UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 23, 2000

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0113

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 23, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-00-0113

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	6/13/00
COMR. DICUS	X				X	6/19/00
COMR. DIAZ	X				X	6/8/00
COMR. McGAFFIGAN	X				X	6/16/00
COMR. MERRIFIELD	X					6/13/00

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and most provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on June 23, 2000.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

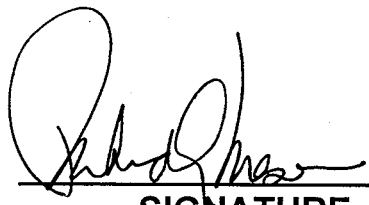
SUBJECT: SECY-00-0113 - DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL

Approved X X w comments **Disapproved** _____ **Abstain** _____

Not Participating _____ **Request Discussion** _____

COMMENTS:

I approve the publication of the Medical Use Policy Statement in the Federal Register subject to the attached edits of the notice.



SIGNATURE

June 13, 2000

DATE

Entered on "STARS" Yes ✓ No ____

ATTACHMENT 1

Draft Federal Register Notice

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Medical Use of Byproduct Material; Policy Statement, Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statement; revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its 1979 policy statement on the medical use of byproduct material. These revisions are one component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and more performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." The policy informs NRC licensees, other Federal and State agencies, and the public of the Commissions's general intentions in regulating the medical use of byproduct material.

EFFECTIVE DATE: [Insert date of publication in the Federal Register.]

On August 6, 1997 (62 FR 42219-42220), NRC published a document in the Federal Register, "Medical Use of Byproduct Material: Issues and Request for Public Input," describing NRC's detailed, four-year examination of the issues surrounding its medical use program. This process started with a 1993 internal senior management review; continued with a 1996 independent external review by the National Academy of Sciences (NAS), Institute of Medicine (IOM); and culminated in NRC's Strategic Assessment and Rebaselining Project (SA). Since that Federal Register notice was issued, NRC conducted an exhaustive and public review of the medical use program. Specifically, in 1997 and 1998, NRC's current and future role in regulating the medical use of byproduct material was discussed at meetings of the Advisory Committee on Medical Uses of Radioisotopes[1] (ACMUI) and the Organization of Agreement States (OAS), and with various professional societies and government agencies. During this period, the NRC staff also presented four proposed revised alternative versions of the 1979 Medical Policy Statement (MPS) to participants at NRC sponsored workshops and public meetings. These workshops and public meetings also included discussions on the major areas that were being considered for revision in 10 CFR Part 35, "Medical Use of Byproduct Material."

On August 13, 1998 (63 FR 43580), a proposed revision to the MPS was published in the Federal Register for a 90 day public comment period. This comment period was later extended 30 days, to December 16, 1998, (63 FR 64829; November 23, 1998) to allow additional time for public, stakeholder, and State comment. In addition, to allow for wide participation in the process, NRC discussed the proposed revision of the MPS with interested individuals and organizations at 3 public meetings during the comment period (i.e., San Francisco, California, on August 19 and 20, 1998; Kansas City, Missouri, September 16 and 17, 1998; and in Rockville, Maryland, October 21 and 22, 1998).

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[1]The ACMUI advises the Commission on regulating and licensing uses of radionuclides in medicine.

administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in Part 35" (60 FR 48623).

The provisions of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to . . . other requirements in this chapter" (Section 30.2). This section requires that "any conflict between the general requirements in Part 30 and the specific requirements in another part" are governed by those specific requirements (Section 30.2). The regulations in Part 35 are designed "to provide for the protection of the public health and safety" and reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, "the patient . . . as well as the general public . . . are all members of the public to be protected by NRC" (44 FR 8242, at 8244).

IV. Discussion of Public Comments

As previously noted, NRC received 42 comments on the proposed revision to the MPS, taken from 10 letters that were submitted and the transcripts of the 3 public meetings. NRC received verbal comments on the proposed MPS (63 FR 43580; August 13, 1998) from stakeholders (e.g., physicians, medical physicists, nuclear medicine technologists, and radiation safety professionals) during the public meetings that were held in August, September, and October 1998). Stakeholders also submitted written comments to NRC in response to that Federal Register document.

Issue 4: Should NRC regulation of the medical use of byproduct material be based on Section 104 of the Atomic Energy Act?

Comment. A commenter disagreed with NRC's interpretation that section104 of the AEA applies only to special nuclear material. In the commenter's opinion, NRC medical use regulation should be based on section 104 of the AEA.

Response. NRC's principal authority for regulating medical use of byproduct material is at Sections 81, 162, and 183 of the AEA. As previously discussed under Section III, "Rationale", NRC regulation of byproduct material is not bound by the limitation in section 104.a. of the AEA, that refers to minimal regulation of reactor facilities or special nuclear material used for medical therapy.

Comments on Statements 1, 2, 3, and 4 of the MPS

Statement 1 **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.**

Issue 1: Should the MPS refer to "radionuclides" or to "byproduct materials?"

Comment. Several commenters noted that Statement 1 made reference to uses of radionuclides in medicine. They indicated that NRC only has the statutory authority to regulate byproduct material.

Response. The Commission believes that the general term "radionuclide" is appropriate for a general statement of policy such as the MPS. The latter is intended to inform the public, NRC licensees, and other Federal and State agencies of the Commission's general intentions

Issue 1: Does this statement provide justification for NRC to interfere in the treatment of patients?

Comment. One commenter was concerned that Statement 2 continues to justify NRC interference in the treatment of patients. According to the comment, there is no supporting data that clearly demonstrates that unsealed byproduct material, when used by qualified authorized users to treat patients, has harmed workers or the public.

Response. Statement 2 does not provide justification for NRC to interfere in the medical treatment of patients. The modifications to this statement express the Commission's policy not to intrude (rather than "minimizing" intrusion as set forth on the 1979 MPS) into judgments affecting patients except to provide for the radiation safety of workers and the general public. Providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection involves a degree of regulation of medical judgments affecting patients, the NRC may find it necessary to intrude, to a certain extent, into medical judgments affecting patients.

