



ACMUI Comments on the Staff's Recommendations for Revisions to the Patient Release Program

Pat Zanzonico, PhD
ACMUI Vice Chairman
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Subcommittee Members

Susan Langhorst, PhD

Christopher Palestro, MD

Laura Weil

Pat Zanzonico, PhD (Chair)

Subcommittee Charge

To review and provide recommendations on the draft SECY paper, “Staff Recommendations for Revisions to the Patient Release Program.”

Background

- The current “dose-based” Patient Release Rule (10 CFR 35.75) replaced the “activity-based” rule (the “30 mCi rule”) in 1997.
- The current dose-based Rule allows a licensee to release a patient if the TEDE to any other individual, from exposure to the patient, is not likely to exceed 5 mSv (0.5 rem).

Background cont.

- COMGBJ-11-0003 (June 23, 2011): Evaluate whether there are gaps in the available data regarding doses received by members of the public from released patients and, if gaps were found, to provide a recommendation on whether and how such data could be accrued.

Background cont.

- SECY-12-0011, “Data Collection Regarding Patient Release” (Jan 25, 2012): Gaps identified related to (1) internal doses to members of the public and (2) internal and external doses to members of the public from patients released to locations other than their primary residences (hotels and nursing homes).

Documents Reviewed

- Draft SECY paper
- Licensee survey: “Assessment of Where Patients Reside Immediately Following Their Release Report”
- Literature review + Model calculations: “Patient Release Following Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations”

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- The literature review was thorough and the model calculations sound.
- The current dose-based approach to assessing patient releasability validated as more protective of public safety than the activity-based approach.
- The current 5-mSv (500-mrem) projected dose limit should remain a per-event limit and is appropriate for all potentially exposed cohorts, including pregnant women and children.

Subcommittee Comments and Recommendations 2

- The assumption in regulatory guidance that the internal dose contribution is negligible has been validated.
- Other assumptions and methods in regulatory guidance are excessively conservative → NCRP Report No 155.
- A patient staying at a hotel following radionuclide therapy is not a widespread practice and is unlikely to result in doses to workers and others > 1 mSv (100 mrem).

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- Instructions should be provided to the patient well in advance of a planned therapy, but specification of a regulatory time interval for pre-therapy instructions is not recommended → NCRP Report No 155.
- The NRC should consider updating Appendix U (NUREG-1556, Volume 9) to reference Regulatory Guide 8.39 rather than eliminating 8.39 or maintaining two separate guidance documents.

Concluding Remarks

- The findings and recommendations in the draft SECY paper and support documents validate those in the ACMUI's "Patient Release Report" (Dec 13, 2010) and the current Patient Release program.
- The Patient Release Program should be applicable to all radionuclides, flexible, and not overly conservative, so as to not encumber the development of new medical procedures.

Acronyms

- ACMUI: Advisory Committee on Medical Uses of Isotopes
- NCRP: National Council on radiation Protection and Measurement
- TEDE: Total effective dose equivalent