PDR
AF-10-2
#3
#3,4

From: Larry W. Camper (LWC)
To: sam2
Date: Friday, April 21, 1995 11:58 am
Subject: Patient Release

Let me clarify my point which we discussed. I did not mean that IMNS would literally concur, what I meant was that the management of IMAB and IMNS want to review the document rather than rely upon our member of the technical working group to suffice for that function. As a result, we will work with Sally to provide input and review and if need be meet with the working group to resolve any remaining issues. This aspproach will allow us to make our recommendation to the Office Director etc.

PDR
AF-10-2
#4

6. Background: The proposed rule was published for public comment on January 25, 1995 (60 FR 4872). Only 4 comments were received on the proposed rule. None of the comments opposed the rule. An early draft of the final rule was sent to working group members on April 5. The package has been revised to reflect the comments received.

   No additional resources are anticipated to implement the rule. A copy of this concurrence package has been forwarded to the Office of the Controller for coordination of resource issues per the EDO memorandum of June 14, 1991.

7. Note: Please note that two other final rulemakings are also changing the definitions of public dose and occupational dose in § 20.1003 and that one other rulemaking is changing the applicability of the public dose limit in § 20.1301(a). Depending on the timing of all three rulemakings, those sections will be revised in each to reflect previous Commission actions.

Attachments: As stated (3)

cc w/atts.: R. M. Scroggins, OC
D. C. Williams, IG

Distribution:
RPHEB R/F
Subj. File

Cognizant individuals, w/enclosures

*See previous concurrence

Offc:	RPHEB:DRA	RPHEB:DRA	RPHEB:DRA	D:DRA:RES	D:RES
Name:	SMcGuire*	SSchneider*	JGlenn*	BMorris*	DMorrison
Date:	5/10/95	5/10/95	5/11/95	5/26/95	5/30/95
Copy:	yes/no	yes/no	yes/no	yes/no	yes/no

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(RES File Code) RES 206
(If more than one File Code) RES _____

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

May 30, 1995

MEMORANDUM TO: Carl J. Paperiello, Director
Office of Nuclear Material Safety & Safeguards

Richard L. Bangart, Director
Office of State Programs

Martin G. Malsch, Deputy General Counsel
Office of the General Counsel

Walter E. Oliu, Acting Chief
Rules Review and Directives Branch
Division of Freedom of Information
and Publications Services
Office of Administration

Gerald F. Cranford, Director
Office of Information Resources Management

James Lieberman, Director
Office of Enforcement

FROM: David L. Morrison, Director M. Wayne Hodges for
Office of Nuclear Regulatory Research

SUBJECT: OFFICE REVIEW AND CONCURRENCE ON A FINAL RULE - MEDICAL ADMINISTRATION OF RADIATION AND RADIOACTIVE MATERIALS (RES-940144) (WITS-940099)

Your concurrence is requested on the attached Commission Paper, Federal Register notice, and Congressional letter for the subject final rule.

The following is a summary of this request:

1. Title: "Final Rule on Medical Administration of Radiation and Radioactive Materials."

2. RES Task Leader: Stephen A. McGuire, 415-6204

3. Cognizant Individuals:
   NMSS - Sally Merchant, Cathy Haney
   RES - Stewart Schneider, Sam Jones
   OGC - Bradley Jones
   SP - Lloyd Bolling

4. Requested Action: Review and concur on the rulemaking package.

5. Requested Completion Date: June 13, 1995.

6. Background: The proposed rule was published for public comment on January 25, 1995 (60 FR 4872). Only 4 comments were received on the proposed rule. None of the comments opposed the rule. An early draft of the final rule was sent to working group members on April 5. The package has been revised to reflect the comments received.

   No additional resources are anticipated to implement the rule. A copy of this concurrence package has been forwarded to the Office of the Controller for coordination of resource issues per the EDO memorandum of June 14, 1991.

7. Note: Please note that two other final rulemakings are also changing the definitions of public dose and occupational dose in § 20.1003 and that one other rulemaking is changing the applicability of the public dose limit in § 20.1301(a). Depending on the timing of all three rulemakings, those sections will be revised in each to reflect previous Commission actions.