For example, the release from a hospital of a patient who has been administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment ("Criteria for the Release of Individuals Administered Radioactive Material," 62 FR 4120; January 29, 1997). From a medical point of view, it may be appropriate for a physician to release from a hospital a patient who has been administered radioactive materials. However, the patient release criteria in NRC regulations may require hospital confinement of that patient if his or her release could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA

(44 FR 8242; February 9, 1979). Commission regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration that are not listed in the FDA-approved package insert. In addition, Commission regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. The recent amendment of 10 CFR 35.75, cited above, substitutes a dose-based limit for patient release (rather than an activity-based limit) that may provide medical use licensees greater flexibility in determining when patients may be released from their control.

Finally, Statement 2 of the MPS is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." (There are certain exceptions to this mandate, which do not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.) "Food and Drug Administration Modernization Act of 1997," Pub. L. No. 105-115, sec. 906, 111 Stat. 2296 (1997).

Issue 2: Is the NRC the appropriate body to be involved in medical judgments affecting patients?

Comment. According to one commenter, the NRC is not the right body to intrude into medical judgments affecting patients because NRC's experience in this area is extremely limited.

Response. As discussed above and noted in Statement 2, the Commission's policy is not to intrude into medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

This comment does not account for the principle that "[t]he substantive area in which an agency is deemed to be expert is determined by statute." Massachusetts v. United States, 856 F.2d 378, 382 (1st Cir. 1988). See also, Commonwealth of Massachusetts v. NRC, 924 F.2d 311, 324 (D.C. Cir), cert. denied, 112 S. Ct. 275 (1991). The AEA commits to the NRC the duty of regulating the use of radioactive byproduct materials, including radiopharmaceuticals, to protect public health and safety.

Issue 3: Should this statement include reference to providing for the radiation safety of workers and the general public?

Comment. Several commenters requested that Statement 2 be revised to read, as follows, "NRC will not intrude into medical judgements." They believed that the last phrase, "... except as necessary to provide for the radiation safety of workers and the general public," should be deleted.

Response. The Commission does not agree that this statement should be revised as indicated by the commenters because providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. The final MPS explicitly states that the Commission's intention is not to intrude into medical judgments affecting patients except to provide for the radiation safety of workers and the general public. When this protection necessitates a degree of regulation of medical judgments affecting patients, the NRC may find it necessary, as previously explained, to intrude, to a certain extent, into medical judgments to protect the public and workers.

Statement 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.**

radiation safety (44 FR 8243; February 9, 1979). NRC will continue to regulate the radiation safety of patients when justified by the risk to patients, primarily to ensure that the authorized user physician's directions are followed. The Commission recognizes that physicians have primary responsibility for the protection of their patients. However, NRC's role is also necessary to ensure radiation safety of patients.

Issue 3: Does NRC regulation of the medical use of byproduct material duplicate FDA regulation?

Comment. One commenter noted that any attempt by NRC to regulate the radiation safety of patients would duplicate the efforts of the FDA and state boards of pharmacy and medicine and, as such, would be an unwarranted intrusion into the practice of medicine.

Response. The Commission disagrees with this comment. NRC is responsible for regulating the actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures to the public, patients, and occupational workers. In general, the FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products (i.e., drugs, devices, and biologics). NRC routinely relies on prior FDA approval of medical devices as an essential component of NRC's sealed source and device safety evaluations. In a "Memorandum of Understanding" (MOU), effective August 26, 1993, NRC and FDA coordinated existing NRC and FDA regulatory programs for these devices, drugs, and products (58 FR 47300; September 8, 1993).

NRC regulation of the medical use of byproduct material does not duplicate licensing by State boards of pharmacy and medicine of pharmacists and physicians, respectively, to practice pharmacy or medicine within their borders. NRC regulations rely on the licensure of these professionals by a State (or Territory of the U.S., the District of Columbia, or Puerto Rico) to practice their

acceptable levels of achieving radiation safety. NRC reviewed industry and professional standards in developing and implementing Part 35 and the guidance document (NUREG 1556, Volume 9). For example, some provisions in 10 CFR Part 35 allow medical licensees the flexibility to meet the performance standards reflected in the rule.

(Part of the thought is missing, deleted in prior editing)

Consideration of industry and professional standards as part of NRC's policy to achieve radiation safety in medical use of byproduct material conforms to the Commission's Strategic Plan[4] that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." This strategy is to increase the involvement of licensees and others in the NRC regulatory development process, based on the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTTAA), Pub. L. No.104-113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies ... as a means to carry out policy objectives or activities, 'except when use of such standards,' is inconsistent with applicable law or otherwise impractical."

Not all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTTAA ("performance-based or design-specific technical specifications and related management systems practices"). Nevertheless, as indicated above, in regulating medical use of byproduct material, the Commission endorses the concept in Section 12 (a) of the NTTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations."

Issue 2: Should NRC consider task group reports of the American Association of Physicists in Medicine (AAPM) for developing approaches for achieving radiation safety?

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[4] Page 10, NUREG-1614, Vol. 1, "Strategic Plan, Fiscal Year 1997 - Fiscal Year 2002"

Comment. A commenter pointed out that, in defining acceptable approaches for achieving radiation safety, NRC should consider the task group reports of the AAPM, which are the latest standards of practice for medical physicists.

Response. The Commission agrees that AAPM standards of practice for professionals involved in the use of certain byproduct material modalities and for radiation safety equipment should be considered as part of NRC's risk-informed and performance-based approaches to regulating the medical use of byproduct material. The Commission acknowledges that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. Therefore, where appropriate, NRC focused Part 35 on performance objectives to be achieved by licensees and is allowing licensees to select among the various performance standards to meet the objective of the regulation. This provides licensees significant flexibility in designing its radiation protection program. For example, in developing the final rule for the therapeutic uses of sealed sources, the NRC consulted several AAPM reports, including the reports from Task Groups 40, 56, and 59, and Report No. 54.

In addition to the AAPM, other groups and societies set professional radiation safety and practice standards for medical use. NRC plans to review such standards for possible use in developing regulatory positions, (e.g., National Council on Radiation Protection and Measurements, Health Physics Society, and Society of Nuclear Medicine).

Issue 3: Does the existence of professional standards mean that NRC regulation is unnecessary?

