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Office of Administration
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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Submitted electronically via www.regulations.gov, Docket ID NRC-2026-3730

**RE: Draft Regulatory Guide DG-8070, "Release of Patients Administered Radioactive Material"
(Proposed Revision 2 to Regulatory Guide 8.39)**

To the Office of Administration:

The Cancer Support Community (CSC) appreciates the opportunity to comment on DG-8070. CSC is a nonprofit organization providing psychosocial support, education, and navigation services to people affected by cancer and their loved ones, and conducting research on the patient and caregiver experience through the CSC Research and Training Institute and the Cancer Experience Registry.

We comment from a perspective largely absent from this docket. Prior comment rounds on this guidance drew responses principally from clinical and technical societies. The people whose daily lives are most directly governed by it — patients sent home while still radioactive, and the family members who care for them there — have had little representation. Our comments address that gap.

Framing and scope of these comments

DG-8070 implements a substantially revised 10 CFR 35.75 that creates a new category of individual — the consenting caregiver — who may receive a total effective dose equivalent of up to 50 mSv (5 rem) per administration regimen. That figure is the annual occupational whole-body dose limit for a radiation worker under 10 CFR 20.1201. A radiation worker who receives it does so with training, dosimetry, an ALARA program, and a permanent dose record. Under DG-8070, a spouse receives it after signing a consent form.

CSC does not oppose the caregiver provisions. They expand outpatient access to therapies our constituents need, and for many families the ability to recover at home rather than remain hospitalized is itself a meaningful benefit. Our position is narrower: if NRC is going to permit an untrained family member to receive a full annual occupational dose, the informed consent obtained, the screening performed, and the records kept must be commensurate with that exposure.

We also wish to be explicit about what we are *not* commenting on. Other commenters, in this and prior dockets, have urged NRC to revise the technical assumptions underlying the release calculation, including the occupancy factor applied at one meter. CSC takes no position on those assumptions. They

are questions of dose modeling on which medical physicists and health physicists are far better placed to advise, and nothing in this letter should be read as support for or opposition to any change to them. Our comments concern the procedural safeguards surrounding whatever dose is ultimately permitted — not the calculation of that dose.

I. Informed consent

Comment 1. The guide should specify minimum required elements of caregiver consent.

Revised 10 CFR 35.75(b) conditions release on written consent from both the patient and the caregiver, each having been instructed on the radiation risks and on managing exposure. DG-8070 provides no content standard for that consent. It does not require disclosure of the estimated dose in numeric terms, any benchmark that would let a layperson interpret that number, documentation of what was actually disclosed, a reading-level or plain-language standard, interpretation for individuals with limited English proficiency, a stated right to withdraw consent, or any interval between disclosure and signature.

The substance of what is being consented to is considerable. Section C.6.2.2 sets out the expected post-release conduct: maintaining distance from others, particularly children and pregnant individuals; sleeping separately; abstaining from all forms of intimate contact; reserving a bathroom for the patient; not preparing or sharing food; separate dishware and separate laundering; gloved cleanup of urine and vomit; and bagging the patient's waste separately and holding it in the home until it decays, because landfills detect the radiation and will refuse it. This regimen may run for days or weeks. A consent process that does not describe it concretely is not informed consent.

CSC requests that NRC specify in Section C.6 the minimum elements of caregiver consent, including a numeric dose estimate with an interpretive benchmark, a concrete description of the required post-release conduct and its expected duration, documentation of what was disclosed, and an explicit right to withdraw.

Comment 2. Consent should be obtained during pretreatment planning, not at discharge.

Section C.6.2 provides that where a patient or caregiver "is mentally or physically unable, does not have the resources, or is not willing to agree to comply with release instructions," the licensee must hold the patient as an inpatient. Section C.3 separately observes that identifying a caregiver can enable licensees to release patients more readily.

Read together, these provisions position the consent conversation at the moment a family is told that agreement is what allows their relative to come home. Consent sought under those conditions is not freely given. Section C.6.2.1 already encourages pretreatment discussion of lodging, travel, and

household composition; caregiver consent belongs in that same conversation, when there is time to consider it and an alternative still exists.

