1. The NRC will continue to regulate the medical use 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 intruder into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal agencies, have been guided by this policy.

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 document was issued, NRC conducted an exhaustive and public review of the medical use program. Specifically, in 1997 and 1998, NRC's current and future roles in regulating the medical use of byproduct material was discussed at meetings of the Advisory Committee on Medical Uses of Radioisotopes (ACMU) 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 proposed revised 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 64669; November 23, 1998) to allow additional time for public, stakeholder, and State comments. 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 (San Francisco, California; on August 19 and 20, 1998; Kansas City, Missouri; on September 16 and 17, 1998; and Rockville, Maryland, on October 21 and 22, 1998). 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 future NRC involvement with other Federal and State agencies will follow this statement of policy. This NRC policy promotes 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.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

III. Rationale

NRC's principal statutory authority for regulating medical use of byproduct material is 85, 161, 182, and 183 of the Atomic Energy Act of 1954, as amended (AEA). See 42 U.S.C. 2111, 2201, 2232, and 2233. Section 81 of the Act prohibits, without NRC authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material (42 U.S.C. 2111). Specifically, section 81 of the AEA provides in pertinent part that:

The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor as approved by the Commission. Id. (emphasis added).

By virtue of section 161 of the Act, the Commission is authorized to undertake a variety of measures "(in) the performance of its functions" (42 U.S.C. 2201). As stated in subsection b, the Commission may "establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable . . . to protect health or to minimize danger to life or property" (42 U.S.C. 2201(b) (emphasis added)). Similarly, section 161(i) 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 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 104a. 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 104a., 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 the portion of these regulations, 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
§ 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 30." (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" (§ 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 (§ 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 (§ 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 the 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 the Commission 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 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, or external, such as technological developments. NRC believes that a set interval to review the MPS would 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 Revisited 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
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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 section
104 of the AEA applies only to special
nuclear material. In the commenter's
opinion, NRC's medical use regulations
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, 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 regarding the regulation of
medical use. The 1979 MPS referred to
"medical uses of radioisotopes" and the
term is now being changed to "uses of
radionuclides in medicine" (see 63 FR
43584; August 13, 1998). As rephrased,
the term "radionuclide" is a more
accurate technical statement of the
scope of NRC regulation in this area.

Issue 2: Is Statement 1 Needed if
Individuals Handling Radioactive Material
Are Properly Trained?

Comment. According to one
commenter, the goal of this statement is
adequately served by assuring
qualification of professionals involved
in nuclear medicine. In the commenter's
opinion, NRC has no evidence that these
individuals do not already adequately
provide for the radiation safety of
workers and the public, and nuclear
medicine is of low risk to workers and
members of the public.

Response. The Commission agrees
that one way of meeting the goal is to
ensure that individuals are adequately
trained in radiation safety practices and
are placed in key positions within a
licensee's organization to maintain
radiation exposures as low as are
reasonably achievable. Statement 1 sets
forth this position. As previously stated,
the Commission is bound by statute to
regulate byproduct material (and source
and special nuclear materials) to
"protect health and minimize danger to
life." Statement 1 of the MPS continues
to provide a regulatory approach to
maintain an adequate level of safety.
The Commission expects all medical
licensees to provide radiation safety for
workers and the general public.

Statement 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.

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
harmful 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,
to medical judgments affecting
patients.

For example, the release from a
hospital of a patient to whom
radioactive materials have been
administered 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 4126;
January 28, 1997). From a medical point
of view, it may be appropriate for a
physician to release from a hospital a
patient to whom radioactive materials
have been administered. 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
regent 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
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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 fact that the 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, 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.

Issue 1: Does This Statement Conflict With Statement 2?

Comment. One commenter believed that, as written, Statement 3 conflicted with Statement 2, unless the word "primarily" was deleted from Statement 3. Without this change, the commenter believed NRC would intrude into medical judgments affecting patients.

