

The OIG substantiated that (b)(7)(C) violated federal and NRC travel policy on 18 occasions. The OIG found (b)(7)(C) engaged in indirect routing on 17 occasions and overcharged the government for multiple modes of travel once. (b)(7)(C) also claimed per diem at an improper TDY location on 3 of the 18 occasions. The overall loss resulting from these 18 incidents was $1701.24. See Table 2.

Table 2: Indirect Routing and Other Travel-Related Issues

Year	Month	Location	Indirect Routing*	Loss ($)	Other Travel-Related Issues*	Loss ($)
2018	January	Turkey Point	Yes	0	No	0
2018	March	Turkey Point	Yes	55.49	No	0
2018	April	Surry	Yes	88.60	Wrong per diem	146.50
2018	April	Browns Ferry	Yes	0	No	0
2018	August	McGuire	Yes	0	No	0
2018	September	NRC HQ	Yes	0	No	0
2019	February	Turkey Point	Yes	46.40	No	0
2019	February	NRC HQ	Yes	62.39	No	0
2019	March	Catawba	Yes	0	No	0
2019	April	Harris	Yes	11.40	No	0
2019	July	Brunswick	Yes	0	No	0
2019	July	Surry	Yes	413.80	Wrong per diem	138
2019	August	McGuire	Yes	0	No	0
2019	August	NEI EP Conference	Yes	110.39	No	0
2019	November	Waterford	Yes	250.40	No	0
2020	February	Turkey Point	Yes	0	No	0
2021	February	Turkey Point	Yes	0	No	0
2021	July	Surry	No	0	Claimed two travel modes and wrong per diem	264.87 (travel modes) + 113 (per diem)
			Total:	$1038.87	Total:	$662.37
Total Trips with Indirect Routing & Other Travel-Related Issues:			**18**		**Total Loss:**	**$1701.24**

*Indirect routing, inappropriate travel method, and excess per diem claims violate regulations within FTR §301 and NRC MD 14.1.

(Source: Exhibits 18–35)

A review of (b)(7)(C)'s travel documents revealed 17 occasions between 2018 and 2021 when he did not travel between his duty station (Region II, Atlanta, Georgia) and his TDY location; instead, he flew into or out of airports near his residence in (b)(7)(C). Such travel is identified as "indirect routing." Indirect travel that is not officially necessary and any reimbursement more than the cost of travel by a direct route violate Federal Travel Regulation (FTR) §301 as well as NRC MD 14.1. In addition, according to NRC travel guidance, travelers are required to book travel outside of the agency's official travel system and submit cost comparison worksheets; however, (b)(7)(C) failed to do so.

(b)(7)(C)'s 17 incidents of indirect travel are summarized in Table 2 and detailed below and in the corresponding exhibits:

1. In January 2018, (b)(7)(C) indirectly routed his travel to the Turkey Point plant in Homestead, Florida. (b)(7)(C) flew from Hartsfield-Jackson Atlanta International Airport (ATL), Georgia, to Orlando International Airport (MCO), which is located near his residence in (b)(7)(C). (b)(7)(C) should have flown directly from ATL to an airport near Turkey Point (Miami International Airport [MIA] or Fort Lauderdale-Hollywood International Airport [FLL]). (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of policy. In this instance, no loss to the government was found related to the indirect routing.

   For further details, see Exhibit 18.

2. In March 2018, (b)(7)(C) indirectly routed his travel to the Turkey Point plant. (b)(7)(C) flew from ATL to MCO, but should have flown directly from ATL into MIA or FLL. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $55.49 was calculated related to the indirect routing.

   For further details, see Exhibit 19.

3. In April 2018, (b)(7)(C) indirectly routed his travel to the Surry plant, located in Surry, Virginia. (b)(7)(C) flew from MCO to Newport News/Williamsburg International Airport (PHF), but should have flown directly from ATL to the airport with the lowest contract carrier fare, identified as Richmond International Airport (RIC). (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $88.60 was calculated related to the indirect routing.

   For further details, see Exhibit 20.

4. In April 2018, (b)(7)(C) indirectly routed his travel to the Browns Ferry plant, located in Athens, Alabama. (b)(7)(C) flew from West Palm Beach International (PBI) to Huntsville International Airport (HSV), but should have flown directly from ATL to HSV. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. In this instance, no loss to the government was found related to the indirect routing.

   For further details, see Exhibit 21.

5. In August 2018, (b)(7)(C) indirectly routed his travel to the McGuire plant, located in Huntersville, North Carolina. (b)(7)(C) flew from Melbourne Orlando International Airport (MLB) to Charlotte Douglas International Airport (CLT), but should have flown directly from ATL to CLT. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC

policy. In this instance, no loss to the government was found related to the indirect routing.

For further details, see Exhibit 22.

6. In September 2018, (b)(7)(C) indirectly routed his travel to NRC Headquarters (HQ) in Rockville, Maryland. (b)(7)(C) flew from MCO to Reagan National Airport (DCA), but should have flown directly from ATL to BWI. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. In this instance, no loss to the government was found related to the indirect routing.

   For further details, see Exhibit 23.

7. In February 2019, (b)(7)(C) indirectly routed his travel to Turkey Point. (b)(7)(C) flew from ATL to PBI; however, he should have flown directly from ATL to MIA or FLL. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $46.40 was calculated related to the indirect routing.

   For further details, see Exhibit 24.

8. In February 2019, (b)(7)(C) indirectly routed his travel to NRC HQ. (b)(7)(C) flew from MCO to DCA; however, he should have flown directly from ATL to IAD. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $62.39 was calculated related to the indirect routing.

   For further details, see Exhibit 25.

9. In March 2019, (b)(7)(C) indirectly routed his travel to the Catawba plant, located in York, South Carolina. (b)(7)(C) flew from MLB to CLT; however, he should have flown directly from ATL to CLT. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. In this instance, no loss to the government was found related to the indirect routing.

   For further details, see Exhibit 26.

10. In April 2019, (b)(7)(C) indirectly routed his travel to the Harris plant, located in New Hill, North Carolina. (b)(7)(C) flew from MCO to Raleigh-Durham International Airport (RDU); however, he should have flown directly from ATL to RDU. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $11.40 was calculated related to the indirect routing.

    For further details, see Exhibit 27.

11. In July 2019, (b)(7)(C) indirectly routed his travel to the Brunswick plant, located in Southport, North Carolina. (b)(7)(C) flew from MLB to CLT; however, he should have flown directly from ATL to CLT. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. In this instance, no loss to the government was found related to the indirect routing.

    For further details, see Exhibit 28.

12. In July 2019, (b)(7)(C) indirectly routed his travel to the Surry plant. (b)(7)(C) flew from MCO to PHF, but should have flown directly from ATL to the airport with the lowest contract carrier fare, identified as RIC. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $413.80 was calculated related to the indirect routing.

    For further details, see Exhibit 29.

13. In August 2019, (b)(7)(C) indirectly routed his travel to the McGuire plant, located in Huntersville, North Carolina. (b)(7)(C) flew from MLB to CLT, but should have flown directly from ATL to CLT. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. In this instance, no loss to the government was found related to the indirect routing.

    For further details, see Exhibit 30.

14. In August 2019, (b)(7)(C) indirectly routed his travel to attend the Nuclear Energy Institute Emergency Preparedness Conference in Arizona. (b)(7)(C) flew from MCO to Phoenix, Arizona (PHX), but should have flown directly from ATL to PHX. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $110.39 was calculated related to the indirect routing.

    For further details, see Exhibit 31.

15. In November 2019, (b)(7)(C) indirectly routed his travel to Waterford plant, located in Killona, Louisiana. (b)(7)(C) flew from MCO to the Louis Armstrong New Orleans International Airport (MSY), but should have flown directly from ATL to MSY. (b)(7)(C) failed to book his flight outside of the SAP Concur system and failed to submit a cost comparison worksheet, in violation of FTR and NRC policy. A loss to the government of $250.40 was calculated related to the indirect routing.

    For further details, see Exhibit 32.

16. In February 2020, (b)(7)(C) indirectly routed his travel to Turkey Point. (b)(7)(C) flew from ATL to MCO, but should have flown directly from ATL to MIA or FLL. (b)(7)(C) failed to book this flight outside of the SAP Concur system as required by policy. (b)(7)(C) also failed to submit a cost comparison worksheet; however, in this instance, no loss to the government was found related to flight costs. Also, (b)(7)(C) conducted interrupted travel by flying in advance of his TDY and remaining several days after his TDY concluded, over non-workdays. (b)(7)(C) obtained a rental car from (b)(7)(C) (b)(7)(C) Airport the Sunday prior to the inspection.

    For further details, see Exhibit 33.

17. In February 2021, (b)(7)(C) indirectly routed his travel to Turkey Point. (b)(7)(C) flew one way from MCO to ATL, but should have flown directly from MIA or FLL. (b)(7)(C) failed to book this flight outside of the SAP Concur system as required by policy. (b)(7)(C) also failed to submit a cost comparison worksheet; however, in this instance, no loss to the government was found related to flight costs.

    For further details, see Exhibit 34.

In addition to instances of indirect travel, the OIG found one occasion in which (b)(7)(C) overcharged the government for multiple modes of travel that were not advantageous to the government.

According to FTR §301, agencies must select the travel method most advantageous to the government, and travel must be by the most expeditious means practicable and commensurate with the nature and purposes of the traveler's duties. The FTR also indicates the order of precedence for travel is common carrier air travel, then government-owned vehicle, then rental vehicle, and lastly POV. In addition, NRC MD 14.1 details authority for use of a POV for official travel, indicating it may be authorized if it is advantageous to the government.

In July 2021, (b)(7)(C) traveled to the Surry Power Station. (b)(7)(C) requested reimbursement for two modes of travel: mileage for his POV to and from the site, and a rental car to use at the site. During the OIG's interview with (b)(7)(C), he acknowledged regular use of a POV instead of a rental car to allow (b)(7)(C) to travel with him, and for this specific trip, stated he drove his POV "so (b)(7)(C) could have the car." A review of emails between (b)(7)(C) and (b)(7)(C) revealed (b)(7)(C) confirmed he obtained both a rental vehicle and claimed POV mileage to provide (b)(7)(C) a vehicle to drive on the trips for which (b)(7)(C) accompanied him. The loss from using multiple modes of travel for this trip totaled $264.87.

For further details, see Exhibit 35.

Lastly, on three of the above-noted occasions, (b)(7)(C) also claimed per diem expenses at a location that was not his TDY location, without justification.

The Federal Travel Regulation (FTR) §301-11.7 and 11.8 state that TDY locations determine the maximum per diem reimbursement rate. If lodging is not available at the TDY location, the

traveler's agency may authorize or approve the maximum per diem rate for the location where lodging is obtained. Further, NRC travel regulations state that the per diem rate is determined by the temporary duty point and not where the traveler chooses to lodge.

During his trips to Surry in April 2018, July 2019, and July 2021, (b)(7)(C) claimed Williamsburg as his TDY location, which had a higher per diem rate than the actual TDY location; however, no justification was provided within (b)(7)(C)'s travel documents to explain the use of an alternate location. The loss from the wrong per diem entitlements on these three trips totaled $397.50. These trips are reflected in Table 2 and in the corresponding exhibits detailed above.

During his interview with the OIG, (b)(7)(C) acknowledged the requirement to conduct travel in the manner most advantageous to the government, and denied taking more expensive flights for his personal benefit or convenience. (b)(7)(C) further reported receiving guidance that he must purchase his own airfare outside of the government system if choosing to travel indirectly. The OIG confirmed this guidance was provided to (b)(7)(C) via email on October 11, 2019; however, (b)(7)(C) traveled indirectly on three occasions after receiving this guidance. In addition, (b)(7)(C) claimed that, prior to receiving this guidance, he compared costs for indirect and direct flights within the travel system, chose the cheaper flight each time he flew, and placed comments within the travel system to reflect this information. (b)(7)(C) was unable to explain the lack of such comments within the system when provided copies of his travel documents. Further, (b)(7)(C) confirmed he flew into airports near his residence to spend time with his family, and claimed he was never questioned regarding the indirect routing.

A review of (b)(7)(C)'s emails revealed that he routinely identified travel-related issues in authorizations or vouchers that (b)(7)(C) submitted, and either denied the requests or asked (b)(7)(C) for explanations. At times, (b)(7)(C) appears to have complied, as the concerns mentioned in emails were not present on some of his final travel vouchers. At other times, (b)(7)(C) failed to follow up, and approved the travel documents although (b)(7)(C) had not corrected the issues. During his interview with the OIG, (b)(7)(C) stated he tries to pay close attention to travel authorization and voucher submissions, and routinely contacted (b)(7)(C) for clarification or corrections, but acknowledged he could have missed some issues.

ISSUE #4. OVERPAYMENT OF TRAVEL VOUCHER EXPENSES

The OIG confirmed that (b)(7)(C) was overpaid on nine travel vouchers, totaling $3,867 in per diem M&IE for which he was not entitled.

A review of (b)(7)(C)'s travel documents revealed multiple occasions when he split his travel over multiple days instead of completing his travel in a single day, and engaged in non-workdays between his days of travel. This is considered "interrupted" travel by both federal regulations and NRC policy. Interrupted travel is allowed; however, reimbursement is limited to the cost of travel on an uninterrupted basis. A review of travel vouchers uncovered reimbursement of per diem M&IE during interrupted travel for nine trips between 2018 and 2020. Overpayments for M&IE totaled $3,867 for the nine trips in question (see Table 3).

Records showed that (b)(7)(C) removed the M&IE for non-workdays from the "M&IE Cost" portion of the Per Diem Allowances section within these vouchers prior to final submission in SAP Concur Gov, the NRC's travel system. However, according to SAP Concur personnel, if a traveler deleted "M&IE Cost" instead of "M&IE Expense," the system will automatically correct what it perceives as an error, and restore the M&IE amount, resulting in payment to the traveler.

For further details, see Exhibit 40.

Table 3: Overpayment of M&IE

Trip	Loss ($)
January 2018 to Turkey Point	512
February 2018 to Saint Lucie	663
March 2018 to Turkey Point	192
June 2018 to NEI EP Conference	767
September 2018 to Rockville, Maryland (NRC)	138
January 2019 to Saint Lucie	275
February 2019 to Turkey Point	198
January 2020 to Saint Lucie	660
February 2020 to Turkey Point	462
Total Loss	**3,867**

(Source: Exhibits 18–19, 23–24, 33, and 36–39)

During his interview with the OIG, (b)(7)(C) stated he did not intentionally request reimbursement of the travel funds, and recalled an issue with the travel documents adding the funds back after he attempted to remove them. (b)(7)(C) acknowledged that (b)(7)(C) contacted him to question him about this issue on at least one occasion, and (b)(7)(C) believed he was successful in removing the funds after additional attempts to do so. (b)(7)(C) said he does not closely follow the travel reimbursements he receives due to the high number of trips he takes, and did not realize he was overpaid. (b)(7)(C) acknowledged he should not have received M&IE reimbursement for non-workdays and told the OIG he is willing and able to pay back the funds. For ease of reference, Table 4 cross-references Issues 3 and 4.

Table 4: Comparison of Travel-Related Issues

Trip	Indirect Routing	Loss from Indirect Routing ($)	Interrupted Travel	Loss from Interrupted Travel ($)	Other Travel-Related Violations
January 2018 to Turkey Point	Yes	0	Yes	512	No
February 2018 to Saint Lucie	No	0	Yes	663	No
March 2018 to Turkey Point	Yes	55.49	Yes	192	No
April 2018 to Surry	Yes	88.60	No	0	Wrong per diem, loss $146.50
April 2018 to Browns Ferry	Yes	0	No	0	No
June 2018 to NEI EP Conference	No	0	Yes	767	No
August 2018 to McGuire	Yes	0	No	0	No
September 2018 to NRC HQ	Yes	0	Yes	138	No
January 2019 to Saint Lucie	No	0	Yes	275	No
February 2019 to Turkey Point	Yes	46.40	Yes	198	No
February 2019 to NRC HQ	Yes	62.39	No	0	No
March 2019 to Catawba	Yes	0	No	0	No
April 2019 to Harris	Yes	11.40	No	0	No
July 2019 to Brunswick	Yes	0	No	0	No
July 2019 to Surry	Yes	413.80	No	0	Wrong per diem, loss: $138
August 2019 to McGuire	Yes	0	No	0	No
August 2019 to NEI EP Conference	Yes	110.39	No	0	No
November 2019 to Waterford	Yes	250.40	No	0	No
January 2020 to Saint Lucie	No	0	Yes	660	No
February 2020 to Turkey Point	Yes	0	Yes	462	No
February 2021 to Turkey Point	Yes	0	No	0	No
July 2021 to Surry	No	0	No	0	Claimed two travel modes and wrong per diem, loss: $377.87
Total Number of Indirect Routing Violations	**17**				
Total Loss from Indirect Routing		**$1038.87**			
Total Instances of Interrupted Travel (non-misconduct)			**9**		
Total Loss from Interrupted Travel				**$3,867**	
Total Loss from Other Violations					**$662.37**
Total Loss for All Issues	**$5,568.24**				

*Indirect routing, inappropriate travel method, and excess per diem claims violate regulations within FTR §301 and NRC MD 14.1. For further details, see Exhibit 40.
(Source: Exhibits 18–39)

REFERRAL

Consistent with the dictates of the Attorney General Guidelines for Offices of Inspector General with Statutory Law Enforcement Authority, CIGIE Quality Standards for Investigations, and other applicable directives and guidance, the ●IG referred this investigation to the Department of Justice for consideration of criminal prosecution. Their discretionary decision was to decline criminal prosecution. This investigation is being referred to NRC management for any action deemed appropriate.

EXHIBITS

1. Memorandum to File, Termination of Telework, dated October 12, 2021
2. Memorandum to File, Review of Travel Records, dated October 4, 2021
3. Memorandum to File, Review of Security Access Logs, dated October 4, 2021
4. Memorandum to File, Receipt of Human Resources Management System (HRMS) Logs, dated November 4, 2021
5. Memorandum to File, 2018 Comparison Calendar, dated December 6, 2021
6. Memorandum to File, Receipt of Additional Human Resources Management System (HRMS) Logs, dated December 16, 2021
7. Memorandum to File, 2019–2021 Comparison Calendars, dated February 8, 2022
8. Memorandum to File, Receipt and Review of Travel Vouchers, Authorizations, and Receipts, dated February 8, 2022
9. Memorandum to File, Receipt of Additional Information Regarding Access Logs, dated February 8, 2022
10. Memorandum to File, Receipt and Review of Internet Protocol Data, dated February 8, 2022
11. Memorandum of Interview, (b)(7)(C), dated February 7, 2022
12. Memorandum of Interview, (b)(7)(C), dated October 4, 2021
13. Memorandum of Interview, (b)(7)(C), dated September 21, 2021
14. Memorandum of Interview, (b)(7)(C), dated September 30, 2021
15. Memorandum to File, Timeline of Events Related to Suspension and Telework, dated December 6, 2021
16. Memorandum to File, Receipt and Review of Email Data, dated February 9, 2022
17. Memorandum of Interview, (b)(7)(C), dated February 7, 2022
18. Memorandum to File, Detailed Review of Records for January 2018 Turkey Point Emergency Preparedness Inspection Visit, dated February 4, 2022

19. Memorandum to File, Detailed Review of Records for March 2018 Turkey Point TI-191 Inspection Visit, dated August 30, 2022

20. Memorandum to File, Review of Records for April 2018 Surry Emergency Preparedness Program Inspection Visit, dated August 29, 2022

21. Memorandum to File, Review of Records for April 2018 Browns Ferry Emergency Preparedness Program Inspection Visit, dated August 29, 2022

22. Memorandum to File, Review of Records for August 2018 McGuire Emergency Preparedness Program Inspection Visit, dated August 29, 2022

23. Memorandum to File, Detailed Review of Records for September 2018 Visit to Rockville, Maryland, dated February 4, 2022

24. Memorandum to File, Detailed Review of Records for February 2019 Turkey Point Exercise Inspection Visit, dated August 30, 2022

25. Memorandum to File, Review of Records for February 2019 Visit to NRC Headquarters, Rockville, Maryland, dated August 29, 2022

26. Memorandum to File, Review of Records for March 2019 Catawba Emergency Preparedness Program Inspection Visit, dated August 30, 2022

27. Memorandum to File, Review of Records for April 2019 Harris Exercise Inspection Visit, dated August 29, 2022

28. Memorandum to File, Review of Records for July 2019 Brunswick Emergency Preparedness Inspection Visit, dated August 29, 2022

29. Memorandum to File, Review of Records for July 2019 Surry Emergency Preparedness Inspection Visit, dated August 29, 2022

30. Memorandum to File, Review of Records for August 2019 McGuire Emergency Preparedness Inspection Visit, dated August 30, 2022

31. Memorandum to File, Review of Records for August 2019 Nuclear Energy Institute Emergency Preparedness Conference, dated August 30, 2022

32. Memorandum to File, Review of Records for November 2019 Waterford Emergency Preparedness Exercise Inspection Visit, dated August 30, 2022

33. Memorandum to File, Detailed Review of Records for February 2020 Turkey Point Emergency Preparedness Inspection Visit, dated February 8, 2022

34. Memorandum to File, Detailed Review of Records for February 2021 Turkey Point Emergency Preparedness Inspection Visit, dated August 30, 2022

35. Memorandum to File, Detailed Review of Records for July 2021 Surry Emergency Preparedness Inspection Visit, dated August 30, 2022

36. Memorandum to File, Detailed Review of Records for January 2020 Saint Lucie Emergency Preparedness Inspection Visit, dated January 4, 2022

37. Memorandum to File, Detailed Review of Records for February 2018 Saint Lucie Emergency Preparedness Inspection Visit, dated February 4, 2022

38. Memorandum to File, Detailed Review of Records for June 2018 Nuclear Energy Institute Emergency Preparedness Conference, dated February 4, 2022

39. Memorandum to File, Detailed Review of Records for January 2019 Saint Lucie Emergency Preparedness Inspection Visit, dated February 4, 2022

40. Memorandum to File, Policy Reference Information Utilized for Detailed Review of Records, dated January 4, 2022

MEMORANDUM

DATE: June 20, 2023

TO: Malion A. Bartley
Assistant Inspector General
for Investigations

Malion A. Bartley
Digitally signed by Malion A. Bartley
Date: 2023.06.20 20:14:12 -04'00'

THROUGH: (b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2023.06.20 20:11:47 -04'00'

THROUGH: (b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2023.06.20 15:42:21 -04'00'

FROM: (b)(7)(C)
(b)(7)(C)
Senior Special Agent
Digitally signed by (b)(7)(C)
Date: 2023.06.20 15:34:15 -04'00'

SUBJECT: CONCERNS OF COUNTERFEIT FRAUDULENT SUSPECT BREAKERS IN U.S. NUCLEAR PLANTS (OIG CASE NO. I22O191)

ALLEGATION

On February 8, 2022, the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), identified from review of (b)(7)(E) that Duke Energy (Duke), the Oconee Nuclear Station licensee, reported an unusual automatic reactor shutdown of Unit 2. Since the reactor was operating when the safety systems initiated the shutdown, the event was required to be reported as a 4-hour, nonemergency notification per 10 Code of Federal Regulations (C.F.R.) 50.72(b)(2)(iv)(B).

