# POLICY ISSUE
## NOTATION VOTE

May 23, 2000 SECY-00-0113

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL

PURPOSE:

To request Commission approval to publish, in the Federal Register, the Year 2000 revision to the Commission's 1979 Medical Use Policy Statement (MPS). (Attachment 1)

CATEGORY:

This paper addresses significant policy issues requiring Commission approval.

BACKGROUND:

Since 1979, the MPS that was published in the Federal Register (FR) on February 9, 1979 (44 FR 8242) (Attachment 2) has provided policy guidance for the Nuclear Regulatory Commission (NRC) activities in the medical area. The 1979 MPS informed "... NRC licensees, other Federal and State agencies, and the general public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes." As stated in that FR notice (FRN), "It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy." (44 FR 8242)

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The three-part 1979 MPS stated:

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 its Staff Requirements Memorandum (SRM) dated March 20, 1997- COMSECY-96-057, "Materials/Medical Oversight (DSI 7)" (Attachment 3), the Commission stated, in part, that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM directed the staff to submit a program for Commission approval for revising 10 CFR Part 35, "Medical Uses of Byproduct Material," and associated guidance documents, and the Commission's 1979 MPS, if necessary.

In its SRM dated June 30, 1997, SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice" (Attachment 4), the Commission approved the staff's proposed plan for the revision of 10 CFR Part 35 and the MPS. The staff implemented that plan by establishing a Working Group and Steering Group to develop the proposed revisions. These groups actively solicited input through facilitated workshops and meetings involving the public, medical professional societies, States, other Federal agencies, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, relevant documents, including the proposed MPS, were posted on the Internet.

Our most recent discussions with the ACMUI on the MPS occurred in March 1998, before the proposed MPS was forwarded to the Commission for approval. The ACMUI voted on suggested changes to the version that the staff was working on at that time. The ACMUI recommended modifying Statement 2 to provide for a risk assessment that references comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice. According to the ACMUI, such an assessment would justify NRC involvement in the radiation safety of patients where voluntary standards or compliance with standards are inadequate. The ACMUI proposed that Statement 3 emphatically state that NRC ...will not intrude ... (rather than "will minimize intrusion") into medical judgments affecting patients, and that the phrase ". . . into other areas traditionally considered to be a part of the practice of medicine" should be deleted. These recommendations were considered during development of the proposed, draft, and final MPS.

In its SRM dated July 9, 1998, "Staff Requirements: SECY-98-127-Draft Proposed Policy Statement on the Medical Use of Byproduct Material" (Attachment 5), the Commission approved publication of a proposed revision of the MPS in the FR. (In the proposed revision to the MPS, statements 2 and 3 of the 1979 MPS were reversed.) The SRM directed staff to solicit specific comment on the proposed change in Statement 2 of the proposed MPS from "NRC will minimize intrusion" to "NRC will not intrude" ["into medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public."]

On August 13, 1998 (63 FR 43852), NRC published the proposed MPS in the FR for a 90-day

comment period, which was later extended an additional 30 days to December 16, 1998. During August, September, and October 1998, the NRC held three transcribed public meetings and participated at the 1998 All-Agreement State meeting to discuss resolution of the major issues associated with the MPS and the major revision to 10 CFR Part 35, "Medical Use of Byproduct Material." There was broad participation from stakeholders at these meetings, including members from various professional societies and representatives from Agreement States and non-Agreement States.

In its SRM dated February 16, 2000, "Staff Requirements: SECY-99-201 - Draft Final Rule - 10 CFR Part 35, 'Medical Use of Byproduct Material'" (Attachment 6), the Commission directed that the staff submit the final Part 35 rulemaking package, including the guidance document and the revised Medical Policy Statement, to the Commission.

DISCUSSION:

The staff extracted 42 specific comments on the proposed MPS from the transcripts of the public meetings and the 10 written comment letters submitted in response to the FRN. Section IV of the draft FRN, "Final Policy Statement on Medical Use of Byproduct Material" (Attachment 1), addresses the 17 issues into which the staff has grouped these comments.

Generally speaking, some comments indicated concurrence with the wording of the proposed MPS (e.g., the revisions improved the 1979 MPS; the revisions were sensible; and the MPS should be issued without further delays). There were very few objections to NRC regulation of the radiation safety of workers and the public. Commenters expressed the following regarding future regulation of patient radiation safety:

1. The NRC should follow the MPS in any future regulatory actions impacting the use of byproduct material for medical use. Prescriptive regulations cannot be justified under either the 1979 MPS or the revised MPS.

