



September 10, 2026

Office of Administration
ATTN: Program Management, Announcements and Editing Staff
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Submitted electronically via www.regulations.gov, Docket ID NRC-2025-1237

RE: Proposed Rule, "Reducing Barriers to Medical Use Licensing" (10 CFR Part 35)

To the Office of Administration:

The Cancer Support Community (CSC) appreciates the opportunity to comment on this proposed rule. CSC is a nonprofit organization providing psychosocial support, education, and navigation services to people affected by cancer and their loved ones. We comment on a single question: whether NRC's requirements are clear enough about who may administer radiopharmaceutical therapies, and what the consequences of that ambiguity are for patients seeking access to them.

CSC supports the clarification of supervision requirements

CSC supports NRC's statement that a supervising authorized user need not be physically present at the location of use, nor personally administer the byproduct material, provided that the administration is conducted in accordance with the licensee's procedures, the written directive, and applicable license conditions. This is a meaningful clarification and we encourage NRC to carry it into its guidance so that licensees can rely on it.

The rule does not address who may perform the administration

The proposed rule clarifies where the authorized user must be. It does not address who may perform the physical act of administration. That question remains open, and in our observation it is the one that could govern whether a therapy is available in a given community.

10 CFR 35.27 already permits a licensee to allow an individual to receive, possess, use, or transfer byproduct material under the supervision of an authorized user, provided the licensee instructs that individual in its written radiation protection and written directive procedures and requires adherence to the authorized user's instructions. Part 35 does not by its terms restrict administration to particular professional categories. But because neither the rule nor the guidance says so affirmatively, some licensees and State programs resolve the ambiguity conservatively, and administration may be limited in practice to authorized users and nuclear medicine technologists.

The effect falls unevenly. Academic and large urban centers can staff to the most restrictive plausible reading. Community hospitals, rural sites, and geographically dispersed health systems frequently cannot, and often decline to offer these therapies at all. Patients in those communities do not

experience this as a regulatory ambiguity. They experience it as a several-hour drive, repeated for each cycle of treatment, or as a therapy that is simply not available to them.

The consequence of leaving this unresolved will grow. A March 2026 analysis of ClinicalTrials.gov identified more than 500 radiopharmaceutical therapy trials underway across more than 20 cancer types, and approved indications are moving earlier in the disease course. Ambiguity that today limits access at some sites will, as these therapies multiply, determine which communities can offer them at all.

We note that the administration of infusion-based radiopharmaceuticals is operationally comparable to the administration of chemotherapy, which trained clinical staff routinely perform under detailed physician orders, standardized protocols, and established safety procedures without the physician present at the point of infusion. We are not asking NRC to relax any qualification standard. We are asking NRC to say plainly what its existing performance-based framework already permits, so that ambiguity itself is not the barrier.

CSC requests that NRC state affirmatively, in the final rule or in accompanying guidance, that a licensee may permit individuals who are trained and qualified commensurate with their duties, and authorized under applicable State scope-of-practice law — including registered nurses and advanced practice providers — to perform the administration of radiopharmaceuticals under the supervision of an authorized user and pursuant to a written directive.

Matters on which CSC does not take a position

We wish to be explicit about the limits of our comment.

NRC has sought feedback on whether supervision requirements should be assigned a different compatibility category for purposes of Agreement State adoption. CSC does not take a position on that question. It concerns the allocation of regulatory authority between NRC and the Agreement States and warrants technical and legal analysis we have not been able to complete within this comment period. We observe only that patients experience State-to-State variation as a difference in access depending on where they live, and we would welcome the opportunity to comment further if NRC develops the question in a future proposed rule.

Nor do we take a position on the technical assumptions used in dose calculation, including occupancy factors, or on the qualification criteria for authorized user status. Those are matters for medical physicists, health physicists, and clinical societies. Our comment is limited to the clarity of the framework and its consequences for patient access.

Related comment

CSC is separately submitting comments today in Docket NRC-2026-3730 on Draft Regulatory Guide DG-8070, "Release of Patients Administered Radioactive Material." Those comments address the caregiver and patient-release provisions of 10 CFR 35.75 and include, at Comment 12, a related request that NRC clarify which supervised personnel may carry out release-related functions under Section C.6 of that guide. We reference them here for the convenience of staff considering both dockets.

CSC appreciates NRC's attention to these comments and would be glad to discuss them with staff.

Respectfully submitted,

A handwritten signature in black ink that reads "Sally Werner". The signature is fluid and cursive, with the first name "Sally" and last name "Werner" clearly legible.

Sally Werner, RN, BSN, MSHA
Chief Executive Officer
Cancer Support Community