Oconee Unit 2 experienced an automatic reactor shutdown from the simultaneous loss of all four-reactor coolant pumps due to the premature failure of a fuse. Although the fuse manufacturer, Eaton, determined this fuse was not counterfeit, we identified the licensee did not authenticate the fuse before installation because such a determination is not a regulatory requirement, as discussed in the NRC OIG's "Special Inquiry into Counterfeit, Fraudulent, and Suspect Items in Operating Nuclear Power Plants." OIG CASE No. 20-022, February 9, 2022.

During the investigation into the Oconee shutdown, the NRC OIG coordinated with Eaton's (b)(7)(C) who reported to the NRC OIG that the U.S. Department of Homeland Security Investigations (HSI) was investigating a Counterfeit Fraudulent Suspect Item (CFSI)

case involving Eaton breakers. In light of this information from Eaton, the NRC OIG opened a proactive investigation to review the breaker issue, as these breakers could possibly be installed in U.S. commercial nuclear plants across the country.

POTENTIAL VIOLATIONS

The potential violations relevant to this investigation are 18 United States Code, Section 2320 – Trafficking in counterfeit goods or services [Whoever intentionally traffics in goods or services and knowingly uses a counterfeit mark on or in connections with goods or services.]

FINDINGS

Although the NRC OIG coordinated with various law enforcement entities and the U.S. Department of Justice (DOJ), we were unable to confirm that counterfeit breakers are being installed in commercial nuclear power plants in the U.S. This was due to the lack of joint investigative interest from other federal law enforcement agencies citing, in part, no identified loss of funds to the federal government.

BASIS OF FINDINGS

BACKGROUND

On September 19, 2022, the OIG coordinated with HSI-Dallas requesting a possible joint investigation of counterfeit breakers due to their safety significance to commercial nuclear power plants, and the potential harm they could cause. A meeting was held on September 27, 2022 and the NRC OIG learned that the HSI-Dallas investigation determined that the counterfeit breakers were shipped to Texas from a business in northern California, and the HSI-Dallas office did not have jurisdiction over the case. HSI-Dallas explained to the OIG that the investigation was referred to the U.S. Attorney's Office (USAO) for the Northern District of California, and the HSI-San Francisco office, but neither entity was interested in pursuing the investigation. The HSI-Dallas told the OIG that the investigation stalled due to the pandemic and HSI staffing shortages. However, HSI-Dallas did not share that information with Eaton concerning the counterfeit breaker investigation.

After the meeting with HIS-Dallas, the NRC OIG coordinated with HSI-Washington DC to see if that office was interested in continuing the investigation. The NRC OIG briefed HSI-Washington DC on the facts of the case, after which HSI-Washington DC confirmed this information with the HSI-Dallas office. HSI-Washington DC explained to the NRC OIG that it would coordinate with the USAO for the Eastern District of Virginia to see if they could get a prosecutor on board with this investigation. This proved unsuccessful, and HSI-Washington DC told the OIG that it was not interested in pursuing the investigation as there was no safety-related incident to investigate.

A briefing was held on February 1, 2023 with the NRC OIG and the U.S. Department of Justice (DOJ) on the counterfeit breaker investigation. On February 28, 2023, the DOJ explained that

the NRC OIG needed to show a federal agency impact. Because no federal impact was identified, DOJ-Civil Division could not pursue the case and open a civil matter at this time. However, the DOJ shared the NRC OIG briefing information with the USAO for the Eastern District of Tennessee and recommended a possible joint investigation with the Tennessee Valley Authority (TVA) Office of Inspector General (TVA OIG) to see if it would be interested in a proactive investigation with a TVA-owned plant.

On March 14, 2023, the NRC OIG coordinated with the TVA OIG and briefed the staff on the investigation concerning the counterfeit breakers. The TVA OIG explained that it will discuss with its leadership the possibility of a joint investigation. On March 30, 2023, a second meeting with the TVA OIG was held to discuss its interest in a joint investigation. The TVA OIG declined to pursue a joint investigation. The TVA OIG Assistant Special Agent in Charge explained that the procurement staff are aware of the ongoing issue with the counterfeit Eaton molded case circuit breakers. However, the online Eaton Circuit Breaker authentication tool to verify that its breakers are genuine is regularly used for verification. The TVA OIG further explained that TVA nuclear plant staff told the TVA OIG that they are not interested in a proactive approach to inspect current operating breakers due to the downtime that would be involved in doing so, and the economic impact. With the information stated above, the TVA OIG declined to pursue any proactive efforts and/or and joint investigations on this issue.

DISPOSITION

This investigation is being closed because the NRC OIG was unable to determine if counterfeit breakers are being installed in U.S. commercial nuclear power plants without a willing federal law enforcement agency with jurisdiction to partner on a joint investigation. The NRC OIG will closely monitor any future allegations of CFSI in U.S. commercial nuclear plants, particularly if a CFSI breaker was used in a safety system.

MEMORANDUM

DATE: December 14, 2023

TO: Daniel H. Dorman
Executive Director for Operations

FROM: Malion A. Bartley
Assistant Inspector General
for Investigations

Malion A. Bartley
Digitally signed by Malion A. Bartley
Date: 2023.12.14 13:57:44 -05'00'

SUBJECT: ALLEGATION REGARDING THE U.S. NUCLEAR REGULATORY COMMISSION'S IMPLEMENTATION OF FUEL FACILITY INSPECTION POLICY (OIG CASE NO. I2303305)

This memorandum conveys the results of our investigation into an allegation that a fuel facility resident inspector was not fully qualified.

Our investigation identified potential issues that need to be addressed. The OIG requests a formal response to this report no later than **March 22, 2024**, providing answers to the questions we pose and describing what actions you will take to address our findings.

cc: Chair Hanson
Commissioner Wright
Commissioner Caputo
Commissioner Crowell
S. Morris, DEDR
L. Dudes, RA
J. Lubinski, NMSS

CONTACT: Malion A. Bartley, AIGI
301.415.5962

EXECUTIVE SUMMARY

The Office of the Inspector General (OIG) substantiated the allegation that (b)(7)(C) (b)(7)(C) (b)(7)(C) is not a fully qualified fuel facility inspector according to Inspection Manual Chapter (IMC) 1247. Additionally, the OIG found that Region II did not adhere to Nuclear Regulatory Commission (NRC) fuel facility policies in two ways:

(1) Contrary to IMC 1247, from ~~September 2022~~ through October 2022, (b)(7)(C) independently inspected areas at the (b)(7)(C) fuel facility for which (b)(7)(C) had neither completed fuel facility qualifications nor received an Interim Qualification Certificate from NRC management.[1] During this time, at least 95 risk-significant inspection samples were completed.

(2) Contrary to IMC 2600, Region II provided (b)(7)(C) only two weeks, rather than the required three-to-six-month turnover period, with (b)(7)(C) (b)(7)(C).

The OIG also found a gap in NRC policy, because IMC 1247 has no specific qualification requirement for fuel facility resident inspectors. As a result, Region II's historical practice has been (b)(7)(C) who are typically qualified inspectors in an operation qualification and have them pursue IMC 1247, Appendix C cross qualification. Region II's practice has not, however, been formally documented.

Our investigation identified potential issues that need to be addressed. Accordingly, the OIG requests a formal response to the following questions, including what actions will be taken to address any related concerns:

1. What steps will the NRC take to ensure compliance with IMC 1247 when inspectors are not interim-qualified to perform inspections?
2. What steps will the NRC take to ensure compliance with IMC 1247 provisions regarding turn-over periods?
3. How and when will the NRC revise IMC 2600 to address the agency's current approach for resident inspector qualification at fuel facilities?

[1] This investigation determined that (b)(7)(C) began independently performing fuel facility resident inspector inspections in September 2022.

ALLEGATION

The OIG initiated this investigation based on an allegation that (b)(7)(C) at the (b)(7)(C) fuel facility, (b)(7)(C), is not a fully qualified fuel facility inspector.

POTENTIAL VIOLATIONS

The OIG investigated potential violations of the following policies:

- Management Directive 9.26, "Organization and Functions, Office of Nuclear Material Safety and Safeguards (NMSS)";
- Inspection Manual Chapter (IMC) 1247, "Qualification Program for Fuel Facility Inspectors in the Nuclear Material Safety and Safeguards Program Area"; and,
- Inspection Manual Chapter (IMC) 2600, Appendix C, "Fuel Cycle Resident Inspection Program."

FINDINGS

Finding 1: The OIG substantiated that (b)(7)(C) is not a fully qualified fuel facility inspector according to IMC 1247; further, (b)(7)(C) has not received an Interim Qualification Certificate from NRC management to conduct inspections while his qualifications are pending. Nonetheless, from September 2022 through October 2023, (b)(7)(C) independently conducted inspections at (b)(7)(C), (b)(7)(C) performed at least 05 risk-significant inspection samples, which included reviews in areas for which (b)(7)(C) had not yet completed his ongoing fuel facility qualifications. Additionally, the OIG found Region II management did not adhere to IMC 2600 because it failed to provide (b)(7)(C) the three-to-six-month turnover period with (b)(7)(C). This investigation found the turnover period was approximately two weeks.

Finding 2: The OIG identified a policy gap in IMC 1247 because there is no specific qualification requirement for fuel facility resident inspectors. As a result, Region II's historical practice, which has not been formally documented, has been (b)(7)(C), who are typically qualified inspectors in an operation qualification, and have them then pursue IMC 1247, Appendix C, cross qualification. This qualification process typically takes approximately 18 months to complete. (b)(7)(C) is pursuing cross-qualification requirements, which in this particular case will take approximately 21 months to complete (i.e., September 2022 through June 2024).

BASIS OF FINDINGS

Background

The NRC regulates the nation's fuel cycle facilities to protect public health and safety, protect the environment, and to ensure the security of nuclear material.

(b)(7)(C) is a Category I fuel fabrication facility, located in (b)(7)(C). The licensee is (b)(7)(C). A Category I Fuel Fabrication Facility is licensed under Title 10 of the *Code of Federal Regulations* (10 C.F.R.) Part 70 to use or possess strategic special nuclear material (Category I quantities of high-enriched uranium or plutonium) in processing, recovery, fuel fabrication, or research and development activities and operations.

NRC Oversight Structure

The Division of Fuel Management (DFM) within the NRC Office of Nuclear Material Safety and Safeguards (NMSS) develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to NRC jurisdiction. DFM also approves changes to the fuel cycle facility inspection program. Region II's Division of Fuel Facility Inspection (DFFI) is responsible for the management and execution of the NRC inspection program conducted at (b)(7)(C).

(b)(7)(C) is stationed at (b)(7)(C). (b)(7)(C) are the NRC's primary eyes and ears at the site and the NRC's main representative to the public and local government. (b)(7)(C) is responsible for conducting the resident inspection program in accordance with IMC 2600 and IMC 2600, Appendix C.

Finding 1: NRC management failed to ensure adherence to inspection program policies.

Issue 1: Fuel facility inspections performed by (b)(7)(C) who was not fully qualified

NRC management did not ensure (b)(7)(C) independently performed only those inspections for which he was qualified as described in policy. The OIG found that (b)(7)(C) has been independently performing the full scope of the resident inspection program since September 2022 even though (b)(7)(C) has neither completed fuel facility qualifications nor received an Interim Qualification Certificate from NRC management.

Inspection Manual Chapter 1247 defines the initial training and qualification requirements for NRC staff performing fuel facility inspections in the NMSS program area. The qualification process is intended to ensure that the NRC staff has the necessary knowledge and skills to successfully implement NMSS fuel facility inspection programs.

Attachment 3 of IMC 1247 provides the fuel facility inspector qualification requirements for NRC staff, such as (b)(7)(C), who were previously qualified as inspectors using IMC 1245, IMC 1246, or IMC 1252.[2]

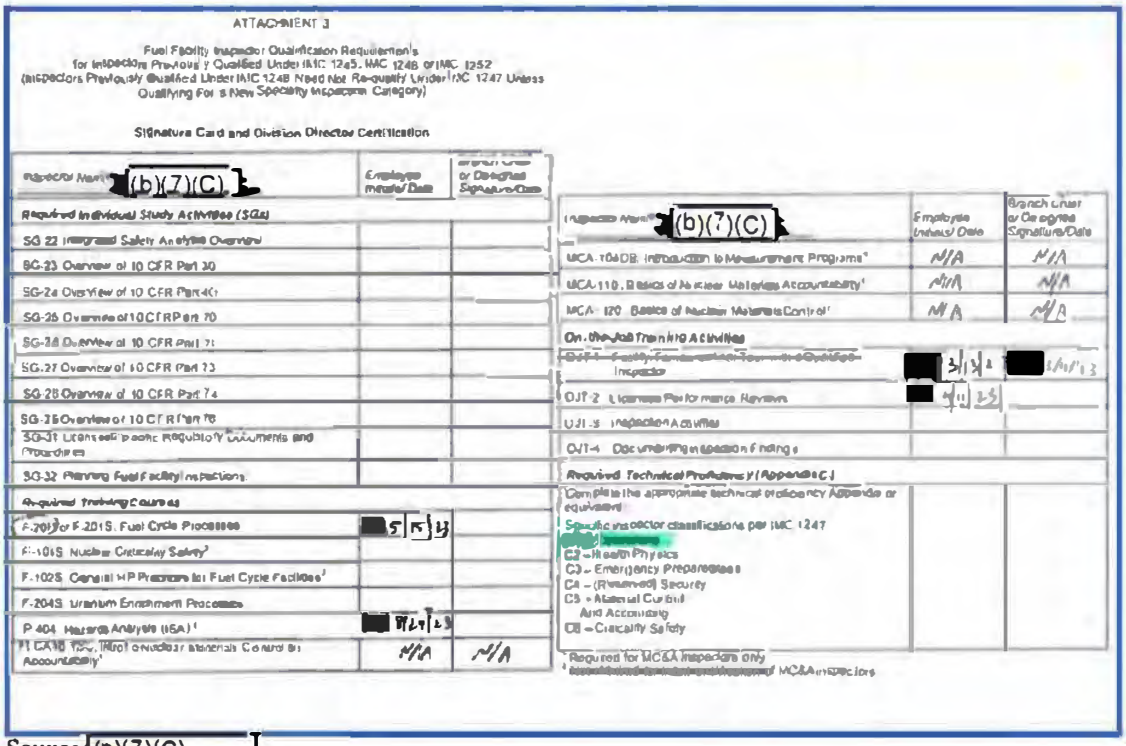
Inspection Manual Chapter 1247, subsection 03.14, defines "Interim Inspector Qualification" as follows:

> A certification by the Regional Administrator or Office Director, the basis of which is a recommendation by the Inspector Qualification Board. Interim Inspector Qualification indicates that the inspector has completed Basic-level and most Proficiency-Level inspector training and qualification requirements. Interim Inspector Qualification may be granted when some required training courses are not offered, and no equivalent courses are available. A limited Interim Qualification can also be granted when proficiency has been completed in some but not all the study guide training related to inspection procedures. A determination must be made that the inspector will be able to conduct inspections without an adverse impact to inspection quality. Achieving Interim Inspector Qualification allows an inspector to be assigned to any and all procedures that the inspector is proficient in, up to the full scope of inspection-related activities, to be performed independently with routine oversight and supervision. Interim Inspector qualification is granted on a case-by-case basis.

The OIG reviewed the qualification status of (b)(7)(C) and confirmed, through records review and testimony, (b)(7)(C) is an IMC 1245 qualified reactor inspector but not an IMC 1247 qualified fuel facility inspector. Furthermore, the OIG determined that (b)(7)(C) had not been granted Interim Inspector Qualification, and that (b)(7)(C) was still in a cross-qualification status while performing resident inspector duties. The OIG found that as of October 2023, after approximately 13 months as (b)(7)(C), most of (b)(7)(C) (b)(7)(C) inspector qualification requirements on the signature card had not been signed off by (b)(7)(C) 's branch chief (see Figure 1).

[2] IMC 1245, "Qualification Program for New and Operating Reactor Programs;" IMC 1246, "Formal Qualification in NMSS Program Areas;" and 1252, "Construction Inspector Training and Qualification Program."

Figure 1: NRC Inspector Qualification Card



ATTACHMENT 3

Fuel Facility Inspector Qualification Requirements
for Inspectors Previously Qualified Under IMC 1245, IMC 1248 or IMC 1252
(Inspectors Previously Qualified Under IMC 1248 Need Not Re-qualify Under IMC 1247 Unless
Qualifying For a New Specialty Inspection Category)

Signature Card and Division Director Certification

Inspector Name: (b)(7)(C)	Employee Initials/ Date	Branch Chief or Designee Signature/Date
Required Individual Study Activities (SGIs)		
SG-22 Integrated Safety Analysis Overview		
SG-23 Overview of 10 CFR Part 30		
SG-24 Overview of 10 CFR Part 40		
SG-25 Overview of 10 CFR Part 70		
SG-26 Overview of 10 CFR Part 71		
SG-27 Overview of 10 CFR Part 73		
SG-28 Overview of 10 CFR Part 74		
SG-29 Overview of 10 CFR Part 76		
SG-31 Licensee-specific Regulatory Documents and Procedures		
SG-32 Planning Fuel Facility Inspections		
Required Training Courses		
F-201 or F-201S, Fuel Cycle Processes	[redacted] 5/15/13	
F-101S, Nuclear Criticality Safety		
F-102S, General HP Practices in Fuel Cycle Facilities		
F-204S, Uranium Enrichment Processes		
P-404, Hazards Analysis (HSA)	[redacted] 9/27/23	
MCA-110, Basics of Nuclear Materials Control and Accountability	N/A	N/A

Inspector Name: (b)(7)(C)	Employee Initials/ Date	Branch Chief or Designee Signature/Date
MCA-104DB, Introduction to Measurements Programs	N/A	N/A
MCA-110, Basics of Nuclear Materials Accountability	N/A	N/A
MCA-120, Basics of Nuclear Materials Control	N/A	N/A
On-the-Job Training Activities		
OJT-1, Facility-Familiarization Tour and Qualified Inspector	[redacted] 5/14/13	[redacted] 5/15/13
OJT-2, Licensee Performance Reviews	[redacted] 9/11/23	
OJT-3, Inspection Activities		
OJT-4, Documenting Inspection Findings		
Required Technical Proficiency (Appendix C)		
Complete the appropriate technical proficiency Appendix or equivalent		
Specific inspector classifications per IMC 1247		
[redacted]		
CB – Health Physics		
CD – Emergency Preparedness		
CA – (Reserved) Security		
CB – Material Control And Accounting		
CB – Criticality Safety		

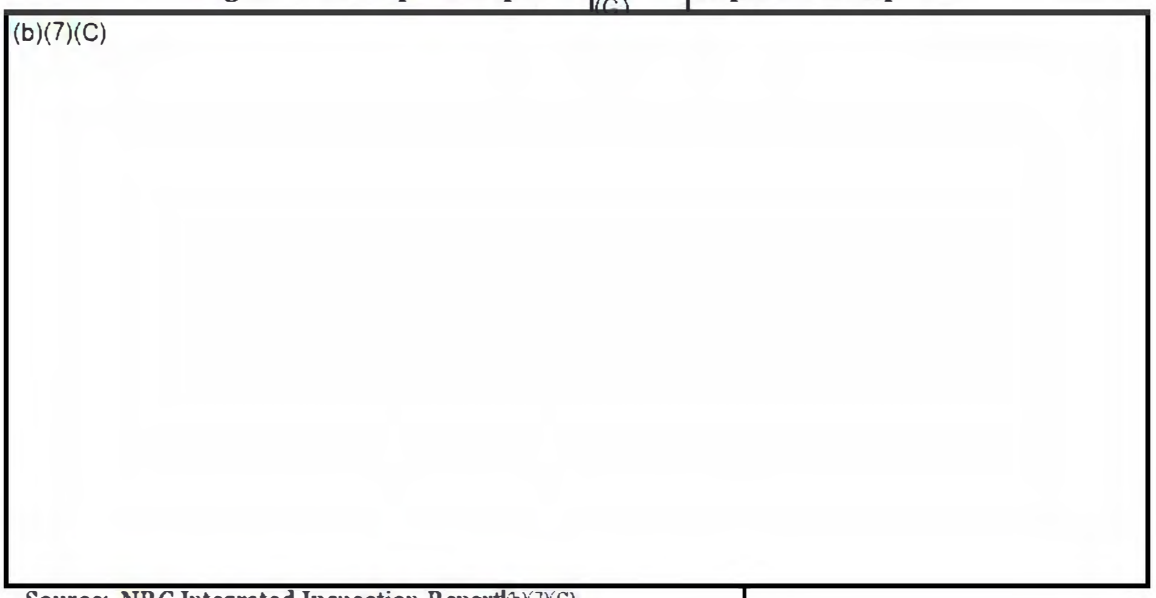
Required for MC&A inspectors only

Source: (b)(7)(C)

While working through the cross-qualification requirements in IMC 1247 Attachment 3, (b)(7)(C) had been implementing the full-scope of the resident inspection program described in NRC Inspection Procedure (IP) 88135, "Resident Inspection Program for Category I Fuel Cycle Facilities." The objectives of IP 88135 are "to provide resident inspector program requirements and guidance to independently gather sufficient information and evaluate the licensee's performance to determine whether it conforms to regulatory requirements, license conditions and other commitments, and is in accordance with established procedures." There are six attachments to IP 88135, and each attachment aligns with the following Performance Areas: Safety Operations (SO), Safeguards (SG), Radiological Controls (RC), and Facility Support (FS).