Comment. Several commenters expressed the opinion that NRC regulations were unnecessary. They believe that NRC should not make regulations or license conditions out of industry or professional standards, because that reduces flexibility (i.e., regulations cannot evolve as quickly and easily as professional standards). In their opinion, NRC should recognize

NOTATION VOTE

RESPONSE SHEET 2000 MAY 24 AM 11:22

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-00-0113 - DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits.

Greta Joy Dicus
SIGNATURE

June 19, 2000
DATE

Entered on "STARS" Yes X No ____

Commissioner Diaz edits.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Medical Use of Byproduct Material; Policy Statement, Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statement; revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its 1979 policy statement on the medical use of byproduct material. These revisions are one component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and more performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." The policy informs NRC licensees, other Federal and State agencies, and the public of the Commissions's general intentions in regulating the medical use of byproduct material.

EFFECTIVE DATE: [Insert date of publication in the Federal Register.]

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[1]The ACMUI advises the Commission on regulating and licensing uses of radionuclides in medicine.

161i. authorizes the Commission to "prescribe such regulations or orders as it may deem necessary" to "(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property" [42 U.S.C. 2201(i) (emphasis added)].

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to "protect health and minimize danger to life." This statutory standard applies to the myriad of uses of byproduct material, including not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104.a. of the AEA, which is often mistakenly cited for the proposition that, in regulating the medical use of byproduct material, the AEA requires that the Commission "impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public" [(42 U.S.C. 2134(a)]. This "minimum regulation" limitation does not apply to the medical use of byproduct material which falls within NRC's broad standard-setting authority in sections 81 and 161. Section 104.a., on its face, applies only to medical therapy licenses for "utilization facilities" (e.g., reactors) and "special nuclear material." This "minimum regulation" directive does not govern the Commission's regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR Parts 30 through 39. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 as stated in section 20.1002 is that, "[t]he limits in this part do not apply to doses due . . . to any medical administration the individual has received or due to voluntary participation in medical research programs." The Commission has clarified that "the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical

administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in Part 35" (60 FR 48623).

The provisions of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to . . . other requirements in this chapter" (Section 30.2). This section requires that "any conflict between the general requirements in Part 30 and the specific requirements in another part" are governed by those specific requirements (Section 30.2). The regulations in Part 35 are designed "to provide for the protection of the public health and safety" and reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, "the patient . . . as well as the general public . . . are all members of the public to be protected by NRC" (44 FR 8242, at 8244).

IV. Discussion of Public Comments

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Comment. A commenter disagreed with NRC's interpretation that section 104 of the AEA applies only to special nuclear material. In the commenter's opinion, NRC medical use regulation should be based on section 104 of the AEA.

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Issue 1: Should the MPS refer to "radionuclides" or to "byproduct materials?"

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Response. The Commission believes that the general term "radionuclide" is appropriate for a general statement of policy such as the MPS. The latter is intended to inform the public, NRC licensees, and other Federal and State agencies of the Commission's general intentions

Issue 1: Does this statement provide justification for NRC to interfere in the treatment of patients?

Comment. One commenter was concerned that Statement 2 continues to justify NRC interference in the treatment of patients. According to the comment, there is no supporting data that clearly demonstrates that unsealed byproduct material, when used by qualified authorized users to treat patients, has harmed workers or the public.

Response. Statement 2 does not provide justification for NRC to interfere in the medical treatment of patients. The modifications to this statement express the Commission's policy not to intrude (rather than "minimizing" intrusion as set forth on the 1979 MPS) into judgments affecting patients except to provide for the radiation safety of workers and the general public. Providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection involves a degree of regulation of medical judgments affecting patients, the NRC may find it necessary to intrude, to a certain extent, into medical judgments affecting patients.

For example, the release from a hospital of a patient who has been administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment ("Criteria for the Release of Individuals Administered Radioactive Material," 62 FR 4120; January 29, 1997). From a medical point of view, it may be appropriate for a physician to release from a hospital a patient who has been administered radioactive materials. However, the patient release criteria in NRC regulations may require hospital confinement of that patient if his or her release could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA

(44 FR 8242; February 9, 1979). Commission regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration that are not listed in the FDA-approved package insert. In addition, Commission regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. The recent amendment of 10 CFR 35.75, cited above, substitutes a dose-based limit for patient release (rather than an activity-based limit) that may provide medical use licensees greater flexibility in determining when patients may be released from their control.

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Comment. According to one commenter, the NRC is not the right body to intrude into medical judgments affecting patients because NRC's experience in this area is extremely limited.

Response. As discussed above and noted in Statement 2, the Commission's policy is not to intrude into medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

acceptable levels of achieving radiation safety. NRC reviewed industry and professional standards in developing and implementing Part 35 and the guidance document (NUREG 1556, Volume 9). For example, some provisions in 10 CFR Part 35 allow medical licensees the flexibility to meet the performance standards reflected in the rule.

Consideration of industry and professional standards as part of NRC's policy to achieve radiation safety in medical use of byproduct material conforms to the Commissions's Strategic Plan[4] that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." This strategy is to increase the involvement of licensees and others in the NRC regulatory development process, based on the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTTAA), Pub. L. No.104-113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies ... as a means to carry out policy objectives or activities, 'except when use of such standards,' is inconsistent with applicable law or otherwise impractical."

Not all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTTAA ("performance-based or design-specific technical specifications and related management systems practices"). Nevertheless, as indicated above, in regulating medical use of byproduct material, the Commission endorses the concept in Section 12 (a) of the NTTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations."

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Comment. A commenter pointed out that, in defining acceptable approaches for achieving radiation safety, NRC should consider the task group reports of the AAPM, which are the latest standards of practice for medical physicists.

Response. The Commission agrees that AAPM standards of practice for professionals involved in the use of certain byproduct material modalities and for radiation safety equipment should be considered as part of NRC's risk-informed and performance-based approaches to regulating the medical use of byproduct material. The Commission acknowledges that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. Therefore, where appropriate, NRC focused Part 35 on performance objectives to be achieved by licensees and is allowing licensees to select among the various performance standards to meet the objective of the regulation. This provides licensees significant flexibility in designing its radiation protection program. For example, in developing the final rule for the therapeutic uses of sealed sources, the NRC consulted several AAPM reports, including the reports from Task Groups 40, 56, and 59, and Report No. 54.