Attachments: As stated (3)

cc w/atts.: R. M. Scroggins, OC
D. C. Williams, IG

COMMISSION PAPER

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: FINAL AMENDMENTS TO 10 CFR PARTS 20 AND 35 ON MEDICAL ADMINISTRATION OF RADIATION AND RADIOACTIVE MATERIALS

PURPOSE:

To obtain Commission approval to publish a notice of final rulemaking in the Federal Register.

BACKGROUND:

In a staff requirements memorandum (SRM) on SECY-94-027, the Commission directed the staff "to proceed with rulemaking to clarify that the medical administration of radioactivity or radioactive materials to a patient (which includes a 'wrong patient') is the exclusive province of the regulations in Part 35."

In addition, the Commission directed the staff to seek public comment on whether to require notification of the individual in the case of administration of the radiopharmaceutical to the wrong individual if the dose to the individual is less than the 5-rem (50-millisievert) value in Part 35 for a misadministration, but more than the 0.1-rem (1-millisievert) dose limit in 10 CFR 20.1301(a) for a member of the public. The Commission wanted comment "on whether there are practical ways to apply 10 CFR Part 20 to such a situation as that described in SECY-94-027 [administration to the wrong patient but with a dose to the patient below the misadministration threshold] without defeating the policies behind Part 35's definition of the term 'misadministration'."

The proposed rule was published on January 25, 1995 (60 FR 4872). Four comments were received. All supported the change. Two of the comments discussed the notification issue.

CONTACT:
Stephen A. McGuire, RES
415-6204

DRAFT: May 12, 1995

DISCUSSION:

The attached Federal Register notice (Attachment 1) contains a final rule to clarify that the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive an administration, is regulated by Part 35 of the NRC's regulations and is not subject to the dose limits in 10 CFR 20.1301(a)(1). The clarification is accomplished by explicitly excluding any medical administration that an individual has received from the Scope of Part 20, from the definitions of public dose and occupational dose, and from the dose limit in 10 CFR 20.1301(a).

The final rule does not change the notification requirement adopted in 1991 as part of the misadministration rulemaking. Two comments addressed the notification issue. 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'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 NRC staff recommends retaining the notification requirements that the Commission established in the misadministration rulemaking and not amending the notification requirements. Under this recommendation, there would be an NRC notification requirement only for the more serious errors. Notification requirements for less serious errors would be left to the medical profession and to State and local regulations. The NRC staff sees no need to interject the NRC into medical judgements or to override State and local regulations for the less serious errors.

RESOURCES:

No resources are needed to implement this rulemaking.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

RECOMMENDATION:

That the Commission:

1. Approve the notice of final rulemaking for publication (Attachment 1).

2. Certify that this rule will not have a significant economic impact on a substantial number of small entities to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

   a. The rule will be effective 30 days following publication in the Federal Register;

   b. The appropriate Congressional committees will be notified of the final rule change; (Attachment 2)

   c. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act;

   d. The final rule contains no information collection requirements that are subject to review by OMB.

   e. Because this is a clarifying amendment with no significant impact, a public announcement will not be issued.

   f. Copies of the Federal Register notice of final rulemaking will be distributed to all Commission medical licensees and each Agreement State. The notice will be sent to other interested parties upon request.

SCHEDULING:

If scheduled on the Commission agenda, I recommend this paper be considered at an open meeting. No specific circumstance is known to staff which would require Commission action by any particular date in the near future.

James M. Taylor
Executive Director
for Operations

Attachments: As Stated (2)

2. Certify that this rule will not have a significant economic impact on a substantial number of small entities to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

   a. The rule will be effective 30 days following publication in the Federal Register;

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SCHEDULING:

If scheduled on the Commission agenda, I recommend this paper be considered at an open meeting. No specific circumstance is known to staff which would require Commission action by any particular date in the near future.