The NRC quarterly inspection reports issued from October 2022 through October 2023, revealed that (b)(7)(C) is the (b)(7)(C) at this facility. During this time, the inspector completed more than 95 inspection samples under procedures specified in the six attachments to IP 88135. Figure 2 provides an example of inspection samples completed in areas for which (b)(7)(C) has yet to receive approval of completion from NRC management.

Figure 2: Example of reported (b)(7)(C) inspection samples



Source: NRC Integrated Inspection Report (b)(7)(C)

(b)(7)(C) stated that since he was qualified as an inspector under IMC 1245, he met "the bare minimum inspector qualification" requirements for his current position when he applied for it in March 2022. (b)(7)(C) further stated that he believes he is qualified to be (b)(7)(C) at (b)(7)(C) because of his nuclear engineering degree, his previous experience, and his IMC 1245 qualifications. According to (b)(7)(C), after qualifying under IMC 1245, he performed 18 months of acting resident inspector duties at various power reactor sites. (b)(7)(C) told the OIG that he is "basically self-directing" and follows the checklist requirements in IMC 1247. He also stated that he did not receive any equivalency determinations or exemptions from management for any of the IMC 1247 requirements. (b)(7)(C) stated that he believes he will be a fully qualified fuel facility inspector before June 2024, but "a lot of classes are still needed."

(b)(7)(C) informed the OIG that he independently conducted six procedures quarterly at (b)(7)(C) from September 2022 through October 2023. When the OIG asked if regional inspectors performed any of the fuel facility resident inspections required in IP 88135, he told us they had conducted only one sample for a plant status meeting on (b)(7)(C) 2023, while he was moving his family from (b)(7)(C).

The Region II DFFI (b)(7)(C) stated that he was aware when the (b)(7)(C) was hired that he was not a fully qualified fuel facility inspector, acknowledging (b)(7)(C) is not yet IMC 1247 qualified but stating that he is nonetheless "a qualified NRC inspector." (b)(7)(C) (b)(7)(C) stated that NMSS was also aware of (b)(7)(C) s qualifications and approved of

Region II's approach. (b)(7)(C) further stated that the regional practice was to hire a reactor qualified inspector for each of the two Category I fuel facilities because the inspector would already know how to inspect, would know the NRC regulations and processes, and would then be able to learn "the fuel facilities and the fuel side."

Additionally, (b)(7)(C) stated to the OIG that he found a "gap" in NRC guidance when he initiated a review of DFFI inspector qualifications after the OIG issued the Special Inquiry Report regarding the inspector qualification program for the Independent Spent Fuel Storage Installations.[3] (b)(7)(C) further stated that, in a March 2023 NMSS/Region II DFFI management meeting, he explained that IMC 2600 needed to be revised to clarify Region II's approach to filling (b)(7)(C) vacancy positions at the Category I fuel facilities. In response, Region II stated that it planned to revise its internal guidance document, "Division of Fuel Facility Inspection (DFFI) Handbook," to add clarifying information and justification.[4] The OIG identified from an NRC email in March 2023, that Region II did communicate to NMSS this "gap" in the agency's guidance.

The OIG asked (b)(7)(C) how he would respond to the allegation that Region II management has allowed a non-fully qualified inspector, as measured against IMC 1247, to be (b)(7)(C) at the (b)(7)(C) facility since August of 2022. (b)(7)(C) (b)(7)(C) stated, "we think that they can do adequate inspection as long as they're an NRC-qualified inspector working on their cross-quals. If that's not the case, then ... we'll have to figure out how to get these two very specific fuel facilities covered when it's time to do a turnover for a new resident inspector, which is interesting." (b)(7)(C) added that "[the OIG's] results and your conclusions will be very interesting timing-wise because we're getting ready to [have (b)(7)(C)] at (b)(7)(C) fuel facility] tour of duty end...next December."

Issue 2: Minimal new resident inspector turnover with previous resident inspector

NRC management did not ensure (b)(7)(C) had the three-to-six-month turnover time with (b)(7)(C) as described in policy. The OIG found that (b)(7)(C) (b)(7)(C) inspector had approximately a two-week turnover with (b)(7)(C) (b)(7)(C).

[3] *Special Inquiry into the U.S. Nuclear Regulatory Commission Region II's Inspections of Independent Spent Fuel Storage Installations at Operating Reactors* (February 21, 2023).
[4] The Region II handbook, "Division of Fuel Facility Inspections" (DFFI handbook) explains how to conduct common tasks in DFFI. Section 4 describes the roles and responsibilities of (b)(7)(C) at fuel facilities.

Inspection Manual Chapter 2600, Appendix C, section 2600C-04, "Resident Inspector Policy," states the following regarding inspector turnover time:

> Incoming permanent resident assignments will typically be made to allow for approximately three months of turnover time with the incumbent resident inspector but shall not exceed six months without approval of the Regional Administrator.
>
> During the resident inspector turnover period, the relieving resident inspector shall only charge direct inspection time to the licensee. All other time will be charged to the appropriate non-fee billable codes.

An NRC principal told the OIG that the turnover period was minimal because (b)(7)(C) (b)(7)(C) had already started a different NRC position by August 2022. Therefore, the turnover period was approximately 2 weeks. Region II managers told the OIG that they believed that the turnover period was adequate because other materials inspectors were performing inspections at (b)(7)(C) and were available if (b)(7)(C) had any questions or concerns.

Finding 2: The NRC lacks a fuel facility resident inspector qualification program.

The OIG found a gap in IMC 1247 because, although Appendix C of IMC 2600 establishes the policy for the fuel facility resident inspection program, there is no specific qualification program for fuel facility resident inspectors. As a result, Region II's historical practice has been (b)(7)(C) who are typically qualified inspectors in an operation qualification and have them pursue IMC 1247, Appendix C, cross qualification, which takes approximately 18 months to complete. (b)(7)(C) (b)(7)(C) who is pursuing cross qualification, expects that he will not complete the fuel facility inspector qualification program until June 2024.

Figure 3 lists the different IMC 1247 qualification programs. As reflected in Figure 3, a specific qualification program for resident inspectors is absent.

Figure 3: Picture from IMC 1247, Table of Contents, Issue Date: 10/28/14

Source: NRC

The Region II (b)(7)(C) agreed that IMC 1247 lacks a specific qualification for resident inspectors at fuel facilities. As stated above, after discovery of this "gap," (b)(7)(C) (b)(7)(C) communicated this issue to NMSS during a senior management meeting in March 2023. As an immediate corrective action, Region II revised its internal guidance document, "Division of Fuel Facility Inspection (DFFI) Handbook," to add clarifying information.

The OIG identified the DFFI Handbook was revised and section 4 now states:

> There is no specific qualification for DFFI SRIs in IMC 1247, instead SRIs are expected to be qualified inspectors in some area and to pursue a qualification under IMC 1247 (typically an OPS qualification under Appendix C1) if they aren't already qualified under IMC 1247. It is anticipated many newly placed SRIs will already be fully-qualified under IMC 1245, and as such will use the cross-qualification process described in IMC 1247. It is expected that these SRI's will follow the turnover recommendations described in IMC 2600, Appendix C, "Fuel Cycle Resident Inspection Program." Given prior full qualifications, an effective turnover, oversight from division management as described in ROI 2213, and frequent visiting inspectors (roughly monthly), those SRI's are

considered provisionally qualified for the sake of site staffing. They should charge their time as a fully-qualified inspector would. The SRI and their supervisor should agree to a schedule for completion of cross-qualification, not normally to exceed eighteen months.

CONCLUSION

The OIG substantiated the allegation that (b)(7)(C) is not a fully qualified fuel facility inspector according to Inspection Manual Chapter 1247. The OIG also found that, contrary to IMC 1247, (b)(7)(C) has independently performed the resident inspector inspection program at (b)(7)(C) and has completed at least 95 risk-significant inspection samples, including samples in areas for which he has neither completed fuel facility qualifications nor received an Interim Qualification Certificate from NRC management. In addition, and contrary to IMC 2600, when (b)(7)(C) began duties at (b)(7)(C), Region II did not provide him the three-to-six-month turnover period with (b)(7)(C) (b)(7)(C) that is provided for in agency policy. This investigation found the turnover period was two weeks.

The OIG also found a gap in IMC 1247 due to a lack of specific qualification criteria for fuel facility resident inspectors. As a result, Region II's historical practice, which has not been formally documented, has been (b)(7)(C) who are typically qualified inspectors in an operation qualification, and have them then pursue IMC 1247, Appendix C, cross qualification.

This investigation aligned with the OIG's annual plan as a follow-up after the issuance of the Special Inquiry into the NRC's oversight of ISFSI's in Region II that indicated an apparent shortcoming in the NRC's regulatory oversight.

Issues identified in this memorandum shall be dispositioned, as appropriate, by the Executive Director for Operations.

MEMORANDUM

DATE: August 21, 2024

TO: (b)(7)(C)

Digitally signed by (b)(7)(C)
Date: 2024.08.21 16:08:29 04'00'

FROM: (b)(7)(C)
Senior Special Agent

(b)(7)(C)

Digitally signed by (b)(7)(C)
Date: 2024.08.21 12:13:23 04'00'

SUBJECT: MISUSE OF DECOMMISSIONING TRUST FUND OF PALISADES NUCLEAR PLANT (OIG CASE NO. I2303311)

ALLEGATION

The Office of the Inspector General (OIG) initiated this investigation based on information the OIG received on April 5, 2023, from Beyond Nuclear and Don't Waste Michigan (two environmental groups concerned with nuclear waste). The information involved Holtec Decommissioning International (Holtec) inappropriately using the Palisades Decommissioning Trust Fund (DTF) to fund non-decommissioning activities. Specifically, allegedly Holtec used the Palisades DTF to pursue governmental aid and to pay salaries of staff working to maintain the plant for restart. These activities are not authorized uses of a DTF.

POTENTIAL VIOLATIONS

The potential violations relevant to this investigation are Title 10 of the Code of Federal Regulations (C.F.R.) Section 50.82(a)(8)(i)(A), "Termination of License," and 10 C.F.R. Section 50.75(h)(1)(iv), "Reporting and recordkeeping for decommissioning planning."

FINDING

The OIG found Holtec misused the Palisades DTF when the company used $53,867.62 of DTF funds to pay for non-decommissioning activities. Through its inspection procedure for DTFs, Inspection Procedure 71801, the NRC identified and pursued the misuses of funds.

BASIS OF FINDING

BACKGROUND

On April 5, 2023, the OIG received the allegation from Beyond Nuclear and Don't Waste Michigan. Upon receipt of the allegation, the OIG learned that the NRC Headquarters Allegation Team had received the same allegation and was pursuing the matter.

On May 16, 2023, the NRC Headquarters Allegation Team issued a Request for Information (RFI) to Holtec concerning the allegation.

On July 13, 2023, Holtec responded to the RFI. Holtec's response states an independent law firm, Balch & Bingham, conducted an evaluation of expenditures. The evaluation concluded:

(b)(4)

Holtec's response describes each instance the independent evaluator identified in which Holtec used the Palisades DTF to reimburse the company for expenditures not associated with authorized decommissioning activities. Those instances are detailed below, as reported by Holtec:

(b)(4)

(b)(4)

On August 24, 2023, under Inspection Procedure 71801, the NRC completed a site inspection of the Palisades DTF activities. The NRC's inspection identified the same misuses of the Palisades DTF as Holtec described in its response to the RFI. The NRC's inspection report identifies several processes Holtec implemented to prevent future unauthorized DTF reimbursements. The NRC did not issue a violation.

Additional DTF Misuse Identified

On February 22, 2024, following a routine announced decommissioning inspection at Indian Point Energy Center, the NRC issued to Holtec a Severity Level IV violation notice for failure to establish proper oversight and controls to ensure that expenditures from the DTF were used only for legitimate decommissioning purposes. Specifically, NRC inspectors determined that Holtec used $63,000 of the Indian Point DTF to support community outreach activities unrelated to decommissioning activities, like removing the facility or site from service safely and reducing residual activity to a level that permits release of the property, for either unrestricted or restricted conditions, and termination of the license.

On February 29, 2024, following a routine announced decommissioning inspection at Oyster Creek Nuclear Generating Station, the NRC issued to Holtec a Severity Level IV violation notice for failure to establish proper oversight and controls to ensure that expenditures from the DTF were used only for legitimate decommissioning purposes. Specifically, NRC inspectors determined that Holtec expended approximately $62,000 from the Oyster Creek DTF for events such as a celebration day for Lacey Township, a donation to a food bank, and certain upgrades to the local community.

On February 29, 2024, following a routine announced decommissioning inspection at Pilgrim Nuclear Power Station, the NRC issued to Holtec a Severity Level IV violation notice for failure to establish proper oversight and controls to ensure that expenditures from the DTF were used only for legitimate decommissioning purposes. Specifically, NRC inspectors determined that Holtec expended approximately $84,000 from the Pilgrim DTF for community outreach activities, including cooperation with the local Chamber of Commerce, a community Thanksgiving celebration, and local community parades.

DISPOSITION

The *OIG's Risk Assessment of the U.S. NRC's Decommissioning Trust Fund Oversight and Related Activities* (OIG-24-RA-01), dated July 1, 2024, discusses the incidents addressed in this report. The risk assessment, as it relates to these incidents, states, "Even though NRC inspection procedures did not require the inspectors to conduct detailed reviews of licensee expenditures, the inspectors, who are not financial experts or auditors, were able to identify these apparent instances of misuse involving DTFs." The OIG shared the risk assessment with the NRC.

The OIG determined that NRC inspection procedures identified Holtec's misuse of DTF funds and that the NRC is addressing the issues through current oversight procedures. The OIG did not identify any lapse of oversight or intent to defraud; therefore, this investigation is closed with no further OIG action taken.

MEMORANDUM

DATE: June 17, 2024

TO: Raymond V. Furstenau
Acting Executive Director
for Operations

FROM: Malion A. Bartley
Assistant Inspector General
for Investigations

Malion A. Bartley Digitally signed by Malion A. Bartley Date:2024.06.17 22:07:47 -04'00'

SUBJECT: THE U.S NUCLEAR REGULATORY COMMISSION'S FAILURE TO EXERCISE OVERSIGHT OF AGREEMENT STATE LICENSEES WITH SPECIAL NUCLEAR MATERIAL OF LOW STRATEGIC SIGNIFICANCE (OIG CASE NO. I2303349)

This memorandum conveys the results of our investigation into an allegation that the U.S. Nuclear Regulatory Commission has not exercised oversight of Agreement State licensees' physical protection of special nuclear material of low strategic significance.

Our investigation identified potential issues that need to be addressed. We respectfully request a formal response to this report by September 2, 2024, which answers the two queries posed in the Executive Summary, and which describes actions, if any, the agency will take to address our findings.

cc: Chair Hanson
Commissioner Wright
Commissioner Caputo
Commissioner Crowell

CONTACT: Malion A. Bartley, AIGI
301.415.5962

EXECUTIVE SUMMARY

Our investigation substantiated that, for more than 40 years, the U.S. Nuclear Regulatory Commission (NRC) failed to exercise common defense and security oversight in accordance with Title 10 of the Code of Federal Regulations (10 C.F.R.) section 150.14. The NRC identified 11 licensees within various Agreement States that currently possess special nuclear material of low strategic significance (SNM-LSS), and hence are required by section 150.14 to meet the physical protection requirements in 10 C.F.R. section 73.67, that the NRC has failed to oversee. [1]

We found the agency became aware in 2018 of its failure to exercise oversight in this area but did not implement actions to remedy the lack of oversight until March 2023, when the NRC issued a 2-year Temporary Instruction.[2] The Temporary Instruction is intended, in part, to help assess if 11 Agreement State licensees possessing SNM-LSS have implemented requisite physical protection measures in accordance with 10 C.F.R. section 73.67.

The OIG determined that the NRC's future actions to enforce section 150.14 and 73.67 requirements for the current Agreement State licensees possessing SNM-LSS remain undecided. We also determined that the agency lacks a formal process to ensure new Agreement State licensees with SNM-LSS comply with 10 C.F.R. section 73.67 requirements. The OIG, therefore, requests a formal response to the following questions:

1. How will the NRC ensure future oversight related to 10 C.F.R. sections 150.14 and 73.67?

2. What steps will the NRC take to ensure it is informed when Agreement States grant new licenses for SNM-LSS?

[1] 10 C.F.R. section 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance," requires licensees to implement measures that would detect theft of special nuclear material of moderate and low strategic significance. This section specifies protection requirements for special nuclear material at fixed sites, including nonpower reactors, and for special nuclear material in transit.

[2] A Temporary Instruction is a temporary inspection procedure focused on safety issues or concerns not currently addressed by established Inspection Procedures or Inspection Manual Chapters. Temporary Instructions are typically limited in time or to the completion of specific inspection activities.

ALLEGATION

The OIG received an allegation that for more than 40 years the NRC failed to oversee physical protection requirements for Agreement State licensees possessing SNM-LSS.

POTENTIAL VIOLATIONS

The potential violations or areas of noncompliance involve 10 C.F.R. section 150.14, "Commission Regulatory Authority for Physical Protection"; 10 C.F.R. section 73.67, "Licensee Fixed Site and In-transit Requirements for the Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance"; Management Directive 9.26, *Office of Nuclear Material Safety and Safeguards*; and Inspection Manual Chapter 2800, "Materials Inspection Program."

FINDINGS

The OIG substantiated that for more than 40 years the NRC failed to exercise common defense and security oversight in accordance with 10 C.F.R. section 150.14 for licensees possessing SNM-LSS in various Agreement States.

The OIG also found that in 2018 agency employees became aware of this failure to exercise regulatory oversight, but the NRC did not implement remedial actions until 2023. Specifically, in March 2023, the agency issued a Temporary Instruction as an interim method to address the issue. Under the Temporary Instruction, regional inspectors are required to conduct specified inspections over a 2-year period that began in March 2023.

In addition, the OIG found that the NRC's future actions to fulfill its regulatory oversight responsibilities are undecided and its timing is indefinite. Additionally, the NRC lacks a formal process to ensure new Agreement State licensees with SNM-LSS notify the NRC when they become subject to 10 C.F.R. section 73.67 inspection requirements.

BASIS OF FINDINGS

Failure to Exercise Section 73.67 Oversight for Agreement State Licensees

Pursuant to 10 C.F.R. section 150.3, an "Agreement State" is any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954. Agreement States have the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. The regulations in 10 C.F.R. Part 150, however, also describe activities in Agreement States over which the NRC's regulatory authority continues.