In addition to the AAPM, other groups and societies set professional radiation safety and practice standards for medical use. NRC plans to review such standards for possible use in developing regulatory positions, (e.g., National Council on Radiation Protection and Measurements, Health Physics Society, and Society of Nuclear Medicine).

Issue 3: Does the existence of professional standards mean that NRC regulation is unnecessary?

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NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-00-0113 - DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits.

RECD BY NJD

24 MAY 00 13 58

SIGNATURE

June 8, 2000

DATE

Entered on "STARS" Yes X No ____

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Medical Use of Byproduct Material; Policy Statement, Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statement; revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its 1979 policy statement on the medical use of byproduct material. These revisions are one component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and more performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." The policy 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.

EFFECTIVE DATE: [Insert date of publication in the Federal Register.]

On August 6, 1997 (62 FR 42219-42220), NRC published a document in the Federal Register, "Medical Use of Byproduct Material: Issues and Request for Public Input," describing NRC's detailed, four-year examination of the issues surrounding its medical use program. This process started with a 1993 internal senior management review; continued with a 1996 independent external review by the National Academy of Sciences (NAS), Institute of Medicine (IOM); and culminated in NRC's Strategic Assessment and Rebaselining Project (SA). Since that Federal Register notice was issued, NRC conducted an exhaustive and public review of the medical use program. Specifically, in 1997 and 1998, NRC's current and future role in regulating the medical use of byproduct material was discussed at meetings of the Advisory Committee on Medical Uses of Radioisotopes[1] (ACMUI) and the Organization of Agreement States (OAS), and with various professional societies and government agencies. During this period, the NRC staff also presented four alternative versions of the 1979 Medical Policy Statement (MPS) to participants at NRC sponsored workshops and public meetings. These workshops and public meetings also included discussions on the major areas that were being considered for revision in 10 CFR Part 35, "Medical Use of Byproduct Material."

On August 13, 1998 (63 FR 43580), a proposed revision to the MPS was published in the Federal Register for a 90 day public comment period. This comment period was later extended 30 days, to December 16, 1998, (63 FR 64829; November 23, 1998) to allow additional time for public, stakeholder, and State comment. In addition, to allow for wide participation in the process, NRC discussed the proposed revision of the MPS with interested individuals and organizations at 3 public meetings during the comment period (i.e., San Francisco, California, on August 19 and 20, 1998; Kansas City, Missouri, September 16 and 17, 1998; and Rockville, Maryland, October 21 and 22, 1998).

[1]The ACMUI advises the Commission on regulating and licensing uses of radionuclides in medicine.

161i. authorizes the Commission to "prescribe such regulations or orders as it may deem necessary" to "(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property" [42 U.S.C. 2201(I) (emphasis added)].

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to "protect health and minimize danger to life." This statutory standard applies to the myriad of uses of byproduct material, including not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104.a. of the AEA, which is often mistakenly cited for the proposition that, in regulating the medical use of byproduct material, the AEA requires that the Commission "impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public" [42 U.S.C. 2134(a)]. This "minimum regulation" limitation does not apply to the medical use of byproduct material which falls within NRC's broad standard-setting authority in sections 81 and 161. Section 104.a., on its face, applies only to medical therapy licenses for "utilization facilities" (e.g., reactors) and "special nuclear material." This "minimum regulation" directive does not govern the Commission's regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR Parts 30 through 39. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 as stated in Section 20.1002 is that, "[t]he limits in this part do not apply to doses due . . . to any medical administration the individual has received or due to voluntary participation in medical research programs." The Commission has clarified that "the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical

administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in Part 35" (60 FR 48623).

The provisions of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to . . . other requirements in this chapter" (Section 30.2). This section requires that "any conflict between the general requirements in Part 30 and the specific requirements in another part" are governed by those specific requirements (Section 30.2). The regulations in Part 35 are designed "to provide for the protection of the public health and safety" and reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, "the patient . . . as well as the general public . . . are all members of the public to be protected by NRC" (44 FR 8242, at 8244).

IV. Discussion of Public Comments

As previously noted, NRC received 42 comments on the proposed revision to the MPS, taken from 10 letters that were submitted and the transcripts of the 3 public meetings. NRC received verbal comments on the proposed MPS (63 FR 43580; August 13, 1998) from stakeholders (e.g., physicians, medical physicists, nuclear medicine technologists, and radiation safety professionals during the public meetings that were held in August, September, and October 1998). Stakeholders also submitted written comments to NRC in response to that Federal Register document.

the radiation safety of patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients. Moreover, there is nothing in the Commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material.

Issue 2: Should the MPS be revised more frequently?

Comment. A commenter noted that the proposed revision is an improvement over the 1979 MPS; however, the commenter recommended that the NRC review the MPS more frequently (e.g., every 10 years).

Response. How often the Commission reviews and/or revises the MPS depends on a variety of factors. These factors may be internal, such as the need for a change in the focus of NRC's regulations, as well as external factors such as technological developments. NRC believes that a set interval to review the MPS would not provide the flexibility needed to respond to the many factors which may influence a decision to revise this policy. For example, this revision of the MPS coincides with the NRC's detailed examination of its medical use program which started in 1993 and includes issuance of the Commission's 1997 Strategic Plan (NUREG-1614, Vol. 1).

Issue 3: Is the MPS being revised to justify the new Part 35?

Comment. Several commenters noted that the current MPS was adequate for effective regulation in safeguarding public health and safety in radiation protection and should not be revised, but simply understood and implemented as originally intended. Several other opinions were stated more strongly. Specifically, ~~that~~ NRC has never paid meaningful attention to the

Issue 4: Should NRC regulation of the medical use of byproduct material be based on Section 104 of the Atomic Energy Act?

Comment. A commenter disagreed with NRC's interpretation that section 104 of the AEA applies only to special nuclear material. In the commenter's opinion, NRC medical use regulation should be based on section 104 of the AEA.

Response. NRC's principal authority for regulating medical use of byproduct material is at Sections 81, 162, and 183 of the AEA. As previously discussed under Section III, "Rationale", NRC regulation of byproduct material is not bound by the limitation in section 104.a. of the AEA, that refers to minimal regulation of reactor facilities or special nuclear material used for medical therapy.

