PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503**

1. Agency/Subagency originating request
U.S. Nuclear Regulatory Commission

2. OMB control number
[X] a. 3150 - 0010 [ ] b. None

3. Type of information collection *(check one)*
[ ] a. New collection
[X] b. Revision of a currently approved collection
[ ] c. Extension of a currently approved collection
[ ] d. Reinstatement, **without change**, of a previously approved collection for which approval has expired
[ ] e. Reinstatement, **with change**, of a previously approved collection for which approval has expired
[ ] f. Existing collection in use without an OMB control number

4. Type of review requested *(check one)*
[X] a. Regular submission [ ] c. Delegated
[ ] b. Emergency - Approval requested by (date):

5. Will this information collection have a significant economic impact on a substantial number of small entities?
[ ] a. Yes [X] b. No

6. Requested expiration date
[X] a. Three years from approval date
[ ] b. Other (Specify):

7. Title
10 CFR 35, Medical Use of Byproduct Material

8. Agency form number(s) *(if applicable)*
NA

9. Keywords
Radiation Safety, Radioactive Materials

10. Abstract
The NRC is amending the criteria for the release of patients administered radioactive material under 10 CFR 35. The final rule requires licensees to provide the patient with instructions on how to maintain doses to others as low as reasonably achievable and requires licensees to maintain records pertaining to the patient.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*
[ ] a. Individuals or households
[P] b. Business or other for-profit
[X] c. Not-for-profit institutions
[ ] d. Farms
[X] e. Federal Government
[X] f. State, Local, or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*
[ ] a. Voluntary
[ ] b. Required to obtain or retain benefits
[X] c. Mandatory

13. Annual reporting and recordkeeping hour burden
a. Number of respondents: 6,937
b. Total annual responses: 6,678,285
1. Percentage of these responses collected electronically: 0 %
c. Total annual hours requested: 1,336,353
d. Current OMB inventory: 1,319,227
e. Difference: 17,126
f. Explanation of difference
1. Program change: 17,126
2. Adjustment:

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs:
b. Total annual costs (O&M):
c. Total annualized cost requested: 0
d. Current OMB Inventory:
e. Difference: 0
f. Explanation of difference
1. Program change:
2. Adjustment:

15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")*
[ ] a. Application for benefits
[ ] b. Program evaluation
[ ] c. General purpose statistics
[ ] d. Audit
[ ] e. Program planning or management
[ ] f. Research
[P] g. Regulatory or compliance

16. Frequency of recordkeeping or reporting *(Check all that apply)*
[X] a. Recordkeeping [ ] b. Third-party disclosure
[X] c. Reporting
[X] 1. On occasion [ ] 2. Weekly [ ] 3. Monthly
[ ] 4. Quarterly [ ] 5. Semi-annually [ ] 6. Annually
[ ] 7. Biennially [X] 8. Other (describe) Renewals every 5 yrs

17. Statistical methods
Does this information collection employ statistical methods?
[ ] Yes [X] No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*
Name: Steward Schneider
Phone: (301) 415-6225

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, or mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions).

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date
/Israel T. Cardona	10/7/96

OMB SUPPORTING STATEMENT FOR 10 CFR PART 35,
Final Rule, "Criteria for the Release of Individuals
Administered Radioactive Material"
(3150-0010)

Description of Information Collection

This clearance package covers the recordkeeping and reporting requirements of amendments to 10 CFR Part 35, "Medical Use of Byproduct Material," § 35.75, "Release of individuals containing radiopharmaceuticals or permanent implants." The existing § 35.75 contains no information collection requirements. The revision to § 35.75 incorporates the information collection required below.

The information collection requirements in the proposed rule were submitted to OMB and approved under OMB control number 3150-0010. The entire collection is being resubmitted at the final rule stage because of some major changes in the information collections.

A. JUSTIFICATION

The amendment to § 35.75 revises the criteria for authorizing the release of individuals administered radioactive material under 10 CFR Part 35 to permit a maximum dose of 5 millisieverts (0.5 rem) to an individual member of the public and requires written instruction on how to maintain doses to others as low as is reasonably achievable if the dose to an individual exposed to a released patient is likely to exceed 1 millisievert (0.1 rem). In those cases where the released individual may be a breast-feeding woman, the instructions must also include guidance on the interruption or discontinuation of breast feeding and information on the consequences of failure to follow the guidance. The amendment also establishes recordkeeping requirements when the release is authorized using other than standard assumptions or when instructions were provided to a breast-feeding woman because the dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

1. Need for and Practical Utility of the Collection of Information

The information collection requirements of the amendments to 10 CFR Part 35 are identified below.

§ 35.75 Release of individuals containing radiopharmaceuticals or permanent implants.

Paragraph (b) of this section requires licensees to provide, upon release, the patient with written instructions on how to maintain doses to other

individuals as low as reasonably achievable if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem). In those cases where the released individual may be a breast-feeding woman, paragraph (b) also requires the instructions to include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The instructions should be specific to the type of treatment given and may include additional information regarding individual situations. The instructions should include a contact and phone number in case the patient has any questions. Instructions should include, as appropriate: (1) maintaining distance from other individuals, including sleeping arrangements and the need to minimize use of public transportation; (2) the interruption period for breast-feeding and the consequences to the breast-feeding child upon failure to follow the guidance, if applicable; (3) minimizing time in public places (such as grocery stores, shopping centers, restaurants, and sporting events); (4) hygiene; and (5) the length of time precautions should be taken. Written instructions are needed to provide a reference available after the patient's release if questions regarding patient care arise, and to reduce the chance of misunderstanding the licensee's instructions as oral instructions may not be properly conveyed to persons not present at the time of release. The written instructions are also necessary to permit the NRC to verify the type of instructions generally given to patients.

Paragraph (c) of this section requires licensees to maintain, for 3 years, a record of the basis for the release if the release is authorized using other than standard assumptions. The records should include Records should include (1) the patient's name, (2) the radioactive material, (3) the administered activity, (4) the date and time of administration, (5) the date and time of the patient's release, (6) the case-specific factors that were used in calculating the dose to the individual, and (7) the estimated dose to an individual exposed to the patient. The records are necessary so that the NRC inspector can review the method for calculating the dose to determine that the method is adequate to show that the requirements for release were met.

Paragraph (d) of this section requires licensees to maintain, for 3 years after release, a record that instructions were provided to a breast-feeding woman if the administered activity could result in a total effective dose equivalent to the breast-feeding infant exceeding 5 millisieverts (0.5 rem) if the woman did not interrupt or discontinue breast-feeding. The records are necessary so that the NRC inspector can verify that instructions were given to the breast-feeding woman to inform her of the need to interrupt or discontinue breast feeding.