For example, an Agreement State can issue licenses for the receipt, possession, use, and transfer of special nuclear material in quantities not sufficient to form a critical mass, but under 10 C.F.R. section 150.14, licensees with SNM-LSS must meet the physical protection requirements of 10 C.F.R. section 73.67.[3] Under section 73.67(a)(1), each licensee who possesses, uses, or transports SNM-LSS must establish and maintain a physical protection system for such material. This system must both minimize the possibilities for unauthorized removal of special nuclear material, consistent with the potential consequences of such actions, and facilitate the location and recovery of missing material.

The OIG found that the NRC failed to exercise oversight of section 73.67 compliance for Agreement State licensees after sections 150.14 and 73.67 were promulgated in 1979. The OIG reviewed a November 2021 internal meeting document that staff from the Office of Nuclear Material Safety and Safeguards (NMSS) prepared regarding the NRC's responsibilities to oversee security provided for SNM-LSS. One of the key messages in the document was that (b)(5) (b)(5) (b)(5) At this meeting, NMSS staff identified Agreement State licensees that possessed SNM-LSS and therefore were subject to section 73.67 physical protection requirements. The meeting document stated:

(b)(5)

The meeting document further stated:

(b)(5)

[3] 10 C.F.R. section 73.2 defines SNM-LSS to include quantities of more than 15 grams of uranium-235 (enriched to 20 percent or more), more than 15 grams of uranium-233, more than 15 grams of plutonium, or a combination of 15 grams of these three isotopes.

Awareness of Failure to Exercise Oversight in 2018 but No Guidance Until 2023

The NRC became aware of its failure to exercise oversight related to section 150.14 in 2018, when NRC employees were working on the rulemaking for "Enhanced Weapons, Firearms Background Checks, and Security Event Notifications."

Thereafter, NMSS staff and staff from the Office of Nuclear Security and Incident Response (NSIR) developed a list of approximately 100 Agreement State licensees that possessed SNM-LSS. An NRC employee with responsibilities related to Agreement States reported to the OIG that, after the gap in regulatory oversight was identified in the fall of 2018, initial work began to identify potential licensees with SNM-LSS in Agreement States, but then an NRC manager told staff to put the issue and the related list of licensees "on hold." The employee did not recall which NRC manager gave that directive, and the OIG's search for email correspondence to that employee from any NRC manager about that directive yielded negative results. An NMSS manager, however, provided to the OIG an email exchange between several NRC principals between June 2019 and March 2020 that indicated at least some work and consideration had taken place on the issue.

Around October 2020, NMSS management directed its staff to re-evaluate the list developed in 2018 and determine if any of the licensees were exempt from the NRC's physical protection requirements.[4] The NRC met with regional Agreement State officers and representatives from seven Agreement States (California, New Jersey, Nevada, Pennsylvania, Tennessee, Texas, and Washington) regulating various licensees possessing SNM that may meet the definition of SNM-LSS and would be subject to section 73.67 physical protection requirements. Based on this meeting and the staff's additional review, the NRC concluded that 11 Agreement State licensees possessed SNM-LSS that was not exempt from the physical protection requirements in 10 C.F.R. section 73.67.

The NMSS evaluation also included reaching out to internal and external stakeholders, including Regions I, III, and IV, the Office of Enforcement, the Office of the General Counsel, NSIR, NRC/Department of Energy Nuclear Materials Management and Safeguards System database staff, and various Agreement States. During this part of the evaluation, the NRC determined it did not have an appropriate 10 C.F.R. section 73.67 inspection procedure to address NRC oversight of Agreement State licensees possessing SNM-LSS.

At NMSS's November 2021 internal meeting, the staff presented four options for management to consider: (b)(5)
(b)(5) The staff proposed to proceed with (b)(5)

[4] Section 73.67 paragraph (b)(1) describes exemptions, like plutonium/beryllium neutron sources totaling 500 grams or less at any one site or contiguous sites, from physical protection requirements for licensees.

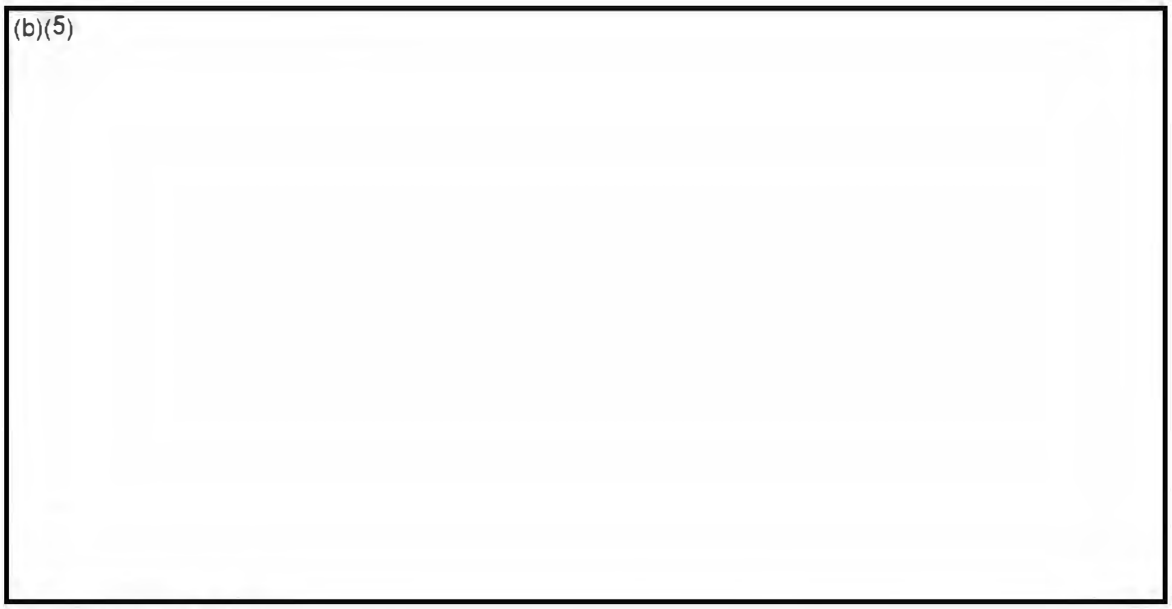
(b)(5)

The OIG learned from Agencywide Documents Access and Management System (ADAMS) logs that in April 2022 the agency initiated draft Temporary Instruction 2800/044, "Assessment of Physical Protection Requirements under 10 C.F.R. 150.14 for Agreement State Licensees Possessing, Using, or Transporting SNM of Low Strategic Significance."[5] Staff in the Source Management and Protection Branch (SMPB) in NMSS's Division of Materials, Safety, Security, State, and Tribal Programs (MSST) worked to create the Temporary Instruction under (b)(7)(C) (b)(7)(C)'s direction. (b)(7)(C) told the OIG she wished SMPB personnel worked at a quicker pace between October 2020 and MSST's initiation of the Temporary Instruction drafting process but said their review had been well-executed and thorough despite other competing priorities. (b)(7)(C) described the 15-month Temporary Instruction process as "a little slow," but again referenced competing priorities for SMPB staff. (b)(7)(C) stated to the OIG that he shared both of these sentiments.

For approximately the first six months of the drafting process, NRC staff continuously worked on development of the Temporary Instruction. For the period April 2022 through September 2022, the OIG found significant activity by NRC staff. For example, there were more than 250 documented events in ADAMS, such as "check in event," "check out event," and "update event."

For the period October 2022 through December 2022, the OIG identified only two ADAMS events. The OIG also found, however, that staff working on the rulemaking efforts in response to SRM-SECY-20-0098, "Path Forward and Recommendations for Certain Low-Level Radioactive Waste Disposal Rulemakings," performed activities regarding changes to 10 C.F.R. section 150.14.[6] Specifically, in November 2022, the rulemaking working group presented a proposal to the Rulemaking Steering Committee to revise 10 C.F.R. section 150.14 to (b)(5), as shown in the figure below.

[5] ADAMS Accession No. ML22091A049.
[6] ADAMS Accession No. ML22095A227.



Source: NRC

(b)(7)(C) told the OIG she had no knowledge of the proposed (b)(5) and did not, and would not, support rulemaking revisions to address this issue prior to the completion of the Temporary Instruction.

Between January 1 and March 3, 2023, staff activity increased to more than 200 ADAMS events and the NRC released the Temporary Instruction to the public with an effective date of March 6, 2023.[7] (b)(7)(C) told the OIG the lack of ADAMS activity between September and December 2022 was due to SMPB staff primarily working on the Temporary Instruction offline. (b)(7)(C) provided a timeline of activity derived from her emails and meeting schedule regarding the Temporary Instruction from September 2022 through its completion in March 2023, showing work continued despite the limited activity in ADAMS.

Both (b)(7)(C) and (b)(7)(C) stated they believed one reason the gap in NRC oversight existed, and why upon learning of the gap the NRC pursued the Temporary Instruction approach, was because they and other NRC staff considered the concern to be of low safety significance. Staff held that belief primarily because the Agreement States had conducted their mandatory inspections under 10 C.F.R. Parts 67 and 73 and, while those inspections did not address the same physical security areas that section 150.14 addressed, issues identified in the Agreement State inspections would have raised alarm bells if there were problems missed by the lack of the section 150.14 inspections.

[7] From September through December 2021, the agency had a Part 61 rulemaking working group. The Commission provided this group direction in SECY-20-0098, which states, "[T]he Commission has approved the staff's recommendation to explore regulatory approaches that would allow for a single regulator for an Agreement State licensee disposing of [Greater than Class C (GTCC)] waste in a land disposal facility, including potential amendment to 10 C.F.R. §§ 150.14 and 150.15."

Further, (b)(7)(C) and (b)(7)(C) explained that the type of materials in question were of low safety significance due to their quantities, difficulty to work with, and limited potential uses by nefarious actors.

In March 2023, the NRC notified the Agreement States of an upcoming NRC effort to inspect Agreement States possessing SNM-LSS. The notification stated, "The NRC has issued and is in the process of implementing Temporary Instruction (TI) 2800/044 'Assessment of Physical Protection Requirements under 10 CFR 150.14 for Agreement State Licensees Possessing, Using, or Transporting SNM of Low Strategic Significance.'"

The Temporary Instruction has 10 requirements, primarily divided between "Fixed Site Requirements" and "In-Transit Requirements," that encompass approximately 21 activities. The resource estimate for the completion of the Temporary Instruction is 8 to 16 hours, including preparation and documentation. Consistent with the Temporary Instruction, qualified inspectors will conduct inspections assessing compliance with 10 C.F.R. section 73.67 and perform Part 37 inspections in accordance with Inspection Procedure 87137, "10 C.F.R. Part 37 Materials Security Programs."

NRC principals told the OIG that the agency pursued the Temporary Instruction approach as an interim and risk-informed method to evaluate the scope of the issue and that they worked on this Temporary Instruction as a collateral job assignment. The impacted licensees were located in Regions I and IV, and regional inspectors were responsible for implementing the Temporary Instruction. (b)(7)(C) and (b)(7)(C) both reported that, as of the time of their OIG interviews, Region IV had completed its inspection activity per the Temporary Instruction and Region I was close to completion.

Undecided Future NRC Actions

Through the Temporary Instruction, the NRC is assessing all 11 current licensees' present compliance with 10 C.F.R. section 73.67. The NRC remains undecided, however, about its broader and future approach to exercising section 150.14 oversight of the physical protection requirements for Agreement State licensees possessing, using, or transporting SNM-LSS.

The Temporary Instruction's stated objectives are:

- 02.01—To assess and document compliance with the physical protection requirements in 10 CFR 73.67(f) and (g), where applicable;

- 02.02—To determine whether any additional physical protection measures are being taken if a 10 CFR 73.67 physical protection system has not been implemented; and,

- 02.03—To support decision making regarding the need for future NRC inspection of Agreement States licensees possessing, using, or transporting SNM-LSS in quantities exceeding the thresholds identified in 10 C.F.R. 150.14.

The Temporary Instruction also states, "At the completion of this inspection, the NRC may develop an inspection procedure under the materials inspection program."

(b)(7)(C) and (b)(7)(C) both told the OIG that the NRC's plan on how to handle these types of inspections in the future depends entirely on the findings of the Temporary Instruction; therefore, they could not provide an answer to the OIG regarding the NRC's plans moving forward.

CONCLUSION

The OIG substantiated the allegation that the NRC has failed to exercise oversight in accordance with 10 C.F.R. section 150.14 for 11 Agreement State licensees possessing SNM-LSS. Although agency employees became aware of this issue in 2018, the NRC did not implement remedial actions until 2023, due to competing priorities for SMPB staff and the NRC's view of the low safety significance of the issue. In March 2023, the agency issued a Temporary Instruction, in part to evaluate the scope of the oversight failure by assessing the extent to which the licensees had independently implemented the requisite physical protection measures in accordance with 10 C.F.R. section 73.67. As of the date of this memorandum, the NRC is close to completing the inspections specified in the Temporary Instruction. While the NRC intends for the Temporary Instruction to support its decision-making, the agency is currently undecided on how to exercise oversight of section 150.14 inspections in Agreement States in the future.

This investigation aligned with the OIG's annual plan regarding concerns about the NRC's regulatory security oversight. Issues identified in this memorandum shall be dispositioned, as appropriate, by the Executive Director for Operations.

MEMORANDUM

DATE: July 16, 2024

TO: Concur: Case Closed
(b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2024.07.16 15:14:38 -04'00'

FROM: (b)(7)(C)
Digitally signed by (b)(7)(C)
(b)(7)(C)
Date: 2024.07.16 15:24:34 -04'00'

SUBJECT: REQUEST FOR ASSISTANCE FROM THE SMITHSONIAN INSTITUTION OIG (I2400032)

ALLEGATION

The Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC) and Defense Nuclear Facilities Safety Board, received a request for assistance from the Smithsonian Institution (SI) OIG. The request for assistance states the SI OIG is conducting a preliminary investigation that involves the SI allegedly possessing more radium that its material license allows, starting in 2008 and possibly continuing to the present (including since the most recent license renewal in 2022). The SI's NRC material license in question is #08-05938-13.

POTENTIAL VIOLATION

The potential violation relevant to this allegation is Title 10 of the Code of Federal Regulations.

FINDING

The NRC OIG collected from NRC files and provided to the SI OIG the information and documents it requested.

BASIS FOR FINDING

The SI OIG specifically requested the following information and documents:

(b)(7)(E)

The NRC OIG provided the requested documents to the SI OIG on January 25, 2024, via Box. The NRC OIG informed the SI OIG that some of the provided documents are nonpublic, that the distribution of the nonpublic documents should be limited to the SI OIG's investigative staff, and that the nonpublic documents may not be released to the public without the NRC OIG's express written permission.

The NRC OIG advised the SI OIG of the requirement for the SI OIG to report the possible license exceedance to the NRC Office of Enforcement (OE). The SI OIG reported the alleged license exceedance to Region I OE in January 2024. Currently, Region I is reviewing this allegation in inspection space (as RI-2024-0005) so that Region I may issue a violation if the need arises.

DISPOSITION

The SI OIG advised the NRC OIG that it was able to access the provided data. In January 2024, the SI OIG reported to the NRC OE that the SI might have, and/or had (at various times in the past), possessed greater quantities of radium than allowed by its NRC license. The NRC OE sent the SI an Acknowledgment Letter dated February 7, 2024. Currently, no further investigative activity by the NRC OIG is required. This matter is now closed in the files of this office.

MEMORANDUM

DATE: March 8, 2024

TO: Ray V. Furstenau
Acting Executive Director for Operations

FROM: Malion A. Bartley
Assistant Inspector General
for Investigations

Malion A. Bartley Digitally signed by Malion A. Bartley Date: 2024.03.08 08:20:11 05'00'

SUBJECT: REFERRAL OF COMPLAINT
(OIG Complaint No. P2400062)

The Office of the Inspector General (OIG) received a complaint in January 2024 alleging failures by Nuclear Regulatory Commission (NRC) managers to address complaints of alleged mismanagement and harassment attributed to (b)(7)(C) Specifically, the complainant alleged that (b)(7)(C) and (b)(7)(C) failed to address misconduct by Ms. (b)(7)(C) identified in the *Allegations of Harassing Conduct Fact-Finding Report* completed by the U.S. Postal Service's (USPS) National Equal Employment Opportunity Investigative Services Office (Report No. NRC-22-HCI-0001). That inquiry was conducted at the request of the NRC, and the report was submitted to the agency on or about November 3, 2022. In January 2024, at the OIG's request, the NRC provided our office a copy of the USPS report.

As background, in November 2022, our office closed a similar complaint concerning Ms. (b)(7)(C) 's alleged management misconduct under Case No. C2302114. The referenced complaint was closed upon confirming that the NRC's requested USPS management inquiry was in progress. In August 2023, we received an additional complaint (Case No. C2303396) alleging several concerns related to Ms. (b)(7)(C) 's behavior, including unprofessional conduct, favoritism, and inappropriate racial comments. The complainant specifically alleged that Ms. (b)(7)(C) hosted an off-site meeting at her residence during work hours, and attendees reportedly felt uncomfortable with her drinking. In addition, Ms. (b)(7)(C) allegedly pressured attendees to engage in similar behavior. According to the complainant, the meeting primarily focused on Ms. (b)(7)(C) 's preferential treatment of three (b)(7)(C) staff

members, who were also in attendance at her residence. The complainant also alleged that Ms. (b)(7)(C) assisted one of the (b)(7)(C) employees at her social event with the employee's Senior Executive Service application responses. The complainant further claimed that some of the same individuals in attendance have since exerted influence on Ms. (b)(7)(C)'s management decisions, against the advice of other managers and experts.

Additionally, the complainant alleged that Ms. (b)(7)(C) has engaged in name-calling and has made racial comments, causing discomfort among (b)(7)(C). The complainant alleged that a fear of retaliation among her staff has deterred employees from speaking out, and that Ms. (b)(7)(C) leverages personal connections to shield her "friends" from consequences.

Our office did not conduct an independent investigation into the veracity of these concerns but, based on the nature and volume of concerns received, we determined that this matter warrants referral to your office for review and response. We respectfully request that your office provide details regarding any actions related to Ms. (b)(7)(C)'s alleged mismanagement and harassment that the NRC has taken since the agency received the USPS management inquiry report. If no actions were initiated, we request supporting details to elucidate the management decision-making process.

Please provide a response to this matter by June 6, 2024. If you have any questions, please contact (b)(7)(C), at (b)(7)(C) or me, at 301.415.3176.

MEMORANDUM

DATE: September 13, 2024

TO: Concur: Case Closed
(b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2024.09.13 11:43:29 04'00'

THROUGH: (b)(7)(C)
Digitally signed by (b)(7)(C)
(b)(7)(C)
Date: 2024.09.13 10:17:31 -04'00'

FROM: (b)(7)(C) (b)(7)(C)
Senior Special Agent
Digitally signed by (b)(7)(C)
Date: 2024.09.13 09:33:53 -04'00'

SUBJECT: FOLLOW-UP INQUIRY REGARDING MANAGEMENT INQUIRY IN OCHCO AND REQUEST FOR OIG SUPPORT (OIG CASE NO. I2400062)

ALLEGATION

The Office of the Inspector General (OIG) received a complaint that U.S. Nuclear Regulatory Commission (NRC) managers failed to address allegations (b)(7)(C), (b)(7)(C), engaged in workplace mismanagement and harassment. Specifically, the complainant alleged that (b)(7)(C) (b)(7)(C), and (b)(7)(C), failed to address (b)(7)(C)'s misconduct as identified in the U.S. Postal Service (USPS) National Equal Employment Opportunity Investigative Services Office's *Allegations of Harassing Conduct Fact-Finding Report*. That report contained the findings of the USPS's inquiry, undertaken at the NRC's request, into (b)(7)(C)'s workplace conduct. The USPS submitted the report to the agency on or about November 3, 2022.

Separately, the OIG received two other complaints regarding (b)(7)(C)'s alleged mismanagement and misconduct. The OIG referred ~~the later complaint~~, received in August 2023, to the NRC with the above-described complaint. The complaint alleged several concerns regarding (b)(7)(C), including unprofessional conduct, favoritism, and inappropriate racial comments; in addition, the complaint specifically alleged (b)(7)(C)

hosted an off-site meeting at her residence during work hours, during which (b)(7)(C) allegedly pressured attendees to drink alcohol and attendees allegedly felt uncomfortable with (b)(7)(C)'s drinking. The OIG closed the earlier complaint in November 2022, after learning the NRC had directly received the same complaint and commissioned the USPS inquiry based on it.

POTENTIAL VIOLATIONS

The potential violations relevant to this investigation are Title 5 of the Code of Federal Regulations (C.F.R.) § 2635, "Standards of Conduct," and 5 C.F.R. § 735.203, "Conduct Prejudicial to the Government."

REFFERAL

The OIG referred this matter to the Office of the EDO for review and response. The OIG requested that in its response, the Office of the EDO include details regarding any actions related to (b)(7)(C)'s alleged mismanagement and harassment that the NRC had taken since the agency received the USPS management inquiry report.

In August 2024, the NRC informed the OIG that, based on the two later complaints the OIG referred, the NRC had detailed (b)(7)(C) to a position outside of the (b)(7)(C) (b)(7)(C) and had requested another administrative inquiry. Consistent with the information found in the second inquiry, the NRC determined that (b)(7)(C) would not return to the position of (b)(7)(C). (b)(7)(C) submitted to the NRC ~~a formal request to~~ retire from federal service.

