



Briefing on Review of Patient Release Issues 10 CFR 35.75

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Subcommittee Charge

Evaluate patient release issues

- Objectively review and analyze data, regulations/guidance, and international recommendations
- Provide statement on issues, including –
 - Release to other than private residence
 - Per-release limit vs. annual limit
- Recommend needed changes/improvements

Statement

Dose to other individuals is safely and cost-effectively controlled by –

- Current 10 CFR 35.75 release criteria
- Scientifically developed, dose-based release calculation methods and physician assessment of patient release suitability
- Patients' and caregivers' understanding of and adherence to release instructions on maintaining dose to others ALARA

Fundamental principles for use of radioactive materials

- Justification
- Optimization of Protection (ALARA) – account for economic and societal as well as medical factors
- Application of Dose Limits

Statements

Current release criteria appropriately balance safety, access to treatment and cost

- Consistent with national and international recommendations in principle/practice
 - 5 mSv/episode for caregivers/relatives
 - 1 mSv/y for child/pregnant woman/public
- Apply to single releases - not annual limit
- Focus on patient precautions to maintain dose to others ALARA

Statements

Concerning a return to previous NRC patient release criteria – “30 mCi rule”

- Has no identifiable scientific basis
- Excessive for some radionuclides and inadequate for other radionuclides
- Does not account for patient actions
- Specifically not recommended as sole release criterion by ICRP and IAEA
- Inappropriate for NRC regulations

Recommendations

NRC guidance on patient release dose calculation

- Update with current information and realistic assumptions
- Support development of computer-based calculation tools available to licensees
- Address different patient living and other release situations

Recommendations

NRC guidance on patient release instructions

- Incorporate new release calculation information, use new communication tools
- Support research efforts to advance understanding and communication of circumstances that impact patient release decisions, instructions and perceptions

Conclusions

- Medical use is important – benefits millions of patient lives each year
- 10 CFR 35.75 should not be changed
- NRC should focus on providing
 - Appropriate/realistic guidance for licensees and patients
 - Research support for understanding and communication of the real-world issues impacting patient care and public safety

Acronyms

- ALARA – As low as reasonably achievable
- CFR – Code of Federal Regulations
- IAEA – International Atomic Energy Agency
- ICRP – International Council on Radiological Protection
- mCi - millicurie
- 1 mSv – 1 millisievert = 100 mrem
- NRC – Nuclear Regulatory Commission
- Patient – includes clinical patients and human research subjects

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