2. Agency Use of Information

Records kept, and written instructions provided by the licensee, will be used by NRC inspectors to evaluate compliance with NRC regulations to assure that the public health and safety are protected.

3. Reduction of Burden Through Information Technology

No responses are submitted to NRC. NRC encourages licensees to utilize any technology which would reduce the burden of recordkeeping and reporting. Archival storage of (1) surveys and prospective evaluations and (2) the content of written instructions lend themselves readily to the use of automated information technology.

4. Effort to Identify Duplication and Use Similar Information

There is no similar information available to the NRC. The Information Requirements Control Automated System (IRCAS) was searched for duplication, and none was found.

5. Effort to Reduce Small Business Burden

The NRC believes that there is no way to reduce the burden on small businesses by less frequent or less complete records while maintaining the required level of safety.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted of Less Frequency

The consequences of less frequent recordkeeping and reporting would be that there would be no basis for demonstrating compliance with the required level of safety through the NRC inspection program.

7. Circumstances Which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultations Outside the Agency

A public meeting to discuss the concepts and approaches of a previous version of the proposed rule with representatives of the Agreement States was held in July 1992 and October 1993. In addition, a draft rule package was sent to the Agreement States for their review and comment in July 1993. The final rule was discussed with the States at a meeting in October 1994. The proposed rule was also discussed with the Advisory Committee on Medical Uses of Isotopes (ACMUI) during public meetings held in October 1992, May 1993, and November 1993. The final rule was discussed with the ACMUI in November 1994, May 1995, and October 1995. The Agreement States and the ACMUI were generally supportive of the approach in the rule.

9. Payment or Gift to Respondents

Not applicable

10. Confidentiality of Information

No information normally considered confidential is requested.

11. Justification for Sensitive Information

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

The total burden to provide instructions and maintain release records is estimated to be about 13 hours per licensee annually, or a total of approximately 17,126 hours annually for all 1,350 NRC and Agreement State medical use of byproduct material licensees. See attached table for details.

13. Estimate of Other Additional Costs

None

14. Estimated Annualized Cost to the Federal Government

The estimated burden on the NRC to review records is estimated to be 1 hour per NRC licensee per year, or 450 hours for all NRC licensees. At a cost of $120 per hour, the annual cost to NRC is $54,000 annually. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Part 171.

The estimated burden on the Agreement States to review records is estimated to be 1 hour per Agreement State licensee per year, or 900 hours for all Agreement State licensees. At a cost of $120 per hour, the annual cost to Agreement States is $108,000 annually.

15. Reasons for Changes in Burden or Cost

The amendment adds recordkeeping and reporting requirements to 10 CFR 35.75 to protect individuals likely to be exposed to patients administered radiopharmaceuticals or permanent implants, for demonstrating compliance with the annual limit for individuals due to the release of patients administered radioactive material. The final rule reflects a burden decrease from that of the proposed rule from 19 to 13 hours per licensee. The proposed rule required records for releases if the total effective dose equivalent to any individual other than the released patient exceeded 0.1 rem. The final rule requires records only for exceptions to standard assumptions and when instructions were provided to a breast-feeding woman if the dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

16. Publication for Statistical Use

There is no application to statistics in the information collected. There is no publication of this information.

17. Reason for not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

Not applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Table 1.

Reporting Requirements

Section	No. of Procedures Requiring Written Instructions Per Year	Hours Per Procedure	Total Burden Hours
35.75(b)			
exceeding 0.1 rem	62,000[1]	1/6	10,333
breast-feeding mothers	27,000[2]	1/6	4,500

Recordkeeping Requirements

Section	No. of Procedures Requiring Records Per Year	Hours Per Licensee	Total Burden Hours
35.75(c)	10,000[3]	2/15	1,333
35.75(d)	7,200[4]	2/15	960

Total burden = 17,126 hours or 13 hours per licensee (17,126 ÷ 1,350) at a cost of $2,055,120 ($120 x 17,126).

[1]50,000 iodine administrations for thyroid ablation + 10,000 iodine administrations for thyroid cancer + 2,000 iodine permanent implants = 62,000.

[2]8,000,000 administrations x 0.5 fraction of the administrations potentially requiring instructions x 0.135 fraction of females of child bearing age (from Table 4.3 of NUREG-1492) x 0.05 breast-feeding = 27,000.

[3]Iodine treatment for thyroid cancer patients.

[4](60,000 iodine + 1,000,000 technetium-99m pertechnetate) x 0.135 fraction of females of child bearing age x 0.05 breast feeding = 7,200.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

RIN 3150-AE41

Criteria for the Release of Individuals Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations concerning the criteria for the release of patients administered radioactive material. The new criteria for patient release are based on the potential dose to other individuals exposed to the patient. The new criteria are consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). This final rule requires the licensee to provide written instructions to patients on how to maintain the doses to others as low as is reasonably achievable if the total effective dose equivalent to any other individual exposed to the released patient is likely to exceed 1 millisievert (0.1 rem). This final rule responds to three petitions for rulemaking regarding the criteria for release of patients administered radioactive material.

EFFECTIVE DATE: _____ (120 days following publication in the Federal Register).

ADDRESSES: Copies of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials"; the final regulatory analysis, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (1997); Revision 2 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (1996); and the public comments received on the proposed rule may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of Regulatory Guide 8.39 may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301) 415-2260. Single copies of NUREG-1492 and NUREG/BR-0058 may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-1800); or from the National Technical Information Service at 5285 Port Royal Road, Springfield, VA 22161.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider or Stepher A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6225.

I. Background

Each year in the United States, radioactive pharmaceuticals or compounds or radioactive implants are administered to approximately 8 to 9 million individuals for the diagnosis or treatment of disease or for human research. These individuals to whom radioactive materials have been administered are

hereinafter referred to as "patients." These patients can expose others around them to radiation until the radioactive material has been excreted from their bodies or the radioactivity has decayed away.

NRC's current patient release criteria in 10 CFR 35.75, "Release of patients or human research subjects containing radiopharmaceuticals or permanent implants," are as follows:

"(a) A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either: (1) The measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter; or (2) The activity in the patient or human research subject is less than 30 millicuries; (b) A licensee may not authorize release from confinement for medical care of any patient or human research subject administered a permanent implant until the measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter."

On May 21, 1991 (56 FR 23360), the NRC published a final rule that amended 10 CFR Part 20, "Standards for Protection Against Radiation." The rule contained limits on the radiation dose for members of the public in 10 CFR 20.1301. However, when 10 CFR part 20 was issued, there was no discussion in the supplementary information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients.