CSC requests that NRC provide that caregiver consent be sought during pretreatment planning rather than at discharge, and that a decision to decline be documented as a non-punitive option with a stated alternative pathway for the patient.

II. Access and equity

Comment 3. "Does not have the resources" operates as a socioeconomic screen on access to treatment.

The pretreatment questions in Section C.6.2.1, taken with the inpatient-hold provision in C.6.2, define in practical terms who may receive these therapies on an outpatient basis. They ask what type of lodging the patient will use — the enumerated list includes group home, nursing home, hotel, and detention facility; whether travel will be by private vehicle or public transportation, which the guide states should be discouraged; whether the patient can be isolated within the household; whether the patient can sleep alone in a separate bedroom; and whether the patient can delay returning to work.

Each of these is a proxy for income and housing. Patients in multigenerational or shared housing, patients without a second bathroom or in-unit laundry, patients dependent on public transit, patients who cannot afford unpaid leave, and patients who are unstably housed will disproportionately fail them. The consequence is an inpatient hold, for which there is no coverage guarantee, or no treatment at all. The guide does not acknowledge this consequence or offer licensees any alternative to denial.

CSC requests that NRC acknowledge the access consequence of these criteria in the final guide; add worked examples in Appendix E covering shared housing, absence of a private bedroom or bathroom, transit-dependent patients, and unstably housed patients; and state that a patient's inability to meet these conditions should prompt care coordination and social work referral rather than automatic denial or hold.

Comment 4. The guide develops only one of the two pathways to release.

A caregiver is not required. Section C.3 provides that a licensee may use the caregiver provisions, and that evaluating caregiver exposure alone is insufficient because bystander exposure must still be shown not likely to exceed 5 mSv. A patient released to an environment with no close contacts is evaluated against that bystander standard alone.

There are therefore two paths to release. In the first, a family member consents to receive up to 50 mSv. In the second, the patient isolates — at home in a separate bedroom and bathroom, or in alternative lodging — and no one approaches the higher figure. The first path requires a person. The second requires financial resources.

The guide contemplates the second path but does not build it. "Hotel" appears in the pretreatment lodging question at C.6.2.1(a), and Appendix B.1 directs licensees to evaluate alternative lodging among bystander exposure scenarios. But Appendix E contains no worked example for a solo patient or for alternative lodging; the guide offers no method for the case in which the maximally exposed bystander is, for instance, housekeeping staff entering daily; and every contamination precaution in C.6.2.2 presumes a household the patient controls — separate laundry, waste held for decay, a reserved bathroom — none of which is available in a hotel where staff handle the linens and the trash. Nor does the guide acknowledge that this pathway carries an out-of-pocket cost with no coverage mechanism.

We note that the guide's own lodging list includes group home, nursing home, and detention facility — settings in which a patient can arrange neither path.

This is the one comment in which CSC asks NRC to make release easier rather than harder. The isolation pathway is the pathway that protects families rather than exposing them, and it is underdeveloped relative to its importance.

CSC requests that NRC develop the isolation pathway in the final guide, including Appendix E worked examples for solo patients and alternative lodging, instruction language adapted to settings where the patient does not control laundry, waste, or cleaning, and acknowledgment of the cost this pathway imposes.

III. Dose accounting and records

Comment 5. The revision eliminates any record of the largest permitted exposure in the framework.

Under Section C.7, the records required are the written release procedure, retained for the duration of the license, and — under 10 CFR 20.2107 — the authorized user's justification for caregiver dose in the case of a patient who cannot be released. For a patient who is released, no record is required of the caregiver's identity, of the estimated dose to that caregiver, or of the calculation supporting release. The Discussion section confirms this is deliberate, describing relief from recordkeeping requirements NRC regards as overly burdensome.

The consequence is that the single largest exposure the framework permits is the one it does not document. There is no means of tracking a caregiver across sequential administration regimens, of identifying an individual serving as caregiver for more than one patient, of evaluating the safety of the caregiver provisions in any future rulemaking, or of allowing a caregiver to learn afterward what dose they received. We recognize the burden-reduction objective, but a record of identity and estimated dose is a minimal obligation relative to a 50 mSv authorization.

