Advisory Committee on Medical Uses of Isotopes
NRC Medical Uses Policy Statement Final Report
May 08, 2014

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***Subcommittee charge*:**
To consider if the Nuclear Regulatory Commission's policy statement on medical uses of byproduct materials should be revised.

Background
The NRC has the responsibility to ensure that the use of radioactive materials under its control is safe for all persons involved with that use as well as the general public. At the same time, the regulations should not be so onerous as to discourage beneficial medical uses. To help balance these potentially conflicting goals, the NRC has established a guidance policy on medical uses of radionuclides. The earliest official policy available to this subcommittee which was developed in 1979, had three principles:

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.

In 2000, the revised policy included four principles:

1. The NRC will continue to regulate the uses of radioisotopes in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

The changes in 2000 clarified that regulations were designed to ensure that a physician's directions are executed correctly and safely and that the development of regulations takes into account professional and industrial standards.

In the middle the past decade it became clear that some aspects of the regulations in 10 CFR 35 were causing problems with medical practice. One example was the definition of a medical event. The definition worked well for external-beam treatment and temporary brachytherapy but was ambiguous and difficult to apply to permanent implants, leading to some conflict between clinicians and regulators. Another problem was the attestation related to preceptor statements, which led some preceptors to refuse to sign the forms required for their trainees to obtain authorization (authorized user status).

This background led to the question of whether the policy on medical uses should be revised.

Subcommittee conclusion

The subcommittee studied the policies from 1979 and 2000 along with the discussions leading to those policies and other proposed policy items. The subcommittee also considered whether or not the current policy fails in either protecting persons or preventing infringement on medical practice.

The subcommittee concluded that the problems encountered with 10 CFR 35 were due to a failure of the regulations to follow the policy, and that the revision of Part 35 brings the regulations into compliance with the policy and eliminates the problems the conflict with policy created. The subcommittee felt that the current policy on medical uses of radionuclides provides effective guidance.

Subcommittee recommendation

The ACMUI feels that the current policy statement provides for the safe medical use of radionuclides for patients, subjects, staff and the general public while avoiding intrusion into the practice of medicine, and no therefore revision is warranted at this time.