PDR
AF-10-2
#1

April 5, 1995

To: Working group on wrong patient rule: Stewart Schneider, Sam Jones, Cathy Haney, Trish Holahan, and Brad Jones

From: Stephen A. McGuire SAM

SUBJECT: TECHNICAL REVIEW OF FINAL RULE ON, "MEDICAL ADMINISTRATION OF RADIATION AND RADIOACTIVE MATERIALS

Attached for your technical review is a draft final FRN on the wrong patient rule. Also attached to aid in your review is a copy of the proposed rule FRN, the comments received on the proposed rule, the FRN for petition for rule making, PRM-35-11, and the comments received on the petition.

I believe that this final rule should be rather straight forward and that this review by the working group can substitute for the division technical review step. Thus, we will be able to go straight to Office Concurrence after your comments have been resolved. We will also have a meeting of the working group to discuss your comments if any significant questions arise as a result of your review.

I would appreciate your comments by April 21. A marked up copy of the FRN is fine.

Attachment: as stated

CC: John Glenn
Cheryl Trottier
Ed Powers

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

RIN 3150-AF10

Medical Administration of Radiation and Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to clarify 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 the dose limits in the NRC's regulations concerning standards for protection against radiation. The rule does not represent a change in policy, but is necessary to indicate clearly that this is the NRC's policy and to clarify the relationship of NRC's regulations.

DATES: Effective date: _____ (30 days following publication in the Federal Register).

ADDRESSES: Examine comments received at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6204.

SUPPLEMENTARY INFORMATION:

I. Background.

Radioactive materials are administered in the practice of medicine to roughly 8 to 9 million patients per year for the diagnosis or treatment of disease. Occasionally, a radioactive material is administered by mistake to an individual for whom it is not intended.

The misadministration of radiopharmaceuticals is dealt with in NRC regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." As defined in § 35.2, misadministrations include administrations of licensed radioactive material in excess of certain specified quantities to the wrong individual. The practical effect of the definition of an misadministration is that some relatively low dose diagnostic administrations of radiopharmaceuticals to individuals for whom they were not intended are not misadministrations as defined in § 35.2, and Part 35 does not require notification of the NRC or the individual.

Separate from the requirements for misadministrations, § 20.1301(a)(1) contains a dose limit for members of the public of 0.1 rem (1 millisievert). However, the scope of Part 20 in § 20.1002 states that, "The limits in this Part do not apply to doses due .... to exposure of patients to radiation for the purpose of medical diagnosis or therapy ...."

A question arose about the applicability of those words in a particular case in which an individual mistakenly received an administration of a diagnostic radiopharmaceutical because of an error on the part of the physician requesting the test. In that particular case the dose to the individual receiving the administration was below the threshold for reporting of the misadministration, but above the 0.1 rem (1 millisievert) dose limit in § 20.1301(a)(1) for a member of the public. The question that arose was whether there was a violation of § 20.1301(a)(1) or did the words in the scope of Part 20 exclude this event from being subject to the dose limits in Part 20. In other words, does the exclusion from the Part 20 dose limits exclude any medical administration to any individual, even an individual not supposed to receive an administration?

This same issue was raised in a Petition for Rulemaking (PRM-35-11) filed by the American Medical Association (59 FR 37950; July 26, 1994). That petition requested, in part, that part 20 specifically exclude all medical administrations.

Because of these concerns, the Commission proposed an amendment to 10 CFR Part 20 to clarify the regulations (60 FR 4872, January 25, 1995). The proposed rule explained that the Commission believed that, in general, the administration of radiopharmaceuticals should be regulated by Part 35 rather than Part 20. The medical administration of radioactive materials is a very special use of radioactive materials that is best dealt with by specific regulations covering those administrations. In particular, the Commission believed that an administration to any individual is and should be subject to the regulations in Part 35. That was the Commission's intent when the current misadministration requirements were adopted in the final rule, "Quality

Management Programs and Misadministrations," (July 25, 1991; 56 FR 34104). Further explanation of the Commission's rationale is contained in the Federal Register Notice for the proposed rule (60 FR 4872, January 25, 1995).

II. Comments on the Proposed Rule and Petition for Rulemaking PRM-35-11.

Three comment letters were received on the proposed rule, two from Agreement States and one from a medical health physicist. All supported the proposed rule. Three comment letters were received on PRM-35-11. Each of the letters supported the petition.

The Federal Register Notice on the proposed rule specifically asked for comment on whether to adopt a requirement to inform an individual of the error in the case of administration of a radiopharmaceutical to the wrong individual, but in a quantity below the misadministration threshold. Section 35.33 generally requires notification of the individual in the case of a misadministration. However, if the dose or the amount is less than the misadministration threshold, § 35.33 does not require that the individual who received an administration of a radiopharmaceutical by mistake be notified of the error. One fundamental difference in the case in which the wrong individual receives the administration is that, unlike the intended patient, who it may be argued may have been informed that he or she will be exposed to radiation and has thereby implicitly or explicitly consented to the procedure, the wrong individual has generally not consented to any radiation dose at all. The NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) has assured the NRC that standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual should and

almost always would notify the individual of the mistake. However, the NRC specifically asked whether Part 35 should require that the individual be notified of the error regardless of the dose that would be received.

The comments addressed this question. One favored an NRC regulation requiring notification of the individual regardless of the dose. The other, an Agreement State, opposed a requirement because it would not be consistent with the NRC's medical policy statement, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The NRC has decided that it agrees with this commenter and is not changing its notification requirements.

III. Summary of the Changes.

Neither the comments received nor any other information available to the Commission provide any reasons not to adopt the amendments substantially as proposed, which would regulate administrations to individuals under Part 35 and not Part 20. Therefore the NRC is adopting the amendments as described below.

To clarify the meaning and intent of Part 20, the NRC is amending the Scope of Part 20, the definitions of public dose and occupational dose, and the wording in § 20.1301(a)(1) on public dose limit to clarify that the dose limit for individual members of the public does not apply to dose contributions from any medical administration the individual has received. Thus, the medical administration of radioactive materials or radiation to any individual, even an individual not supposed to receive an administration, is

not subject to the public dose limit in § 20.1301(a)(1), but is within the scope of Part 35.

The changes in Part 20 replace the word "patient" with the word "individual." The word "patient" has sometimes been taken to mean only the individual intended to receive the administration. At other times, the view has been that anyone who receives a medical procedure is a "patient." Replacing "patient" with "individual" clarifies that the statement refers to anyone receiving a medical administration. For consistency, in terminology between parts, the word "patient" in the definition of misadministration in § 35.2, "Definitions," and in certain locations in paragraph (a)(2) of § 35.33 are replaced by the word "individual."

In § 20.1002, the phrase "for the purpose of medical diagnosis and therapy" is replaced by the phrase "any medical administration the individual has received." The existing wording raised the question of whether an administration was within the scope of Part 20 if the administration had no valid medical purpose. The new wording makes it clear that regardless of the purpose or lack of purpose, dose to an individual from any medical administration the individual has received is not within the scope of Part 20, but is within the scope of Part 35.

For the sake of consistency and clarity, the same words are used in § 20.1002, "Scope," in § 20.1003, "Definitions," (in the definitions of both public dose and occupational dose), and in § 20.1301, "Dose limits for individual members of the public." Also for consistency and clarity, the exclusion of dose from background radiation and from voluntary participation in medical research programs that are now included in §§ 20.1002 and 20.1003 are added to § 20.1301(a).