Some licensees were uncertain about what effect the revised 10 CFR Part 20 would have on patient release criteria, and two petitions for rulemaking were received on the issue. On June 12, 1991 (56 FR 26945), the NRC published in the Federal Register a notice of receipt of, and request for

comment on, a petition for rulemaking (PRM-20-20) from Dr. Carol S. Marcus. In addition, Dr. Marcus submitted a letter dated June 12, 1992, further characterizing her position.

On March 9, 1992 (57 FR 8282), the NRC published a notice of receipt and request for comment in the Federal Register on another petition for rulemaking (PRM-35-10) on patient release criteria from the American College of Nuclear Medicine (ACNM). On May 18, 1992 (57 FR 21043), the NRC published in the Federal Register notice of an amendment submitted by the ACNM to its original petition (PRM-35-10A).

In addition, a third petition (PRM-35-11) dealing, in part, with these same issues was submitted by the American Medical Association (AMA). That petition was noticed in the Federal Register on July 26, 1994 (59 FR 37950). The main point raised in the petition was that the radiation dose limits in 10 CFR part 20 should not apply to individuals exposed to the patient and that the dose limit to the individuals should be 500 millirems per year. The AMA believed that 10 CFR 20.1301 would have an adverse impact on the availability and the cost of treatment of thyroid disease, which would outweigh the advantages of reduced radiation exposure to the public. The AMA stated that treatment of up to 10,000 cancer patients annually for thyroid carcinoma would require the hospitalization of the patients under the revised regulation (10 CFR 20.1301), reducing both early release of patients and the treatment of patients at home.

II. Publication of the Proposed Rule

On June 15, 1994 (59 FR 30724), in response to the first two petitions, the NRC published a proposed rule on criteria for the release of patients administered radioactive material. The proposed rule discussed the public comment letters received on the first two petitions. Three additional comment letters were received on the third petition (PRM-35-11). These letters each supported the petition but did not contain any additional information not covered by the letters on the first two petitions.

The NRC proposed to amend 10 CFR 20.1301(a)(1) to specifically state that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensed operation under the provisions of 10 CFR 35.75. This was to clarify that the Commission's policy is that patient release is governed by 10 CFR 35.75, not 10 CFR 20.1301.

The NRC proposed to amend 10 CFR 20.1301(a)(2) to specifically state that the limit on dose in unrestricted areas does not include dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75. The purpose was to clarify that licensees would not be required to control areas (such as waiting rooms) simply because of the presence of a patient released pursuant to 10 CFR 35.75. If a patient has been released from licensee control pursuant to 10 CFR 35.75, licensees would not be required to limit the radiation dose from a patient to members of the public (e.g., visitors in a waiting room) to 0.02 millisievert (2 millirems) in any 1 hour. Patient waiting rooms or hospital rooms would need only be controlled for those patients not meeting the release criteria in 10 CFR Part 35.

The NRC proposed to adopt a new 10 CFR 35.75(a) to change the patient release criteria from 1,110 megabecquerels (30 millicuries) of activity in a patient or a dose rate of 0.05 millisievert (5 millirems) per hour at 1 meter from a patient to a total effective dose equivalent not to exceed 5 millisieverts (0.5 rem) in any 1 year to an individual from exposure to a released patient. A dose-based limit provides a single limit that could be used to provide an equivalent level of risks from all radionuclides. Also, the proposed changes were supported by the recommendations of the ICRP and the NCRP that an individual could be allowed to receive an annual dose up to 5 millisieverts (0.5 rem) in temporary situations when exposure to radiation is not expected to result in annual doses above 1 millisievert (0.1 rem) for long periods of time.

The NRC proposed to adopt a new 10 CFR 35.75(b)(1) to require that the licensee provide released patients with written instructions on how to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in any 1 year. A requirement to give instructions to certain patients was already contained in 10 CFR 35.315(a)(6) and 35.415(a)(5), but the proposed requirement would also require instructions for an additional 50,000 individuals who are administered iodine-131 for the treatment of hyperthyroidism and another 27,000 individuals who are breast-feeding and administered various diagnostic and therapeutic radioactive materials. The purpose of the instructions is to maintain doses to individuals exposed to patients as low as is reasonably achievable.

The NRC proposed to adopt a new 10 CFR 35.75(b)(2) to require that licensees maintain, for 3 years, a record of the released patient and the

calculated total effective dose equivalent to the individual likely to receive the highest dose if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration. The major purpose was to provide a record to allow licensees to assess the need to limit the dose to individuals exposed to a patient who may receive more than one administration in a year.

Finally, the NRC proposed to amend its requirements on instructions in 10 CFR 35.315(a)(6) and 35.415(a)(5). These regulations already required instructions (not necessarily written) in certain cases, but the phrase "if required by § 35.75(b)" was added to each. The purpose of this change was to make Part 35 consistent as to when instructions must be given.

In addition, the NRC concurrently issued an associated draft regulatory guide and supporting draft regulatory analysis for public comment. The draft regulatory guide, DG-8015, "Release of Patients Administered Radioactive Materials," proposed guidance on determining the potential doses to an individual likely to receive the highest dose from exposure to a patient and established appropriate activities and dose rates for release of a patient. The draft guide also proposed guidelines on instructions for patients on how to maintain doses to other individuals as low as is reasonably achievable and it described recordkeeping requirements. The draft regulatory analysis, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (May 1994), examined the benefits and impacts of the proposed rule considered by the NRC.

III. Public Comments on the Proposed Rule

A total of 63 comment letters were received on the proposed rule, the draft regulatory guide, and the draft regulatory analysis. A majority of the comment letters were from medical practitioners and medical organizations, but there were also comment letters from private individuals, public-interest groups, and regulatory agencies in Agreement States. Overall, the majority of comment letters supported a dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients released with radioactive material. However, about one-fourth of the comment letters opposed the proposed recordkeeping requirement. The significant comments are discussed below, arranged by subject.

EXCLUSION OF PATIENT RELEASE FROM § 20.1301(a)

All the commenters except one supported governing patient release by the regulations in 10 CFR 35.75 and excluding the dose to individuals exposed to a released patient from 10 CFR 20.1301(a).

Comment. One commenter, representing a public-interest group, objected to any exposure of a member of the general public who has not consented freely to the dosage. They said that such exposure would lead to widespread morbidity and mortality.

Response. In its revision of 10 CFR Part 20 (56 FR 23360; May 21, 1991), the NRC determined that, while doses should be maintained as

low as is reasonably achievable, a dose limit of 1 millisievert (0.1 rem), or a dose limit of 5 millisieverts (0.5 rem) in certain special circumstances, provides adequate protection. The revised Part 20 is based, in part, upon the recommendations of the International Commission on Radiological Protection (ICRP) and the recommendations of the National Council on Radiation Protection and Measurements (NCRP). The NCRP recommends public dose limits of 1 millisievert (0.1 rem) for continuous or frequent exposure and 5 millisieverts (0.5 rem) for infrequent exposure.

