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

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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

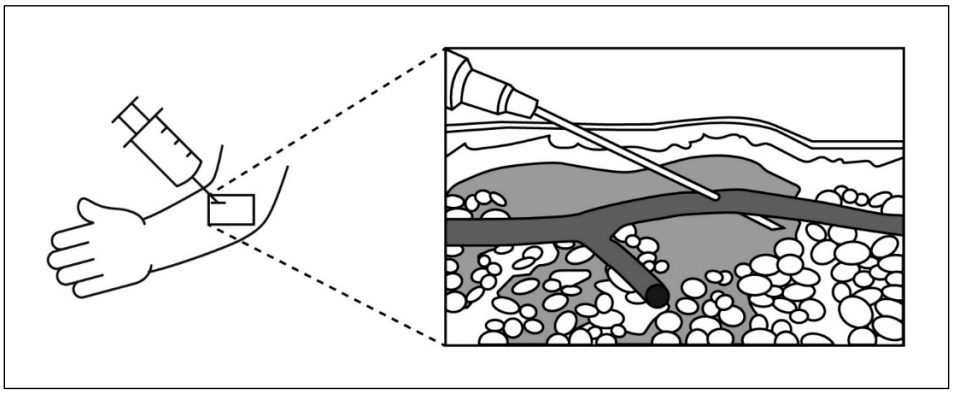
10 C.F.R. Part 35, Medical Use of Byproduct Material

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]

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[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

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[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

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[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."

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[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.

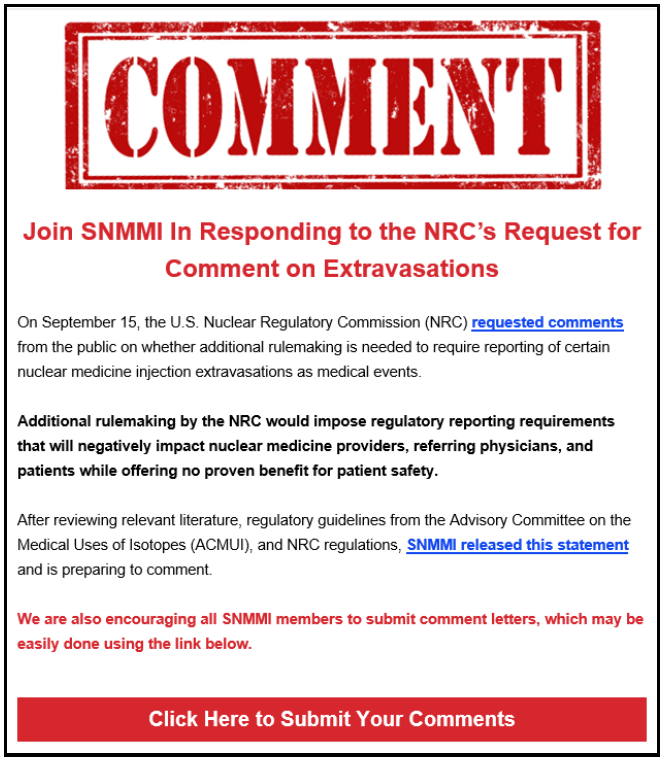
APPENDIX

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]

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[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.

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[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.

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[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.