DISPOSITION

NRC management addressed the complaints and selected a new (b)(7)(C) to replace (b)(7)(C). (b)(7)(C) has requested to retire from federal service. This investigation is closed to the files of this office.

MEMORANDUM

DATE: October 8, 2024

TO: Concur: Case Closed
(b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2024.10.08 14:08:57 -04'00'

THROUGH: (b)(7)(C)
Digitally signed by (b)(7)(C)
Date: 2024.10.08 10:29:51 -04'00'

FROM: (b)(7)(C) (b)(7)(C)
Senior Special Agent
Digitally signed by (b)(7)(C)
Date: 2024.10.08 07:02:11 -04'00'

SUBJECT: ALLEGED NRC IMPROPER HANDLING OF SALT RIVER PROJECT ALLEGATIONS AND CONCERNS ABOUT ETHICAL VIOLATIONS BY (b)(7)(C) (OIG CASE NO. P240●191)

ALLEGATION

The Office of the Inspector General (OIG) received a complaint that the U.S. Nuclear Regulatory Commission (NRC) failed to review adequately assertions of safety issues at Palo Verde Nuclear Generating Station (PVNGS) in Maricopa County, Arizona. In a letter to the Inspector General, (b)(7)(C) alleged the Salt River Project (SRP), which is a part owner of PVNGS, influenced safety decisions at the plant while also having "potential criminal influences in (b)(7)(C)" and a high risk tolerance. (b)(7)(C) also alleged that when declining further consideration of the safety issues he had raised, the NRC misrepresented the focus and nature of his assertions.

POTENTIAL VIOLATIONS

The potential violations relevant to this investigation are Title 5 of the Code of Federal Regulations Section 2635, "Standards of Conduct," and NRC Management Directive 8.8, *Management of Allegations*.

FINDING

The OIG did not substantiate that the NRC failed to address adequately (b)(7)(C)'s assertions.

BASIS OF FINDING

When the NRC receives a declaration, statement, or assertion of impropriety or inadequacy, the NRC reviews the issue to determine whether it falls within the NRC's jurisdiction. NRC staff in Region IV reviewed (b)(7)(C)'s assertions of SRP improprieties, and the NRC's review file for (b)(7)(C)'s assertions contains an email from a Region IV Branch Chief providing the NRC's rationale for its stance that the assertions did not fall under the NRC's purview. The email states, "I still do not believe that this is [our] regulatory purview. Yes, SRP is an owner, they have influence and provide guidance... However...APS runs the day-to-day activities." The email further states, "SRP is not the majority owner. No one owner is a majority owner so no one owner can decide the direction of [PVNGS]."

(b)(7)(C) responded to the NRC's initial determination and provided to the agency additional information regarding (b)(7)(C) and SRP's high risk tolerance. The NRC held an Allegation Review Board meeting to discuss (b)(7)(C)'s assertions. Following the Allegation Review Board meeting, Region IV ~~maintained its~~ position that the issues were unfounded, primarily because the licensee, Arizona Public Service Company (APS), maintained day-to-day control over PVNGS. Further, while SRP maintained 20-percent ownership of PVNGS, no one owner of PVNGS can make safety decisions for the plant because the plant's safety committee decides safety issues by a consensus vote.

After the Allegation Review Board meeting, Region IV sent a letter to (b)(7)(C), notifying him of the NRC's decision not to open an "allegation" based on his assertions of SRP impropriety (and hence, not to review the issues further) as the information (b)(7)(C) provided did not meet "the NRC's definition of an allegation, ~~because it does not fall~~ within the NRC's regulatory purview."[1]

The OIG's Technical Services Section (TSS) reviewed the NRC's file regarding (b)(7)(C)'s assertions of SRP impropriety and provided to the OIG Investigations Division an analysis of the issues in this case. According to TSS's analysis, regardless of whether (b)(7)(C)'s assertions about (b)(7)(C) and risk tolerance are valid, under NRC regulations the NRC issues violations to the licensed owner of a plant. In this case, the licensed owner is APS—not SRP. Further, TSS noted that the NRC-mandated safety

[1] The letter Region IV sent to (b)(7)(C) mentions only a dispute between (b)(7)(C) and SRP, regarding SRP's refusal to involve itself in a non-NRC, local matter about a citation (b)(7)(C) received for electrical issues at a property he owns. The letter does not mention (b)(7)(C)'s assertions of SRP impropriety, but the Allegation Review Board meeting notes address the SRP safety issues.

committee for PVNGS requires a consensus vote: SRP is a minority owner and serves as one of seven owners on the safety committee. TSS informed the OIG Investigations Division that TSS believes the NRC adequately reviewed (b)(7)(C)'s assertions of SRP impropriety and that TSS concurs with Region IV's assessment of NRC jurisdiction over the assertions.

DISPOSITION

The NRC adequately reviewed (b)(7)(C)'s assertions of SRP impropriety and correctly found that the issues (b)(7)(C) raised do not fall within the NRC's jurisdiction. This inquiry is closed to the files in this office.

Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the Advisory Committee on the Medical Uses of Isotopes

OIG Case No. I2200187
March 26, 2024

All publicly available OIG reports, including this report, are accessible through the OIG's website at:
nrcoig.oversight.gov

MEMORANDUM

DATE: March 26, 2024

TO: Christopher T. Hanson
Chair

FROM: Robert J. Feitel
Inspector General

Robert J. Feitel Digitally signed by Robert J. Feitel Date: 2024.03.26 08:35:45 -04'00'

SUBJECT: SPECIAL INQUIRY INTO THE APPEARANCE OF A CONFLICT OF INTEREST INVOLVING MEMBERS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (OIG CASE NO. I2200187)

The attached report by the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), is furnished for whatever action you deem appropriate. Please notify the OIG by July 1, 2024, what corrective actions, if any, the NRC will be taking based on the results of this Special Inquiry.

cc: Commissioner Wright
Commissioner Caputo
Commissioner Crowell
R. Furstenau, Acting EDO
J. Weil, OPA

Why the OIG conducted this Special Inquiry

The Office of the Inspector General (OIG) initiated this Special Inquiry based on allegations of a conflict of interest involving certain Nuclear Regulatory Commission (NRC) advisory committee members. The allegations related to the NRC's consideration of a petition for rulemaking (PRM-35-22) that requested the NRC amend its regulations to require medical-event reporting of radiopharmaceutical extravasations that result in localized dose equivalents exceeding 0.5 Sv (50 rem). Specifically, the allegers claimed that several members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) who advised the NRC on matters related to PRM-35-22 were affiliated with a professional organization that promotes the interests of NRC-regulated entities. These outside affiliations, in the view of the allegers, created a conflict of interest that called into question the integrity of the NRC's decision-making with respect to PRM-35-22.

This report is an investigative product documenting instances where inadequacies in the NRC's internal oversight led to circumstances that raised questions regarding the integrity of the agency's decision-making on a matter pertaining to public health and safety.

Findings

Two ACMUI members failed to follow the procedures in Title 5 of Code of Federal Regulations (C.F.R.) section 2635.502, "Personal and business relationships," when they participated in matters related to PRM-35-22 without obtaining prior authorization to do so. These members were active participants in the Society of Nuclear Medicine and Molecular Imaging (SNMMI), a 15,000-member scientific and professional organization that carried out a campaign opposing PRM-35-22, at the same time they worked for the ACMUI on matters related to the petition.

The NRC's policies for the ACMUI may be insufficient to ensure compliance with 5 C.F.R. section 2635.502 and certain conflict-of-interest requirements tied to the Federal Advisory Committee Act (FACA) at 5 U.S.C. sections 1001–1014. Specifically, the NRC does not currently have a policy requiring staff to perform conflict-of-interest reviews before assigning particular tasks to ACMUI members. The NRC, therefore, lacks internal controls in this context that could facilitate compliance with federal ethics requirements and help avoid both actual and apparent conflicts of interest.

TABLE OF CONTENTS

I. ALLEGATION/INCIDENT

The OIG received allegations relating to the recommendation for PRM-35-22 that the NRC staff presented to the Commission in SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events" (May 9, 2022). The allegers included organizations and individuals that focus on issues related to nuclear medicine. Certain allegers believed that the NRC allowed the SNMMI, an organization representing NRC-regulated entities, to have inappropriate influence in the agency's review of the petition. This inappropriate influence, in the allegers' views, resulted in an NRC staff recommendation that allowed "clear medical events [to] remain concealed from patients."

Potential violations relevant to this Special Inquiry include the failure to adhere to 5 C.F.R. section 2635.502, which addresses circumstances involving the appearance of a conflict of interest, and 5 U.S.C. section 1007, which requires agencies to establish guidelines and management controls for their advisory committees that are consistent with the directives of the Administrator of the General Services Administration (GSA).

II. BACKGROUND

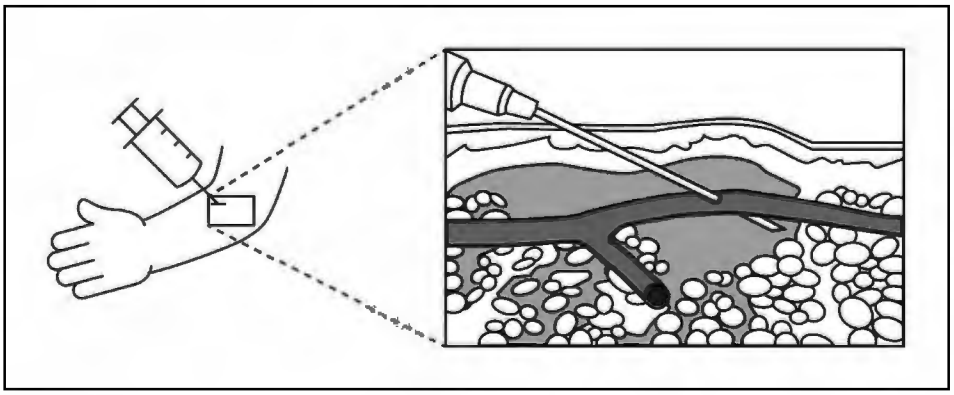
10 C.F.R. Part 35, Medical Use of Byproduct Material

The NRC's regulations in 10 C.F.R. Part 35 establish standards for the medical use of byproduct material and the issuance of licenses authorizing the use of such material. These standards, together with requirements found in other parts of the NRC's regulations, are designed to protect workers, patients, human-research subjects, and the public from undue radiological risks.

An "extravasation" is the unintentional leakage of an intravenously administered solution around the infusion or injection site into the surrounding tissue. (See Figure 1 for a depiction of an extravasation.) As far back as 1980, the NRC considered whether its licensees should be required to report radiopharmaceutical extravasations to the agency. That year, the NRC amended Part 35 to require the reporting of medical "misadministrations" (later renamed "medical events"). Misadministration reporting enabled the NRC to investigate these events for possible violations, evaluate licensee corrective actions, inform other licensees of potential problems, and take generic corrective actions. In response to a comment on the proposed Part 35 amendments, the NRC stated that it did not consider an extravasation to be a misadministration because extravasations occur frequently in otherwise normal intravenous or intraarterial injections and are virtually impossible to avoid.[1]

The NRC made substantive changes to the misadministration reporting requirements in 1991, and again in 2002, but without addressing its prior statement that extravasations are exempt from Part 35 reporting requirements.[2] As a result, the NRC does not currently classify radiopharmaceutical extravasations as medical events that must be reported to the agency.

Figure 1: Extravasation



Source: NRC

[1] *Misadministration Reporting Requirements*, 45 Fed. Reg. 31,701, 31,703 (May 14, 1980).
[2] *Quality Management Program and Misadministrations*, 56 Fed. Reg. 34,104 (July 25, 1991); *Medical Use of Byproduct Material*, 67 Fed. Reg. 20,250 (April 24, 2002).

Petition for Extravasation Rulemaking

In May 2020, the NRC docketed a petition for rulemaking requesting that the agency amend Part 35 to require the reporting of certain extravasations as medical events (PRM-35-22). The petition raised the following issues:

- The exemption of radiopharmaceutical extravasations from medical reporting is based on incorrect assertions that such extravasations are virtually impossible to avoid, and this approach does not protect the public from unsafe irradiation; and,
- The exemption of extravasations from medical reporting requirements results in a lack of transparency to patients, the public, and the NRC.

The petitioner specifically requested the NRC amend 10 C.F.R. section 35.3045(a)(1), "Report and Notification of a Medical Event," by adding a new paragraph (iv) requiring medical providers to report to the NRC: "An extravasation that leads to an irradiation resulting in a localized dose equivalent exceeding 0.5 Sieverts (Sv)(50 rem)."

In SECY-22-0043 (May 2022), the NRC staff provided the Commission a rulemaking plan for adding extravasation-reporting requirements to Part 35. In the plan, the staff recommended amending Part 35 to require reporting of extravasations when a patient needs medical attention for suspected radiation injury. The staff did not, however, recommend adopting the petitioner's proposal to require reporting of all extravasations resulting in a localized dose equivalent exceeding 0.5 Sv (50 rem).

In December 2022, the Commission issued a Staff Requirements Memorandum (SRM) for the rulemaking plan (SRM-SECY-22-0043). In the SRM, the Commission approved the staff's recommendation to initiate a rulemaking that would amend Part 35 to require licensees to report nuclear medicine injection extravasations as medical events, but only if the extravasation requires medical attention for suspected radiation injury.

Also in December 2022, the NRC published a notice in the Federal Register announcing the agency's intent to consider PRM-35-22 in the rulemaking process.[3] The NRC established a public web page for the rulemaking, and in the "Public Involvement" section of this page the staff stated that it would coordinate with the ACMUI in an open and transparent manner during the rulemaking.

In April 2023, the NRC published preliminary language for the proposed extravasation rule[4] and provided a comment period for the language that extended through September 1, 2023.[5] The NRC currently projects issuing a notice of proposed rulemaking in December 2024 and a final rule in September 2026.[6]

---

[3] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 87 Fed. Reg. 80,474 (Dec. 30, 2022) (petition for rulemaking; consideration in the rulemaking process).
[4] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 88 Fed. Reg. 24,130 (April 19, 2023) (preliminary proposed rule language; notice of availability and public meeting).
[5] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 88 Fed. Reg. 45,824 (July 18, 2023) (preliminary proposed rule language; extension of comment period).
[6] https://www.regulations.gov/docket/NRC-2022-0218/unified-agenda (accessed March 19, 2024).

Advisory Committee on the Medical Uses of Isotopes

The NRC's predecessor, the Atomic Energy Commission, established the ACMUI in 1958 under the authority of the Atomic Energy Act of 1954 (42 U.S.C. § 2011 *et seq*). Advisory committees such as the ACMUI are structured to provide a forum where experts representing many perspectives can provide independent advice that supports an agency's decision-making processes. The NRC's use of the ACMUI must comply with both FACA and the NRC's agency-specific FACA regulations in 10 C.F.R. Part 7, "Advisory Committees." Furthermore, the NRC's regulations must be consistent with the GSA's regulations in 41 C.F.R. Part 102-3, "Federal Advisory Committee Management."[7]

The ACMUI serves the NRC through the advice and recommendations it gives agency staff. Because the advice of ACMUI members is often informed by their non-governmental positions or relationships, the NRC must ensure the members do not inappropriately advance outside interests. According to the NRC publication NUREG/BR-0309, *Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI): A Member's Guide* (2004), at pages 3–4:

> The NRC staff understands that the ACMUI is composed of stakeholder licensees, and as such, will represent licensee concerns to some extent. This is not only inevitable, but desirable. Nonetheless, ACMUI members must remember that, as compensated Federal Government employees, they are subject to the laws and regulations on conflict-of-interest. Under those laws and regulations, they should not advise the NRC or participate in any ACMUI matter when doing so will directly and predictably affect their financial interest or the financial interest of members of their families; their employers; or anyone else with whom they have a business relationship. ACMUI members also must not inappropriately advance the views or positions of professional associations or the regulated community.

This publication further reminds ACMUI members, on page 4, that, "[w]henever a conflict-of-interest issue arises, the affected ACMUI member must recuse himself or herself from voting on the particular matter that will cause the conflict-of-interest."

[7] FACA requires each agency head to "establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Administrator under sections 1006 and 1009 of this title." 5 U.S.C. § 1007(a). Among these directives are the FACA regulations in 41 C.F.R. Part 102-3.

III. DETAIL

Finding 1: Appearance of a conflict of interest arising from the participation of certain ACMUI members in matters related to PRM-35-22

The ethics standards in 5 C.F.R. Part 2635 require employees to avoid conflicts of interest between their outside interests and their government work. These rules also require employees to avoid circumstances that could create the appearance of such conflicts. In particular, section 2635.502 states that an employee should seek authorization from his or her agency before working on certain matters that would directly and predictably affect the financial interests of a person or entity with whom the employee has a "covered relationship."[8] The rule lists five categories of persons or entities that give rise to a covered relationship, including "[a]n organization . . . in which the employee is an active participant." An employee's participation in an outside organization is considered "active" if "for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization."[9]

The OIG found that two ACMUI members were in covered relationships with the SNMMI while they also performed work for the NRC related to PRM-35-22. Neither member requested prior authorization to work on matters related to the petition, even though their affiliations with the SNMMI raised reasonable questions regarding their impartiality in such matters. Under these circumstances, the members' actions were inconsistent with section 2635.502.

Specifically, during the same time period the ACMUI was reviewing matters related to PRM-35-22, one ACMUI member served as an SNMMI official, while the other member served in a capacity similar to that of a committee chairperson. These members were therefore in "covered relationships" with the SNMMI as defined in 5 C.F.R. section 2635.502(b)(1)(v). In addition, each member had served as an SNMMI officer within one year of working for the ACMUI on matters related to PRM-35-22, meaning that

---

[8] See 5 C.F.R. section 2635.502(a), "Consideration of appearances by the employee," and section 2635.502(a)(2) ("An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."). In addition, 5 C.F.R. section 2635.101, "Basic obligation of public service," establishes general principles reinforcing the requirement that employees avoid both actual conflicts of interest and the appearance of such conflicts. For example, under subsection (b)(8) of section 2635.101, "[e]mployees shall act impartially and not give preferential treatment to any private organization or individual." And, under subsection (b)(14), "[e]mployees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in [5 C.F.R. Part 2635]."

[9] 5 C.F.R. § 2635.502(b)(1)(v). A "covered relationship" also exists with respect to "[a]ny person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee[.]" 5 C.F.R. § 2635.502(b)(1)(iv).

each member was also in a covered relationship with the SNMMI under section 2635.502(b)(1)(iv).[10]

The OIG further determined that one of these ACMUI members was part of the Subcommittee on Extravasation that reviewed and provided a recommendation on the NRC staff's "Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting." Both members were part of the ACMUI's full committee, which approved the subcommittee's recommendation.

The evidence the OIG gathered shows that the proceeding for PRM-35-22 was vigorously contested, with many groups and individuals supporting the petition, while others, including the SNMMI, opposed the petition in whole or in part. These divergent viewpoints should have raised heightened awareness, both on the part of the ACMUI members and the NRC, that a reasonable person might question whether the members' affiliations with the SNMMI would compromise their impartiality in matters related to PRM-35-22.

The SNMMI did not merely oppose PRM-35-22; rather, it ran an active campaign opposing the petitioner's request that the NRC classify diagnostic extravasations as reportable medical events.[11] The campaign emailed SNMMI members an automated link with a form letter that a member could submit in response to the request for comment on PRM-35-22 that the NRC had published in the Federal Register.[12] The appendix to this report provides examples of the SNMMI's campaign opposing PRM-35-22.

In April 2021, the NRC staff requested that the ACMUI review the staff's preliminary evaluation for the petition. The ACMUI thereafter referred this matter to its Subcommittee on Extravasation, which consisted of five members, including one member who was an active participant in the SNMMI.

In July 2021, the subcommittee issued a draft report that contained its review and comments on the NRC staff's preliminary evaluation of issues raised by PRM-35-22. In its draft report the subcommittee supported Option 4, "Extravasation events that require medical attention." Under this option, the NRC would not require dosimetry to

---

[10] The OIG found that a third ACMUI member with ties to the SNMMI was part of the ACMUI's Subcommittee on Extravasation and voted as a member of its full committee. This person was not an SNMMI official or committee chairperson, but the person was a member of various SNMMI committees, including a committee that advocates for the availability of radionuclides essential to medicine and research. Where a person is not acting as an official of the outside organization, or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, "significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation." 5 C.F.R. § 2635.502(b)(1)(v). Here, however, the OIG was unable to clearly determine whether this member's SNMMI-related activities were extensive enough to create a covered relationship with the organization.

[11] The SNMMI, together with the American Society of Nuclear Cardiology and the American College of Nuclear Medicine, took the position that "although therapeutic extravasations should be 100% reportable medical events, diagnostic extravasations should not." See the Appendix to this report at page 17.