The ICRP recommends that the limit for public exposure should be expressed as an effective dose of 1 millisievert (0.1 rem) in a year, except that, in special circumstances, the dose could be higher in a single year provided the average over 5 years does not exceed 1 millisievert (0.1 rem) per year. In ICRP Publication 60, in defining medical exposure, ICRP stated that medical exposure includes "exposures (other than occupational) incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis or treatment." Furthermore, in explaining dose limits in medical exposure, the ICRP stated in the same publication that "the Commission therefore recommends that dose limits should not be applied to medical exposures." Thus, in ICRP's opinion, family members who are helping in the support and comfort of patients would not be restricted under the dose limit stated above.

The revision of Part 20 incorporated the long-term objective as the dose limit and included a provision (§ 20.1301(c)) to allow for alternative limits on an occasional basis. Section 20.1301(c) provides that an annual dose of up to 5 millisieverts (0.5 rem) is acceptable if there is a need for it and if

steps are taken to reduce the dose to as low as is reasonably achievable. The NRC reaffirms that previous determination in this rulemaking.

In the case of released patients, it would be unlikely for a single individual exposed to a patient to receive a dose in a year of over 5 millisieverts (0.5 rem) because large therapeutic doses (greater than 3,700 megabecquerels (100 millicuries)) are usually not administered more than once to the same patient in a given year.

Comment. One commenter said that the NRC should change the 0.1 rem dose limit for the public in 10 CFR 20.1301(a)(1) to 0.5 rem for all licensed activities because a dose limit of 0.5 rem offers adequate protection and is a dose that has no proven effects.

Response. This issue of the general public dose limit is outside the scope of this rulemaking. The issue was dealt with when 10 CFR Part 20 was recently revised (56 FR 23360; May 21, 1991). That rulemaking explained the NRC's rationale for adopting the 1-millisievert (0.1-rem) dose limit in 10 CFR 20.1301(a)(1).

ACTIVITY-BASED VS. DOSE-BASED RELEASE LIMIT

The issue is whether to retain the current patient release limit in 10 CFR 35.75, which is expressed as an activity limit together with an alternative but approximately equivalent limit on dose rate at 1 meter, or to express the release limit as a dose to an individual exposed to the patient.

The majority of commenters supported the dose-based limit. However, some commenters opposed the dose-based approach.

Comment. A number of commenters said that 10 CFR 35.75 should not be changed and that the 30 millicurie or 5 millirem per hour release criteria should be retained because they are working well. Some commenters said that a dose-based release limit as proposed would cause confusion and potential problems. One commenter said that the Part 20 revision was not intended to alter the status quo for patient release. Commenters objected to the dose-based release limit because they thought the dose estimates to the public would be very inaccurate as these estimates are based on the unreliable method of predicting the anticipated time and proximity to others. Commenters also said that dose estimation and the subsequent recordkeeping would be time consuming and would add to the cost of treatment without a probable significant decrease in radiation exposure.

Response. The NRC is adopting a dose-based limit rather than an activity-based limit because the dose-based limit better expresses the NRC's primary concern for the public's health and safety. A single activity requirement was not retained because different radionuclides with the same activity can give very different doses under identical exposure conditions. Likewise, a single dose rate requirement for all radionuclides was not retained because different radionuclides with the same dose rate, at the time of release, can give very different doses depending upon the half-life of the radionuclide. The total dose depends on the effective half-life of the

radioactive material in the body of the patient and other factors that vary for different materials. For these reasons, the NRC is establishing a dose limit rather than an activity or dose rate limit.

The NRC is establishing a dose limit of 5 millisieverts (0.5 rem) total effective dose equivalent to an individual from exposure to the released patient for each patient release. This dose limit is consistent with the underlying risk basis of the current 10 CFR 35.75 (50 FR 30627; July 26, 1985), the recommendations of the NCRP and the ICRP, and the provisions in 10 CFR 20.1301(c) pertaining to temporary situations in which there is justification for a dose limit higher than 1 millisievert (0.1 rem).

The NRC believes that the dose-based release limit can and will work well because the associated Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," can be used to relate the dose to the quantity of activity in the patient. The guide provides conservative estimates of activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in the final rule. The approach used in the regulatory guide is based on NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."[1] In the case of iodine-131, the most significant radionuclide, the release quantity based on the standard conservative assumptions is 1.2 gigabecquerels (33 millicuries), which is essentially the same as the current release quantity.

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[1]National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37 (October 1, 1970). (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

NUREG-1492 contains a detailed examination of the benefits and impacts of the final rule that includes dose estimation, recordkeeping, and radiation exposure. Single copies of the final regulatory analysis and Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," are available as indicated in the ADDRESSES heading.

Comment. A commenter said that the calculational approach in the rule would require the physician to ask many personal questions of the patient.

Response. The commenter is incorrect in believing that the dose-based approach will generally require personal information from the patient. The NRC anticipates that nearly all patients will be released based on default assumptions which do not require any personal information from the patient. A table of release quantities, based on standard conservative assumptions, is provided in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." However, the rule does allow the physician to calculate patient-specific dose estimates to allow early release of a patient not otherwise subject to release under the default values in Regulatory Guide 8.39. Personal information may be necessary for such patient-specific cases.

Comment. One commenter said that it should continue to be acceptable to release patients based on the dose rate at 1 meter.

Response. The rule authorizes release of patients based on the dose to an individual for each patient release. However, release quantities based on dose rate and conservative assumptions can be calculated. The table of release quantities in Regulatory Guide 8.39, "Release of Patients Administered

Radioactive Materials," specifies the dose rate at 1 meter of commonly used radionuclides that allow licensees to authorize patient release.

RELEASE QUANTITIES

Using a dose-based system based on a dose to the most highly exposed individual of 5 millisieverts (0.5 rem) would, in some circumstances, allow release of a patient with more than 1,110 megabecquerels (30 millicuries) of activity. Some commenters were opposed to allowing releases with higher activities than are now permitted.

Comment. Several commenters said that the release of patients with more than 30 millicuries of iodine-131 should not be permitted because of concerns about the risk of internal exposure. One commenter said that doses to family members from the patient vomiting were not adequately considered. The same commenter also said that a study indicated that in-home contamination by patients dosed with I-131 could double family members' risk of developing thyroid cancer.