Comments on Statements 1, 2, 3, and 4 of the MPS

Statement 1 **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.**

Issue 1: Should the MPS refer to "radionuclides" or to "byproduct materials?"

Comment. Several commenters noted that Statement 1 made reference to uses of radionuclides in medicine. They indicated that NRC only has the statutory authority to regulate byproduct material.

Response. The Commission believes that the general term "radionuclide" is appropriate for a general statement of policy such as the MPS. The latter is intended to inform the public, NRC licensees, and other Federal and State agencies of the Commission's general intentions

Issue 1: Does this statement provide justification for NRC to interfere in the treatment of patients?

Comment. One commenter was concerned that Statement 2 continues to justify NRC interference in the treatment of patients. According to the comment, there is no supporting data that clearly demonstrates that unsealed byproduct material, when used by qualified authorized users to treat patients, has harmed workers or the public.

Response. Statement 2 does not provide justification for NRC to "interfere" in the medical treatment of patients. The modifications to this statement express the Commission's policy not to intrude (rather than "minimizing" intrusion as set forth in the 1979 MPS) into judgments affecting patients except to provide for the radiation safety of workers and the general public. Providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection involves a degree of regulation of medical judgments affecting patients, the NRC may find it necessary to intrude, to a certain extent, into medical judgments affecting patients.

For example, the release from a hospital of a patient who has been administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment ("Criteria for the Release of Individuals Administered Radioactive Material," 62 FR 4120; January 29, 1997). From a medical point of view, it may be appropriate for a physician to release from a hospital a patient who has been administered radioactive materials. However, the patient release criteria in NRC regulations may require hospital confinement of that patient if his or her release could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA

(44 FR 8242; February 9, 1979). Commission regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration that are not listed in the FDA-approved package insert. In addition, Commission regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. The recent amendment of 10 CFR 35.75, cited above, substitutes a dose-based limit for patient release (rather than an activity-based limit) that may provide medical use licensees greater flexibility in determining when patients may be released from their control.

Finally, Statement 2 of the MPS is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." (There are certain exceptions to this mandate, which do not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.) "Food and Drug Administration Modernization Act of 1997," Pub. L. No. 105-115, sec. 906, 111 Stat. 2296 (1997).

Issue 2: Is the NRC the appropriate body to be involved in medical judgments affecting patients?

Comment. According to one commenter, the NRC is not the right body to intrude into medical judgments affecting patients because NRC's experience in this area is extremely limited.

Response. As discussed above and noted in Statement 2, the Commission's policy is not to intrude into medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

acceptable levels of achieving radiation safety. NRC reviewed industry and professional standards in developing and implementing Part 35 and the guidance document (NUREG 1556, Volume 9). For example, some provisions in 10 CFR Part 35 allow medical licensees the flexibility to meet the performance standards reflected in the rule.

Consideration of industry and professional standards as part of NRC's policy to achieve radiation safety in medical use of byproduct material conforms to the Commission's Strategic Plan[4] that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." This strategy is to increase the involvement of licensees and others in the NRC regulatory development process, based on the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTTAA), Pub. L. No.104-113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies ... as a means to carry out policy objectives or activities, 'except when use of such standards,' is inconsistent with applicable law or otherwise impractical."

Not all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTTAA ("performance-based or design-specific technical specifications and related management systems practices"). Nevertheless, as indicated above, in regulating medical use of byproduct material, the Commission endorses the concept in Section 12 (a) of the NTTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations."

Issue 2: Should NRC consider task group reports of the American Association of Physicists in Medicine (AAPM) for developing approaches for achieving radiation safety?

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[4] Page 10, NUREG-1614, Vol. 1, "Strategic Plan, Fiscal Year 1997 - Fiscal Year 2002"

Comment. A commenter pointed out that, in defining acceptable approaches for achieving radiation safety, NRC should consider the task group reports of the AAPM, which are the latest standards of practice for medical physicists.

Response. The Commission agrees that AAPM standards of practice for professionals involved in the use of certain byproduct material modalities and for radiation safety equipment should be considered as part of NRC's risk-informed and performance-based approaches to regulating the medical use of byproduct material. The Commission acknowledges that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. Therefore, where appropriate, NRC focused Part 35 on performance objectives to be achieved by licensees and is allowing licensees to select among the various performance standards to meet the objective of the regulation. This provides licensees significant flexibility in designing its radiation protection program. For example, in developing the final rule for the therapeutic uses of sealed sources, the NRC consulted several AAPM reports, including the reports from Task Groups 40, 56, and 59, and Report No. 54.

In addition to the AAPM, other groups and societies set professional radiation safety and practice standards for medical use. NRC plans to review such standards for possible use in developing regulatory positions, (e.g., National Council on Radiation Protection and Measurements, Health Physics Society, and Society of Nuclear Medicine).

Issue 3: Does the existence of professional standards mean that NRC regulation is unnecessary?

Comment. Several commenters expressed the opinion that NRC regulations were unnecessary. They believe that NRC should not make regulations or license conditions out of industry or professional standards, because that reduces flexibility (i.e., regulations cannot evolve as quickly and easily as professional standards). In their opinion, NRC should recognize

published protocol that was accepted by a nationally recognized body in order to meet the performance objectives of these regulations. This approach is consistent with the Commission's goal to develop performance-based regulations. The Commission believes this approach provides significant flexibility for medical use licensees to design their radiation protection programs that, when fully implemented, maintain radiation exposures to workers, patients, and the public to levels that are as low as are reasonably achievable.

Dated at Rockville, Maryland, this _____day of _____, 2000.

For the Nuclear Regulatory Commission.

_____
Annette L. Vietti-Cook,
Secretary of the Commission.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-00-0113 - DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL**

Approved w/edits X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits.

Edward McGaffigan Jr.
SIGNATURE

June 16, 2000
DATE

Entered on "STARS" Yes X No ____

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Medical Use of Byproduct Material; Policy Statement, Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statement; revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its 1979 policy statement on the medical use of byproduct material. These revisions are one component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and more performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." The policy 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.

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[1]The ACMUI advises the Commission on regulating and licensing uses of radionuclides in medicine.

