



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 31, 2025

MEMORANDUM TO: Dr. Michael R. Folkert, Member
Advisory Committee on the
Medical Uses of Isotopes

FROM: John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

A handwritten signature in blue ink, appearing to be "J. Lubinski".

Signed by Lubinski, John
on 01/31/25

SUBJECT: AUTHORIZATION CONCERNING PARTICIPATION IN MATTERS
ON THE ADVISORY COMMITTEE ON THE MEDICAL USES OF
ISOTOPES

In accordance with U. S. Nuclear Regulatory Commission (NRC) Management Directive (MD) 7.9, "Ethics Approvals and Waivers," this confirms that you are authorized to participate personally and substantially in particular matters before the Advisory Committee on the Medical Uses of Isotopes (ACMUI) that are related to, or may inform, the following NRC rulemaking activity:

- Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material (NRC-2018-0297; RIN 3150-AK80)

Specifically, this confirms in accordance with 5 C.F.R. § 2635.502(d) that the NRC's interest in your full participation in activities of the ACMUI sufficiently outweighs any reasonable concern that the integrity or impartiality of the rulemaking activity identified above will be adversely affected because of your outside professional affiliation(s) with the American Society for Radiation Oncology (ASTRO), American Brachytherapy Society (ABS), American Radium Society (ARS), and American College of Radiology (ACR), Southwest Oncology Group (SWOG), and National Cancer Institute Research Group (NRG) Oncology (NRG).¹ This regulation requires that Federal employees (including special government employees (SGEs) serving on an advisory committee) obtain prior written authorization before participating in any "particular matter involving specific parties" where the employee knows a person with whom they have a "covered relationship" is a party or represents a party to the matter. 5 C.F.R. § 2635.502(a)(2). The definition of "covered relationship" includes, among other things, any organization in which the employee is an "active participant." 5 C.F.R. § 2635.502(b)(1)(v).

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¹ Per MD 7.9, the agency designee for this type of authorization is the employee's office director. MD 7.9, section III.F.1(b) Agencywide Document Access and Management System (ADAMS) accession number (ML23230A067). Although the ACMUI is an independent advisory body to the NRC, the committee reports to the Division of Materials, Safety, Security, State, and Tribal Programs (MSST) within the Office of Nuclear Material Safety and Safeguards (NMSS).

I understand that you identified and disclosed to the ACMUI Designated Federal Officer a potential appearance issue, because you hold a committee position and are an active member of two professional medical organizations, ASTRO and ACR, that has also submitted a formal docketed comment on the NRC rulemaking activity identified above. Thus, you sought advice from NRC ethics officials in the Office of the General Counsel (OGC) on whether you needed to recuse from participating in ACMUI matters, including matters before the full committee or subcommittee(s) on which you serve, that could potentially inform or support this NRC rulemaking activity. OGC ethics officials have confirmed that your recusal is not required by 5 C.F.R. § 2635.502 because this NRC rulemaking is a matter of general applicability, and not a “particular matter involving specific parties.”² However, the regulation also includes a catch-all provision that encourages employees to seek prior authorization in any set of circumstances where their participation could raise a question regarding their impartiality (5 C.F.R. § 2635.502(a)(3)). Because ASTRO and ACR have filed comments on the rulemaking docket, OGC ethics officials have advised that a written authorization is desirable, in the interests of transparency and out of an abundance of caution.

Considering the circumstances, I confirm that the NRC’s interest in your full participation in ACMUI activities outweighs any reasonable concern of an appearance of a lack of integrity or impartiality. SGEs serving on advisory committees are accomplished experts in their respective fields and are employed by the NRC on a part-time basis. It is thus customary and expected for SGEs to have affiliations with, and be active participants in, professional organizations outside the agency. Indeed, it would defeat the purpose of your appointment to impose an overly conservative recusal obligation in a matter of general applicability that is of interest to the medical community at large and deprive the NRC of your expertise in radiation oncology. Additionally, the ACMUI is solely an advisory body whose activities are governed by the Federal Advisory Committee Act. This also significantly diminishes the potential for an appearance of improper influence because the business activities of the ACMUI are performed transparently through open public meetings and publicly available records, and thus your contributions to the committee are subject to public scrutiny.

You should not advise the NRC staff on how to resolve or respond to any specific docketed comment(s) submitted by an organization which you have a “covered relationship,” such as ASTRO and ACR.

Additionally, this does not authorize you to participate in a matter involving specific parties before the ACMUI in which an organization which you have a “covered relationship,” such as ASTRO and ACR is or represents one of those specific parties, such as an individual licensing matter or a petition for rulemaking. However, you are authorized to participate in matters of general applicability before the ACMUI, including those that relate to or may inform the NRC rulemaking activity identified above.

² See 5 C.F.R. § 2640.102(l) (defining the term to include “a specific proceeding affecting the legal rights of the parties, or an isolatable transaction or related set of transactions between identified parties”); see also U.S. OFFICE OF GOVERNMENT ETHICS, Legal Advisory 06x9 (Oct. 4, 2006), at 3-4 (stating that “particular matters involving specific parties” does not include “particular matters of general applicability such as rulemaking” or policy-making of general applicability, “unless they focus narrowly on identified parties”).

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