Response. The concern over contamination is not justified by the radiation doses that are likely to be caused by the removal of radionuclides from the patient's body by the pathways of exhaled air, feces, saliva, sweat, urine, and vomit. Measurements from several studies, as discussed in the supporting regulatory analysis, have shown that a relatively small proportion of the radioactive material administered will appear as contamination. Doses to family members exposed to contamination from living in close contact with

released patients have been measured in several studies and in every case were less than 10 percent of the 5-millisievert (0.5-rem) total effective dose equivalent limit and were most often less than 1 percent of the 5-millisievert (0.5-rem) limit. In addition, the internal doses resulting from contamination were always less and generally far less than the external dose, meaning that contamination was the less important source of radiation exposure. These measurements show that even if the family members repeatedly touched household items touched by the patient, contamination does not cause unacceptably high doses. These findings were true even in the case of a British study where eleven patients volunteered to disregard special precautions against contamination and minimizing spousal and family exposure. These measurements are discussed in NUREG-1492. Also, the NCRP recently addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," and concluded that, "... a contamination incident that could lead to a significant intake of radioactive material is very unlikely."[2]

In general, the physical reactions (e.g., vomiting) that a patient may experience from the administration of any radiopharmaceutical are rare. Vomiting is seldom an important elimination route for radiopharmaceuticals after the patient has left the medical facility since orally administered radiopharmaceuticals such as iodine-131 are rapidly absorbed, within a half hour, by the gastrointestinal system.

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[2]National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," NCRP Commentary No. 11 (February 28, 1995). (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

Regarding the comment on the doubling of risk of developing thyroid cancer, there is no scientific consensus by the United Nations Scientific Committee on the Effects of Atomic Radiation, ICRP, or NCRP to support the suggested increased risk of thyroid cancer following ingestion of iodine-131. Based on the information currently available, the Commission continues to conclude that the benefits outweigh the potential of small increased risks associated with this rule.

Comment. One commenter noted that hospitals now make great efforts to control contamination from patients who are now hospitalized because they contain more than 30 millicuries of iodine-131. This commenter stated that it would not be possible to maintain the same level of contamination control at these patients' homes if these patients were released with more than 30 millicuries of iodine-131.

Response. The NRC agrees that, even though released patients are given instructions on how to limit the hazard from contamination, contamination control in a hospital can be more effective than contamination control out of the hospital. However, the two situations are not really comparable. In the case of the released patient at home, therapeutic administrations usually occur no more than once in a year and probably no more than once in a lifetime; but in the case of a hospital, large therapeutic administrations are done repeatedly on many patients. Therefore, areas in hospitals have the potential for contamination from many patients, and people who frequent the hospital (e.g., clergy or a hospital orderly) have the potential to be exposed to contamination from many patients. In addition, the 5-millisievert

(0.5-rem) limit that is applied to household members exposed to a patient is a special limit that is appropriate for only occasional use and for use where there is a definite need. This special limit fits the case of doses received by the household members of a released patient, but does not fit the case of people who frequent a hospital on a routine basis. Lastly, in limiting doses, the NRC considers what is reasonably achievable. The mere fact that a home cannot control contamination as well as a hospital does not mean that the contamination control achieved in homes is not adequate. Actual measurements of doses to household members from contamination, as discussed in NUREG-1492, show that the doses from contamination are low, demonstrating that the degree of contamination control that was achieved is adequate.

Comment. One commenter said that the proposed rule did not adequately address the concerns that the Agreement States expressed on the petitions for rulemaking concerning releasing patients with quantities of iodine-131 in excess of 30 millicuries.

Response. In commenting on the petitions, a number of States expressed concerns about releasing patients administered 14.8 gigabecquerels (400 millicuries) of iodine-131, which one of the petitioners had requested. However, the States that commented were generally favorable to the proposed rule limiting the dose to the most exposed individual to 5 millisieverts (0.5 rem), and none of the States indicated that their concerns were misrepresented. In fact, one Agreement State commented that it was pleased that the NRC had considered the comments made by the Agreement States at various meetings with the NRC. The dose-based limit would generally permit releases if the dose to another individual would not be likely to exceed

5 millisieverts (0.5 rem). For example, if a licensee uses the default table of release quantities provided in the regulatory guide as the basis for release, a patient administered 1.2 gigabecquerels (33 millicuries) or less of iodine-131 could be immediately released and no record of release is required. However, if the licensee wishes to release a patient with an activity that is greater than the value in the default table, the licensee must do a dose calculation using case-specific factors to demonstrate compliance with the release criteria. Furthermore, if the table is used as the basis for release but the administered activity exceeds the value in the table, the licensee must hold the patient until the time at which the retained activity is no greater than the quantity in the table or the dose rate at 1 meter is no greater than the value in the table. When the administered activity is greater than the value in the default table, a record of the basis for the release must be maintained for NRC review during inspection. Regardless of the method used by the licensee to authorize release, the dose limit of 5 millisieverts (0.5 rem) in the revised 10 CFR 35.75 applies. By identifying more than one method for calculating the release of a patient in accordance with 10 CFR 35.75, the NRC provides greater flexibility for licensees to achieve compliance with the new requirement while still providing adequate protection of public health and safety.

Comment. One commenter said that in some cases it should be permissible to authorize the release of a patient even if the dose to a family member might exceed 0.5 rem because the release might be beneficial and acceptable to family members. Another commenter said that a dose of 0.5 rem to an

individual exposed to a patient has so little hazard that the NRC should not be concerned with it.

Response. The NRC does not believe that individuals exposed to a patient should, in general receive doses in excess of 5 millisieverts (0.5 rem). This is consistent with the recommendations of the ICRP in ICRP Publication 60,[3] "1990 Recommendations of the International Commission on Radiological Protection"; and the recommendations of the NCRP in NCRP Report No. 116,[4] "Limitation of Exposure to Ionizing Radiation." Each of these recommendations provides a basis for allowing individuals to receive annual doses up to 5 millisieverts (0.5 rem) under certain circumstances. Both the ICRP and the NCRP recommend that an individual can receive a dose up to 5 millisieverts (0.5 rem) in a given year in situations when exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) per year for a long period of time, as would be the case for doses from released patients. In NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients,"[2] the NCRP recommended a dose limit of 5 millisieverts (0.5 rem) annually for members of the patient's family. However, on the recommendation of the treating physician, the NCRP considered it acceptable that members of the patient's family be permitted to receive doses as high as 50 millisieverts (5 rems).

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[3]International Commission on Radiological Protection (ICRP), "1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication No. 60 (November 1990). Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.

[4]National Council on Radiation Protection and Measurements, "Limitation of Exposure to Ionizing Radiation," NCRP Report No. 116 (March 31, 1993). Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.

The NRC does not agree that the latter NCRP recommendation should apply in general. The NRC believes that if the dose to another individual is likely to exceed 5 millisieverts (0.5 rem), the patient should remain under the control of the licensee. Licensee control is necessary to provide adequate protection to the individuals exposed to the patient.