James M. Taylor
Executive Director
for Operations

Attachments: As Stated (2)

RECORD NOTE: A draft of the final rule was sent to OIG for information on _____, 1995. 5/12 (H) jmt

Offc:	RPHEB:DRA*	RPHEB:DRA*	RPHEB:DRA*	D:DRA:RES	D:NMSS	D:SP	ADM
Name:	SMcGuire	SSchneider	JGlenn	DMorris	CPaperiello	RBangart	PNorry
Date:	05/10/95	05/10/95	05/11/95	5/26/95	/ /95	/ /95	/ /95
Copy:	Yes - No	Yes - No	Yes - No	Yes - ~~No~~	Yes - No	Yes - No	Yes - No

Offc:	D:IRM	OGC	D:OE	D:RES	EDO
Name:	GCranford	KCyr	JLieberman	DMorrison	JMTaylor
Date:	/ /95	/ /95	/ /95	5/30/95	/ /95
Copy:	Yes - No	Yes - No	Yes - No	Yes - No	Yes - No

OFFICIAL RECORD COPY

ATTACHMENT 1

[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 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 to the wrong individual in excess of certain specified quantities ("30 microcuries of either sodium iodide I-125 or I-131") or doses ("5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ"). The practical effect of the definition of a misadministration is that some diagnostic administrations of radiopharmaceuticals to individuals for whom they were not intended are not misadministrations as defined in § 35.2 because the specified quantities or doses are not exceeded, and therefore 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 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.

Four comment letters were received on the proposed rule, three 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 error be notified of the error. The NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI), an advisory committee on rulemakings and other initiatives related to the medical use of byproduct materials, 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.

Two comments addressed this question. One, from an employee at a medical facility, favored an NRC regulation requiring notification of the individual regardless of the dose because sometimes there might be an attempt to keep this information from the individual. 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 to retain the notification requirements that it established in the misadministration rulemaking and thus not amend the notification requirements. Therefore, there will be an NRC notification requirement only for the more serious errors. Notification requirements for less serious errors are left to the medical profession and to State and local regulations. The NRC sees no need to interject itself into medical judgements or to override State and local regulations for the less serious errors.

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 phrase "patient or human research subject" in the definition of misadministration in § 35.2, "Definitions," and in the misadministration reporting requirements in § 35.33, "Notifications, reports, and records of misadministrations," is 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 also added to the definition of public dose in § 20.1003 for the sake of consistency.

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 part 20.

IV. Consistency with the 1979 Medical Policy Statement.

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 the Advisory Committee on Medical Uses of Isotopes

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 is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. 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 medical practice and should not be regulated. A transcript of the meeting has been placed in and is available for examination at the NRC Public Document Room, 2120 L St. NW. (Lower Level), Washington, DC.

VI. 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 appear to regulate such administrations consistent with 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 essentially identical for effective communication of basic radiation concepts. One Agreement State commenting on the compatibility issue supported a Division 1 level. Another Agreement State supported Division 1 compatibility "provided that Division 1 compatability means the intent, but not the language must be identical."

VII. 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.

VIII. 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.

IX. 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.

X. 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.

XI. 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).

XII. 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. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from voluntary participation in medical research programs, or from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

* * * * *

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 term *"patient or human research subject"* and inserting the word *"individual."*

7. In § 35.33, paragraphs (a)(2), (b), and (c) are 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 who received the misadministration; 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), and if not, why not; and if there was notification, what information was provided. The report must not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary

remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual, and the individual's referring physician), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

* * * * *

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

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,
Secretary of the Commission.

remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individualwho received the misadministration, and that individual's referring physician), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

* * * * *

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

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,
Secretary of the Commission.

ATTACHMENT 2

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed final amendments to the Commission's rules in 10 CFR Parts 20 and 35. The amendments revise Parts 20 and 35 to make clear that the dose to an individual from a medical administration of radiation or radioactive materials, even an individual not supposed to receive an administration, is regulated by Part 35 of NRC's regulations rather than Part 20.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Frank Pallone

DRAFT: May 12, 1995

Attachment 2

The Honorable Lauch Faircloth, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
Washington, DC 20510

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed proposed amendments to the Commission's rules in 10 CFR Parts 20 and 35. The amendments, if adopted, would revise Parts 20 and 35 to make clear that the dose to an individual from a medical administration of radiation or radioactive materials, even an individual not supposed to receive an administration, is regulated by Part 35 of NRC's regulations rather than Part 20.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham