



Status on Data Collection on Patient Release

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Purpose

- To provide an overview and an update of NRC initiatives related to the release of patients administered I-131, especially those who do not immediately return to their primary residences.

Background:

Release Regulations

- May 1997 - NRC revised the patient release regulation (10 CFR 35.75) to release the patient based on the dose to the maximally exposed individual.
- Patients can be released if: The dose to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem).

Background: Release Regulations

- The regulations require that written instructions on how to keep doses to other individuals as low as reasonably achievable (ALARA) be given to patients if there is a possibility that doses to any other individual would exceed 1 mSv (0.1 rem).
- The licensee is required to maintain a record of the basis for authorizing the release.

Iodine-131 Administration

- Increased activities
 - Increased number of procedures
 - Wide variability of administered activities
- Unique Characteristics
 - Volatility
 - Increased potential for external/internal radiation doses
 - Contamination
- Emissions

Current Guidance

- Regulatory Guide 8.39: Release of Patients Administered Radioactive Materials
- NUREG-1556 Vol. 9: Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Licenses
- NRC RIS: 2008-07 Dose Limit For Patient Release Under 10 CFR 35.75

Current Guidance

- NRC RIS: 2008-11 Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration Of Iodine-131
- NRC RIS: 2011-01 NRC Policy On Release Of Iodine-131 Therapy Patients Under 10 CFR 35.75 To Locations Other Than Private Residences

Recent Initiatives

- Commission directed NRC Staff to:
 - Evaluate whether there are gaps in the available empirical data on doses received by members of the public from release of patients treated with medical isotopes.
 - Determine how the agency could go about collecting additional data, if needed.
 - Assess the feasibility of revisiting the dose assessment used to support the 1997 patient release rulemaking.

Data Collection Regarding Patient Release

- In March 2012, the Commission directed staff to perform analytical and limited empirical research/data collection, and revisit calculations and methods described in the Regulatory Guide 8.39 for patient release.

Staff's Proposed Research

- Literature Review
- Review assumptions used in Reg. Guide 8.39
- Survey habits of Released Patients
- Perform empirical measurements
- Assess internal and external radiation exposure
- Re-assess the adequacy of Regulatory Guide 8.39

Conclusions

- Depending on the outcome of the research NRC may:
 - Update Regulatory Guide 8.39
 - Take other actions, as appropriate.



QUESTIONS?