RECORDKEEPING

The strongest opposition to the proposed rule was to the proposed requirement to maintain a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose if the dose to that person is likely to exceed 1 millisievert (0.1 rem). Under the proposed rule, if a patient had or might have had one or more administrations within the same year, the licensee would use the records to determine the dose from the previous administrations so that the total dose to an individual exposed to a patient from all administrations would not exceed 5 millisieverts (0.5 rem).

Comment. Many commenters indicated that this requirement would cause excessive costs in time, effort, and money to track down records of previous administrations, to perform calculations, and to keep records of all the work and asked that the requirements to make calculations and keep records be removed. The commenters believed that the work would not produce an increased level of safety, that the NRC greatly underestimated the cost, and that the recordkeeping would be unnecessary, inappropriate, and impractical. Some commenters said that multiple administrations that would result in a total

effective dose equivalent greater than 1 millisievert (0.1 rem) are not done to the same patient routinely. Other commenters said that there have been decades of experience unencumbered by any paperwork burden at all with no evidence that a lack of paperwork has resulted in any additional problems. One commenter said that if 0.5 rem is acceptably safe, why have the documentation required at the 0.1 rem level.

Another commenter said that it cannot be a licensee's responsibility to know the details of a radionuclide therapy performed by another licensee in terms of which members of the public received the most radiation dose from that other licensee's therapy procedure.

One commenter said that the excessive recordkeeping cost would be a nonreimbursable cost, and the burden will cause many physicians to stop offering iodine therapy, which would force patients to travel to large medical facilities in cities and cause problems with patient access in sparsely populated areas.

Response. Upon reconsideration, the NRC has decided to delete the requirement to keep records when the dose to the most highly exposed individual is likely to exceed 1 millisievert (0.1 rem). The requirement was proposed so that it would be possible to account for the dose from multiple administrations in the same year to ensure that the total dose to an individual exposed to the patient did not exceed 5 millisieverts (0.5 rem).

The NRC has an advisory committee, the Advisory Committee on the Medical Uses of Isotopes, or "ACMUI," which advises the NRC on rulemakings and other initiatives related to the medical use of byproduct materials. The NRC also has a visiting medical fellows program that recruits selected physicians or

pharmacists to work for the NRC for a period of 1 to 2 years. Both the ACMUI and the current Visiting Medical Fellow, Myron Pollycove, M.D., provided advice to the NRC during the development of this rule. In addition, Barry A. Siegel, M.D., Chairman of the ACMUI, reviewed the patient records at his medical facility for the 1-year period from July 1, 1993, to June 30, 1994 (Mallinckrodt Institute of Radiology, St. Louis, Missouri). Drs. Siegel and Pollycove concluded that no common nuclear medicine practice, be it diagnostic, therapeutic, or a combination of the two, results in multiple large administrations that would be likely to cause the 5-millisievert (0.5-rem) dose limit to be exceeded because of multiple administrations in a year.

While the proposed requirement to maintain a record of the dose to another individual if the dose is likely to exceed 1 millisievert (0.1 rem) has been deleted, a recordkeeping requirement with a reduced impact has been retained as discussed under the heading, "Discussion of Text of Final Rule."

Comment. Several commenters said that those who pay for health care will put great pressure on physicians to optimize calculations to reduce in-patient days and to justify out-patient treatments.

Response. There is no objection to optimizing calculations to reduce in-patient days as long as the calculations are realistic and the 5-millisievert (0.5-rem) limit in 10 CFR 35.75 is met. Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes examples of calculations that are acceptable to the NRC.

WRITTEN INSTRUCTIONS TO PATIENTS

In general, there was little objection to providing instructions to patients on how to minimize the dose to others, but there was significant opposition to the proposed requirement that the instructions would have to be written.

Comment. One commenter said that the Statement of Considerations for the proposed rule was in error in stating that the existing regulations already required that the instructions to patients be written.

Response. The commenter is correct. The Statement of Considerations was in error on that point. The existing regulations do not specify that instructions have to be in written form.

Comment. A number of commenters said that instructions should not need to be written and that oral instructions should be permissible. Some of these commenters said that oral instructions are more effective and that how the instructions should be given is within the province of the doctor-patient relationship and that the NRC and its regulations should not interfere with that relationship. One commenter said that the physical condition of the patient could lessen the patient's ability to follow the instructions. Another commenter said that the standard written instructions require too much time explaining how each patient varied from the standard instruction sheet. However, one Agreement State and a major health maintenance organization strongly supported the requirement that the instructions be written.

Response. The NRC believes that providing written instructions has a significant value because often patients will not remember all of the instructions given orally. In addition, written instructions can be read by other family members or care-givers. The requirement to provide the instructions in written form was also supported by the ACMUI.

This regulation allows the licensee to determine the form of the written instructions. The NRC believes that for the majority of releases requiring written instructions, the written instructions can be prepared in a generic form. For example, the Society of Nuclear Medicine has prepared a brief pamphlet, "Guidelines for Patients Receiving Radioiodine Treatment," which can be given to patients at nominal cost (less than $1 per patient). However, oral instructions may also be provided in all cases.

Comment. Several commenters said that dictating to a physician how and what he or she must tell a patient is not the purview, mandate, or competence of the NRC and interferes with an essential part of medical practice, which is communication between physician and patient.

Response. In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," the NRC made three specific statements. The third statement of the policy is "The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The final rule is consistent with this statement because it does not dictate the choice of medical treatment or diagnosis, does not specify the details of what the physician must say or must

include in the contents of the written instructions, and is directed at minimizing the risk to the patient's family who have no doctor-patient relations to the prescribing or administering personnel. However, Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," recommends contents of the written instructions.

Further discussion of the 1979 Medical Policy Statement is presented under the heading, "VIII. Consistency with 1979 Medical Policy Statement."

Comment. Several commenters asked whether written instructions were appropriate if the patient was blind, illiterate, or did not read English. Another commenter said that the instructions should be both written and oral and should be in the primary language of the patient.

Response. The NRC believes that written instructions are useful and should be required. If the patient is blind, illiterate, or does not read English, it is likely that someone else will be able to read the instructions for the patient. NRC considers it too much of a burden to require that the instructions be given in the primary language of the patient, although the regulations do not preclude foreign language written instructions if the licensee chooses to provide them. In most situations, it will be possible to find someone who can translate for the patient if necessary. The requirement that written instructions be given to the patient does not preclude additional oral instructions.

Comment. Several commenters asked how the NRC would enforce implementation of the instructions given to the patient. Another commenter

asked how the licensee could verify that the instructions are followed. Another commenter said that a sizable fraction of patients may not follow radiation safety instructions to protect spouses and may be even less careful about protecting total strangers. This commenter also asked whether it is reasonable to expect that released patients will alter their behavior and limit their activities for the protection of others.

