POLICY ISSUE

(Notation Vote)

October 31, 2014 SECY-14-0122

FOR: The Commissioners

FROM: Mark. A. Satorius
Executive Director for Operations

SUBJECT: RECOMMENDATION ON WHETHER TO UPDATE THE MEDICAL POLICY STATEMENT

PURPOSE:

This paper provides the staff's recommendation on whether to update the policy statement on Medical Uses of Byproduct Material (Medical Policy Statement). This paper does not address any new commitments or resource implications.

BACKGROUND:

The NRC publishes policy statements to cover broad areas where radiation safety is concerned. Examples include consumer products, decommissioning, medical uses, nuclear fuel, radioactive waste, and safety culture. Policy statements are not considered rules or regulations; however, they do allow the Commission to clarify positions regarding radiation safety issues.

In SRM SECY-13-0084, the Commission approved publication in the *Federal Register* of a proposed rule that would revise regulations related to the medical use of byproduct material in Title 10 *Code of Federal Regulations* (CFR) Part 35. In that SRM, the Commission also directed the staff to provide a voting paper to the Commission that described the staff's recommendation on whether to update the Medical Policy Statement.

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The Medical Policy Statement informs NRC licensees, other Federal and State agencies, and the public of the Commission's general intentions in regulating the medical use of byproduct material. The NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal and State agencies, are guided by the NRC's Medical Policy Statement.

The Medical Policy Statement was initially published on February 2, 1979 (44 FR 8242). Subsequently, following an extensive and public review of the medical use program, the Medical Policy Statement was updated and revised on August 3, 2000 (65 FR 47654). The final Medical Policy Statements, as published in the *Federal Register* in 1979 and 2000, are enclosed for reference. See Enclosures 1 and 2, respectively. The 1979 and 2000 Medical Policy Statements, together with a description of the significant changes made to the 1979 Medical Policy Statement, is provided below.

1979 Medical Policy Statement

Based on experience, comments, and advice from the public, other Federal agencies, the Agreement States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the Commission developed the following statement of general policy in 1979 to guide regulation of the medical uses of radioisotopes:

- 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.
- 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.
- 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.

2000 Medical Policy Statement

On August 3, 2000, the NRC published a revised Medical Policy Statement, which guides NRC's current regulation of the medical use of byproduct material. The changes to the Medical Policy Statement in 2000 were intended to clarify that regulations should assure that a physician's directions are executed correctly and safely and that development of regulations considers professional and industrial standards. The purpose of the revision was also to make clear NRC's intent to *avoid* intrusion into medical judgments affecting patients, rather than the policy of *minimizing* such intrusions. In addition, the Commission rejected the regulation of the medical use of byproduct material on the basis of "*comparable* risk" because of the lack of acceptable data to compare the risks from medical use of byproduct material with risks in other medical modalities. The following is the Commission's policy as set forth in the current Medical Policy Statement:

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

- The 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.
- The NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

DISCUSSION:

The NRC amended its regulations related to the medical use of byproduct material in 10 CFR Part 35 in 2002 and in 2005. Over the last 12 years, medical practitioners have identified certain issues in implementing these regulations. One such issue involves the current criteria for reporting medical events to the NRC. According to practitioners, these criteria appear to work well for external-beam treatments and temporary implant brachytherapy but are problematic with regard to permanent implant brachytherapy. Another concern raised by practitioners was the requirement that preceptor statements attest to the "competency" of individuals in order for them to gain authorization for the medical use of byproduct material. Both the medical event reporting and preceptor attestation issues are being specifically addressed in the proposed rule revising 10 CFR Part 35 that was published in the *Federal Register* on July 21, 2014 (79 FR 42410). In approving publication of the proposed rule, the Commission raised the question to the staff as to whether the Medical Policy Statement needed to be revised in parallel with the regulations.

Options

The NRC staff is providing two options for the Commission's consideration:

Option 1 – The NRC staff should not update the Medical Policy Statement.
Option 2 – The NRC staff should update the Medical Policy Statement.