NRC received 42 specific comments on the proposed MPS from various organizations and individuals. These comments were extracted from the transcripts of the 3 public meetings and the 10 written comment letters submitted in response to the Federal Register document. Additional details about the comments are provided in Section IV, "Discussion of Public Comments." These comments were similar to the comments that were discussed in the August 13, 1998 (63 FR 43582-43583), Federal Register. Based on NRC's consideration of all the comments, no changes to the proposed MPS are being made. (See the final statements that appear in Section II, below.)

II. Statement of General Policy

This NRC policy statement informs NRC licensees, other Federal and State agencies, and the public of the Commission's general intentions regarding the regulation of the medical use of byproduct material. The current revision of 10 CFR Part 35 is based on this statement of NRC policy. The Commission expects that future NRC rulemaking activities in the medical area and involvement with other Federal and State agencies will follow this statement of policy. This NRC policy promotes ~~the~~ a more risk-informed approach to regulation of byproduct material.

The following is the final Medical Use Policy Statement to guide NRC's future regulation of the medical use of byproduct material.

1. 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. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

161.i.

161i. authorizes the Commission to "prescribe such regulations or orders as it may deem necessary" to "(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property" [42 U.S.C. 2201(l) (emphasis added)].

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to "protect health and minimize danger to life." This statutory standard applies to the myriad of uses of byproduct material, including not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104.a. of the AEA, which is often mistakenly cited for the proposition that, in regulating the medical use of byproduct material, the AEA requires that the Commission "impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public" [42 U.S.C. 2134(a)]. This "minimum regulation" limitation does not apply to the medical use of byproduct material which falls within NRC's broad standard-setting authority in sections 81 and 161. Section 104.a., on its face, applies only to medical therapy licenses for "utilization facilities" (e.g., reactors) and "special nuclear material." This "minimum regulation" directive does not govern the Commission's regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR Parts 30 through 39. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 as stated in section 20.1002 is that, "[t]he limits in this part do not apply to doses due . . . to any medical administration the individual has received or due to voluntary participation in medical research programs." The Commission has clarified that "the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical

administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in Part 35" (60 FR 48623).

The provisions of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to . . . other requirements in this chapter" (Section 30.2). This section requires that "any conflict between the general requirements in Part 30 and the specific requirements in another part" are governed by those specific requirements (Section 30.2). The regulations in Part 35 are designed "to provide for the protection of the public health and safety" and reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, "the patient . . . as well as the general public . . . are all members of the public to be protected by NRC" (44 FR 8242, at 8244).

IV. Discussion of Public Comments

As previously noted, NRC received 42 comments on the proposed revision to the MPS, taken from 10 letters that were submitted and from the transcripts of the 3 public meetings. NRC received verbal comments on the proposed MPS (63 FR 43580; August 13, 1998) from stakeholders (e.g., physicians, medical physicists, nuclear medicine technologists, and radiation safety professionals) during the public meetings that were held in August, September, and October 1998. Stakeholders also submitted written comments to NRC in response to that Federal Register document.

NRC has reviewed all comments, identified the issues raised by the commenters, and combined comments where appropriate. The following discussion includes these issues, the combined comments, and the NRC responses to these combined comments.

General Comments

Issue 1: Absent harm, what is the purpose of NRC regulation?

Comment. A commenter stated that only physicians can determine what is unnecessary radiation exposure to patients. This commenter cited the "Rationale" portion of the August 13, 1998 (63 FR 43584) document about the responsibility of NRC to regulate actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures. According to the commenter, "If the patient exposure is unnecessary and harm is done, then the physician may be guilty of malpractice (monetary awards, civil penalties, possible loss of medical license, etc.). NRC regulations won't prevent malpractice and NRC penalties are the least of the guilty physician's worries. If the patient exposure is unnecessary but no harm is done, then the physician may be still guilty of fraud (billing for unnecessary procedures). But if no harm is done, what is the purpose of NRC regulation?"

Response. The purpose of NRC regulation of the medical use of byproduct material is to reduce unnecessary radiation exposure to patients, workers, and the public. Protection of patient radiation safety is an overall goal in regulating the medical use of byproduct material. The focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radiation or radionuclide, rather than to other, non-radiation related aspects of the administration. Although the Commission recognizes that physicians have primary responsibility for the protection of their patients, NRC also has a necessary role with respect to

the radiation safety of patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients. Moreover, there is nothing in the Commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material.

Issue 2: Should the MPS be revised more frequently?

Comment. A commenter noted that the proposed revision is an improvement over the 1979 MPS; however, the commenter recommended that the NRC review the MPS more frequently (e.g., every 10 years).

Response. How often the Commission reviews and/or revises the MPS depends on a variety of factors. These factors may be internal, such as the need for a change in the focus of NRC's regulations, ~~as well as~~ or external factors such as technological developments. NRC believes that a set interval to review the MPS would not provide the flexibility needed to respond to the many factors which may influence a decision to revise this policy. For example, this revision of the MPS coincides with the NRC's detailed examination of its medical use program which started in 1993 and includes issuance of the Commission's 1997 Strategic Plan (NUREG-1614, Vol. 1).

Issue 3: Is the MPS being revised to justify the new Part 35?

Comment. Several commenters noted that the current MPS was adequate for effective regulation in safeguarding public health and safety in radiation protection and should not be revised, but simply understood and implemented as originally intended. Several other opinions were stated more strongly. Specifically, one commenter stated that NRC has never paid meaningful attention to the

MPS because most existing provisions of Part 35 do not "pass muster" under the MPS, particularly as they apply to physicians conducting nuclear medicine procedures. Another commenter's opinion was that the proposed MPS was a step backward and the MPS is being revised to justify the proposed rule.

Response. The Commission agrees that the 1979 MPS was adequate. However, based on the Commission's recent review of its regulatory framework for medical use of byproduct material, these revisions are being made to emphasize a risk-informed regulatory approach. The Commission strongly disagrees with the commenters' opinions that the medical use regulations in Part 35 were promulgated without considering the 1979 MPS. In point of fact, all Part 35 rulemaking activities have been issued after ensuring compatibility with the 1979 MPS.

