

INSPECTOR GENERAL REPORT: NRC ADVISORS VIOLATED FEDERAL ETHICS RULES

*Patients for Safer Nuclear Medicine coalition demands action on legislation
to protect patients from harmful medical error called extravasation*

WASHINGTON D.C. - A scathing report from the U.S. Nuclear Regulatory Commission's (NRC) own Office of the Inspector General (OIG) has found that two members of NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) violated federal ethics rules regarding rulemaking around radiopharmaceutical extravasations.

The OIG report highlighted the fact that the two ACMUI committee members were also active participants in the Society of Nuclear Medicine and Molecular Imaging (SNMMI), an organization devoted to blocking the reporting of large extravasations.

According to the OIG report, two members of the ACMUI - a committee of paid external advisors - **"failed to follow the procedures in Title 5 of Code of Federal Regulations ..., 'Personal and business relationships,'** when they participated in matters related to PRM-35-22 [extravasation rulemaking petition]." **"These members...carried out a campaign opposing PRM-35-22, at the same time they worked for the ACMUI on matters related to the petition."** (emphasis added)

The OIG report also revealed systemic deficiencies in the NRC's ability to adhere to federal ethics standards, stating, **"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." (emphasis added)

The full OIG report is accessible here: www.oversight.gov/report/NRC/Special-Inquiry-Appearance-Conflict-Interest-Involving-Members-Advisory-Committee-Medical

An extravasation occurs when radioactive drugs are injected into a patient's tissue instead of a vein. Due to a federal regulatory loophole that has been in place since 1980, providers are currently not required to report an extravasation and patients do not even need to be notified.

However, extravasation can be harmful in a number of ways - including exposing patients to radiation levels that exceed the current medical event reporting criteria, compromising the images used to diagnose and treat medical conditions, and also potentially causing cancer.

[Patients for Safer Nuclear Medicine \(PSNM\)](#), a coalition comprising 30 non-profit patient organizations dedicated to enhancing safety and transparency in radiopharmaceutical administrations, praised the OIG report and noted that it is the culmination of more than two years of tireless advocacy.

"From the beginning, NRC and its advisory committee have flat-out dismissed our every attempt to work with them to develop an extravasation policy that protects patients instead of providers," Simon Davies, Executive Director, Teen Cancer America and coalition spokesperson notes. "NRC clearly prioritizes the industry it regulates over the patients it is supposed to protect, and we knew something was up virtually from the start.

“Thankfully, OIG has taken our concerns seriously and raised red flags about the unhealthy ACMUI/SNMMI connection while noting that two members straight-up violated federal ethics rules,” Davies adds. “As patient advocates, we have been let down by the NRC. We have to question whether this Commission can be trusted to protect patients, with their own advisors misleading them. We still urge them to take action because our only recourse now is to take our voice to Congress.”

To that end, while PSNM will continue to monitor developments in the wake of the OIG report, the coalition is now focused on passage of the [Nuclear Medicine Clarification Act \(HR 6815\)](#), which would require the NRC to treat large extravasations like any other medical event.

“HR 6815 represents real patient protection, while improving transparency and encouraging health systems to self-correct their procedures,” Davies says. “The Nuclear Medicine Clarification Act will encourage improved monitoring, stronger reporting, and the development of processes that minimize patient harm while improving outcomes.

“Every day we wait is another day that more patients are harmed by extravasations,” Davies adds. “The time to pass HR 6815 is right now.”