document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the brucellosis status of Louisiana from Class A to Class Free will promote economic growth by reducing certain testing and other requirements governing the interstate movement of cattle from this State. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis-free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Louisiana, as well as buyers and importers of cattle from this State.

There are an estimated 15,500 cattle herds in Louisiana that will be affected by this rule. About 98 percent of these are owned by small entities. Test-eligible cattle offered for sale interstate from other than certified-free herds must have a negative test under present Class A status regulations, but not under regulations concerning Class Free status. If such testing were distributed equally among all animals affected by this rule, Class Free status would save approximately $4 per head.

Therefore, we believe that changing the brucellosis status of Louisiana will not have a significant economic effect on the small entities affected by this interim rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 9 CFR part 78 as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 is revised to read as follows:

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7CFR 2.22, 2.80, and 371.4.

§ 78.41 [Amended]

2. Section 78.41 is amended as follows:

a. In paragraph (a), by adding ''Louisiana,'' in alphabetical order.

b. In paragraph (b), by removing ''Louisiana,''.

Done in Washington, DC, this 27th day of July 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–19608 Filed 8–2–00; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR CH. I

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: August 3, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas Young, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–5795, E-Mail: *tfy@nrc.gov* or Marjorie U. Rothschild, Office of the General Counsel, Nuclear Regulatory Commission, Washington, DC, 20555–0001, telephone (301) 415–1633, E-Mail: *mur@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, the NRC published a policy statement, ''Regulation of the Medical Uses of Radioisotopes,'' (44 FR 8242, February 9, 1979) in which it informed NRC licensees, other Federal and State agencies, and the public of the Commission's general intention in regulating the medical use of byproduct material. Specifically,

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

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 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 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 64829; 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.)

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

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 at sections 81, 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 or 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 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

§ 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'' (§ 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 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, or external, 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 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 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 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 4120; January 29, 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 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,'' Public Law 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, 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 radiation 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 an additional limitation or control on a particular radiation or radionuclide modality, 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 (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 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-informed'' 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

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.[2]'' 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.[3]

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 and the associated revision 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 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 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 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.'' 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), Public Law 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?

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

[2] Page 11, NUREG–1614, Vol. 1, ''Strategic Plan, Fiscal Year 1997–Fiscal Year 2002''.

[3] Id.; and SRM dated March 20, 1997, COMSECY–96–057, ''Materials/Medical Oversight (DSI 7) at 2.

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

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, the 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 a licensee 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 Radiation Therapy Committee Reports, including: Task Group 40 (Comprehensive QA for Radiation Oncology, 1994); Task Group 56 (Code of Practice for Brachytherapy Physics, 1998); Task Group 59 (HDR Treatment Delivery Safety, 1997 Draft); and AAPM Report No. 54 (Stereotactic Radiosurgery, 1995).

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 that these standards are implemented by other appropriate oversight bodies and that the existence of professional standards should signal to the NRC that regulation is unnecessary. Finally, these commenters indicated that a mechanism is needed to require the NRC to justify why an implemented industry standard is not acceptable.

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 NTTAA. As such, not all professional standards are adequate to meet the Commission's objectives for the regulation of medical use of byproduct material.

The Commission must consider industry consensus standards before a ''government-unique standard'' is promulgated. The process is described in NRC Management Directive 6.5, ''NRC Participation in the Development and Use of Consensus Standards.'' Further information on this topic is available on the NRC's web site, *www.nrc.gov/reference__library/standards program/reference documents*, e.g., Public Law 104–113, ''National Technology Transfer Advancement Act of 1995'' (NTTAA), OMB Circular on implementation of the NTTAA, NRC Annual Standards Reports (listings of consensus standards endorsed by NRC).

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 AAPM. 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.

[FR Doc. 00–19573 Filed 8–2–00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–100–AD; Amendment 39–11843; AD 2000–15–11]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–8 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–8 series airplanes that have been converted from a passenger to a cargo-carrying (''freighter'') configuration. This amendment requires a revision to the Airplane Flight Manual Supplement to ensure that the main deck cargo door is closed, latched, and locked; inspection of the door wire bundle to detect discrepancies and repair or replacement of discrepant parts. This amendment also requires, among other actions, modification of the hydraulic and indication systems of the main deck cargo door, and modification of the existing means to prevent pressurization to an unsafe level if the main deck cargo door is not closed, latched, and locked. This amendment is prompted by the FAA's determination that certain main deck cargo door systems and the existing means to prevent pressurization to an unsafe level if the main deck cargo door is not closed, latched, and locked, do not provide an adequate level of safety. The actions specified by this AD are intended to prevent opening of the cargo door while the airplane is in flight, and consequent rapid decompression of the airplane including possible loss of flight control or severe structural damage.

EFFECTIVE DATE: September 7, 2000.

ADDRESSES: Information pertaining to this AD may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los