After the Commission initiated the review process in 1993, the policy and the rule were revised in parallel in order to achieve a consistent regulatory framework for medical use of byproduct material. As stated before in response to other comments and explanations of the background for this matter, the Commission's Strategic Assessment in 1997 included a decision to consider developing a more risk-informed, performance-based approach. In the process, the three-part 1979 MPS was revised into a four-part MPS with re-arranged statements to clarify NRC's policy.

The revised MPS was published for public comment in the Federal Register (63 FR 43580 - 43586; August 13, 1998) and was discussed at meetings with stakeholders and Agreement States. Discussions with stakeholders were meaningful and beneficial, and addressed substantive issues from the medical community (e.g., patient safety, perceived NRC intrusion into the practice of medicine, and regulatory relief for diagnostic nuclear medicine). No new issues were identified during the public comment period and NRC has not revised the MPS any further.

Issue 4: Should NRC regulation of the medical use of byproduct material be based on Section 104 of the Atomic Energy Act?

Comment. A commenter disagreed with NRC's interpretation that section104 of the AEA applies only to special nuclear material. In the commenter's opinion, NRC medical use regulation should be based on section 104 of the AEA.

Response. NRC's principal authority for regulating medical use of byproduct material is at Sections 81, ~~182~~ 161, 182, and 183 of the AEA. As previously discussed under Section III, "Rationale", NRC regulation of byproduct material is not bound by the limitation in section 104.a. of the AEA, that refers to minimal regulation of reactor facilities or special nuclear material used for medical therapy.

Comments on Statements 1, 2, 3, and 4 of the MPS

Statement 1 **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.**

Issue 1: Should the MPS refer to "radionuclides" or to "byproduct materials?"

Comment. Several commenters noted that Statement 1 made reference to uses of radionuclides in medicine. They indicated that NRC only has the statutory authority to regulate byproduct material.

Response. The Commission believes that the general term "radionuclide" is appropriate for a general statement of policy such as the MPS. The latter is intended to inform the public, NRC licensees, and other Federal and State agencies of the Commission's general intentions

Issue 1: Does this statement provide justification for NRC to interfere in the treatment of patients?

Comment. One commenter was concerned that Statement 2 continues to justify NRC interference in the treatment of patients. According to the comment, there is no supporting data that clearly demonstrates that unsealed byproduct material, when used by qualified authorized users to treat patients, has harmed workers or the public.

Response. Statement 2 does not provide justification for NRC to interfere in the medical treatment of patients. The modifications to this statement express the Commission's policy not to intrude (rather than "minimizing" intrusion as set forth in the 1979 MPS) into judgments affecting patients except to provide for the radiation safety of workers and the general public. Providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection involves a degree of regulation of medical judgments affecting patients, the NRC may find it necessary to intrude, to a certain extent, into medical judgments affecting patients.

For example, the release from a hospital of a patient ~~who has~~ to whom radioactive materials have been administered ~~radioactive materials~~ has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment ("Criteria for the Release of Individuals Administered Radioactive Material," 62 FR 4120; January 29, 1997). From a medical point of view, it may be appropriate for a physician to release from a hospital a patient ~~who has~~ to whom radioactive materials have been administered ~~radioactive materials~~. However, the patient release criteria in NRC regulations may require hospital confinement of that patient if his or her release could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA

(44 FR 8242; February 9, 1979). Commission regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration that are not listed in the FDA-approved package insert. In addition, Commission regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. The recent amendment of 10 CFR 35.75, cited above, substitutes a dose-based limit for patient release (rather than an activity-based limit) that may provide medical use licensees greater flexibility in determining when patients may be released from their control.

Finally, Statement 2 of the MPS is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." (There are certain exceptions to this mandate, which do not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.) "Food and Drug Administration Modernization Act of 1997," Pub. L. No. 105-115, sec. 906, 111 Stat. 2296 (1997).

Issue 2: Is the NRC the appropriate body to be involved in medical judgments affecting patients?

Comment. According to one commenter, the NRC is not the right body to intrude into medical judgments affecting patients because NRC's experience in this area is extremely limited.

Response. As discussed above and noted in Statement 2, the Commission's policy is not to intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

This comment does not account for the principle that "[t]he substantive area in which an agency is deemed to be expert is determined by statute." Massachusetts v. United States, 856 F.2d 378, 382 (1st Cir. 1988). See also, Commonwealth of Massachusetts v. NRC, 924 F.2d 311, 324 (D.C. Cir), cert. denied, 112 S. Ct. 275 (1991). The AEA commits to the NRC the duty of regulating the use of radioactive byproduct materials, including radiopharmaceuticals, to protect public health and safety.

Issue 3: Should this statement include reference to providing for the radiation safety of workers and the general public?

Comment. Several commenters requested that Statement 2 be revised to read, as follows, "NRC will not intrude into medical judgments." They believed that the last phrase, "... except as necessary to provide for the radiation safety of workers and the general public," should be deleted.

Response. The Commission does not agree that this statement should be revised as indicated by the commenters because providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. The final MPS explicitly states that the Commission's intention is not to intrude into medical judgments affecting patients except to provide for the radiation safety of workers and the general public. When this protection necessitates a degree of regulation of medical judgments affecting patients, the NRC may find it necessary, as previously explained, to intrude into medical judgments to protect the public and workers.

Statement 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.**

radiation safety (44 FR 8243; February 9, 1979). NRC will continue to regulate the radiation safety of patients when justified by the risk to patients, primarily to ensure that the authorized user physician's directions are followed. The Commission recognizes that physicians have primary responsibility for the protection of their patients. However, NRC's role is also necessary to ensure radiation safety of patients.

Issue 3: Does NRC regulation of the medical use of byproduct material duplicate FDA regulation?

Comment. One commenter noted that any attempt by NRC to regulate the radiation safety of patients would duplicate the efforts of the FDA and state boards of pharmacy and medicine and, as such, would be an unwarranted intrusion into the practice of medicine.

Response. The Commission disagrees with this comment. NRC is responsible for regulating the actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures to the public, patients, and occupational workers. In general, the FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products (i.e., drugs, devices, and biologics). NRC routinely relies on prior FDA approval of medical devices as an essential component of NRC's sealed source and device safety evaluations. In a "Memorandum of Understanding" (MOU), effective August 26, 1993, NRC and FDA coordinated existing NRC and FDA regulatory programs for these devices, drugs, and products (58 FR 47300; September 8, 1993).

