



Patient Release Subcommittee Report

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Advisory Committee on the Medical Uses of Isotopes

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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**

Discussion

- **Justification (benefits)**
- **Maintaining doses as low as reasonably achievable**
- **Applying appropriate limits**

Discussion

- **Per release vs. annual limit**
- **I-131 vs. other medical radionuclides**
- **NCRP, ICRP and IAEA recommendations - consistency in principle and practice**

Discussion

- **Use of realistic assumptions to assess patient release**
- **Different release scenarios, e.g., hotels**
- **Actual data on exposure to other individuals**

Discussion

- **Written/oral instructions**
- **When given and at what level**
- **Determining suitability of patient release**
- **Development of communication tools**

Discussion

Licensee accountability in regard to

- Released patient waste**
- Death of released patient**
- Patient self-discharge (State use of quarantine authority)**
- Documentation of patient housing arrangements**

Discussion

Comments concerning 30-mCi rule

Discussion

Need for scientific data on patient behavior and effectiveness of communication for patient comprehension

Acronyms

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