2. The NRC should not interfere in the practice of medicine or with medical judgments affecting patients. (The comments cited the NRC patient notification requirement associated with a medical event as a major interference in the patient/physician relationship.)

3. The NRC should regulate medical use of byproduct material only after determining that voluntary medical practice standards are inadequate.

4. NRC's regulations must be based on the potential risk for the type of use (risk of injury from radiation as compared with the risks of injury from other medical procedures).

5. The NRC must restrict its regulation of patient radiation safety to only requiring that the physician's directions are followed.

Several individuals chose to respond to our specific question, in the proposed FRN, on whether Statement 2 should be revised to state that NRC "will not intrude" rather than "will minimize intrusion" into medical judgments. Some commenters appreciated NRC's intent to not intrude into medical judgments, except when necessary to provide radiation safety for workers and the public. These comments noted that the change in emphasis from "minimize" to "not intrude" was important and significant. Other commenters were concerned about

Statement 2, indicating the statement justifies continued intrusion into medical judgments by the NRC, an agency that, in their views, is not the appropriate agency to do so. These commenters believe the NRC has only limited experience in this area. Section IV of the draft FRN (Attachment 1) addresses specific comments on Statement 2 in detail.

Based on the staff's evaluation of all the written comments and input from the public meetings, we are not recommending any changes in the proposed MPS that was published in 1998. The staff believes the 1979 MPS should be revised to incorporate the following four statements from the proposed MPS.

1. 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.

2. 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.

3. 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.

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

In the staff's view, the final MPS affirms the Commission determination that it shall continue its role in regulating the uses of radionuclides in medicine with the goal of providing radiation safety for workers, the public, and patients. The staff believes the MPS appropriately focuses the Commission's direction on radiation safety issues. Moreover, the final MPS includes the objective of using industry and professional standards that define acceptable levels of radiation safety.

COORDINATION:

The Office of the General Counsel has reviewed this paper and the FRN containing the final MPS and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. Resources to develop this policy statement have already been expended as a subcomponent of the effort underway to revise 10 CFR Part 35 in its entirety. The Office of the Chief Information Officer has reviewed the final policy statement for information technology and information management and concurs in it.

RECOMMENDATION:

That the Commission:

1. Approve the final policy statement for publication in the FR.

2. Note:

   A. The MPS will become effective on publication in the FR. It is expected that this statement will be in effect when the revised Part 35 is published in the Federal Register.

   B. The appropriate Congressional committees will be informed.

   C. The Office of Public Affairs has determined that a press release should be issued.

   D. Copies of the FRN will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States, and to other interested parties, on request.

***/RA/***
William D. Travers
Executive Director
for Operations

Attachments:
1. Draft Federal Register Notice
2 1979 Medical Use Policy Statement (44 FR 8242)
3. SRM-COMSECY-96-057, dtd, 3/20/97
4. SRM-SECY-97-115, dtd, 6/30/97
5. SRM-SECY-98-127, dtd, 7/9/98
6. SRM-SECY-99-201, dtd, 2/26/00

RECOMMENDATION:

That the Commission:

1. Approve the final policy statement for publication in the FR.

2. Note:

   A. The MPS will become effective on publication in the FR. It is expected that this statement will be in effect when the revised Part 35 is published in the Federal Register.

   B. The appropriate Congressional committees will be informed

   C. The Office of Public Affairs has determined that a press release should be issued.

   D. Copies of the FRN will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States, and to other interested parties, on request.

***/RA/***

William D. Travers
Executive Director
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Attachments:
1. Draft Federal Register Notice, Accession No. ML003694807
2 1979 Medical Use Policy Statement (44 FR 8242), Accession No. ML003695576
3. SRM-COMSECY-96-057, dtd, 3/20/97. Accession No. ML003695004
4. SRM-SECY-97-115, dtd, 6/30/97, Accession No. ML003695012
5. SRM-SECY-98-127, dtd, 7/9/98, Accession No. ML003695163
6. SRM-SECY-99-201, dtd, 2/26/00, Accession No. ML003695190

ADAMS PACKAGE ACCESSION NO. ML003714748
File Name: (g:\haney\mpscp3.wpd) Accession No. ML003694795

*See previous page for concurrences.

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