The existing § 20.1301(a) also excludes dose contributions from the licensee's disposal of radioactive material into sanitary sewerage. That exclusion was not be added to §§ 20.1002 and 20.1003 because the question of dose from sewer disposal of radioactive material is now under consideration by the NRC. When that issue is resolved, it is intended that the wording concerning dose from sewer disposal will be made consistent in §§ 20.1002, 20.1003, and 20.1301(a).

A recently published proposed rule (June 15, 1994; 59 FR 30724), which deals with criteria for the release of individuals administered radioactive material, would also amend § 20.1301(a)(1). When that amendment of § 20.1301(a)(1) is published in final form, the wording on what is excluded from the dose limit will be inserted in §§ 20.1002 and 20.1003 (in the definitions of public dose and occupational dose) so that the same parallelism will exist throughout.

IV. Consistency with the 1979 Medical Policy Statement and Coordination with ACMUI.

On February 9, 1979 (44 FR 8242), the NRC published a Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes. The first statement of the policy states, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The rule is consistent with this statement because it continues to provide for administrations of radioactive materials to be regulated under 10 CFR Part 35. The rule further clarifies that additional regulations are not considered necessary.

The second statement of the policy states, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." The rule is consistent with the statement because it clarifies that existing requirements concerning misadministrations continue to be concentrated on administrations having the greatest risk significance.

The third statement of the policy states, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The rule is consistent with this statement because it limits its specific regulatory requirements for notification to the most serious errors in administration and minimizes requirements on errors in administrations that have less risk significance.

Thus, the rule is considered to be consistent with the 1979 medical policy statement.

The subject of this final rule was discussed with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 11, 1995. The ACMUI agreed that medical administrations, including those to an individual not supposed to receive an administration, should be regulated by Part 35 rather than Part 20. The ACMUI stated that notification of an individual of an error in administration below the misadministration threshold is the current practice and should not be regulated.

V. Coordination with and Issue of Compatibility for Agreement States.

This rulemaking was discussed with representatives of Agreement States at a meeting in Portland, ME, on October 24, 1994. The States were polled on how they regulated an administration to the wrong individual, and it was found that they regulate the administration the same way as in this rule. Two States commented on the rule, and both fully supported the rule.

The NRC believes that the modification of Part 20 should be a Division 1 matter of compatibility consistent with past practice of requiring basic definitions to be uniform for effective communication of basic radiation concepts. The only Agreement State commenting on the compatibility issue supported a Division 1 level.

VI. Finding of No Significant Environmental Impact.

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of Part 51, that this rule is not be a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

The NRC prepared an environmental assessment for the proposed rule, which was contained within the Federal Register Notice for that rule. That assessment continues to stand for the final rule.

VII. Paperwork Reduction Act Statement.

This rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980

(44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0014 and 3150-0010.

VIII. Regulatory Analysis.

The regulatory analysis prepared for the proposed rule and published as part of the Federal Notice on the proposed rule is still valid for this final rule.

IX. Regulatory Flexibility Certification.

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. The impact of the revised regulation will not be significant because the amendment represents a continuation of current practice and merely clarifies existing requirements.

X. Backfit Analysis.

The NRC has determined that the backfit rule, § 50.109, does not apply to this rule and, therefore, that a backfit analysis is not required for this rule, because these amendments do not involve any provisions which impose backfits as defined in § 50.109(a)(1).

XI. List of Subjects.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recording requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and Recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR parts 20 and 35.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 35, 39, 40, 50, 60, 61, 70, or 72 of this chapter. The limits in this part do not apply to doses due to background radiation, due to any medical administration the individual has received, or due to voluntary participation in medical research programs.

3. In § 20.1003, the definitions of *occupational dose* and *public dose* are revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Occupational dose means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from voluntary participation in medical research programs, or as a member of the general public.

Public dose means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, or from voluntary participation in medical research programs.

* * * * *

4. In § 20.1301, paragraph (a)(1) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, any medical administration the individual has received, voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

* * * * *

5. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

6. In § 35.2, the definition for misadministration is revised at paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) by removing the word *"patient"* and inserting the word *"individual."*

7. In § 35.33, paragraph (a)(2) is revised to read as follows:

Section 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, or the individual's responsible relative or guardian (this person will be subsequently referred to as ''the patient'' in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

RIN 3150–AF10

Medical Administration of Radiation and Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to clarify 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 the dose limits in the NRC's regulations concerning standards for protection against radiation. The proposed rule does not represent a change in policy, but is necessary to indicate clearly that this is the NRC's policy and to clarify the relationship of NRC's regulations.

DATES: The comment period expires April 10, 1995. Comments received after this date will be considered if it is practicable to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: *Send comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:45 am and 4:15 pm on Federal workdays.

Examine comments received at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6204.

SUPPLEMENTARY INFORMATION:

I. Background.
II. Summary of the Proposed Changes.
III. Request for Comment on Notification.
IV. Consistency With the 1979 Medical Policy Statement and Coordination With ACMUI.
V. Coordination With and Issue of Compatibility With Agreement States.
VI. Finding of No Significant Environmental Impact: Availability.
VII. Paperwork Reduction Act Statement.
VIII. Regulatory Analysis.
IX. Regulatory Flexibility Certification.
X. Backfit Analysis.

I. Background

Radioactive materials are administered in the practice of medicine to roughly 8 to 9 million patients per year for the diagnosis or treatment of disease. Occasionally, a radioactive material is administered by mistake to an individual for whom it is not intended. For the years 1989 and 1990 combined, the NRC is aware of about 200 cases out of 5 to 6 million administrations performed under NRC license in which a diagnostic radiopharmaceutical was administered to the wrong individual.

The misadministration of radiopharmaceuticals is dealt with in NRC regulations in 10 CFR part 35, "Medical Use of Byproduct Material." As defined in § 35.2, misadministrations include administrations of licensed radioactive material or the radiation therefrom to the wrong individual, using the wrong radiopharmaceutical, in the wrong amount, by the wrong route, or to the wrong treatment site. This proposed rule only concerns administrations to the wrong individual.

An administration to the wrong individual is a misadministration, as defined in § 35.2, if it involves: (1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131; (2) any therapeutic administration other than sodium iodide I–125 or I–131; (3) any gamma stereotactic radiosurgery radiation dose; (4) any teletherapy dose; (5) any brachytherapy radiation dose; or (6) a diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I–125 or I–131, when the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ. The practical effect of this definition of a misadministration is that some relatively low dose diagnostic administrations of radiopharmaceuticals to individuals for whom they were not intended are not misadministrations as defined in § 35.2.

If a misadministration occurs, § 35.33 requires that the NRC, the referring physician, and the individual receiving the administration (or a responsible relative or guardian) be informed of the misadministration (unless the referring physician makes a decision based on medical judgement that telling the individual or responsible relative or guardian would be harmful.) If the dose from a diagnostic administration to the wrong individual does not exceed the threshold for a misadministration, the administration is not a misadministration as defined in § 35.2, and part 35 does not require notification of the NRC or the individual.

Separate from the requirements for misadministrations, § 20.1301(a)(1) contains a dose limit for members of the public of 0.1 rem (1 millisievert). However, the scope of part 20 in § 20.1002 states that, "The limits in this Part do not apply to doses due * * * to exposure of patients to radiation for the purpose of medical diagnosis or therapy. * * *"

A question arose about the applicability of those words in a specific case in which an individual mistakenly received an administration of a diagnostic radiopharmaceutical because of an error on the part of the physician requesting the test. In that particular case the dose to the individual receiving the administration was below the threshold for reporting of the misadministration, but above the 0.1 rem (1 millisievert) dose limit in § 20.1301(a)(1) for a member of the public. Was there a violation of § 20.1301(a)(1) or do the words in the scope of part 20 exclude this event from being subject to the dose limits in part 20? In other words, does the exclusion from the part 20 dose limits exclude any medical administration to any individual, even an individual not supposed to receive an administration?

The Commission concludes that, in general, the administration of radiopharmaceuticals should be regulated by part 35 rather than part 20. The medical administration of radioactive materials is a very special use of radioactive materials that is best dealt with by specific regulations covering those administrations. In particular, the Commission believes that an administration to any individual is and should be subject to the regulations in part 35. This was the Commission's intent when the current misadministration requirements were adopted in the final rule, "Quality Management Programs and Misadministrations," (July 25, 1991; 56 FR 34104) and continues to be the Commission's intent.

In establishing which errors in administration should be under the misadministration reporting requirements, the NRC sought to optimize the cost effectiveness of the rule by concentrating its regulatory requirements on those events with the greatest risk and placing fewer requirements on those with relatively low risk, such as most diagnostic uses of radiopharmaceuticals. In the final rule on "Quality Management Programs and Misadministrations" (July 25, 1991; 56 FR 34104), the Commission stated that the proposed requirements that would have had minimal impact on risk were eliminated to make the final rule more cost effective (e.g., deleting the diagnostic components of the proposed rule).

In reaching its conclusion, the Commission recognized that in the event of administration of radioactive material to the wrong individual, the ability to control the dose to that individual has been lost. One cannot decide to terminate the exposure at a certain point to prevent exceeding a dose limit. Therefore, the relevant questions are: What steps are appropriate to reduce the likelihood of

an administration to the wrong individual; what corrective actions should be taken if the mistake occurs; and what regulatory response is appropriate if such a mistake occurs?

Each of these questions was dealt with in developing the rule on quality management programs and misadministrations. The Commission considered, in the rulemaking on quality management program and misadministrations, what steps should be taken to avoid the administration of radioactive materials to an individual not supposed to receive the administration. Those steps are contained in § 35.32, "Quality management program." In adopting those requirements, the Commission decided to apply the requirements in § 35.32 only to administrations with the potential for relatively high doses and to exclude most diagnostic administrations from the requirements. For those diagnostic administrations not covered by § 35.32, it was considered adequate to rely on the normal and traditional methods and techniques that medical care providers use to ensure that medications are given to the right individual in the right amount at the right time.

Similarly, the NRC's requirements that licensees take appropriate corrective actions in response to a misadministration are contained in § 35.32. The specific requirements dealing with corrective actions apply to any administration requiring a quality management program.

With regard to the appropriate regulatory response to mistakes in administrations, the Commission decided that violation of the quality management program requirements, which apply to the more significant administrations, were significant enough that they may result in a civil penalty.

Thus, in the quality management program and misadministrations rulemaking, the Commission clearly addressed the issue of when the administration of a radioactive material to the wrong individual was sufficiently significant to warrant certain actions. Specific thresholds were established and codified to reflect the Commission's view of a reasonable balance between harm and burden. In particular, the Commission concluded that lower thresholds would not significantly reduce risk and would divert resources that should be directed toward reducing the more serious of those errors. The Commission continues to endorse the judgement that it made in that rulemaking.

II. Summary of the Proposed Changes

To clarify the meaning and intent of part 20, the NRC is proposing to amend the scope of part 20, the definitions of public dose and occupational dose, and the wording in § 20.1301(a)(1) on public dose limit to clarify that the dose limit for individual members of the public does not apply to dose contributions from any medical administration the individual has received. Thus, the medical administration of radioactive materials or radiation to any individual, even an individual not supposed to receive an administration, is not subject to the public dose limit in § 20.1301(a)(1), but is within the scope of part 35.

The proposed changes in part 20 would replace the word "patient" with the word "individual." The word "patient" has sometimes been taken to mean only the individual intended to receive the administration. At other times, the view has been that anyone who receives a medical procedure is a "patient." Replacing "patient" with "individual" would clarify that the statement refers to anyone receiving a medical administration. For consistency, in terminology between parts, the word "patient" in the definition of misadministration in § 35.2, "Definitions," and in certain locations in paragraph (a)(2) of § 35.33 would be replaced by the word "individual."

In § 20.1002, the phrase "for the purpose of medical diagnosis and therapy" would be replaced by the phrase "any medical administration the individual has received." The existing wording raised the question of whether an administration was within the scope of part 20 if the administration had no valid medical purpose. The proposed wording would make it clear that regardless of the purpose or lack of purpose, dose to an individual from any medical administration the individual has received is not within the scope of part 20, but is within the scope of part 35.

For the sake of consistency and clarity, the same words would be used in § 20.1002, "Scope," in § 20.1003, "Definitions," (in the definitions of both public dose and occupational dose), and in § 20.1301, "Dose limits for individual members of the public." Also for consistency and clarity, the exclusion of dose from background radiation and from voluntary participation in medical research programs that are now included in §§ 20.1002 and 20.1003 would be added to § 20.1301(a).

The existing § 20.1301(a) also excludes dose contributions from the licensee's disposal of radioactive material into sanitary sewerage. That exclusion would not be added to §§ 20.1002 and 20.1003 because the question of dose from sewer disposal of radioactive material is now under consideration by the NRC. When that issue is resolved, it is intended that the wording concerning dose from sewer disposal will be made consistent in §§ 20.1002, 20.1003, and 20.1301(a).

Another recently published proposed rule (June 15, 1994; 59 FR 30724), which deals with criteria for the release of individuals administered radioactive material, would also amend § 20.1301(a)(1). When that amendment of § 20.1301(a)(1) is published in final form, the wording on what is excluded from the dose limit will be inserted in §§ 20.1002 and 20.1003 (in the definitions of public dose and occupational dose) so that the same parallelism will exist throughout.

In addition, another proposed rule (February 3, 1994; 59 FR 5132) would amend the definitions of public dose and occupational dose in 10 CFR part 20. However, that proposed rule would only amend the first sentence in the definitions and would not change the wording associated with what is excluded from public dose. Therefore, this proposed rule and that proposed rule do not conflict.

III. Request for Comment on Notification

Another question related to the administration of radioactive materials to the wrong individual concerns informing the individual of the error. Section 35.33 generally requires notification of the individual in the case of a misadministration. However, if the dose or the amount is less than the misadministration threshold, § 35.33 does not require that the individual who received an administration of a radiopharmaceutical by mistake be notified of the error. One fundamental difference in the case in which the wrong individual receives the administration is that, unlike the intended patient, who it may be argued may have been informed that he or she will be exposed to radiation and has thereby implicitly or explicitly consented to the procedure, the wrong individual has generally not consented to any radiation dose at all. The question then becomes, should part 35 require that the individual be notified of the error regardless of the dose that would be received?

The Commission was divided on whether the individual should be notified. The NRC's Advisory Committee on Medical Uses of Isotopes

(ACMUI) has assured the NRC that standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual should and almost always would notify the individual of the mistake. The current quality management program and misadministrations rule does not require the physician to notify the individual if the dose or amount is below the threshold for a misadministration. The NRC is now seeking comment on whether it should continue to rely on standard medical practice below the misadministration threshold or whether it is appropriate to impose an NRC requirement for notification below the misadministration threshold if the administration is to the wrong individual. For example, the NRC would like comments on whether a broader notification requirement would implicitly impose recordkeeping and procedural requirements upon licensees beyond those explicitly set forth in part 35.

IV. Consistency With the 1979 Medical Policy Statement and Coordination With ACMUI

On February 9, 1979 (44 FR 8242), the NRC published a Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes. The first statement of the policy states, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because it continues to provide for administrations of radioactive materials to be regulated under 10 CFR part 35. The proposed rule further clarifies that additional regulations are not considered necessary.

The second statement of the policy states, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." The proposed rule is consistent with the statement because it clarifies that existing requirements concerning misadministrations continue to be concentrated on administrations having the greatest risk significance.

The third statement of the policy states, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The proposed rule is consistent with this statement because it limits its specific regulatory requirements for notification to the most serious errors in administration and minimizes requirements on errors in administrations that have less risk significance.

Thus, the proposed rule is considered to be consistent with the 1979 medical policy statement.

The subject of this proposed rule was discussed with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 19, 1994. The ACMUI agreed that medical administrations, including those to an individual not supposed to receive an administration, should be regulated by part 35 rather than part 20. The ACMUI stated that notification of an individual of an error in administration below the misadministration threshold is the current practice and should not be regulated.

V. Coordination With and Issue of Compatibility for Agreement States

This proposed rulemaking was discussed with representatives of Agreement States at a meeting, "Organization of Agreement State Managers Workshop and Public Meeting on Rulemaking," in Herndon, VA, on July 12, 1994. There was some concern that the NRC approach was different from how State regulations address inadvertent x-ray exposures, but no strong opposition. The proposed rule was revised to address the concerns of the States and then discussed at a subsequent meeting of the Agreement States in Portland, ME, on October 24, 1994. The States were polled on how they regulated an administration to the wrong individual, and it was found that they would regulate the administration the same way as in this proposed rule.

The NRC believes that the proposed modification of part 20 should be a Division 1 matter of compatibility consistent with past practice of requiring basic definitions to be uniform for effective communication of basic radiation concepts. The Commission specifically requests comments on whether the proposed modification to part 20 should be made a Division 1 matter of compatibility.

VI. Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

The NRC has not prepared a separate environmental assessment. The following discussion constitutes the assessment. The proposed rule would not change the NRC's requirements concerning the administration of radiation and radioactive materials. Those requirements are and would continue to be contained in part 35 of the NRC's regulations. When the potential ambiguity concerning application of part 20 and part 35 requirements was recognized, the Commission specifically informed the staff of its view that the proper interpretation was that the more specific part 35 requirements should govern all medical administrations and directed that action be taken to remove from the regulations any ambiguity on this issue. The staff has, accordingly, not interpreted § 20.1301(a)(1) as applying to any medical administrations, but has proceeded with this rulemaking to remove any ambiguity in the regulations. The proposed rule would merely amend part 20 to make it clear that part 20 does not address medical administrations. Thus, the proposed rule, if adopted, would clarify the NRC's requirements rather than change them, and there would be no environmental impact.

VII. Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150–0014 and 3150–0010.

VIII. Regulatory Analysis

The regulatory analysis for this proposed rulemaking is as follows:

1. Alternatives

Alternative 1: Part 20 Regulates Doses to Wrong Individuals

In this alternative, a medical administration of radiation or radioactive material to an individual when no administration is intended that results in a total effective dose equivalent greater than 1 millisievert (0.1 rem) would be a violation of § 20.1301. If the event did not meet the threshold definition of a misadministration, NRC would receive a notification of the event from the licensee pursuant to § 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits" and the individual involved would receive notification of

the exposure from the licensee pursuant to § 19.13(d), "Notifications and reports to individuals."

Under this alternative, notification and recordkeeping requirements of 10 CFR parts 19 and 20 would apply to the medical administration of radiation or radioactive material to the wrong individual that involves a dose to the individual above 1 millisievert (0.1 rem) but less than the threshold definition of a misadministration.

Alternative 2: Part 35 Regulates Doses to Wrong Individuals

In this alternative, the medical administration of radiation or radioactive material to any individual would be the exclusive province of the regulations in 10 CFR part 35. Section 20.1301 would not be applicable. Under this alternative, errors in the administration of radiation or radioactive material to individuals would be subject to the reporting and notification requirements of 10 CFR part 35 rather than the reporting and notification requirements in 10 CFR parts 19 and 20. This alternative is consistent with the Commission's determination, published in the rule on quality management programs and misadministrations (July 25, 1991; 56 FR 34104), that licensees should direct their resources toward preventing the more serious errors in the administration of byproduct material.

However, there would be no requirement in the event of errors in the administration of byproduct material to individuals who were not intended to receive any administration for the medical licensee to notify either the NRC or the individual of the error unless the error meets the threshold definition of a misadministration in § 35.2. In general, standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual would notify the individual of the mistake.

Preferred Alternative

Alternative 2 (Part 35 is controlling) is preferable because it maintains the intent of the rulemaking on quality management programs and misadministrations by concentrating regulatory requirements on those events with the greatest risk and placing fewer requirements on those with relatively low risk, such as most diagnostic uses of radiopharmaceuticals. Also, this alternative would allow the Commission to treat all medical administrations of licensed material consistently under the regulations in Part 35.

2. Impact of Proposed Action

Licensees. There is no anticipated impact on licensees, except that licensees will more clearly understand the meanings of the regulations.

Individuals. There is no anticipated impact on an individual because this action will not increase or decrease the error rate for administrations of radiation or radioactive material.

NRC Resources. No NRC resources would be required to implement the rule.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, if adopted, this proposed rule would not have a significant economic impact on a substantial number of small entities. The impact of the revised regulation would not be significant because the proposed amendment represents a continuation of current practice and merely clarifies existing requirements.

X. Backfit Analysis

The NRC has determined that the backfit rule, § 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule, because these amendments do not involve any provisions which would impose backfits as defined in § 50.109(a)(1).

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements. For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR parts 20 and 35.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 35, 39, 40, 50, 60, 61, 70, or 72 of this chapter. The limits in this part do not apply to doses due to background radiation, due to any medical administration the individual has received, or due to voluntary participation in medical research programs.

3. In § 20.1003, the definitions of Occupational dose and Public dose are revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Occupational dose means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from voluntary participation in medical research programs, or as a member of the general public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, or from voluntary participation in medical research programs.

* * * * *

4. In § 20.1301, paragraph (a)(1) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, any medical administration the individual has received, voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

* * * * *

5. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

6. In § 35.2, the definition for *misadministration* is revised at paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) by removing the word "patient" and inserting the word "individual."

7. In § 35.33, paragraph (a)(2) is revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, or the individual's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

* * * * *

Dated at Rockville, Maryland, this 19th day of January, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

[FR Doc. 95-1817 Filed 1-24-95; 8:45 am]

BILLING CODE 7590-01-P

MALLINCKRODT
Nuclear Medicine

(1)

Mallinckrodt Medical, Inc.
NMA Medical Physics Consultation
9457 Midwest Avenue
Garfield Heights, Ohio 44125

Telephone (216) 663-7000
Facsimile (216) 663-6234

February 2, 1995

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

RE: RIN3150-AF10

To Whom It May Concern:

These are comments regarding the proposed rule change published in the January 25, 1995 Federal Register (60FR4872) dealing with the medical administration of radiation and radioactive materials. I support and concur with the proposed rule change in its entirety. As described in the Federal Register publication, the administration of a radiopharmaceutical or radiation dose to the wrong individual should be regulated by the more specific requirements of Part 35 rather than Part 20. Limiting the exposure to such individuals to the values specified in 20.1301, places unnecessary burdens on medical licensees. Further, this would be in contrast to the recommendations of the international and national agencies that promulgate radiation safety recommendations. These agencies recognize that individuals receiving a dose in excess of 100 mrem in unusual situations does not represent a significant hazard to the individual. Therefore, the proposed changes should be made as published.

As regards the request for comment on notification, it is felt that Part 35 should require that, when the wrong individual receives an administration, the individual should be notified of the error. It is agreed that it is current practice that such individuals are routinely notified. In such cases, the requirement to notify the individual would not pose any additional requirements on the licensees. However, there are those who would attempt to keep this information from the individual. Considering the trend in right-to-know laws, the NRC should assure the appropriate information is provided to the individual. As all therapeutic administrations to the

wrong patient are currently considered misadministrations, only administrations of radiopharmaceuticals not currently defined as misadministrations, would need to be considered. Part 35 should require that in the event of any radiopharmaceutical administration to the wrong individual, the individual must be notified as described in 35.33. Other than requiring a record of the notification be made, no other action should be required of the licensee.

As regards whether the proposed modification to Part 20 should be made a Division I matter of compatibility, this should be so done. The basic definitions utilized by the States must be uniform with the NRC and with each other in order for effective communication. This item should also be a Division I matter of compatibility to assure that the States address this basic concept in the same manner.

These comments represent my personal position. Thank you for considering these comments.

Sincerely,

David Close

David Close
Medical Health Physicist

DC/kl

P/Proprule.chg

CABINET FOR HUMAN RESOURCES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621-0001

DEPARTMENT FOR HEALTH SERVICES

March 7, 1995

SECRETARY
US NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20555

DOCKET NUMBER
PROPOSED RULE PR 20+35
(60FR04872) (2)

Dear Secretary:

This letter provides comments to the proposed rulemaking "Medical Administration of Radiation and Radioactive Materials" published in the Federal Register on January 25, 1995.

We support Alternative 2 for Part 35 to regulate doses to wrong individuals.

If you require any additional comments, please contact me.

Sincerely,

Vicki D. Jeffs

Vicki D. Jeffs, Supervisor
Radioactive Materials Section
Radiation Control Branch

VDJ/tg

Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354
Joe D. Tanner, Commissioner
Harold F. Reheis, Assistant Director
Environmental Protection Division
404/362-2675

March 17, 1995

(3)

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

Dear Mr. Secretary:

This is in reference to the notice that appeared in the Federal Register in which the Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to clarify that the medical administration of radiation or radioactive materials to any individual not supposed to receive a medical administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than the dose limits in the NRC's regulations concerning standards for protection against radiation.

Basically we are in agreement with the proposed changes; however, we have the following comments:

1. The question is asked if the administration of radioactive materials to the wrong individual should result in informing that individual if the dose or the amount is less than the misadministration threshold. We concur with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) position that a physician who becomes aware that a medical procedure has been performed on the wrong individual should and almost always would notify the individual of the mistake. We feel this type of decision concerns the practice of medicine and as such the decision should rest with the physician.

2. It is indicated that the proposed modification of Part 20 will be a Division 1 matter of compatibility item. Since there has always been a requirement that basic definitions contained within the NRC and Agreement State regulations be uniform for effective communication of basic radiation concepts we have no problem with this requirement.

Thank you for the opportunity to comment on the proposed rulemaking and if there are questions do not hesitate to contact me.

Sincerely,

Thomas E. Hill

Thomas E. Hill, Manager
Radioactive Materials Program

TEH/klc

Proposed Rules

Federal Register
Vol. 59, No. 142
Tuesday, July 26, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

[Docket No. PRM–35–11]

American Medical Association

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking, dated March 28, 1994, which was filed with the Commission by the American Medical Association (AMA). The petition was docketed by the NRC on April 20, 1994, and has been assigned Docket No. PRM–35–11. The petitioner requests that the NRC amend its regulations to recognize that current medical practice concerning the therapeutic uses of I^{131}, particularly in outpatient settings, is effective and safe for the public. The petitioner also requests that the NRC formally recognize that adequate home confinement precautions reduce the hazards associated with radioisotopes sufficiently to eliminate the need for hospitalization following therapeutic administration of radiopharmaceuticals. The petitioner also requests that the NRC increase the external radiation limit for the public from 100 mRem/year to 500 mRem/year.

DATES: Submit comments by October 11, 1994. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm Federal workdays.

For a copy of the petition, write the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–415–7163 or Toll Free: 800–368–5642.

SUPPLEMENTARY INFORMATION:

Background

The petitioner states that in order to "provide adequate protection of public health and safety" and to observe "the principle of keeping all radiation exposures 'as low as is reasonably achievable,'" the NRC has revised its standards for protection against radiation. NRC proposed a revision of the regulations governing radiation use and exposure limits in 1976. Modifications of the revised regulation were proposed in 1979, 1980, 1983, 1985, and 1986. Revised regulations were published May 21, 1991 (56 FR 23360), to become effective June 21, 1991, and to be fully implemented by January 1, 1993 (later extended to January 1, 1994, see 57 FR 38588; August 26, 1992). The petitioner states that the section of the final rule relevant to outpatient treatment with I^{131} or other radiopharmaceuticals (§ 20.1301) reduces the radiation exposure limit to the public from 500 mRem/year to 100 mRem/year.

The petitioner believes that § 20.1301 will have an adverse impact on the availability and the cost of treatment of thyroid disease, which will outweigh the advantages of reduced radiation exposure to the public. Therefore, the petitioner requests that this provision be amended to restore the previous external radiation limit of 500 mRem/year.

Petition

The AMA, following a report of its Council on Scientific Affairs (CSA Report F (A–92)), submitted a petition for rulemaking to the NRC. The petitioner also submitted CSA Report F in support of the petition. The petitioner states that the medical use of inorganic sodium I^{131} has been an effective component of medical practice for over 35 years. The petitioner also states that radioactive biologicals, such as monoclonal antibodies labeled with I^{131}, have been added to the physician's armamentarium. The petitioner believes that the ability of the physician to administer I^{131} on an outpatient basis has maintained the accessibility and minimized the costs of these treatments. According to the petitioner, patients treated with I^{131} must contain no more than 30 mCi total body activity before they may be released from the treatment facility. The petitioner states that therapeutic use of I^{131}, particularly in the treatment of thyroid carcinoma, often requires doses in excess of 30 mCi, and may require doses as great as 400 mCi.

The petitioner states that because doses of 30 mCi of I^{131} are substantially below the doses typically used to treat thyroid carcinoma, treatment of up to 10,000 cancer patients annually with appropriate doses would require the hospitalization of the patients under the revised regulation (10 CFR 20.1301). The petitioner argues that this new radiation exposure limit set by the NRC is inconsistent with medical experience and is not necessary in order to protect the public from radiation hazards. The petitioner states that the new radiation exposure limit will reduce both early release of patients and the treatment of patients at home, thus creating potentially avoidable hospital inpatient costs and burdens on the health care delivery system.

Suggested Changes to the Regulations

The petitioner requests that the following amendments to the NRC's regulations be made:

1. Reinstate § 20.107 from the regulations in effect before the 1991 amendments to Part 20. The added section would read as follows:

Section 20.107 Medical Diagnosis and Therapy.

Nothing in the regulations of this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy.

2. Section 35.75 should be revised to read as follows:

Section 35.75 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical or a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter or the cumulative dose to individual members of the public will be less than 500 millirems per year.

3. In § 35.310(a), the introductory text of paragraph (a) should be revised to read as follows:

Section 35.310 Safety Instruction.

(a) A licensee shall provide reasonable and adequate radiation instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and confined for compliance with § 35.75 of this chapter.

* * * * *

4. In § 35.315(a), the introductory paragraph should be revised to read as follows:

Section 35.315 Safety Precautions.

(a) For each patient receiving radiopharmaceutical therapy and confined for compliance with § 35.75 of this chapter, a licensee shall:

* * * * *

The AMA believes that these amendments will have a beneficial impact on the availability and cost of treatment of thyroid disease while maintaining safeguards to the health of the public.

Related Petitions and Proposed Rule

On December 26, 1990, Carol S. Marcus, MD, filed a petition for rulemaking with the NRC (PRM–20–20). Dr. Marcus requested that the NRC restore the radiation dose limit in the amended standards for protection against radiation that can be absorbed by members of the public from patients receiving radiopharmaceuticals for diagnosis or therapy from 100 mRem/year to 500 mRem/year. Dr. Marcus opposed the newly effective radiation dose limit in 10 CFR 20.1301 because of the impact of this lower limit on outpatient medical procedures. She believed that therapeutically effective doses of I^{131} may result in exposure to the public within the immediate surroundings of greater than 100 but less than 500 mRem/year. She stated that some procedures utilizing radioisotopic materials that have routinely been performed on an outpatient basis would require hospitalization for regulatory rather than medical reasons. She also believed that enforced hospitalization would significantly increase the cost of medical care and possibly result in the patient's inability to receive that care.

On October 5, 1991, the American College of Nuclear Medicine (ACNM) filed a petition for rulemaking with the NRC (PRM–35–10). On April 14, 1992, the ACNM filed an amendment to its original petition (PRM–35–10A). The ACNM requested that the NRC adopt a dose limit of 500 mRem/year for nonpatients and permit licensees to authorize release from hospitalization any patient administered a radiopharmaceutical regardless of the activity in the patient by defining "confinement" to include not only confinement in a hospital, but also confinement in a private residence. The ACNM stated that their request is in the best interest of patients who require access to affordable quality care while allowing them to be diagnosed and treated on an outpatient basis instead of being confined to a hospital. The ACNM believed that temporary home confinement should be allowed instead of mandating hospitalization. The ACNM stated that published scientific papers attest to the safety of outpatient radiopharmaceutical therapy in doses of up to 400 millicuries of I^{131} NaI.

On June 15, 1994 (59 FR 30724), the Commission published a proposed rule addressing the issues raised in PRM–20–20 and PRM–35–10. The petitioner and commenters are advised to review and comment on this proposed rule. It provides the Commission's position on the fundamental concern underlying the current petition. In the proposed rule, the Commission states that the provisions of 10 CFR 35.75 govern the release of patients, not the provisions in 10 CFR 20.1301. Consequently, commenters should comment on PRM–35–11 in this context because most of the issues raised in this petition are addressed in the proposed rule. The NRC staff also issued NRC Information Notice No. 94–09, dated February 3, 1994, entitled "Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas Due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20," which provided the NRC staff's interim guidance governed by 10 CFR 35.75.

Dated at Rockville, Maryland, this 20th day of July 1994.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

[FR Doc. 94–18112 Filed 7–25–94; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

Steel Erection Negotiated Rulemaking Advisory Committee

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Notice of meetings and agendas.

SUMMARY: Under the provisions of the Federal Advisory Committee Act (FACA), notice is hereby given of the schedule of two Committee meetings of the Steel Erection Negotiated Rulemaking Advisory Committee (SENRAC). Notice is also given of the locations and agendas for the meetings. These meetings are open to the public. Information on room numbers will be available in the lobby of the designated building. A schedule of additional meetings will be provided in a future notice.

DATES: (1) Boston: August 16–18, 1994 The meeting will begin at 10 a.m. on August 16, 1994.

(2) Washington, DC: September 20–22, 1994. The meeting will begin at 10 a.m. on September 20, 1994.

ADDRESSES: (1) Boston: Swissotel, One Avenue de Lafayette, Boston, MA 02111, (617) 451–2600.

(2) Washington, DC: Quality Hotel—Capitol Hill, 415 New Jersey Avenue, NW., Washington, DC 20001, (202) 638–1616.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Information and Consumer Affairs, Room N–3647, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone: (202) 219–8151.

SUPPLEMENTARY INFORMATION: On May 11, 1994, OSHA announced that it had established the Steel Erection Negotiated Rulemaking Advisory Committee (SENRAC) (59 FR 24389) in accordance with the Federal Advisory Committee Act (FACA), the Negotiated Rulemaking Act of 1990 (NRA) and section 7(b) of the Occupational Safety and Health Act (OSH Act) to resolve issues associated with the development of a Notice of Proposed Rulemaking on Steel Erection. Appointees to the

DOCKET NUMBER
PETITION RULE PRM 35-11
(59FR37950) DOCKETED
USNRC

RA 94-059 ATS

(1)

Westinghouse Electric Corporation | Energy Systems | Box 355 Pittsburgh Pennsylvania 15230-0355

'94 SEP 29 P4:07

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

September 26, 1994

The Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

ATTN: Docketing and Service Branch

SUBJECT: Ref. 59FR37950 Petition for Rulemaking - - "American Medical Association." - - (10 CFR Parts 20 and 35)

Gentlemen:

The Westinghouse Electric Corporation appreciates the opportunity to provide comments on the Petition for Rulemaking referenced above.

Westinghouse supports the AMA's petition in general, and particularly in the following areas:

To include the reinstatement of Section 20.107 from the regulations in effect before the 1991 amendments to Part 20;

The proposed changes in Section 35.75;

The provisions of Section 35.310(a); and,

The revised introductory paragraph of Section 35.315

These comments are presented for consideration by the Commission in this Petition for Rulemaking proceeding.

Sincerely,

Andy Sabo

A. T. Sabo, Manager
Regulatory Affairs

dh

D510

DOCKET NUMBER
PETITION RULE PRM 35-11
(59FR 37950)

October 11, 1994

(2)

AMERICAN MINING CONGRESS
FOUNDED 1897

1920 N Street NW, Suite 300
Washington, DC 20036-1662
202/861-2800
Fax: 202/861-7535

BY HAND DELIVERY

Secretary of the Commission
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20850

Attention: Docketing and Service Branch

Re: American Medical Association's Petition for Rulemaking - Docket No. PRM-35-11

Dear Secretary:

The American Mining Congress (AMC) submits these comments in response to the Nuclear Regulatory Commission's (NRC) notice of receipt of a petition for rulemaking by the American Medical Association (AMA). 59 Fed. Reg. 37950 (July 26, 1994). AMA's petition requests the Commission to amend its regulations to increase the external radiation limit to the public from 100 mrem/yr to 500 mrem/yr for the purpose of medical diagnosis and therapy. AMC supports AMA's petition.

AMC is a national trade association representing: (1) producers of most of the United States' metals, uranium, coal, and industrial and agricultural minerals; (2) manufacturers of mining and mineral processing machinery equipment and supplies; and (3) engineering and consulting firms and financial institutions that serve the mining industry.

AMA's petition expressed concern that 10 CFR 20.1301, which reduced the radiation exposure limit from 500 mrem/yr to 100 mrem/yr, would have an adverse impact on the availability and cost of treatment with radiopharmaceuticals, which outweighs the advantages of reduced radiation exposure to the public. AMA also argued that the 100 mrem/yr exposure limit is inconsistent with medical experience and not necessary to protect the public from radiation hazards.

