

September 30, 1997

1979 MEDICAL POLICY STATEMENT

NOTE

Following Commission approval of the staff's program to revise 10 CFR Part 35 and associated guidance documents, the NRC staff initiated development of draft rule language, using a modality-based approach. As directed by the Commission, the staff has developed alternatives, with draft rule text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during the NRC's public meetings and the meetings with medical professional societies during the Fall of 1997 and to assist the staff in developing the proposed rule language. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The NRC staff has not selected any alternative at this time, and is open to additional alternatives which might be proposed that are consistent with the guidance provided by the Commission.

9/25/97

**RECOMMENDATION FOR REVISION TO
NRC'S 1979 MEDICAL POLICY STATEMENT**

OPTION 1: Status Quo

Current statement of general policy to guide regulation of medical uses of radioisotopes states:

1. The NRC will continue to regulate the medical uses of radioisotopes as *necessary to provide for the radiation safety of workers and the general public.*
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

Pros

1. Consistent with NRC's authority in the Atomic Energy Act of 1954, as amended, to regulate domestically the uses of byproduct material, including medical use, to protect public health and minimize danger to life and property.
2. Recognizes that physicians have primary responsibility for protection of their patients, by stating that the NRC will minimize intrusion into medical judgments affecting safety.
3. Regulation of the radiation safety of patients is risk-based.
4. For higher risk activities, NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.
5. Current statement provides for balance between protection of the patient and avoiding intrusion into the practice of medicine.

Cons

1. Allows for some, although minimal, NRC involvement in medical judgements affecting patients.

OPTION 2: April 1997 recommendation of the Advisory Committee on the Medical Uses of Isotopes (ACMUI)

ACMUI recommended statement of general policy to guide regulation of medical uses of radioisotopes would be:

1. [No change.]
2. The NRC will regulate the radiation safety of patients only where justified by the risk to the patients, and only where voluntary standards or compliance with these standards are inadequate. Assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.
3. The NRC will not intrude into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

Pros:

1. Regulation of the radiation safety of patients is risk-based.
2. Acceptable level of risk associated with regulating the medical use of byproduct material may be lower than in other areas of medicine.
3. Clearly states that NRC will not be involved with the physician-patient interface.
4. Recognizes that physicians have primary responsibility for protection of their patients.

Cons

1. Requires NRC to assess risks in other types of medical practices, which may be problematic.
2. Implementation of statements #2 and #3 could be in conflict when the level of risk justifies intrusion.

OPTION 3:

Revised statement of general policy to guide regulation of medical uses of radioisotopes would be:

1. [No change.]
2. The NRC will regulate the radiation safety of patients only where justified by the risk to the patients, and only where voluntary standards or compliance with these standards are inadequate.
3. The NRC will continually strive to minimize involvement in medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

Pros

1. Consistent with NRC's authority in the Atomic Energy Act of 1954, as amended, to regulate domestically the uses of byproduct material, including medical use, to protect public health and minimize danger to life and property.
2. Regulation of the radiation safety of patients is risk-based.
3. For higher risk activities, NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.
4. Recognizes that physicians have primary responsibility for protection of their patients.
5. Provides additional emphasis that NRC's policy is to minimize intrusion into medical practice.

Cons

1. Acceptable level of risk associated with regulating the medical use of byproduct material may be lower than for other areas of medicine.
2. Allows for some, although minimal, NRC involvement in medical judgments affecting patients.

OPTION 4:

Revised statement of general policy to guide regulation of medical uses of radioisotopes would be:

1. [No change.]
2. The NRC will regulate the radiation safety of patients consistent with the risk posed by the radioactive materials. In regulating the radiation safety of patients, NRC's role is to assure that the physician's prescription is accurately delivered to the correct patient.
3. The NRC will not intrude into the medical judgement forming the basis of the physicians' prescription.

Pros

1. Consistent with NRCs authority in the Atomic Energy Act of 1954, as amended, to regulate domestically the uses of byproduct material, including medical use, to protect public health and minimize danger to life and property.
2. Recognizes that physicians have primary responsibility for protection of their patients, by stating that the NRC will not intrude into medical judgements forming the basis of the physicians' prescription.
3. Regulation of the radiation safety of patients is risk-based.

Cons

1. NRC's role in regulating the radiation safety of patients is narrowly focused.