Under Option 1, the NRC staff would not take any action to revise the current Medical Policy Statement. The staff would continue to use the existing Medical Policy Statement to guide NRC activities in the medical area. The staff would continue to focus efforts on the ongoing 10 CFR Part 35 rulemaking and other high-priority tasks.

Under Option 2, the NRC staff would plan public meetings and workshops and would seek recommendations from ACMUI on potential changes to the Medical Policy Statement. The NRC staff would provide a proposed revised Medical Policy Statement for the Commission's consideration and for publication in the *Federal Register* for public comment. The NRC staff expects that the process could be done with currently budgeted resources.

ACMUI Position

An ACMUI subcommittee reviewed the Medical Policy Statements from 1979 and 2000, together with transcripts of the discussions leading to those policies. The subcommittee also considered whether the current policy had failed in either protecting workers, the public, or patients, or in preventing intrusion into medical practice. The subcommittee concluded that the proposed revision of 10 CFR Part 35 would alleviate concerns of medical practitioners regarding the current regulations in 10 CFR Part 35, specifically with regard to medical event reporting

criteria for permanent implant brachytherapy and attestations for authorized individuals. The subcommittee presented its findings to the full ACMUI for discussion on May 9, 2014. Because the proposed rule changes for 10 CFR Part 35 addresses these concerns, and these proposed changes were promulgated in accordance with the existing Medical Policy Statement, the ACMUI supports Option 1. The ACMUI believes that the current Medical Policy Statement provides for the safe medical use of radionuclides for patients, medical research subjects, workers, and the general public while guarding against intrusion into the practice of medicine, and believes, therefore, that no revision is warranted to the Medical Policy Statement at this time.

Agreement State Views

The NRC staff solicited input from the Agreement States on a draft version of this paper. In response, NRC received one comment from the State of New York. The commenter stated that many of the Agreement State programs are “imbedded” in State Health Departments. These departments have the responsibility to oversee physicians and medical facilities and also have the authority to revoke licenses and permits held by them. The commenter stated that they did not believe that the issue of avoiding a conflict with a State’s oversight of medicine had ever been considered by the ACMUI, and, therefore, the policy did not currently address this issue. The commenter later clarified this concern in a telephone conversation with the staff. As the staff understands the concern from the conversation, it is that there is a difference between the State’s definition of Authorized User and that in the NRC regulations, and that this situation creates a conflict between the State’s regulation of the practice of medicine and the NRC’s regulation of the medical use of radioactive materials. The commenter believes that ACMUI has not considered this issue, and it is not addressed in the Medical Policy Statement.

The NRC staff believes that the issue raised by the commenter is outside of the scope of the Medical Policy. NRC does not require that State medical regulations outside the NRC’s jurisdiction use the same definitions as are used in regulations associated with safe use of radioactive materials. No changes are recommended to the Medical Policy Statement as a result of this comment.

RECOMMENDATION:

The NRC staff recommends Option 1 for the following reasons:

1. The staff believes that the current Medical Policy Statement is effective and sufficiently flexible so as to allow for a balance between the appropriate level of licensee oversight to maintain radiation safety of workers, the public, and patients, and the need to avoid intrusion into the practice of medicine.

2. The staff believes that the proposed changes in the current 10 CFR Part 35 rulemaking would improve the balance needed by physicians to take actions deemed medically necessary, while continuing to enable the NRC to detect deficiencies in processes, procedures, and training. These changes, which the ACMUI has concluded would resolve their existing concerns, were proposed in accordance with the current Medical Policy Statement and thus revisions to the policy statement do not appear to be warranted.

3. The NRC staff relies on the medical expertise of the ACMUI, and the ACMUI does not recommend any changes at this time.

4. The staff notes that the previous revision to the Medical Policy Statement took considerable time, resources, and involved significant public outreach through meetings and workshops. The staff does not foresee significant resulting changes to the existing Medical Policy Statement warranting the reprioritization of existing work.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. This paper represents the views and recommendations of NRC staff, ACMUI, and the Agreement States. The ACMUI and Agreement States received a draft of this paper for comment during the concurrence process.

/RA/

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Enclosures:
1. 1979 Medical Policy Statement (ML003695576)
2. 2000 Medical Policy Statement (ML13270A425)

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