[12] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 85 Fed. Reg. 57,148 (Sept. 15, 2020) (petition for rulemaking; notification of docketing and request for comment).

determine whether an extravasation should be reported—the approach sought by the petitioners in PRM-35-22—although dosimetry would be required if an extravasation appears severe enough to trigger "abnormal occurrence" criteria.[13]

In September 2021, the ACMUI's full committee of 13 members voted unanimously to approve the subcommittee's report and the rulemaking approach described in Option 4 of that report. One additional ACMUI member who actively participated in the SNMMI was on the full committee.[14] The ACMUI's support for Option 4 was consistent with SECY-22-0043, where the NRC staff recommended that the Commission take substantively the same approach.

The circumstances surrounding PRM-35-22 could have led a reasonable person to conclude that the ACMUI members affiliated with the SNMMI may have inappropriately prioritized the outside organization's interests during their review of issues related to the petition. The petition, if granted in full by the NRC, would directly affect a large number of patients, hospitals, and other healthcare providers. Providers in particular would incur significant costs if, as requested in the petition, the NRC issues a rule requiring them to broadly report radionuclide extravasations. While the rule may not have a direct monetary effect on the SNMMI itself, it could have a large effect on many of the NRC-regulated entities or individuals that the SNMMI represents.[15] In these circumstances, the involvement of certain active participants in the SNMMI in the NRC's deliberations over PRM-35-22 could have given a person ample reason to question the members' impartiality in PRM-related matters.

The OIG did not identify any information suggesting that the ACMUI members affiliated with the SNMMI had financial interests that would have been directly and predictably affected by the PRM-35-22 proceeding. Thus, the members were not necessarily prohibited from participating in the ACMUI's consideration of matters related to the petition. Because a reasonable person could have questioned each member's impartiality in such matters, however, the proper course would have been for the NRC to consider, under 5 C.F.R. section 2635.502(d), whether "in light of all relevant circumstances...the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations." Consistent with section 2635.502(e), "Disqualification," and section IV of NRC Directive Handbook 7.9, "Ethics Approvals and Waivers," the ACMUI members should have recused themselves from matters

---

[13] Section 208 of the Energy Reorganization Act of 1974, as amended, defines an "abnormal occurrence" as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. 42 U.S.C. § 5848. The NRC periodically publishes criteria for determining whether an incident or event constitutes an abnormal occurrence.

[14] The subcommittee members also voted as part of the full committee. Thus, 2 active participants in the SNMMI were among the 13 members of the full committee.

[15] According to its website, the "SNMMI's worldwide membership totals more than 15,000, including physicians, scientists, technologists, chemists, radiopharmacists, students and industry representatives from 82 countries around the world." (https://www.snmmi.org/international?navItemNumber=28696) (accessed March 19, 2024).

related to PRM-35-22 pending agency review of the issue, and they should not have participated in the matters without written authorization from the agency.

Finding 2: NRC's policies for the ACMUI are insufficient

The ACMUI members who participated actively in the SNMMI told the OIG that they believed the term "conflict of interest" referred primarily to personal financial gains, and they, therefore, did not consider their involvement with the SNMMI as presenting the appearance of a conflict of interest. Accordingly, neither member recused themselves from matters related to PRM-35-22 or requested authorization from the NRC before participating in such matters.

Each of the ACMUI members received annual ethics training conducted by the NRC's Office of the General Counsel (OGC), which contained at least one slide mentioning the "appearance" standard at 5 C.F.R. section 2635.502. The members also filed confidential financial-disclosure reports (OGE Form 450) annually, which OGC reviewed for potential conflicts of interest.

Because these agency actions—training and the review of financial-disclosure reports—were not sufficient to avoid the "appearance" concern presented by having active participants in the SNMMI work on ACMUI matters involving a rulemaking petition that the SNMMI actively opposed, the NRC should consider strengthening the conflict-of-interest screening policies for ACMUI members. Strengthening these policies would help ensure that the advice and recommendations of the ACMUI, and by extension the decisions of the NRC, do not appear to be inappropriately influenced by a member's affiliations with external entities such as professional organizations.

Regulatory framework

As required by FACA, the GSA Administrator has issued regulations establishing administrative guidelines and management controls for federal advisory committees. The GSA's regulations include a provision, currently at 41 C.F.R. section 102-3.105(h), stating that the head of each agency must—

> Assure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes, regulations issued by the U.S. Office of Government Ethics (OGE) including any supplemental agency requirements, and other Federal ethics rules.

FACA also requires agencies to have their own regulations that are consistent with the GSA's relevant directives.[16] The NRC's implementing regulations are in 10 C.F.R. Part 7, "Advisory Committees." One of these regulations, 10 C.F.R. section 7.20, "Conflict-of-interest reviews of advisory members' outside interests," states:

[16] 5 U.S.C. § 1007(a).

> The Designated Federal Officer or alternate for each NRC advisory committee and the General Counsel or designee shall review the interests and affiliations of each member of the Designated Federal Officer's advisory committee annually, and upon the commencement of the member's appointment to the committee, for the purpose of ensuring that such appointment is consistent with the laws and regulations on conflict-of-interest applicable to that member.

For the reasons stated below, the reviews specified in 10 C.F.R. section 7.20, standing alone, may not be sufficient to ensure ACMUI members comply with the "appearance" rule in 5 C.F.R. section 2635.502 and other ethics rules pertaining to conflicts of interest.

Lack of conflict-of-interest reviews and documentation for subcommittee and full committee meetings

The two principal advisory committees for NRC programs are the Advisory Committee on Reactor Safeguards (ACRS) and the ACMUI. The NRC's advisory committee members are "special Government employees," which under 18 U.S.C. section 202(a) include any officer or employee of an executive-branch agency who is retained, designated, appointed, or employed to perform duties for not more than 130 days during any period of 365 consecutive days.

As discussed in the Background section of this report, the ACMUI considers medical questions referred to it by the NRC staff and gives expert opinions on the medical uses of radioisotopes. Internal oversight of the ACMUI is provided by the Medical Safety and Events Assessment (MSEA) Branch in the NRC's Office of Nuclear Material Safety and Safeguards (NMSS).

The OIG determined that the ACMUI has no formal procedures under which NMSS staff screen members' outside interests or affiliations for possible conflicts before a member is assigned work on a particular NRC matter.[17] Instead, the ACMUI relies primarily on its members to notify NMSS staff of any conflict or potential conflict. An NRC manager stated to the OIG that the Designated Federal Officer (DFO)[18] asks ACMUI members at the outset of every public meeting to declare whether they have a conflict of interest regarding the subject of the meeting; however, the MSEA Branch does not document the declarations or have a system to track them. This manager also stated that if the NRC suspects a conflict of interest, the agency brings the issue to OGC for review. He added, however, that "[t]he last time the agency had to refer a possible COI [conflict of interest] issue to OGC was about 10 years ago."

---

[17] Consistent with 10 C.F.R. section 7.20, the ACMUI periodically receives notifications from OGC regarding outside positions listed on a member's financial-disclosure reports that may present the potential for a conflict of interest. The OIG determined, however, that the ACMUI does not routinely review these notifications before assigning members to work on particular matters.

[18] As stated in 10 C.F.R. section 7.2, "*Designated Federal Officer* means a government employee appointed, pursuant to § 7.11(a), to chair or attend each meeting of an NRC advisory committee to which he or she is assigned."

In contrast, the ACRS's procedures provide for conflict-of-interest reviews by the DFO, or an alternate such as a designated staff engineer, before every subcommittee and full committee meeting. The ACRS documents these reviews in writing and saves its determinations in the NRC's Agencywide Documents Access and Management System (ADAMS) for each meeting. Figure 2 below is an example of how the ACRS assigns roles and responsibilities to the DFO and various ACRS employees for these determinations.

Figure 2: Excerpt from ACRS full committee procedures

Step	Activity	Expected Due Date	Available Tools	Reference
11	The designated Staff Engineer will draft conflict-of-interest (COI) memorandum for the Full Committee Meeting with input from the Lead Engineer(s). The Lead Engineer will verify that no COIs exist and will review and comment on the draft COI memorandum. The designated Staff Engineer will finalize the COI memo and prepare it for the TSB Branch Chief signature. The AA will enter the document into ADAMS and distribute it. Note: A COI can be verified by reviewing Members' previous employment/consulting history, reviewing the SC COI, and communicating with Members should the Lead Engineer think a COI exists.	1 Week before FC meeting		

Source: NRC

An NRC manager familiar with the ACRS stated to the OIG that the DFOs for each subcommittee and full committee meeting have procedures for completing conflict-of-interest reviews and documenting the reviews in memoranda before ACRS meetings. The manager also stated that all ACRS members have been trained on FACA's requirements, including its financial and nonfinancial conflict-of-interest provisions. The manager added, "We follow FACA and 10 C.F.R. [section] 7.20." The manager further stated that conflict-of-interest reviews are done when "new members are vetted—OGC is involved in that—and any issues existing at the time of appointment are documented in the appointment letter to become an ACRS member."

The manager provided additional information regarding the ACRS's screening procedures:

> [T]he staff use an internal IT system called WebACTS to document potential conflicts (previous work, etc.) for each member. These are completed when a new member comes onboard and then annually to identify any new potential conflicts. If there is a conflict, it is documented in the memo and disclosed at the beginning of each meeting (usually publicly) and the member will comply with Section 10 of the bylaws

> regarding how he or she may or may not participate in the meeting and deliberations. For each FC [full committee] and SC [subcommittee] meeting, we have folders set up in [S]harepoint that are required to contain various documents needed in support of each meeting such as agendas, meeting slides, COIs [(conflicts of interest)], etc.... The COI memos are official agency and FACA records and are kept in ACRS's ADAMS folder.

The NRC manager added that if there are any questions between the staff and a member, "we consult OGC for guidance." The manager stated that the key part of the conflict-of-interest review process is keeping this topic in the forefront of the members' minds, which is done through familiarity with the bylaws, annual ethics training, and frequent communication between the members and NRC management and staff.

A senior NRC manager with responsibilities related to the ACMUI stated to the OIG that clarity in guidance is "something we should look into." The manager added, "No one wants to do anything that is unethical.... If the clarity is not there, we need to provide that." When the OIG asked the manager if the evidence gathered during this Special Inquiry revealed the appearance of a conflict of interest, the manager stated: "I wouldn't agree or disagree. [The ACMUI members] were performing their function." The manager further stated, "ACMUI members are asked if they are able to maintain their objectivity when deciding on issues and they said 'yes.'"

The NRC's former Executive Director for Operations (EDO) stated to the OIG that because the ACMUI is an advisory committee with a role similar to that of the ACRS, it could be beneficial for the ACMUI to look at the ACRS's guidance and procedures for members' conflict-of-interest reviews. When the OIG described the SNMMI's campaign opposing PRM-35-22 and explained that certain ACMUI members had leadership positions within the SNMMI at that time, the former EDO stated, "It gives the appearance of a conflict of interest."

Inadequate conflict-of-interest provisions in ACMUI bylaws

The ACMUI's bylaws contain only a single subsection that provides guidance to members on avoiding conflicts of interest. Subsection 4.1 states:

> All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest, as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest, unless they receive a waiver or prior authorization from the appropriate NRC official.

In contrast, Section 10 of the ACRS's bylaws contains detailed procedures explaining how the committee will evaluate potential conflicts of interest and ensure compliance with applicable rules. This section contains three pages of procedures addressing both actual conflicts of interest and the appearance of such conflicts. Section 10 also includes procedures for addressing conflicts arising from an ACRS member's outside affiliations. For example, section 10.4 of the bylaws states:

> The report preparation part of the ACRS meetings is the most significant part of the meetings where both actual and perceived conflicts of interest should be avoided. Government ethics rules and procedures must be observed to protect the integrity of the committee process, in addition to avoiding violation of ethics regulations. The committee process should not be perceived as being "biased" as a result of a member's organizational affiliation or contractual arrangements.

The ACRS's bylaws further provide, in sections 10.4-1 through 10.4-6, a detailed list of actions a member with a conflict should avoid, such as not expressing opinions that would influence the committee's position on the matter (section 10.4-2), and not providing input to the committee report that relates to the matter (section 10.4-3).

Unlike the ACRS's bylaws, subsection 4.1 of the ACMUI's bylaws fails to explain that ACMUI members should be mindful not only of circumstances that would create an actual conflict of interest for them, but also those that might create the appearance of a conflict of interest. Nor does this subsection remind members that a conflict of interest, or the appearance of a conflict, might arise from their affiliation with outside organizations or other non-financial connections. These were areas of confusion for the ACMUI members the OIG interviewed during this Special Inquiry. For example, one ACMUI member stated, with respect to subsection 4.1, "I think [it] could be improved ... right now, it looks very financially focused." In addition, although subsection 4.1 directs members to recuse themselves from agenda items in which they have a conflict of interest, unlike the ACRS's bylaws, this subsection lacks guidance on the scope of any recusal or examples of what recusal means in practical terms.

The ACMUI members affiliated with the SNMMI stated to the OIG they were generally aware of federal ethics laws and had attended annual training on ethics requirements. The members acknowledged, however, that they lacked a full understanding of the circumstances in which they must recuse themselves from ACMUI matters or seek authorization before participating in matters such as those related to PRM-35-22. In particular, the two active participants in the SNMMI stated that they were not aware they were in covered relationships based on their roles with that organization. Accordingly, the members did not seek NRC authorization before working on matters related to PRM-35-22 and recuse themselves from PRM-related matters while their requests were pending, nor did they consult with ethics officials in OGC before beginning such work. Revising the ACMUI's bylaws along the lines of the ACRS's

bylaws, so that the ACMUI's bylaws more specifically address organizational conflicts of interest and the appearance of such conflicts, could help members determine the proper steps to take if they are assigned work on matters that relate to areas of interest for their outside organizations.

IV. CONCLUSION

Because two ACMUI members were active participants in the SNMMI, and because the SNMMI actively opposed PRM-35-22, the members' work on petition-related matters resulted in the appearance of a conflict of interest. Under federal ethics rules, the members should not have worked on matters related to the petition without the NRC first reviewing whether, in light of all relevant circumstances, each member's participation in those matters was appropriate.

The NRC should consider strengthening its procedures for the ACMUI to ensure the committee adequately screens for both conflicts of interest and the appearance of such conflicts before assigning members to work on particular matters. The NRC should also consider enhancing the ACMUI's training, policies, or office instructions to ensure members fully understand when their outside affiliations may create concerns under federal ethics rules. Revising the ethics section of the ACMUI's bylaws so that it more closely resembles the analogous section of the ACRS's bylaws would reinforce these other approaches and help promote compliance with ethics rules.

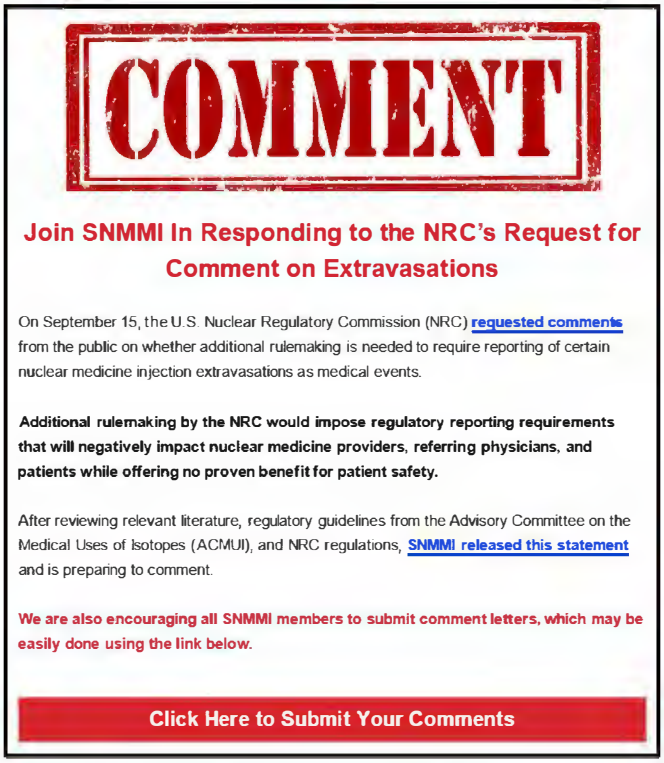
APPENDIX

Summary of the SNMMI's campaign opposing PRM-35-22

Between September and November 2020, the NRC sought public comments on PRM-35-22 (85 Fed. Reg. 57,148) (Sept. 15, 2020). The NRC requested public comment on eight specific questions regarding "Injection Quality Monitoring" and "Medical Event Classification and Reporting Criteria."

The SNMMI conducted a campaign opposing PRM-35-22, which included retaining a contractor to handle certain aspects of the campaign. Specifically, in October 2020, the SNMMI sent an email to all of its approximately 15,000 members asking them to review and comment on the petition for rulemaking. In the email, the SNMMI stated, "Additional rulemaking by the NRC would impose regulatory reporting requirements that will negatively impact nuclear medicine providers, referring physicians, and patients while offering no proven benefit for patient safety." The email contained a link through which members could submit comments. Following the email campaign, the NRC received over 300 comments opposing PRM-35-22 that used language virtually identical to that suggested by the SNMMI. The SNMMI also provided campaign updates on its website. See examples in Figures 3, 4, and 5.

Figure 3: Excerpt from SNMMI email



Source: SNMMI website. See the SNMMI statement cited on the following pages.

Figure 4: SNMMI statement opposing additional rulemaking on extravasations (3 pages)

On May 18, 2020, Lucerno Dynamics, LLC ("Lucerno") filed a petition for rulemaking with the Nuclear Regulatory Commission (NRC) to amend 10 C.F.R. § 35.2 and 10 C.F.R. § 35.3045 to require the reporting of extravasations that exceed the 0.5 Sv dose equivalent to tissue as medical events. In their petition Lucerno cites the NRC's final ruling in May, 1980, which exempted extravasations from medical event reporting with the understanding that extravasations are virtually impossible to avoid. Lucerno further states that "ample evidence has been published that nuclear medicine extravasations are, in fact, avoidable and are capable of causing considerable harm to the patients," and conclude by requesting that the NRC revisit the policy established in 1980 and require the reporting of certain extravasations as medical events.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American Society of Nuclear Cardiology (ASNC), and the American College of Nuclear Medicine (ACNM) have reviewed Lucerno's petition and the relevant literature, and our position is as follows.

The NRC's policy regarding extravasations established in May 1980 does not require additional rulemaking

Although the NRC considered the question of radiopharmaceutical extravasations in 1980, the Commission has also revisited this issue several times since then. In August, 2000, the NRC issued a revised Medical Use Policy Statement to focus its regulatory emphasis on those medical procedures that pose the highest, potentially significant, risks.[1] In April, 2002, 10 CFR §35 was revised to be more risk-informed and performance-based, consistent with the revised Medical Use Policy Statement. Specifically, the term, "Misadministration," was changed to "Medical Event," and the reporting criteria were revised to include different types of deviations from the radiopharmaceutical administration that was prescribed (i.e., wrong activity, wrong radioactive drug, wrong route of administration, wrong patient, wrong mode of treatment, wrong treatment site, or implantation of leaking sealed source). The definition of a Medical Event also includes dose-threshold criteria: an effective dose equivalent exceeding 0.05 Sv (5 rem), an organ or tissue dose equivalent exceeding 0.5 Sv (50 rem), or a shallow (skin) dose equivalent exceeding 0.5 Sv (50 rem).[2] There was also an exclusion from the Medical Event reporting requirement for an event that results from "patient intervention."[3]

---

[1] The policy statement outlined the intent of the NRC to regulate the medical use of radioisotopes based on the following four guiding principles:

1. The NRC will continue to regulate the medical use of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into the medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's direction.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

[2] 10 CFR §35.3045(a)

[3] "Patient intervention" is defined as: "actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration" (10 CFR §35.2)

However, a licensee must report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.[4] This statement encompasses the societies view that although therapeutic extravasations should be 100% reportable medical events, diagnostic extravasations should not.

SNMMI agrees with the current NRC position that extravasations are a practice-of-medicine issue and therefore not subject to NRC regulation

This issue of extravasations has been addressed by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) several times in recent years. In 2017, the ACMUI Patient Intervention Subcommittee examined unintentional treatment outcomes with Y-90 microsphere therapy and introduced the concept of "passive" rather than "active" patient intervention.[5] It stated, "Unintentional treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met. Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated."[6]

Most recently, in 2019 ACMUI Subcommittee on Extravasation reviewed the 1980 NRC decision to exclude extravasations from being considered a misadministration (medical event).[7] The Subcommittee agreed with the 1980 assessment that extravasations frequently occur in otherwise normal intravenous or intra-arterial injections and are virtually impossible to avoid. They concluded that extravasations are a practice-of-medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight. The Subcommittee reconfirmed that the exclusion of extravasation from medical-event reporting was appropriate for both diagnostic and therapeutic procedures. However, one of its recommendations was for extravasations to be considered a type of passive "patient intervention" and that extravasations that lead to "unintended permanent functional damage" be reportable as a Medical Event under 10 CFR §35.3045(b). This is not inconsistent with the NRC's policy from 1980 and therefore such policy is still current. The literature confirms this. A systematic review performed by van der Pol, et al. concluded that, although extravasation of diagnostic radiopharmaceuticals is not uncommon, of more than 3,000 reported cases of extravasation of diagnostic radiopharmaceuticals, only 3 cases (<0.1%) resulted in patient symptoms that required follow-up.[8] More specifically, none of the reported cases of extravasation of ^{99m}Tc-, ^{123}I-, ^{18}F-, and ^{68}Ga-labelled tracers required intervention; the only cases where patient symptoms were reported were for the less-often-used tracers ^{201}Tl and ^{131}I- iodocholesterol. In summary, there is no clinical data that supports Lucerno Dynamic's claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue.