Response. The NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility. However, it is the responsibility of licensees to provide instructions to the patients. Following the instructions is normally the responsibility of the patient. However, American medical practice routinely depends on patients following instructions, such as instructions on when and how to take medications.

With regard to compliance with the instructions, surveys of patients and their spouses, as discussed in the supporting regulatory analysis, indicate that most will attempt to follow the instructions faithfully, especially with regard to protecting their children, although some patients and their spouses indicated that they might not keep physically distant from their spouse for prolonged periods of time.

Comment. One commenter said that instructions should be given for all administrations of radioactive material, regardless of the quantity administered.

Response. The NRC does not agree. In some cases, particularly in the large number of diagnostic administrations, the potential doses are so small

that the burden of requiring instructions cannot be justified. Under the final rule, if the dose to any individual exposed to the patient is not likely to exceed 1 millisievert (0.1 rem), instructions are not required but the physician could give any instructions that he or she considers desirable.

CONFINEMENT OF PATIENTS

Comment. Two commenters said that patients cannot be confined against their wishes and that the rule provides no penalty for the patient who leaves confinement in the hospital "against medical advice." Another commenter said that the rule seems to require that the licensee have control of the patient's activities after release.

Response. The NRC recognizes that patients cannot be held against their will. The rule deals with the conditions under which the licensee may authorize release. The NRC would not penalize a licensee for the activities of the patient after release or if the patient were to leave "against medical advice."

Comment. One commenter asked whether a patient who was releasable but was still hospitalized for other reasons would still be considered under the licensee's control.

Response. Once the licensee has authorized the release of the patient, there is no need to keep the patient under licensee control for radiation protection purposes if the patient remains hospitalized for other reasons.

However, good health physics practice would be to continue to make efforts to maintain doses to people at the facility as low as is reasonably achievable.

Comment. Commenters also asked how a patient can be confined to his or her house.

Response. These commenters misunderstood the concept of confinement. As explained in the Statement of Considerations for the proposed rule (59 FR 30724), the term "confinement" no longer applies to the revision to 10 CFR 35.75. Instead, the text of the rule uses the phrase "licensee control" to more clearly reflect the NRC's intent.

The NRC believes that there is a distinct difference between a patient being under licensee control in a hospital or other licensee facility (e.g., a hospice or nursing home) and being at home. In a hospital or other area or address of use listed on the NRC license, the licensee has control over access to the patient as well as having trained personnel and instrumentation available for making radiation measurements not typically available at the patient's home. In addition, while under licensee control, a licensee has control over the dose by limiting the amount of time that individuals are in close proximity to the patient. A patient who goes home is released from licensee control.

Comment. One commenter thought that the rule should define the term "release."

Response. The term "release from licensee control," when read in context, refers to radiation protection considerations and is sufficiently clear that there is no need to define the term.

MISCELLANEOUS COMMENTS ON THE RULE

Comment. Several commenters said that the rule should not be a matter of Agreement State compatibility at any level.

Response. The NRC does not agree. The NRC conducts an assessment of each proposed requirement or rule to determine what level of compatibility will be assigned to the rule. These case-by-case assessments are based, for the most part, on protecting public health and safety. NRC has evaluated the final rule and assigned compatibility designations ranging from level 1 (full compatibility required) to level 3 (uniformity not required) as detailed later in this Federal Register notice.

Comment. Several commenters said that a breast-feeding infant should not be considered as an individual exposed to the patient for the purposes of determining whether patient release may be authorized. These commenters said that consideration of the breast-feeding infant should be under the jurisdiction of the physician, that the issue is a medical issue rather than a regulatory issue, and that the NRC should not interfere in medical issues.

Response. The NRC does not agree. The NRC has a responsibility to protect the public health and safety, and that responsibility extends to all individuals exposed to a patient administered licensed radioactive materials, including breast-feeding children. When the release is authorized, it is

based on the licensee's determination that the total effective dose equivalent to an individual from the released patient is not likely to exceed 5 millisieverts (0.5 rem). The dose to the breast-feeding child from breast-feeding is a criterion for release but it can be controlled by giving the woman guidance on the interruption or discontinuation of breast-feeding, as required by the new 10 CFR 35.75. However, the release could be based on the default table of release activities in the regulatory guide or a patient-specific calculation, as required by the new 10 CFR 35.75. The issue of the dose to the breast-feeding child is discussed in NUREG-1492 and Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials."

Comment. One commenter said that the proposed rule did not accurately represent the position of the Advisory Committee on Medical Uses of Isotopes.

Response. A review of the transcript for the ACMUI meeting in May 1992 shows that the Federal Register Notice provided an accurate description of the ACMUI position. The final rule was discussed with the ACMUI on October 18, 1995, and the ACMUI, in general, supported the rule. (For ACMUI's comments and NRC's responses, see Section V. Coordination with the Advisory Committee on Medical Uses of Isotopes.)

Comment. One commenter said that its facility treated many foreign patients with therapeutic pharmaceuticals. These patients frequently may leave the hospital and immediately board a plane to return home. Thus, there is a limit to the amount of control that a licensee has over the patient.

Response. The NRC recognizes that the licensee has no control over the patient after the patient has been released. The quantities for release listed in Table 1 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," were calculated using conservative assumptions (for example, by using the physical half-life of the radioactive material rather than the more realistic effective half-life). Thus, the NRC considers it unlikely that the dose to an individual in real circumstances would approach 5 millisieverts (0.5 rem).

In special situations, such as when a released patient would immediately board an airplane and would therefore be in close contact with one or more individuals, it may be necessary to base the release on a more realistic case-specific calculation. Once the patient is released, the responsibility for following the instructions is entirely the patient's, not the licensee's.

COMMENTS ON THE DRAFT REGULATORY GUIDE

Comments were also requested on Draft Regulatory Guide, DG-8015, "Release of Patients Administered Radioactive Materials," associated with this rulemaking. Because the guide is associated with the rule, the comments received on the draft guide are discussed here. Most of the comments concerned the method and the assumptions used to calculate the dose to the individual likely to receive the highest dose.

Comment. Several commenters said that the calculational methodology in the draft guide is too complex and that the assumptions are too conservative. As an example, several commenters said that the assumed 24-hour nonvoiding

assumption used in calculating doses is too conservative. As evidence that the calculations are too conservative, several commenters said that the doses measured using dosimeters were much lower than doses calculated using the models in the draft guide.

