



General Views on the Regulation of Medical Uses of Byproduct Material – Part 35

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NRC Medical Use Policy

NRC will, when justified by the risk to the patient, regulate the radiation safety to patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

Medical use of radiation is different.

It involves purposely exposing an individual to radiation to diagnose or treat what can be a serious or life-threatening illness.

Medical use of radiation is different.

**Most NRC regulations -
radiation risk, dose limits, and ALARA**

**Notable exception -
no NRC regulations set a dose limit for
patients; recognize personal benefits**

Medical use of radiation is different.

Medical use regulation requires resources and expertise to develop rules that protect the patient and does not adversely impact the patient-physician relationship.

NRC's Medical staff & resources?

- **6 staff members assigned to NRC Medical Team**
- **Lack practicing medical professionals (physicians and medical physicists) on NRC Staff**
- **ACMUI – Advisory committee to NRC Staff**
- **Who routinely provides the Commission with medical use advice?**

Medical use of radiation is different.

- **“Patient centered”**
- **Requires unique regulatory model which recognizes and respects culture of healthcare**
- **NRC’s Medical Use Policy - promote patient safety without inhibiting patient access to medical care**

- **No medical diagnosis or therapy comes with a guarantee of success no matter how hard we all try to make it so.**
- **It is a challenge to set reasonable controls and to choose reasonable compliance measurements in support of patient safety.**

Challenge of Implementing NRC Medical Use Policy

**Measuring and Documenting
Compliance?**

**Establishing Compliance
Measures?**

Medical use of radiation is different.

Determining reasonable, understandable, and consistent regulatory control of patient safety deserves more resources, different models of using medical expertise, and a more combined effort between NRC, including Agreement States, and the medical community.

Acronyms

**ACMUI – The Advisory Committee
on Medical Uses of Isotopes**

**NRC – U.S. Nuclear Regulatory
Commission**