---

[4] 10 CFR §35.3045(b)

[5] "Passive" patient intervention type was intended to address situations where there was a stasis of arterial flow or shunting of microspheres through aberrant vessels, resulting in a medical event for the Y-90 microsphere therapy. ACMUI Subcommittee on Patient Intervention, Draft Report, Part II, April 27, 2017.

[6] *Id.*

[7] ACMUI, Subcommittee on Extravasation, Final Report, October 23, 2019

[8] van der Pol, J., Vöö1, S., Bucerius, J., and Mottaghy, F. "Consequences of radiopharmaceutical extravasation and therapeutic interventions: a systematic review." Eur J Nucl Med Mol Imaging (2017) 44:1234–1243.

This systematic review also noted that extravasation of therapeutic radiopharmaceuticals is a more significant event that can potentially induce severe soft-tissue reactions and possibly require surgical intervention.[9] In this context, it is important to point out that extravasation of chemotherapeutic agents is an on-going safety concern in medical oncology and that there are well-established procedures for management of extravasated chemotherapeutic agents, similar to those in place for extravasated radiotherapeutic agents.

In summary, we believe that extravasations are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation. Furthermore, the Society recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies, and is actively addressing this as the quality-control issue that it is, rather than a patient-safety issue.

Alan B. Packard, PhD
President, SNMMI

Tina M. Buehner, PhD, CNMT, FSNMMI-TS
President SNMMI-TS

Yang Lu, MD, PhD, FACNM
President, ACNM

Sharmila Dorbala, MD, FASNC
President, ASNC

[9] *Id.* at 1234.

Figure 5: Excerpt from SNMMI campaign monitoring

Source: SNMMI website

TO REPORT FRAUD, WASTE, OR ABUSE

Please Contact:

Online:	Hotline Form
Telephone:	1.800.233.3497
TTY/TDD:	7-1-1, or 1.800.201.7165
Address:	U.S. Nuclear Regulatory Commission Office of the Inspector General Hotline Program Mail Stop O12-A12 11555 Rockville Pike Rockville, Maryland 20852

COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email the OIG.

Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the Advisory Committee on the Medical Uses of Isotopes

OIG Case No. I2200187
March 26, 2024

All publicly available OIG reports, including this report, are accessible through the OIG's website at:
nrcoig.oversight.gov

MEMORANDUM

DATE: March 26, 2024

TO: Christopher T. Hanson
Chair

FROM: Robert J. Feitel
Inspector General

Robert J. Feitel Digitally signed by Robert J. Feitel Date: 2024.03.26 08:35:45 -04'00'

SUBJECT: SPECIAL INQUIRY INTO THE APPEARANCE OF A CONFLICT OF INTEREST INVOLVING MEMBERS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (OIG CASE NO. I2200187)

The attached report by the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), is furnished for whatever action you deem appropriate. Please notify the OIG by July 1, 2024, what corrective actions, if any, the NRC will be taking based on the results of this Special Inquiry.

cc: Commissioner Wright
Commissioner Caputo
Commissioner Crowell
R. Furstenau, Acting EDO
J. Weil, OPA

Why the OIG conducted this Special Inquiry

The Office of the Inspector General (OIG) initiated this Special Inquiry based on allegations of a conflict of interest involving certain Nuclear Regulatory Commission (NRC) advisory committee members. The allegations related to the NRC's consideration of a petition for rulemaking (PRM-35-22) that requested the NRC amend its regulations to require medical-event reporting of radiopharmaceutical extravasations that result in localized dose equivalents exceeding 0.5 Sv (50 rem). Specifically, the allegers claimed that several members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) who advised the NRC on matters related to PRM-35-22 were affiliated with a professional organization that promotes the interests of NRC-regulated entities. These outside affiliations, in the view of the allegers, created a conflict of interest that called into question the integrity of the NRC's decision-making with respect to PRM-35-22.

This report is an investigative product documenting instances where inadequacies in the NRC's internal oversight led to circumstances that raised questions regarding the integrity of the agency's decision-making on a matter pertaining to public health and safety.

Findings

Two ACMUI members failed to follow the procedures in Title 5 of Code of Federal Regulations (C.F.R.) section 2635.502, "Personal and business relationships," when they participated in matters related to PRM-35-22 without obtaining prior authorization to do so. These members were active participants in the Society of Nuclear Medicine and Molecular Imaging (SNMMI), a 15,000-member scientific and professional organization that carried out a campaign opposing PRM-35-22, at the same time they worked for the ACMUI on matters related to the petition.

The NRC's policies for the ACMUI may be insufficient to ensure compliance with 5 C.F.R. section 2635.502 and certain conflict-of-interest requirements tied to the Federal Advisory Committee Act (FACA) at 5 U.S.C. sections 1001–1014. Specifically, the NRC does not currently have a policy requiring staff to perform conflict-of-interest reviews before assigning particular tasks to ACMUI members. The NRC, therefore, lacks internal controls in this context that could facilitate compliance with federal ethics requirements and help avoid both actual and apparent conflicts of interest.

TABLE OF CONTENTS

I. ALLEGATION/INCIDENT

The OIG received allegations relating to the recommendation for PRM-35-22 that the NRC staff presented to the Commission in SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events" (May 9, 2022). The allegers included organizations and individuals that focus on issues related to nuclear medicine. Certain allegers believed that the NRC allowed the SNMMI, an organization representing NRC-regulated entities, to have inappropriate influence in the agency's review of the petition. This inappropriate influence, in the allegers' views, resulted in an NRC staff recommendation that allowed "clear medical events [to] remain concealed from patients."

Potential violations relevant to this Special Inquiry include the failure to adhere to 5 C.F.R. section 2635.502, which addresses circumstances involving the appearance of a conflict of interest, and 5 U.S.C. section 1007, which requires agencies to establish guidelines and management controls for their advisory committees that are consistent with the directives of the Administrator of the General Services Administration (GSA).

II. BACKGROUND

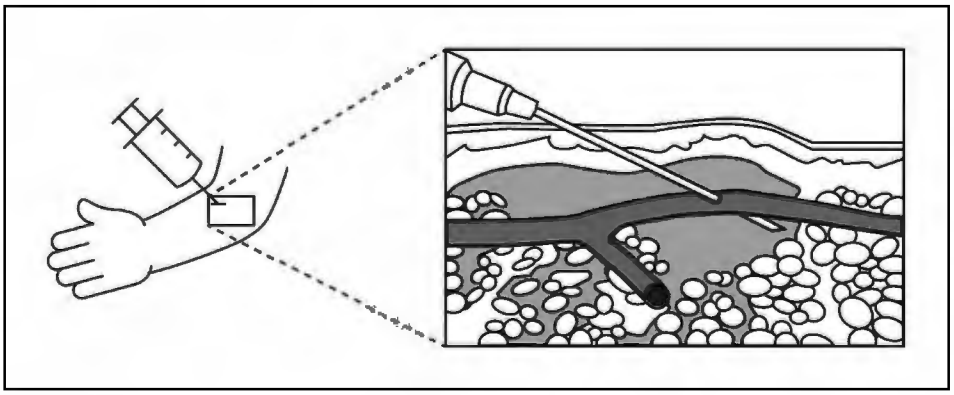
10 C.F.R. Part 35, Medical Use of Byproduct Material

The NRC's regulations in 10 C.F.R. Part 35 establish standards for the medical use of byproduct material and the issuance of licenses authorizing the use of such material. These standards, together with requirements found in other parts of the NRC's regulations, are designed to protect workers, patients, human-research subjects, and the public from undue radiological risks.

An "extravasation" is the unintentional leakage of an intravenously administered solution around the infusion or injection site into the surrounding tissue. (See Figure 1 for a depiction of an extravasation.) As far back as 1980, the NRC considered whether its licensees should be required to report radiopharmaceutical extravasations to the agency. That year, the NRC amended Part 35 to require the reporting of medical "misadministrations" (later renamed "medical events"). Misadministration reporting enabled the NRC to investigate these events for possible violations, evaluate licensee corrective actions, inform other licensees of potential problems, and take generic corrective actions. In response to a comment on the proposed Part 35 amendments, the NRC stated that it did not consider an extravasation to be a misadministration because extravasations occur frequently in otherwise normal intravenous or intraarterial injections and are virtually impossible to avoid.[1]

The NRC made substantive changes to the misadministration reporting requirements in 1991, and again in 2002, but without addressing its prior statement that extravasations are exempt from Part 35 reporting requirements.[2] As a result, the NRC does not currently classify radiopharmaceutical extravasations as medical events that must be reported to the agency.

Figure 1: Extravasation



Source: NRC

[1] *Misadministration Reporting Requirements*, 45 Fed. Reg. 31,701, 31,703 (May 14, 1980).
[2] *Quality Management Program and Misadministrations*, 56 Fed. Reg. 34,104 (July 25, 1991); *Medical Use of Byproduct Material*, 67 Fed. Reg. 20,250 (April 24, 2002).

Petition for Extravasation Rulemaking

In May 2020, the NRC docketed a petition for rulemaking requesting that the agency amend Part 35 to require the reporting of certain extravasations as medical events (PRM-35-22). The petition raised the following issues:

- The exemption of radiopharmaceutical extravasations from medical reporting is based on incorrect assertions that such extravasations are virtually impossible to avoid, and this approach does not protect the public from unsafe irradiation; and,
- The exemption of extravasations from medical reporting requirements results in a lack of transparency to patients, the public, and the NRC.

The petitioner specifically requested the NRC amend 10 C.F.R. section 35.3045(a)(1), "Report and Notification of a Medical Event," by adding a new paragraph (iv) requiring medical providers to report to the NRC: "An extravasation that leads to an irradiation resulting in a localized dose equivalent exceeding 0.5 Sieverts (Sv)(50 rem)."

In SECY-22-0043 (May 2022), the NRC staff provided the Commission a rulemaking plan for adding extravasation-reporting requirements to Part 35. In the plan, the staff recommended amending Part 35 to require reporting of extravasations when a patient needs medical attention for suspected radiation injury. The staff did not, however, recommend adopting the petitioner's proposal to require reporting of all extravasations resulting in a localized dose equivalent exceeding 0.5 Sv (50 rem).

In December 2022, the Commission issued a Staff Requirements Memorandum (SRM) for the rulemaking plan (SRM-SECY-22-0043). In the SRM, the Commission approved the staff's recommendation to initiate a rulemaking that would amend Part 35 to require licensees to report nuclear medicine injection extravasations as medical events, but only if the extravasation requires medical attention for suspected radiation injury.

Also in December 2022, the NRC published a notice in the Federal Register announcing the agency's intent to consider PRM-35-22 in the rulemaking process.[3] The NRC established a public web page for the rulemaking, and in the "Public Involvement" section of this page the staff stated that it would coordinate with the ACMUI in an open and transparent manner during the rulemaking.

In April 2023, the NRC published preliminary language for the proposed extravasation rule[4] and provided a comment period for the language that extended through September 1, 2023.[5] The NRC currently projects issuing a notice of proposed rulemaking in December 2024 and a final rule in September 2026.[6]

---

[3] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 87 Fed. Reg. 80,474 (Dec. 30, 2022) (petition for rulemaking; consideration in the rulemaking process).
[4] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 88 Fed. Reg. 24,130 (April 19, 2023) (preliminary proposed rule language; notice of availability and public meeting).
[5] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 88 Fed. Reg. 45,824 (July 18, 2023) (preliminary proposed rule language; extension of comment period).
[6] https://www.regulations.gov/docket/NRC-2022-0218/unified-agenda (accessed March 19, 2024).

Advisory Committee on the Medical Uses of Isotopes

The NRC's predecessor, the Atomic Energy Commission, established the ACMUI in 1958 under the authority of the Atomic Energy Act of 1954 (42 U.S.C. § 2011 *et seq*). Advisory committees such as the ACMUI are structured to provide a forum where experts representing many perspectives can provide independent advice that supports an agency's decision-making processes. The NRC's use of the ACMUI must comply with both FACA and the NRC's agency-specific FACA regulations in 10 C.F.R. Part 7, "Advisory Committees." Furthermore, the NRC's regulations must be consistent with the GSA's regulations in 41 C.F.R. Part 102-3, "Federal Advisory Committee Management."[7]

The ACMUI serves the NRC through the advice and recommendations it gives agency staff. Because the advice of ACMUI members is often informed by their non-governmental positions or relationships, the NRC must ensure the members do not inappropriately advance outside interests. According to the NRC publication NUREG/BR-0309, *Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI): A Member's Guide* (2004), at pages 3–4:

> The NRC staff understands that the ACMUI is composed of stakeholder licensees, and as such, will represent licensee concerns to some extent. This is not only inevitable, but desirable. Nonetheless, ACMUI members must remember that, as compensated Federal Government employees, they are subject to the laws and regulations on conflict-of-interest. Under those laws and regulations, they should not advise the NRC or participate in any ACMUI matter when doing so will directly and predictably affect their financial interest or the financial interest of members of their families; their employers; or anyone else with whom they have a business relationship. ACMUI members also must not inappropriately advance the views or positions of professional associations or the regulated community.

This publication further reminds ACMUI members, on page 4, that, "[w]henever a conflict-of-interest issue arises, the affected ACMUI member must recuse himself or herself from voting on the particular matter that will cause the conflict-of-interest."

[7] FACA requires each agency head to "establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Administrator under sections 1006 and 1009 of this title." 5 U.S.C. § 1007(a). Among these directives are the FACA regulations in 41 C.F.R. Part 102-3.

III. DETAIL

Finding 1: Appearance of a conflict of interest arising from the participation of certain ACMUI members in matters related to PRM-35-22

The ethics standards in 5 C.F.R. Part 2635 require employees to avoid conflicts of interest between their outside interests and their government work. These rules also require employees to avoid circumstances that could create the appearance of such conflicts. In particular, section 2635.502 states that an employee should seek authorization from his or her agency before working on certain matters that would directly and predictably affect the financial interests of a person or entity with whom the employee has a "covered relationship."[8] The rule lists five categories of persons or entities that give rise to a covered relationship, including "[a]n organization . . . in which the employee is an active participant." An employee's participation in an outside organization is considered "active" if "for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization."[9]

The OIG found that two ACMUI members were in covered relationships with the SNMMI while they also performed work for the NRC related to PRM-35-22. Neither member requested prior authorization to work on matters related to the petition, even though their affiliations with the SNMMI raised reasonable questions regarding their impartiality in such matters. Under these circumstances, the members' actions were inconsistent with section 2635.502.

Specifically, during the same time period the ACMUI was reviewing matters related to PRM-35-22, one ACMUI member served as an SNMMI official, while the other member served in a capacity similar to that of a committee chairperson. These members were therefore in "covered relationships" with the SNMMI as defined in 5 C.F.R. section 2635.502(b)(1)(v). In addition, each member had served as an SNMMI officer within one year of working for the ACMUI on matters related to PRM-35-22, meaning that

---

[8] See 5 C.F.R. section 2635.502(a), "Consideration of appearances by the employee," and section 2635.502(a)(2) ("An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."). In addition, 5 C.F.R. section 2635.101, "Basic obligation of public service," establishes general principles reinforcing the requirement that employees avoid both actual conflicts of interest and the appearance of such conflicts. For example, under subsection (b)(8) of section 2635.101, "[e]mployees shall act impartially and not give preferential treatment to any private organization or individual." And, under subsection (b)(14), "[e]mployees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in [5 C.F.R. Part 2635]."

[9] 5 C.F.R. § 2635.502(b)(1)(v). A "covered relationship" also exists with respect to "[a]ny person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee[.]" 5 C.F.R. § 2635.502(b)(1)(iv).

each member was also in a covered relationship with the SNMMI under section 2635.502(b)(1)(iv).[10]

The OIG further determined that one of these ACMUI members was part of the Subcommittee on Extravasation that reviewed and provided a recommendation on the NRC staff's "Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting." Both members were part of the ACMUI's full committee, which approved the subcommittee's recommendation.

The evidence the OIG gathered shows that the proceeding for PRM-35-22 was vigorously contested, with many groups and individuals supporting the petition, while others, including the SNMMI, opposed the petition in whole or in part. These divergent viewpoints should have raised heightened awareness, both on the part of the ACMUI members and the NRC, that a reasonable person might question whether the members' affiliations with the SNMMI would compromise their impartiality in matters related to PRM-35-22.

The SNMMI did not merely oppose PRM-35-22; rather, it ran an active campaign opposing the petitioner's request that the NRC classify diagnostic extravasations as reportable medical events.[11] The campaign emailed SNMMI members an automated link with a form letter that a member could submit in response to the request for comment on PRM-35-22 that the NRC had published in the Federal Register.[12] The appendix to this report provides examples of the SNMMI's campaign opposing PRM-35-22.

In April 2021, the NRC staff requested that the ACMUI review the staff's preliminary evaluation for the petition. The ACMUI thereafter referred this matter to its Subcommittee on Extravasation, which consisted of five members, including one member who was an active participant in the SNMMI.

In July 2021, the subcommittee issued a draft report that contained its review and comments on the NRC staff's preliminary evaluation of issues raised by PRM-35-22. In its draft report the subcommittee supported Option 4, "Extravasation events that require medical attention." Under this option, the NRC would not require dosimetry to

---

[10] The OIG found that a third ACMUI member with ties to the SNMMI was part of the ACMUI's Subcommittee on Extravasation and voted as a member of its full committee. This person was not an SNMMI official or committee chairperson, but the person was a member of various SNMMI committees, including a committee that advocates for the availability of radionuclides essential to medicine and research. Where a person is not acting as an official of the outside organization, or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, "significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation." 5 C.F.R. § 2635.502(b)(1)(v). Here, however, the OIG was unable to clearly determine whether this member's SNMMI-related activities were extensive enough to create a covered relationship with the organization.

[11] The SNMMI, together with the American Society of Nuclear Cardiology and the American College of Nuclear Medicine, took the position that "although therapeutic extravasations should be 100% reportable medical events, diagnostic extravasations should not." See the Appendix to this report at page 17.

[12] *Reporting Nuclear Medicine Injection Extravasations as Medical Events*, 85 Fed. Reg. 57,148 (Sept. 15, 2020) (petition for rulemaking; notification of docketing and request for comment).

determine whether an extravasation should be reported—the approach sought by the petitioners in PRM-35-22—although dosimetry would be required if an extravasation appears severe enough to trigger "abnormal occurrence" criteria.[13]

In September 2021, the ACMUI's full committee of 13 members voted unanimously to approve the subcommittee's report and the rulemaking approach described in Option 4 of that report. One additional ACMUI member who actively participated in the SNMMI was on the full committee.[14] The ACMUI's support for Option 4 was consistent with SECY-22-0043, where the NRC staff recommended that the Commission take substantively the same approach.

The circumstances surrounding PRM-35-22 could have led a reasonable person to conclude that the ACMUI members affiliated with the SNMMI may have inappropriately prioritized the outside organization's interests during their review of issues related to the petition. The petition, if granted in full by the NRC, would directly affect a large number of patients, hospitals, and other healthcare providers. Providers in particular would incur significant costs if, as requested in the petition, the NRC issues a rule requiring them to broadly report radionuclide extravasations. While the rule may not have a direct monetary effect on the SNMMI itself, it could have a large effect on many of the NRC-regulated entities or individuals that the SNMMI represents.[15] In these circumstances, the involvement of certain active participants in the SNMMI in the NRC's deliberations over PRM-35-22 could have given a person ample reason to question the members' impartiality in PRM-related matters.

The OIG did not identify any information suggesting that the ACMUI members affiliated with the SNMMI had financial interests that would have been directly and predictably affected by the PRM-35-22 proceeding. Thus, the members were not necessarily prohibited from participating in the ACMUI's consideration of matters related to the petition. Because a reasonable person could have questioned each member's impartiality in such matters, however, the proper course would have been for the NRC to consider, under 5 C.F.R. section 2635.502(d), whether "in light of all relevant circumstances...the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations." Consistent with section 2635.502(e), "Disqualification," and section IV of NRC Directive Handbook 7.9, "Ethics Approvals and Waivers," the ACMUI members should have recused themselves from matters

---

[13] Section 208 of the Energy Reorganization Act of 1974, as amended, defines an "abnormal occurrence" as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. 42 U.S.C. § 5848. The NRC periodically publishes criteria for determining whether an incident or event constitutes an abnormal occurrence.

[14] The subcommittee members also voted as part of the full committee. Thus, 2 active participants in the SNMMI were among the 13 members of the full committee.

[15] According to its website, the "SNMMI's worldwide membership totals more than 15,000, including physicians, scientists, technologists, chemists, radiopharmacists, students and industry representatives from 82 countries around the world." (https://www.snmmi.org/international?navItemNumber=28696) (accessed March 19, 2024).

related to PRM-35-22 pending agency review of the issue, and they should not have participated in the matters without written authorization from the agency.