Response. The Commission does not agree that, as written, Statement 3 conflicts with Statement 2. Statement 3 makes clear that 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. Statement 2 emphasizes the intent of NRC to avoid intrusion into medical judgments affecting patients, except where necessary to provide for the radiation safety of workers and the public. NRC's goal in this aspect of medical use regulation is focused on the physician's directions as they pertain to the administration of a radiopharmaceutical or a radionuclide, rather than to other, non-radiation-related aspects of the administration. Consistent with its statutory authority, if a situation should arise in the future that identifies an additional risk to a patient's health and safety, the Commission will consider adopting additional limitation or control on a particular radiation or radionuclide, as necessary.

Issue 2: Does the Commission Have Any Useful Role in Assuring the Accurate Delivery of Byproduct Material to Patients? Should References to Patient Radiation Safety Be Deleted?

Comment. Several commenters indicated that NRC has no useful role in assuring the accurate delivery of byproduct material to patients. They believe that all references to patient radiation safety should be removed, and that NRC should simply state that it will make regulatory efforts to ensure the physician's orders are followed.

Response. The Commission has a role in assuring accurate delivery of radiation doses and dosages to patients and has rejected the notion that NRC should not regulate patient 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 (drugs 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 28, 1983, 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 in their borders. NRC regulations apply to the licensure of these professionals by a State (or Territory of the U.S., the District of Columbia, or the Commonwealth of Puerto Rico) to practice their respective professions as a prerequisite to NRC authorizing them to use byproduct material in pharmacy or medicine.

Issue 4: Should NRC Regulation Be Risk-Based and, If So, Should NRC Share Such an Approach With the Medical Community?

Comment. A commenter insisted that NRC regulation should be "risk-based" (i.e., justified by risk analysis), and if NRC adopts such an approach, the risk analysis should be shared with the medical community.

Response. The Commission believes the regulations for use of byproduct material in medicine should be "risk-based" rather than "risk-based." In March 1997, the Commission directed the revision and restructuring of part 35 into a risk-informed and, where appropriate, more performance-based"
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regulation. The Commission is attempting to make its medical use regulatory framework more "risk-informed" and agreeable with its regulatory strategy of regulating "material uses consistent with the level of risk involved, by decreasing oversight of those materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities." In addition, this portion of the MPS reflects the Commission's strategy of identifying those regulations and processes that are now or can be made risk-informed. The Commission's efforts to make the regulations more risk-informed are evidenced in its recent actions to revise part 35. Before initiating the rulemaking requirements of the MPS, the Commission thoroughly reviewed several extensive assessments, as previously noted. In developing the overall revision of part 35 and the MPS, the Commission considered information on risk provided by members of the public and professional societies, professional 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 high-risk activities was needed. In addition, throughout the development of the proposed rule and associated MFR, 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 the 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 regulations of the radiation safety of patients to 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.

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 that encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry." The NRC's intention is to consider industry and professional standards in developing regulations and guidance for the medical use program, consistent with the concept in the "National Technology Transfer and Advancement Act of 1986" (the NTTAA), Public Law 100-113, 110 Stat. 775 (1990). 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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Response. The Commission disagrees with the comment about professional standards necessarily replacing NRC’s radiation safety requirements. Many of the professional standards are voluntary in nature, do not have the force of law, and may not meet the definition of a consensus standard under the NTCAA. As such, not all professional standards are adequate to meet the Commission’s objectives for the regulation of medical use of byproduct material.


For example, NRC reviewed the technical literature to identify consensus standards and protocols that could be used or referenced in the rule and guidance document, thereby avoiding promulgation of “government-unique standards” when revising the MPS, 10 CFR part 35, and NUREG 1556 (Volume 9). Part 35, subparts C, F, and H, describe various performance objectives to be achieved (e.g., calibration of survey instruments, calibration of radiation sources used for manual brachytherapy and used in radiation therapy devices, and acceptance testing of treatment planning computers). A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the AAPP. Alternatively, a licensee may select and implement an appropriate voluntary performance standard from a 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 regulations that are more performance-based. The Commission believes this approach provides significant flexibility for medical use licensees to design 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 27th day of July, 2000.
For the Nuclear Regulatory Commission.
Annette L. Vietti-Cook,
Secretary of the Commission.