American College of Radiology

May 28, 2024

The Honorable Cathy McMorris Rodgers, Chair
U.S. House Energy and Commerce Committee
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
U.S. House Energy and Commerce Committee
2107 Rayburn House Office Building
Washington, DC 20515

Dear Chair Rodgers and Ranking Member Pallone:

The American College of Radiology (ACR)—a professional association representing over 40,000 physicians and medical physicists with radiation safety expertise—would like to express **strong opposition to H.R. 6815, *The Nuclear Medicine Clarification Act***. If implemented, this bill would have significant harmful impacts for patients in need of nuclear medicine (NM) imaging and cancer care, as well as for all healthcare facilities in which NM services are provided.

The Nuclear Regulatory Commission (NRC) is currently in rulemaking to enable outcome-based reporting of extravasation Medical Events. This NRC rulemaking was the result of a multiyear exploration, with several public comment opportunities, followed by a bipartisan (5-0) decision by NRC Commissioners. If allowed to proceed, H.R. 6815 would undermine the current public process and replace it with unilaterally mandated dose estimates which would be:

- Impractical and costly; requiring novel methods for radiation dose calculations that are insufficiently validated, of contested accuracy, and inappropriate for use by NRC as a regulatory criterion;
- Without any known radiation safety or clinical benefit, or for any meaningful regulatory purpose for the NRC to monitor; and,
- Devised and implemented with sponsorship from, and of singular financial benefit to, one commercial vendor that sells unique injection site probes and calculational software.

Extravasation and Nuclear Medicine

Extravasation (or *infiltration*) occurs when traces of drugs/substances injected into a blood vessel partially leak into surrounding tissue. Extravasation is a known potential occurrence during any intravenous injection and does not indicate error or substandard care. Its occurrence is most frequent with peripheral vascular access (e.g., hand or limb) and in patients in whom vascular access may be more challenging (due to age, obesity, disease/conditions, clotted veins, etc.). Minor leakage, such as typical for NM injections, is often asymptomatic or only mildly symptomatic, transient, and self-limited due to the rapid reabsorption of the extravasated substance and clearance by the body's natural systems without requiring medical intervention.

Extravasation can occur with any intravenously administered substance; however, the injury risk depends on the nature and toxicity of the leaked substance and its volume. Injuries related to extravasation are more likely to occur in the setting of large-volume extravasation (enough to affect adjacent tissues due to the volume), or when the extravasated substance has damaging physiochemical properties such that any contact with soft tissue creates a serious health concern (for example, chemotherapy agents).

In this context, NRC-regulated NM agents are typically low-volume injections of non-caustic/non-damaging compounds, which rapidly disperse and are reabsorbed via physiologic venous and lymphatic channels with ultimate delivery of the reabsorbed substance in the venous system and subsequently to the intended target. Furthermore, the personnel involved in NM agent instillations are highly trained and certified in NM agent

handling and administration as well as possible complications that may be encountered, including extravasation monitoring, mitigation, and management. Therefore, the standard concerns over extravasation injury are not practically applicable to the intravenous administration of NM agents.

As with any known medical complication or side effect, the possibility of extravasation is factored into risk-informed, patient-centric medical decision-making and the consent process. Providers and their patients consider this possibility in context with other risks and benefits of the administered drugs or substances, vascular access sites and the size and stability of the catheter in the vascular access site, as well as the method of administration and how it will be monitored. The goal of this decision-making is to optimize care with minimal overall risk to the patient.

NRC Medical Events (10 CFR 35.3045(a) and (b))

NRC's *Medical Event* rule is used by the agency to collect data and identify trends following major errors of wrong dose/drug/patient/route or serious patient harm. Reported data is housed in a federal database to enable nonpunitive analysis. It is critical that this oversight mechanism be reserved for compiling NRC-actionable data of significance and relevance to the agency. Most current NRC Medical Events involving radioactive materials pertain to sealed sources (e.g., implanted sources) and are not relevant to unsealed NM agents that are injected intravenously. In fact, out of more than 20 million NM procedures and intravenous administrations of NM agents performed annually, there are on average only 8 reported NRC Medical Events involving intravenous NM agents (0.00004% of total procedures).

Patients subject to NRC Medical Events cannot opt out of NRC collecting their data. NRC requires formal notification of referring physicians and/or patients/guardians to ensure they are aware their data is being sent to a federal database. These notifications are exclusively regulatory in nature—they are not medical communications and do not improve care delivery or patient monitoring.

Negative Impacts of H.R. 6815

Despite the low extravasation risk of, and complications related to, intravenously administered NM agents, H.R. 6815 would mandate dose estimates devised by a particular device vendor for use with specific proprietary probes and calculational software during these 20 million NM procedures annually. It would oblige every NRC-licensed facility to purchase several such systems, hire additional personnel to manage the operational aspects, and unjustifiably change how NM agents are administered in ways outside medical standards of care and with no known patient benefit in attempt to address a concern already addressed in the current practice of medicine and not shown to cause significant patient harm. To reiterate, these necessary compliance changes would not be driven by demonstrated or inferable improvements to patient care or radiation safety, but rather only by a need to meet the highly technical and novel compliance calculation in H.R. 6815. This would have **major unintended negative effects and added administrative burden and costs to health care** nationwide:

- All U.S. healthcare facilities that offer NM care, including critical access hospitals and small/rural facilities, would need to acquire new proprietary compliance systems and services requiring significant resources. Based on cost estimates, the compliance burden of H.R. 6815 is likely prohibitively expensive for many smaller facilities, imaging centers, and community hospitals, which may discontinue providing these critical diagnostic and therapeutic procedures thus limiting patient access.
- Patients would have additional out-of-pocket care costs unrecoverable from Medicare/Medicaid or other insurers. Access to NM care would be reduced to fewer facilities, and scheduling in any remaining facilities would be limited by onsite compliance tool availability, delaying cancer diagnoses, assessments, and treatments.

- Some patients—such as those with vascular function irregularities or those medically unable to be probed for the H.R. 6815 calculation—may require more complex, higher risk medical procedures, or alternatively may be unable to benefit from NM imaging and therapy.
- The U.S. availability of NRC compliance systems would be dependent on one device vendor, rendering NM highly sensitive to supply chain disruptions, outages, and ransomware attacks.
- NRC would be forced to collect low quality data of questionable regulatory utility and accuracy, taking oversight resources away from radiation safety priorities and creating data collection burdens for federal and state regulators, despite such data being inactionable.

To summarize, the American College of Radiology is strongly opposed to H.R. 6815, *The Nuclear Medicine Clarification Act,* for the reasons stated. Thank you for your consideration. Please contact Gloria Romanelli, JD, ACR Senior Director, Legislative and Regulatory Relations, at gromanelli@acr.org; or Michael Peters, ACR Senior Government Affairs Director, at mpeters@acr.org, with questions.

Sincerely,

William T. Thorwarth Jr., MD, FACR
Chief Executive Officer
American College of Radiology