Finding 2: NRC's policies for the ACMUI are insufficient

The ACMUI members who participated actively in the SNMMI told the OIG that they believed the term "conflict of interest" referred primarily to personal financial gains, and they, therefore, did not consider their involvement with the SNMMI as presenting the appearance of a conflict of interest. Accordingly, neither member recused themselves from matters related to PRM-35-22 or requested authorization from the NRC before participating in such matters.

Each of the ACMUI members received annual ethics training conducted by the NRC's Office of the General Counsel (OGC), which contained at least one slide mentioning the "appearance" standard at 5 C.F.R. section 2635.502. The members also filed confidential financial-disclosure reports (OGE Form 450) annually, which OGC reviewed for potential conflicts of interest.

Because these agency actions—training and the review of financial-disclosure reports—were not sufficient to avoid the "appearance" concern presented by having active participants in the SNMMI work on ACMUI matters involving a rulemaking petition that the SNMMI actively opposed, the NRC should consider strengthening the conflict-of-interest screening policies for ACMUI members. Strengthening these policies would help ensure that the advice and recommendations of the ACMUI, and by extension the decisions of the NRC, do not appear to be inappropriately influenced by a member's affiliations with external entities such as professional organizations.

Regulatory framework

As required by FACA, the GSA Administrator has issued regulations establishing administrative guidelines and management controls for federal advisory committees. The GSA's regulations include a provision, currently at 41 C.F.R. section 102-3.105(h), stating that the head of each agency must—

> Assure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes, regulations issued by the U.S. Office of Government Ethics (OGE) including any supplemental agency requirements, and other Federal ethics rules.

FACA also requires agencies to have their own regulations that are consistent with the GSA's relevant directives.[16] The NRC's implementing regulations are in 10 C.F.R. Part 7, "Advisory Committees." One of these regulations, 10 C.F.R. section 7.20, "Conflict-of-interest reviews of advisory members' outside interests," states:

[16] 5 U.S.C. § 1007(a).

> The Designated Federal Officer or alternate for each NRC advisory committee and the General Counsel or designee shall review the interests and affiliations of each member of the Designated Federal Officer's advisory committee annually, and upon the commencement of the member's appointment to the committee, for the purpose of ensuring that such appointment is consistent with the laws and regulations on conflict-of-interest applicable to that member.

For the reasons stated below, the reviews specified in 10 C.F.R. section 7.20, standing alone, may not be sufficient to ensure ACMUI members comply with the "appearance" rule in 5 C.F.R. section 2635.502 and other ethics rules pertaining to conflicts of interest.

Lack of conflict-of-interest reviews and documentation for subcommittee and full committee meetings

The two principal advisory committees for NRC programs are the Advisory Committee on Reactor Safeguards (ACRS) and the ACMUI. The NRC's advisory committee members are "special Government employees," which under 18 U.S.C. section 202(a) include any officer or employee of an executive-branch agency who is retained, designated, appointed, or employed to perform duties for not more than 130 days during any period of 365 consecutive days.

As discussed in the Background section of this report, the ACMUI considers medical questions referred to it by the NRC staff and gives expert opinions on the medical uses of radioisotopes. Internal oversight of the ACMUI is provided by the Medical Safety and Events Assessment (MSEA) Branch in the NRC's Office of Nuclear Material Safety and Safeguards (NMSS).

The OIG determined that the ACMUI has no formal procedures under which NMSS staff screen members' outside interests or affiliations for possible conflicts before a member is assigned work on a particular NRC matter.[17] Instead, the ACMUI relies primarily on its members to notify NMSS staff of any conflict or potential conflict. An NRC manager stated to the OIG that the Designated Federal Officer (DFO)[18] asks ACMUI members at the outset of every public meeting to declare whether they have a conflict of interest regarding the subject of the meeting; however, the MSEA Branch does not document the declarations or have a system to track them. This manager also stated that if the NRC suspects a conflict of interest, the agency brings the issue to OGC for review. He added, however, that "[t]he last time the agency had to refer a possible COI [conflict of interest] issue to OGC was about 10 years ago."

---

[17] Consistent with 10 C.F.R. section 7.20, the ACMUI periodically receives notifications from OGC regarding outside positions listed on a member's financial-disclosure reports that may present the potential for a conflict of interest. The OIG determined, however, that the ACMUI does not routinely review these notifications before assigning members to work on particular matters.

[18] As stated in 10 C.F.R. section 7.2, "*Designated Federal Officer* means a government employee appointed, pursuant to § 7.11(a), to chair or attend each meeting of an NRC advisory committee to which he or she is assigned."

In contrast, the ACRS's procedures provide for conflict-of-interest reviews by the DFO, or an alternate such as a designated staff engineer, before every subcommittee and full committee meeting. The ACRS documents these reviews in writing and saves its determinations in the NRC's Agencywide Documents Access and Management System (ADAMS) for each meeting. Figure 2 below is an example of how the ACRS assigns roles and responsibilities to the DFO and various ACRS employees for these determinations.

Figure 2: Excerpt from ACRS full committee procedures

Step	Activity	Expected Due Date	Available Tools	Reference
11	The designated Staff Engineer will draft conflict-of-interest (COI) memorandum for the Full Committee Meeting with input from the Lead Engineer(s). The Lead Engineer will verify that no COIs exist and will review and comment on the draft COI memorandum. The designated Staff Engineer will finalize the COI memo and prepare it for the TSB Branch Chief signature. The AA will enter the document into ADAMS and distribute it. Note: A COI can be verified by reviewing Members' previous employment/consulting history, reviewing the SC COI, and communicating with Members should the Lead Engineer think a COI exists.	1 Week before FC meeting		

Source: NRC

An NRC manager familiar with the ACRS stated to the OIG that the DFOs for each subcommittee and full committee meeting have procedures for completing conflict-of-interest reviews and documenting the reviews in memoranda before ACRS meetings. The manager also stated that all ACRS members have been trained on FACA's requirements, including its financial and nonfinancial conflict-of-interest provisions. The manager added, "We follow FACA and 10 C.F.R. [section] 7.20." The manager further stated that conflict-of-interest reviews are done when "new members are vetted—OGC is involved in that—and any issues existing at the time of appointment are documented in the appointment letter to become an ACRS member."

The manager provided additional information regarding the ACRS's screening procedures:

> [T]he staff use an internal IT system called WebACTS to document potential conflicts (previous work, etc.) for each member. These are completed when a new member comes onboard and then annually to identify any new potential conflicts. If there is a conflict, it is documented in the memo and disclosed at the beginning of each meeting (usually publicly) and the member will comply with Section 10 of the bylaws

> regarding how he or she may or may not participate in the meeting and deliberations. For each FC [full committee] and SC [subcommittee] meeting, we have folders set up in [S]harepoint that are required to contain various documents needed in support of each meeting such as agendas, meeting slides, COIs [(conflicts of interest)], etc.... The COI memos are official agency and FACA records and are kept in ACRS's ADAMS folder.

The NRC manager added that if there are any questions between the staff and a member, "we consult OGC for guidance." The manager stated that the key part of the conflict-of-interest review process is keeping this topic in the forefront of the members' minds, which is done through familiarity with the bylaws, annual ethics training, and frequent communication between the members and NRC management and staff.

A senior NRC manager with responsibilities related to the ACMUI stated to the OIG that clarity in guidance is "something we should look into." The manager added, "No one wants to do anything that is unethical.... If the clarity is not there, we need to provide that." When the OIG asked the manager if the evidence gathered during this Special Inquiry revealed the appearance of a conflict of interest, the manager stated: "I wouldn't agree or disagree. [The ACMUI members] were performing their function." The manager further stated, "ACMUI members are asked if they are able to maintain their objectivity when deciding on issues and they said 'yes.'"

The NRC's former Executive Director for Operations (EDO) stated to the OIG that because the ACMUI is an advisory committee with a role similar to that of the ACRS, it could be beneficial for the ACMUI to look at the ACRS's guidance and procedures for members' conflict-of-interest reviews. When the OIG described the SNMMI's campaign opposing PRM-35-22 and explained that certain ACMUI members had leadership positions within the SNMMI at that time, the former EDO stated, "It gives the appearance of a conflict of interest."

Inadequate conflict-of-interest provisions in ACMUI bylaws

The ACMUI's bylaws contain only a single subsection that provides guidance to members on avoiding conflicts of interest. Subsection 4.1 states:

> All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest, as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest, unless they receive a waiver or prior authorization from the appropriate NRC official.

In contrast, Section 10 of the ACRS's bylaws contains detailed procedures explaining how the committee will evaluate potential conflicts of interest and ensure compliance with applicable rules. This section contains three pages of procedures addressing both actual conflicts of interest and the appearance of such conflicts. Section 10 also includes procedures for addressing conflicts arising from an ACRS member's outside affiliations. For example, section 10.4 of the bylaws states:

> The report preparation part of the ACRS meetings is the most significant part of the meetings where both actual and perceived conflicts of interest should be avoided. Government ethics rules and procedures must be observed to protect the integrity of the committee process, in addition to avoiding violation of ethics regulations. The committee process should not be perceived as being "biased" as a result of a member's organizational affiliation or contractual arrangements.

The ACRS's bylaws further provide, in sections 10.4-1 through 10.4-6, a detailed list of actions a member with a conflict should avoid, such as not expressing opinions that would influence the committee's position on the matter (section 10.4-2), and not providing input to the committee report that relates to the matter (section 10.4-3).

Unlike the ACRS's bylaws, subsection 4.1 of the ACMUI's bylaws fails to explain that ACMUI members should be mindful not only of circumstances that would create an actual conflict of interest for them, but also those that might create the appearance of a conflict of interest. Nor does this subsection remind members that a conflict of interest, or the appearance of a conflict, might arise from their affiliation with outside organizations or other non-financial connections. These were areas of confusion for the ACMUI members the OIG interviewed during this Special Inquiry. For example, one ACMUI member stated, with respect to subsection 4.1, "I think [it] could be improved ... right now, it looks very financially focused." In addition, although subsection 4.1 directs members to recuse themselves from agenda items in which they have a conflict of interest, unlike the ACRS's bylaws, this subsection lacks guidance on the scope of any recusal or examples of what recusal means in practical terms.

The ACMUI members affiliated with the SNMMI stated to the OIG they were generally aware of federal ethics laws and had attended annual training on ethics requirements. The members acknowledged, however, that they lacked a full understanding of the circumstances in which they must recuse themselves from ACMUI matters or seek authorization before participating in matters such as those related to PRM-35-22. In particular, the two active participants in the SNMMI stated that they were not aware they were in covered relationships based on their roles with that organization. Accordingly, the members did not seek NRC authorization before working on matters related to PRM-35-22 and recuse themselves from PRM-related matters while their requests were pending, nor did they consult with ethics officials in OGC before beginning such work. Revising the ACMUI's bylaws along the lines of the ACRS's

bylaws, so that the ACMUI's bylaws more specifically address organizational conflicts of interest and the appearance of such conflicts, could help members determine the proper steps to take if they are assigned work on matters that relate to areas of interest for their outside organizations.

IV. CONCLUSION

Because two ACMUI members were active participants in the SNMMI, and because the SNMMI actively opposed PRM-35-22, the members' work on petition-related matters resulted in the appearance of a conflict of interest. Under federal ethics rules, the members should not have worked on matters related to the petition without the NRC first reviewing whether, in light of all relevant circumstances, each member's participation in those matters was appropriate.

The NRC should consider strengthening its procedures for the ACMUI to ensure the committee adequately screens for both conflicts of interest and the appearance of such conflicts before assigning members to work on particular matters. The NRC should also consider enhancing the ACMUI's training, policies, or office instructions to ensure members fully understand when their outside affiliations may create concerns under federal ethics rules. Revising the ethics section of the ACMUI's bylaws so that it more closely resembles the analogous section of the ACRS's bylaws would reinforce these other approaches and help promote compliance with ethics rules.

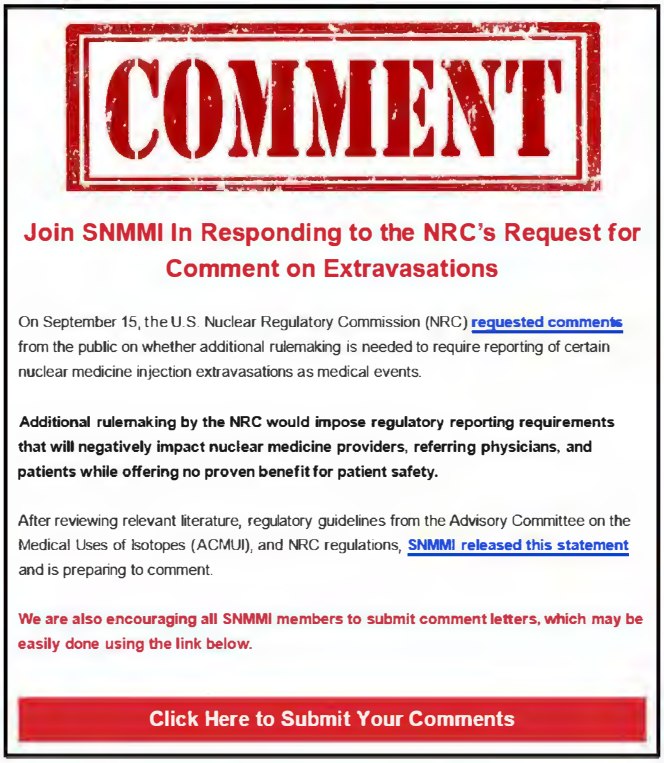
APPENDIX

Summary of the SNMMI's campaign opposing PRM-35-22

Between September and November 2020, the NRC sought public comments on PRM-35-22 (85 Fed. Reg. 57,148) (Sept. 15, 2020). The NRC requested public comment on eight specific questions regarding "Injection Quality Monitoring" and "Medical Event Classification and Reporting Criteria."

The SNMMI conducted a campaign opposing PRM-35-22, which included retaining a contractor to handle certain aspects of the campaign. Specifically, in October 2020, the SNMMI sent an email to all of its approximately 15,000 members asking them to review and comment on the petition for rulemaking. In the email, the SNMMI stated, "Additional rulemaking by the NRC would impose regulatory reporting requirements that will negatively impact nuclear medicine providers, referring physicians, and patients while offering no proven benefit for patient safety." The email contained a link through which members could submit comments. Following the email campaign, the NRC received over 300 comments opposing PRM-35-22 that used language virtually identical to that suggested by the SNMMI. The SNMMI also provided campaign updates on its website. See examples in Figures 3, 4, and 5.

Figure 3: Excerpt from SNMMI email



Source: SNMMI website. See the SNMMI statement cited on the following pages.

Figure 4: SNMMI statement opposing additional rulemaking on extravasations (3 pages)

On May 18, 2020, Lucerno Dynamics, LLC ("Lucerno") filed a petition for rulemaking with the Nuclear Regulatory Commission (NRC) to amend 10 C.F.R. § 35.2 and 10 C.F.R. § 35.3045 to require the reporting of extravasations that exceed the 0.5 Sv dose equivalent to tissue as medical events. In their petition Lucerno cites the NRC's final ruling in May, 1980, which exempted extravasations from medical event reporting with the understanding that extravasations are virtually impossible to avoid. Lucerno further states that "ample evidence has been published that nuclear medicine extravasations are, in fact, avoidable and are capable of causing considerable harm to the patients," and conclude by requesting that the NRC revisit the policy established in 1980 and require the reporting of certain extravasations as medical events.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American Society of Nuclear Cardiology (ASNC), and the American College of Nuclear Medicine (ACNM) have reviewed Lucerno's petition and the relevant literature, and our position is as follows.

The NRC's policy regarding extravasations established in May 1980 does not require additional rulemaking

Although the NRC considered the question of radiopharmaceutical extravasations in 1980, the Commission has also revisited this issue several times since then. In August, 2000, the NRC issued a revised Medical Use Policy Statement to focus its regulatory emphasis on those medical procedures that pose the highest, potentially significant, risks.[1] In April, 2002, 10 CFR §35 was revised to be more risk-informed and performance-based, consistent with the revised Medical Use Policy Statement. Specifically, the term, "Misadministration," was changed to "Medical Event," and the reporting criteria were revised to include different types of deviations from the radiopharmaceutical administration that was prescribed (i.e., wrong activity, wrong radioactive drug, wrong route of administration, wrong patient, wrong mode of treatment, wrong treatment site, or implantation of leaking sealed source). The definition of a Medical Event also includes dose-threshold criteria: an effective dose equivalent exceeding 0.05 Sv (5 rem), an organ or tissue dose equivalent exceeding 0.5 Sv (50 rem), or a shallow (skin) dose equivalent exceeding 0.5 Sv (50 rem).[2] There was also an exclusion from the Medical Event reporting requirement for an event that results from "patient intervention."[3]

---

[1] The policy statement outlined the intent of the NRC to regulate the medical use of radioisotopes based on the following four guiding principles:

1. The NRC will continue to regulate the medical use of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into the medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's direction.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

[2] 10 CFR §35.3045(a)

[3] "Patient intervention" is defined as: "actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration" (10 CFR §35.2)

However, a licensee must report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.[4] This statement encompasses the societies view that although therapeutic extravasations should be 100% reportable medical events, diagnostic extravasations should not.

SNMMI agrees with the current NRC position that extravasations are a practice-of-medicine issue and therefore not subject to NRC regulation

This issue of extravasations has been addressed by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) several times in recent years. In 2017, the ACMUI Patient Intervention Subcommittee examined unintentional treatment outcomes with Y-90 microsphere therapy and introduced the concept of "passive" rather than "active" patient intervention.[5] It stated, "Unintentional treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met. Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated."[6]

Most recently, in 2019 ACMUI Subcommittee on Extravasation reviewed the 1980 NRC decision to exclude extravasations from being considered a misadministration (medical event).[7] The Subcommittee agreed with the 1980 assessment that extravasations frequently occur in otherwise normal intravenous or intra-arterial injections and are virtually impossible to avoid. They concluded that extravasations are a practice-of-medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight. The Subcommittee reconfirmed that the exclusion of extravasation from medical-event reporting was appropriate for both diagnostic and therapeutic procedures. However, one of its recommendations was for extravasations to be considered a type of passive "patient intervention" and that extravasations that lead to "unintended permanent functional damage" be reportable as a Medical Event under 10 CFR §35.3045(b). This is not inconsistent with the NRC's policy from 1980 and therefore such policy is still current. The literature confirms this. A systematic review performed by van der Pol, et al. concluded that, although extravasation of diagnostic radiopharmaceuticals is not uncommon, of more than 3,000 reported cases of extravasation of diagnostic radiopharmaceuticals, only 3 cases (<0.1%) resulted in patient symptoms that required follow-up.[8] More specifically, none of the reported cases of extravasation of ^{99m}Tc-, ^{123}I-, ^{18}F-, and ^{68}Ga-labelled tracers required intervention; the only cases where patient symptoms were reported were for the less-often-used tracers ^{201}Tl and ^{131}I- iodocholesterol. In summary, there is no clinical data that supports Lucerno Dynamic's claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue.

---

[4] 10 CFR §35.3045(b)

[5] "Passive" patient intervention type was intended to address situations where there was a stasis of arterial flow or shunting of microspheres through aberrant vessels, resulting in a medical event for the Y-90 microsphere therapy. ACMUI Subcommittee on Patient Intervention, Draft Report, Part II, April 27, 2017.

[6] *Id.*

[7] ACMUI, Subcommittee on Extravasation, Final Report, October 23, 2019

[8] van der Pol, J., Vöö1, S., Bucerius, J., and Mottaghy, F. "Consequences of radiopharmaceutical extravasation and therapeutic interventions: a systematic review." Eur J Nucl Med Mol Imaging (2017) 44:1234–1243.

This systematic review also noted that extravasation of therapeutic radiopharmaceuticals is a more significant event that can potentially induce severe soft-tissue reactions and possibly require surgical intervention.[9] In this context, it is important to point out that extravasation of chemotherapeutic agents is an on-going safety concern in medical oncology and that there are well-established procedures for management of extravasated chemotherapeutic agents, similar to those in place for extravasated radiotherapeutic agents.

In summary, we believe that extravasations are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation. Furthermore, the Society recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies, and is actively addressing this as the quality-control issue that it is, rather than a patient-safety issue.

Alan B. Packard, PhD
President, SNMMI

Tina M. Buehner, PhD, CNMT, FSNMMI-TS
President SNMMI-TS

Yang Lu, MD, PhD, FACNM
President, ACNM

Sharmila Dorbala, MD, FASNC
President, ASNC

[9] *Id.* at 1234.

Figure 5: Excerpt from SNMMI campaign monitoring

Source: SNMMI website

TO REPORT FRAUD, WASTE, OR ABUSE

Please Contact:

Online:	Hotline Form
Telephone:	1.800.233.3497
TTY/TDD:	7-1-1, or 1.800.201.7165
Address:	U.S. Nuclear Regulatory Commission Office of the Inspector General Hotline Program Mail Stop O12-A12 11555 Rockville Pike Rockville, Maryland 20852

COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email the OIG.