AMC agrees with AMA that the an increased exposure limit for medical diagnosis and therapy is more than adequately justified in the interest of public health. This is particularly true since AMC believes that in reducing the exposure limit from 500 mrem/yr to 100 mrem/yr, NRC appeared to be making a conservative policy decision rather than a scientific determination based on adverse effects seen at higher exposure levels.

DS10

If you have any questions or we can be of further assistance, please call me at (202) 861-2876 or Katie Sweeney, Counsel, at (202) 861-2812.

Yours very truly,

Roderick T. Dozer
for James E. Gilchrist
Vice President

ACNP 1200 19th Street, N.W. • Suite 300 • Washington, D.C. 20036-2401 SNM

American College of Nuclear Physicians (202) 429-5120 Fax (202) 223-4579 The Society of Nuclear Medicine

October 14, 1994

DOCKET NUMBER
PETITION RULE PRM 35-11
(59 FR 37950)

John C. Hoyle
Acting Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Docketing and Service Branch

RE: Comments on Petition for Rulemaking filed by the American Medical Association; 59 FR 37950 - July 26, 1994.

Dear Mr. Hoyle:

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM)[1] wish to comment on the petition filed by the American Medical Association. We support the petitioners request that NRC amend its regulations to recognize that current medical practice concerning the therapeutic uses of I^{131}, particularly in outpatient settings, is effective and safe for the public. We also support the petitioner's request that NRC formally recognize that adequate home confinement precautions reduce the hazards associated with radioisotopes sufficiently to eliminate the need for hospitalization following therapeutic administration of radiopharmaceuticals. Finally, we support the petitioner's recommendation that NRC increase the external radiation limit for the public from 100 mrem/year to 500 mrem/year.

The ACNP and SNM refer the NRC to comments filed on the patient release criteria proposed rule (59 FR 30724) which outlines our support for rasing the level from 100 mrem to 500 mrem/year. In addition to our comments filed on this rule we feel that the construct offered by the petitioner attempts to eliminate the burdensome paperwork discussed by NRC in their proposed rule on patient release criteria. ACNP and SNM wholeheartedly support any effort by NRC to reduce the amount of paperwork necessary, lower the level of regulatory compliance costs, and implement sound scientific regulations in conjunction with the medical community. In comments to NRC by ACNP/SNM we recommend alternative language similar to that offered by petitioners. This language would make it possible to have an effective rule without the burden of unnecessary paperwork.

ACNP and SNM believe that one major goal for the NRC should be to drastically reduce the amount of paperwork to only that level which is required to protect public health and safety. Currently NRC far exceeds that level placing an unnecessary burden on Nuclear Medicine practitioners and the public. By altering the language in this petition consistent with ACNP/SNM's comments, without any additional paperwork, NRC would move significantly towards this goal.

In conclusion, we support the issues and suggestions raised in the petition by the American Medical Association and urge NRC to adopt this language as part of the proposed patient release criteria rule. If you have any questions please feel free to call Mr. David Nichols, Regulatory Affairs Coordinator at (202) 429-5120.

Sincerely,

William H. McCartney

William H. McCartney, M.D.
President
American College of Nuclear Physicians

James J. Conway, M.D.
President
Society of Nuclear Medicine

[1]ACNP and SNM are composed of over 15,000 nuclear medicine physicians, nuclear pharmacists, nuclear medicine scientists, and nuclear medicine technologists involved in the delivery of essential health care.

STATE OF ILLINOIS
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Jim Edgar
Governor

Thomas W. Ortciger
Director

April 10, 1995

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Re: 60 FR 4872-4877, 10 CFR Parts 20 and 35. Proposed Rule, "Medical Administration of Radiation and Radioactive Materials"

Gentlemen:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the referenced proposed rulemaking. The Federal Register notice indicates that the proposed modifications should be a Division 1 matter of compatibility since basic definitions should be uniform for communication of basic radiation concepts. We realize that NRC is still working on the Compatibility Policy, and we would agree that these modifications to definitions should be Division 1, provided that Division 1 compatibility means the intent, but not the language must be identical.

NRC's interpretation that medical administration of radiation or radioactive material to the wrong individual should be regulated in accordance with 10 CFR Part 35 is parallel to the Department's interpretation. The proposed language modifying "patient" to "individual" should clarify this situation for licensees.

In summary, the Department agrees with the proposed changes described in this Federal Register notice, but cautions against the assignment of compatibility levels when there is no compatibility policy. I you have any questions regarding these comments, please contact me or Kathy Allen at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

cc: Jim Lynch, State Agreements Officer

Done - 4/6/95 - PDR
AF-10-2
#3.1

April 5, 1995

4/17

To: Working group on wrong patient rule: Stewart Schneider, Sam Jones, Cathy Haney, Trish Holahan, and Brad Jones

From: Stephen A. McGuire SAM

SUBJECT: TECHNICAL REVIEW OF FINAL RULE ON, "MEDICAL ADMINISTRATION OF RADIATION AND RADIOACTIVE MATERIALS

Attached for your technical review is a draft final FRN on the wrong patient rule. Also attached to aid in your review is a copy of the proposed rule FRN, the comments received on the proposed rule, the FRN for petition for rule making PRM-35-11, and the comments received on the petition.

I believe that this final rule should be rather straight forward and that this review by the working group can substitute for the division technical review step. Thus, we will be able to go straight to Office Concurrence after your comments have been resolved. We will also have a meeting of the working group to discuss your comments if any significant questions arise as a result of your review.

I would appreciate your comments by April 21. A marked up copy of the FRN is fine.

Attachment: as stated

CC: John Glenn
Cheryl Trottier
Ed Powers

Please pay attention to the wording in the rule as it relates to patient release and to use of "individual" vs. "patient"

Seems Okay -

Stew

~~46 [illegible]~~ 9pp

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

RIN 3150-AF10

Medical Administration of Radiation and Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to clarify 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 the dose limits in the NRC's regulations concerning standards for protection against radiation. The rule does not represent a change in policy, but is necessary to indicate clearly that this is the NRC's policy and to clarify the relationship of NRC's regulations.

DATES: Effective date: _____ (30 days following publication in the Federal Register).

ADDRESSES: Examine comments received at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6204.

SUPPLEMENTARY INFORMATION:

I. Background.

Radioactive materials are administered in the practice of medicine to roughly 8 to 9 million patients per year for the diagnosis or treatment of disease. Occasionally, a radioactive material is administered by mistake to an individual for whom it is not intended.

The misadministration of radiopharmaceuticals is dealt with in NRC regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." As defined in § 35.2, misadministrations include administrations of licensed radioactive material in excess of certain specified quantities to the wrong individual. The practical effect of the definition of an misadministration is that some relatively low dose diagnostic administrations of radiopharmaceuticals to individuals for whom they were not intended are not misadministrations as defined in § 35.2, and Part 35 does not require notification of the NRC or the individual.

Separate from the requirements for misadministrations, § 20.1301(a)(1) contains a dose limit for members of the public of 0.1 rem (1 millisievert). However, the scope of Part 20 in § 20.1002 states that, "The limits in this Part do not apply to doses due .... to exposure of patients to radiation for the purpose of medical diagnosis or therapy ...."