CSC requests that NRC require a record of caregiver identity and estimated dose for released patients, retained for a defined period, and provide that a caregiver may obtain their own estimated dose on request.

Comment 6. Caregiver doses do not aggregate, and no annual limit applies.

Section C.4.4 provides that a caregiver may visit a patient held as an inpatient under 10 CFR 20.1301(c) and states that dose received in that manner is independent of dose to bystanders or caregivers after release. The effective ceiling for a single individual is therefore approximately 70 mSv per administration regimen. Because an administration regimen is defined by reference to a given radiopharmaceutical, a patient who moves to a second agent begins a new regimen and a new allowance. No annual aggregate limit on caregiver dose appears anywhere in the framework.

This is not a hypothetical accumulation, and it does not depend on a patient receiving more than one course of treatment. A caregiver supporting a patient through a single course of Pluvicto may be authorized for 50 mSv following release, and a further 20 mSv in visits during any inpatient hold, within a period of less than one year.

Repeat treatment compounds this. The American Thyroid Association recommends that radioiodine-avid pulmonary micrometastases be treated with repeat I-131 every six to twelve months so long as disease continues to concentrate iodine and respond clinically, at activities exceeding the caregiver release threshold in table 3. While multiple administration regimens within a single year are not common today, this may change in the future. Indications are moving earlier in the disease course — on July 31, 2026, FDA approved Pluvicto in combination with androgen receptor pathway inhibitor therapy for PSMA-positive metastatic hormone-sensitive prostate cancer — and a March 2026 analysis of ClinicalTrials.gov identified more than 500 radiopharmaceutical therapy trials underway across more than 20 cancer types. As more of these therapies reach approval and patients live longer with metastatic disease, it may become more common for a patient to receive more than one course of radiopharmaceutical therapy, and for one family member to serve as caregiver throughout. Guidance written now should anticipate that.

Under Section C.7, none of this exposure generates a record. Nothing in the framework requires the licensee administering a second course to know that the first occurred, or what dose that caregiver already received. The cumulative exposure of the individual most likely to be exposed is, by design, neither limited nor observable.

CSC requests that NRC establish an annual constraint on the dose any individual may receive as a caregiver, encompassing both post-release exposure and visits during an inpatient hold under 10 CFR 20.1301(c); and, separately, provide a means by which cumulative caregiver dose across successive administration regimens can be identified, whether through the record proposed in Comment 5 or otherwise.

IV. Who may serve as a caregiver

Comment 7. The caregiver definition contains no exclusions for individuals at heightened risk.

The definition at 10 CFR 35.2 requires only that a caregiver be an adult providing support or comfort for non-commercial gain. Nothing excludes an individual who is pregnant, who is breastfeeding, who is immunocompromised, or who is themselves undergoing cancer treatment.

The guide is internally inconsistent on this point. Its model instructions in Section C.6.2 direct patients to maintain distance from pregnant individuals, while its definitions permit a pregnant spouse to consent to 50 mSv. For comparison, 10 CFR 20.1208 limits the dose to the embryo or fetus of a declared pregnant radiation worker to 5 mSv over the entire pregnancy — one-tenth of what an untrained pregnant caregiver could consent to under this framework, and with monitoring the caregiver would not receive.

CSC requests that NRC exclude pregnant individuals from caregiver designation, or apply the 10 CFR 20.1208 constraint to them; and require that pregnancy and breastfeeding status be assessed for the prospective caregiver, not only for the patient.

V. Instructions and comprehension

Comment 8. Language access and comprehension standards are too weak for the function these instructions serve.

Section C.6.2 states that consideration should be given to providing instructions in the patient's native or primary language. This is the weakest formulation available, and these instructions are the operative control on an exposure of up to 50 mSv. NRC's own patient brochure is available only in Spanish, French, and Mandarin.