NRC regulation of the medical use of byproduct material does not duplicate licensing by State boards of pharmacy and medicine of pharmacists and physicians, respectively, to practice pharmacy or medicine within their borders. NRC regulations rely on the licensure of these professionals by a State (or Territory of the U.S., the District of Columbia, or Puerto Rico) to practice their

medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased. The Commission also examined whether continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated MPS, NRC held public workshops with early opportunities for comment from potentially affected parties. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

Although a formal risk assessment was not performed, the Commission believes that the risks associated with use of byproduct material in medicine have been adequately evaluated and considered. Based on these considerations, the revised regulatory approach is more risk-informed and more performance-based and significantly reduces regulatory burden in many areas. The Commission has retained prescriptive regulatory requirements (e.g., in Part 35) only where it believes they are necessary to ensure adequate protection of workers, patients, and the public. However, there is nothing in the NRC's regulations that prohibits the medical community or other stakeholders from conducting an independent formal risk assessment of the medical use of byproduct material and forwarding its analysis and recommendations for Commission consideration.

Issue 5: Should NRC be involved with prescriptions for the medical use of byproduct material?

Comment. A commenter pointed out that NRC should not be involved with prescriptions because the requirements for accurate delivery of prescriptions are covered under state medical and pharmacy law. The commenter believes that written directives are not necessary to ensure high confidence that the actual administration of radiation to the patient was intended by the authorized user.

Response. The Commission's statutory authority to regulate the medical use of byproduct material provides for NRC to have a role with respect to patient radiation safety. Statement 3 narrows the primary focus of NRC regulation of the radiation safety of patients primarily on whether the physician's directions for the administration of byproduct material are followed. This regulatory role is in contrast to the broad regulation by a State board of pharmacy or medicine of the general practice of those disciplines within its borders.

The Commission is not using the term "prescription" because it might typically include aspects of the administration that are outside NRC's purview. Instead, the term "written directive" (as defined in Part 35) is used to specify the physician's directions (i.e., the procedure to be performed and the dose or dosage). This regulatory objective is currently reflected in provisions of Part 35 requiring "high confidence" that byproduct material will be administered as directed by an authorized user physician.

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

Issue 1: How should industry standards be used in regulating the medical use of byproduct material?

Comment. According to several commenters, the NRC ignores professional standards and regulates as it pleases. In the commenters' opinions, NRC should accord industry and professional standards the respect they deserve. They believe that if NRC in fact endorses standards developed by private, consensus organizations, the revised MPS would be improved.

Response. The Commission believes that Statement 4 commits NRC to an approach for regulation of medical use that considers both industry and professional standards that define

acceptable levels of achieving radiation safety. NRC reviewed industry and professional standards in developing and implementing Part 35 and the guidance document (NUREG 1556, Volume 9). For example, some provisions in 10 CFR Part 35 allow medical licensees the flexibility to use standards from nationally recognized organizations to meet the performance standards reflected in the rule.

Consideration of industry and professional standards as part of NRC's policy to achieve radiation safety in medical use of byproduct material conforms to the Commission's Strategic Plan[4] that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." ~~This strategy is to increase the involvement of licensees and others in the NRC regulatory development process, based on~~ the NRC's intention is to consider industry and professional standards in developing regulations and guidance for the medical use program, consistent with the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTTAA), Pub. L. No.104-113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies ... as a means to carry out policy objectives or activities, 'except when use of such standards,' is inconsistent with applicable law or otherwise impractical."

Not all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTTAA ("performance-based or design-specific technical specifications and related management systems practices"). Nevertheless, as indicated above, in regulating medical use of byproduct material, the Commission endorses the concept in Section 12 (a) of the NTTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations."

Issue 2: Should NRC consider task group reports of the American Association of Physicists in Medicine (AAPM) for developing approaches for achieving radiation safety?

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[4] Page 10, NUREG-1614, Vol. 1, "Strategic Plan, Fiscal Year 1997 - Fiscal Year 2002"

Comment. A commenter pointed out that, in defining acceptable approaches for achieving radiation safety, NRC should consider the task group reports of the AAPM, which are the latest standards of practice for medical physicists.

Response. The Commission agrees that AAPM standards of practice for professionals involved in the use of certain byproduct material modalities and for radiation safety equipment should be considered as part of NRC's risk-informed and performance-based approaches to regulating the medical use of byproduct material. The Commission acknowledges that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. Therefore, where appropriate, NRC focused Part 35 on performance objectives to be achieved by licensees and is allowing licensees to select among the various performance standards to meet the objective of the regulation. This provides licensees significant flexibility in designing its radiation protection program. For example, in developing the final rule for the therapeutic uses of sealed sources, the NRC consulted several AAPM reports, including the reports from Task Groups 40, 56, and 59, and Report No. 54.

In addition to the AAPM, other groups and societies set professional radiation safety and practice standards for medical use. NRC plans to review such standards for possible use in developing regulatory positions (e.g., National Council on Radiation Protection and Measurements, Health Physics Society, and Society of Nuclear Medicine).

Issue 3: Does the existence of professional standards mean that NRC regulation is unnecessary?

Comment. Several commenters expressed the opinion that NRC regulations were unnecessary. They believe that NRC should not make regulations or license conditions out of industry or professional standards, because that reduces flexibility (i.e., regulations cannot evolve as quickly and easily as professional standards). In their opinion, NRC should recognize

published protocol that was accepted by a nationally recognized body in order to meet the performance objectives of these regulations. This approach is consistent with the Commission's goal to develop more performance-based regulations. The Commission believes this approach provides significant flexibility for medical use licensees to design ~~their~~ radiation protection programs that, when fully implemented, maintain radiation exposures to workers, patients, and the public to levels that are as low as are reasonably achievable.

Dated at Rockville, Maryland, this _____day of _____, 2000.

For the Nuclear Regulatory Commission.

_____
Annette L. Vietti-Cook,
Secretary of the Commission.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-00-0113 - DRAFT FINAL POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT MATERIAL**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

6/13/00

DATE

Entered on "STARS" Yes ✓ No ____