A question arose about the applicability of those words in a particular case in which an individual mistakenly received an administration of a diagnostic radiopharmaceutical because of an error on the part of the physician requesting the test. In that particular case, the dose to the individual receiving the administration was below the threshold for reporting of the misadministration, but above the 0.1 rem (1 millisievert) dose limit in § 20.1301(a)(1) for a member of the public. The question that arose was whether there was a violation of § 20.1301(a)(1) or did the words in the scope of Part 20 exclude this event from being subject to the dose limits in Part 20. In other words, does the exclusion from the Part 20 dose limits exclude any medical administration to any individual, even an individual not supposed to receive an administration?

This same issue was raised in a Petition for Rulemaking (PRM-35-11) filed by the American Medical Association (59 FR 37950; July 26, 1994). That petition requested, in part, that part 20 specifically exclude all medical administrations.

Because of these concerns, the Commission proposed an amendment to 10 CFR Part 20 to clarify the regulations (60 FR 4872, January 25, 1995). The proposed rule explained that the Commission believed that, in general, the administration of radiopharmaceuticals should be regulated by Part 35 rather than Part 20. The medical administration of radioactive materials is a very special use of radioactive materials that is best dealt with by specific regulations covering those administrations. In particular, the Commission believed that an administration to any individual is and should be subject to the regulations in Part 35. That was the Commission's intent when the current misadministration requirements were adopted in the final rule, "Quality

Management Programs and Misadministrations," (July 25, 1991; 56 FR 34104). Further explanation of the Commission's rationale is contained in the Federal Register Notice for the proposed rule (60 FR 4872, January 25, 1995).

II. Comments on the Proposed Rule and Petition for Rulemaking PRM-35-11.

Three comment letters were received on the proposed rule, two from Agreement States and one from a medical health physicist. All supported the proposed rule. Three comment letters were received on PRM-35-11. Each of the letters supported the petition.

The Federal Register Notice on the proposed rule specifically asked for comment on whether to adopt a requirement to inform an individual of the error in the case of administration of a radiopharmaceutical to the wrong individual, but in a quantity below the misadministration threshold. Section 35.33 generally requires notification of the individual in the case of a misadministration. However, if the dose or the amount is less than the misadministration threshold, § 35.33 does not require that the individual who received an administration of a radiopharmaceutical by mistake be notified of the error. One fundamental difference in the case in which the wrong individual receives the administration is that, unlike the intended patient, who it may be argued may have been informed that he or she will be exposed to radiation and has thereby implicitly or explicitly consented to the procedure, the wrong individual has generally not consented to any radiation dose at all. The NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) has assured the NRC that standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual should and

almost always would notify the individual of the mistake. However, the NRC specifically asked whether Part 35 should require that the individual be notified of the error regardless of the dose that would be received.

The comments addressed this question. One favored an NRC regulation requiring notification of the individual regardless of the dose. The other, an Agreement State, opposed a requirement because it would not be consistent with the NRC's medical policy statement, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The NRC has decided that it agrees with this commenter and is not changing its notification requirements.

III. Summary of the Changes.

Neither the comments received nor any other information available to the Commission provide any reasons not to adopt the amendments substantially as proposed, which would regulate administrations to individuals under Part 35 and not Part 20. Therefore the NRC is adopting the amendments as described below.

To clarify the meaning and intent of Part 20, the NRC is amending the Scope of Part 20, the definitions of public dose and occupational dose, and the wording in § 20.1301(a)(1) on public dose limit to clarify that the dose limit for individual members of the public does not apply to dose contributions from any medical administration the individual has received. Thus, the medical administration of radioactive materials or radiation to any individual, even an individual not supposed to receive an administration, is

not subject to the public dose limit in § 20.1301(a)(1), but is within the scope of Part 35.

The changes in Part 20 replace the word "patient" with the word "individual." The word "patient" has sometimes been taken to mean only the individual intended to receive the administration. At other times, the view has been that anyone who receives a medical procedure is a "patient." Replacing "patient" with "individual" clarifies that the statement refers to anyone receiving a medical administration. For consistency, in terminology between parts, the word "patient" in the definition of misadministration in § 35.2, "Definitions," and in certain locations in paragraph (a)(2) of § 35.33 are replaced by the word "individual."

In § 20.1002, the phrase "for the purpose of medical diagnosis and therapy" is replaced by the phrase "any medical administration the individual has received." The existing wording raised the question of whether an administration was within the scope of Part 20 if the administration had no valid medical purpose. The new wording makes it clear that regardless of the purpose or lack of purpose, dose to an individual from any medical administration the individual has received is not within the scope of Part 20, but is within the scope of Part 35.

For the sake of consistency and clarity, the same words are used in § 20.1002, "Scope," in § 20.1003, "Definitions," (in the definitions of both public dose and occupational dose), and in § 20.1301, "Dose limits for individual members of the public." Also for consistency and clarity, the exclusion of dose from background radiation and from voluntary participation in medical research programs that are now included in §§ 20.1002 and 20.1003 are added to § 20.1301(a).

The existing § 20.1301(a) also excludes dose contributions from the licensee's disposal of radioactive material into sanitary sewerage. That exclusion was not be added to §§ 20.1002 and 20.1003 because the question of dose from sewer disposal of radioactive material is now under consideration by the NRC. When that issue is resolved, it is intended that the wording concerning dose from sewer disposal will be made consistent in §§ 20.1002, 20.1003, and 20.1301(a).

A recently published proposed rule (June 15, 1994; 59 FR 30724), which deals with criteria for the release of individuals administered radioactive material, would also amend § 20.1301(a)(1). When that amendment of § 20.1301(a)(1) is published in final form, the wording on what is excluded from the dose limit will be inserted in §§ 20.1002 and 20.1003 (in the definitions of public dose and occupational dose) so that the same parallelism will exist throughout.

IV. Consistency with the 1979 Medical Policy Statement and Coordination with ACMUI.

On February 9 1979 (44 FR 8242), the NRC published a Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes. The first statement of the policy states, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The rule is consistent with this statement because it continues to provide for administrations of radioactive materials to be regulated under 10 CFR Part 35. The rule further clarifies that additional regulations are not considered necessary.

The second statement of the policy states, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." The rule is consistent with the statement because it clarifies that existing requirements concerning misadministrations continue to be concentrated on administrations having the greatest risk significance.

The third statement of the policy states, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The rule is consistent with this statement because it limits its specific regulatory requirements for notification to the most serious errors in administration and minimizes requirements on errors in administrations that have less risk significance.

Thus, the rule is considered to be consistent with the 1979 medical policy statement.

V. Coordination with ACMUI

The subject of this final rule was discussed with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 11, 1995. The ACMUI agreed that medical administrations, including those to an individual not supposed to receive an administration, should be regulated by Part 35 rather than Part 20. The ACMUI stated that notification of an individual of an error in administration below the misadministration threshold is the current practice and should not be regulated.

V. VI. Coordination with and Issue of Compatibility for Agreement States.

Roecklein
PDR
AF-10-2
#32

* * * * *

Occupational dose means the dose received by an individual in ~~a restricted area or in~~ the course of employment in which the individual's assigned duties involve exposure to radiation ~~and to~~ and/or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from voluntary participation in medical research programs, or as a member of the general public.

Public dose means the dose received by a member of the public from exposure to radiation ~~and to~~ and/or radioactive material released by a licensee, or to ~~another~~ any other source of radiation ~~either within a licensee's controlled area or in unrestricted areas.~~ under the control of a licensee It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, or from voluntary participation in medical research programs. Public dose

* * * * *

4. In § 20.1301, paragraph (a)(1) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year,