Comprehension is not incidental here. The guide acknowledges that once a patient is released the licensee has no control over what happens, and that release rests on the patient or caregiver having demonstrated they are able and willing to follow instructions. That demonstration is only meaningful if the instructions were understood.

CSC requests that NRC replace the permissive formulation with a requirement that instructions be provided in a language the patient and caregiver understand; adopt a plain-language and reading-level standard; provide for teach-back confirmation before release; and expand the languages in which NRC's patient materials are available.

Comment 9. Tables 7 and 8 conflict with the approved labeling for the therapeutic agents they cover, and the guidance arrives months after the decision it governs.

CSC welcomes the substantive improvement represented by Section C.5 and Tables 7 and 8. Radionuclide-specific thresholds and interruption intervals are a real advance over prior guidance. Three issues remain, the first two of which we regard as significant.

First, the interruption times in Table 8 conflict with the approved labeling for the therapeutic agents to which they apply. For I-131 sodium iodide at 5.6 GBq, footnoted as the thyroid cancer scenario, Table 8 states an interruption of 1,900 hours — approximately 79 days. The approved labeling contraindicates the drug during lactation and provides that where the drug is administered postpartum, breastfeeding should not be restarted for the remainder of the postpartum period. Professional society patient guidance is to the same effect: a woman must stop before treatment and should not resume for that child, though future children are unaffected.

For Lu-177 octreotate, Table 8 states 540 hours — approximately 23 days — against a single administration of 7.8 GBq. The approved labeling for that product advises women not to breastfeed during treatment and for 2.5 months after the last dose. Across a four-administration regimen at eight-week intervals, that is a period of roughly eight months. A licensee following Table 8 would advise resumption at 23 days per administration, rather than following the guideline-concordant approved labeling.

Second, the guidance arrives too late to be useful. Because lactating breast tissue concentrates iodide, the clinical recommendation for therapeutic radioiodine is to stop breastfeeding well before administration — the labeling directs that breastfeeding and pumping be discontinued at least six weeks beforehand to limit dose to the breast. The decision a breastfeeding patient faces needs to be made at least six weeks before treatment, and it concerns her own breast tissue as well as her infant.

DG-8070 addresses breastfeeding within the release instructions, delivered at discharge. By then the decision has been made, possibly badly, and cannot be revisited. Section C.6.2.1 lists breastfeeding only among factors that "might prevent treatment," which treats it as an eligibility screen rather than as a subject on which the patient is owed timely counseling.

This gap has been brought to the agency's attention before, in a proceeding directly on point. In February 2016, a patient diagnosed with thyroid cancer while breastfeeding a six-month-old infant submitted a comment to Docket NRC-2015-0020, "Sodium Iodide I-131 Patient Release Information Collection." She reported that her endocrinologist knew she had to stop breastfeeding but not for how long, that a consulting oncologist advised six weeks, and that a specialist at another institution advised three months. She resolved the question herself by locating the American Thyroid Association's radiation safety recommendations, which she provided to the agency, and she recommended that any NRC patient-facing materials on I-131 preparation incorporate or link to that guidance. No such provision appears in the draft before us, and the matter is still framed as an interruption addressed at discharge.

Third, the guide identifies the same product under three different conventions. Tables 1 through 3 identify agents by radionuclide alone. Tables 7 and 8 use "Lu-177 octreotate." Appendices E and F use "Lu-177 dotatate (Lutathera®)." These denote the same product. The guide contains no glossary and no cross-reference. A clinician who searches Tables 7 and 8 for the agent named on the order being filled may reasonably conclude it is not listed and that no instruction requirement is triggered. This is a foreseeable error with a direct consequence for an infant, and it is avoidable at the cost of a parenthetical.

CSC requests that NRC: (a) reconcile Tables 7 and 8 with the approved labeling for each listed product, and where the labeling directs that breastfeeding not resume, or not resume for a period exceeding the calculated interruption, state the labeling instruction rather than the calculated figure; (b) provide in Section C.6.2.1 that breastfeeding status be identified and discussed during treatment planning, in sufficient time for a patient to cease lactation before administration, and that the radiation dose to her own breast tissue be addressed; (c) provide that referral to lactation support be offered; (d) state interruption times in days as well as hours, so that they can be used in a conversation with a patient; and (e) adopt consistent pharmaceutical nomenclature across the tables and appendices, including trade names on first use.

VI. Consistency and process

Comment 10. Agreement State variation will produce geographic inconsistency in what patients are told and when they may go home.

Section C.3.1 directs Agreement State licensees to confirm the applicability of the activity thresholds with their respective State authority. Patients experience the resulting variation as a difference in access and in household disruption depending on where they happen to live. We ask NRC to minimize divergence in the provisions that determine what a patient and caregiver are told and what they must do at home. We do not take a position on the compatibility mechanism by which that is accomplished; that is a question of regulatory authority on which we defer to NRC and the Agreement States.

CSC requests that NRC take such steps as are available to it to limit State-to-State divergence in the release thresholds and instruction requirements addressed in Section C.3.1.

Comment 11. The guide presents proposed requirements as settled.

The Introduction and Discussion describe 10 CFR 35.75 as revised. The rule remains proposed. Commenting on implementation guidance for requirements that are not final constrains the public's ability to comment meaningfully on either. This is of particular consequence here because the comment period on the underlying rulemaking closed on August 31, 2026, making this docket the only remaining opportunity to address the caregiver framework on the record.

CSC requests that NRC re-notice DG-8070 for public comment once the underlying revisions to 10 CFR 35.75 are final.

VII. Personnel who may carry out release requirements

Comment 12. The guide should state that qualified supervised individuals may perform the release functions described in Section C.6.

Section C.6 assigns responsibility for the pretreatment interview, caregiver consent, the release survey, and delivery of instructions to "the licensee," without identifying which personnel may carry out those functions. The authorized user is named only in connection with the determination under 10 CFR 20.1301(c) regarding visits to a held patient.

Silence on this point will be resolved conservatively. Licensees uncertain whether these functions may be delegated will assign them to the authorized user, whose availability then governs when a patient can be discharged. The practical result is longer holds, and community and rural sites declining to offer therapies they could otherwise support. 10 CFR 35.27 already permits a licensee to allow an individual to act under the supervision of an authorized user, provided the licensee instructs that individual in its radiation protection and written directive procedures.

CSC requests that NRC state affirmatively in Section C.6 that qualified individuals supervised under 10 CFR 35.27 — including registered nurses and nuclear medicine technologists — may conduct the pretreatment interview, obtain caregiver consent, perform the release survey, and deliver release instructions.

Supporting data and further engagement

NRC's evidentiary basis for patient release has been drawn substantially from licensee-side sources, including a survey of licensees regarding where patients reside following release, together with literature review and dose modeling. Patients and caregivers have not been the source of that evidence.

Cancer Support Community maintains the Cancer Experience Registry, a research study collecting patient-reported and caregiver-reported data on the emotional, physical, practical, and financial impact of cancer, including caregiver burden and training, financial hardship, transportation barriers, disruption to work and household life, and distress. CSC would welcome the opportunity to provide relevant existing findings to NRC staff in support of this rulemaking. We note candidly that these data reflect a sample of Registry participants, are not generalizable to all people affected by cancer, and are not specific to patients receiving radiopharmaceutical therapy. We offer them as evidence of the household and financial conditions the release criteria assume, not as evidence about this patient population in particular.

We also note that DG-8070 incorporates recommendations of the Advisory Committee on the Medical Uses of Isotopes, including on the content of patient instructions. ACMUI includes a standing Patients' Rights Advocate position among a membership otherwise composed of clinical, technical, and regulatory representatives.

CSC requests that NRC refer the questions raised in Comments 1, 2, 7, and 8 — concerning caregiver consent, caregiver screening, and instruction comprehension — to the ACMUI Patients' Rights Advocate and to patient organizations before this guidance is finalized. CSC would welcome the opportunity to serve in that capacity or to support the work of the Committee.

CSC appreciates NRC's attention to these comments and would be glad to discuss any of them with staff. Please direct questions to the undersigned.

Respectfully submitted,

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

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