Response. The NRC has revised the guide to use a phased approach for determining when release can be authorized. While the calculations can sometimes be complex, the results of calculations that use conservative assumptions are given in a table of release quantities in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." Of the 8 to 9 million administrations performed annually, in all except about 10,000 cases (radioiodine therapy for thyroid cancer), release can be authorized based on conservative assumptions and using Table 1 with no calculational effort on the part of the licensee and no additional recordkeeping beyond what is already required. For permanent implants, the guide provides dose rates at 1 meter from the patient at which release may be authorized. Thus, for implants, there would be no calculational effort needed. In addition, the guide provides information on iodine therapy for thyroid cancer that can be used for determining release based on retention and elimination. This additional information in the guide will allow the licensee to perform the calculation with relatively little effort.

With regard to the comments that the methodology is too conservative and that measured values are lower than calculated by the methodology, the methodology in the table giving default release quantities is intended to be conservative. The NRC believes it is appropriate and prudent to be conservative when providing generally applicable release quantities that may

be used with little consideration of the specific details of a particular patient's release. A review of published information, as described in the regulatory analysis, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (1997), finds that measured doses are generally well below those predicted by the methodology used to calculate the table of default release quantities. Thus, the default release quantities are conservative as the NRC intended. However, the licensee is given the option of using case-specific calculations that may be less conservative.

Nevertheless, the NRC agrees that the assumption used in the draft guide of 24-hour nonvoiding in the thyroid cancer example was overly conservative. The thyroid cancer example was modified to include a more realistic assumption for the non-voiding period.

Comment. One commenter said that the occupancy factor (generally assumed to be 0.25 at 1 meter) should not be left to the discretion of the licensee because low occupancy factors could easily be justified by providing strict safety instructions without any verification that the instructions will be followed. Another commenter liked the flexibility provided by being able to adjust the occupancy factor, but wanted to know if other considerations are allowed and if it is acceptable to use values lower than 0.125.

Response. Draft Regulatory Guide 8.39 discussed situations in which it might be permissible to lower the occupancy factor from 0.25 to 0.125, but did not recommend occupancy factors less than 0.125. Occupancy factors less than 0.125 may be difficult to justify because it is generally not realistic to

assume that the patient can avoid all contact with others. However, lower values for the occupancy factor are not prohibited by the regulation, but they must be justified in the record of the calculation, as the record will be subject to inspection.

Comment. Several commenters said that the iodine-131 retention fraction of 0.3 used in the draft guide for treatment of thyroid cancer is too large and that the correct value should be 0.05 or less. Another commenter said that the biological half-life of extrathyroidal iodine should be 0.5 day for both the euthyroid and hyperthyroid condition. One commenter said that the biological half-lives from ICRP Publication No. 53 should be used for thyroid cancer.

Response. The NRC agrees that the commenters raised valid points. In Regulatory Guide 8.39, the iodine retention fraction for thyroid cancer was changed to 0.05. The biological half-life for the extrathyroidal fraction has been modified. Regarding ICRP Publication No. 53, it does not contain specific biological half-lives for thyroid cancer. Thus, these half-lives were derived from information found in the published literature.

Comment. One commenter said the table of release quantities in the draft guide should be expanded to include beta emitters such as strontium-89 and phosphorous-32. Another commenter said that the table should be expanded to include chromium-51, selenium-75, ytterbium-90, tin-117m, and iridium-192.

Response. Values for the beta emitters strontium-89 and phosphorous-32 have been added to the table of release quantities in Regulatory Guide 8.39. The table of release quantities was also expanded to add values for chromium-51, selenium-75, ytterbium-90, tin-117m, and iridium-192.

Comment. The table of release quantities in the draft regulatory guide should be expanded to include accelerator-produced radioactive materials as an aid to Agreement States.

Response. Several accelerator-produced materials were added to Regulatory Guide 8.39 as an aid to the States and to medical facilities. The NRC has no regulatory authority over the release of patients administered accelerator-produced materials and would not inspect the release of patients administered accelerator-produced materials.

Comment. One commenter said that the regulatory guide should have a table of release quantities based on biological half-life rather than only the physical half-life.

Response. Regulatory Guide 8.39 now provides more information on release quantities for iodine-131 based on biological half-lives.

Comment. One commenter said that the factor of 10^{-6} used in the draft guide to estimate internal dose is not well supported for nonoccupational exposures. Another commenter said that the calculation of dose to individuals exposed to the patient ignores the potential of radiation dose from the

excretion of radioactive material from the patient, and this could present a significant radiological hazard to family members.

Response. It is true that there is not a great deal of information on the use of the factor in nonoccupational settings, but measurements (described in NUREG-1492) have been made in which iodine uptake was measured in people exposed to a patient. These data suggest that the fractional uptake of the administered activity will be on the order of 10^{-6}. Since iodine is among the most soluble and volatile radiopharmaceuticals, it can be expected that the transfer to others of less soluble and less volatile radiopharmaceuticals would be less than that of iodine.

In addition, the NCRP recently concluded that, for individuals exposed to radionuclide therapy patients, the risks of external irradiation and potential contamination are minor from a public health viewpoint; therefore a significant intake from a contamination incident is very unlikely.[2]

Comment. A medical organization commented that the draft guide is not complete and does not provide sufficient comprehensive examples to assist licensees in complying with the rule.

Response. The NRC has expanded the guide to include information and further examples on the biological elimination of iodine-131 and on when guidance on the interruption or discontinuation of breast-feeding should be given. Expanded examples are now given in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." The example on thyroid cancer was revised to include more realistic assumptions, and an additional example

on hyperthyroidism was added. The NRC believes that the examples provided illustrate the techniques sufficient to perform the whole range of potential calculations.

Comment. One commenter said that the draft regulatory guide did not provide enough information on when and for how long breast-feeding of infants should be interrupted.

Response. Regulatory Guide 8.39 has been greatly expanded with respect to information on the breast-feeding child, including a table on recommendations for the interruption or discontinuation of breast-feeding for specific radiopharmaceuticals.

Comment. One commenter said that the sample instructions in the draft guide concerning implants should include a picture of an implant seed.

Response. The sample instructions were not expanded to include this because of graphics limitations, but licensees may add photos if desired.

Comment. Several commenters asked whether multiple individual calculations have to be done or if a generally applicable calculation could be done once and used for many patients.

Response. The NRC believes that there may be some situations for which a case-specific calculation could be done for a class of patients. The record for a particular patient's release could then reference the calculation done

for the class of patients. However, depending on a patient's individual status (e.g., lower occupancy factor), there may be cases when the calculation will be done for a specific individual.

Comment. One commenter said that the discussion on radiolabeled antibodies in the draft guide was wrong because antibodies labeled with iodine-131 will be deiodinated in the body and the iodine will behave like other iodine. None of the radiolabeled antibodies now being developed or planned for the future should have an internal dose hazard for the general public.

Response. The NRC agrees with this comment. Statements in Regulatory Guide 8.39 are now modified.

COMMENTS ON THE DRAFT REGULATORY ANALYSIS (DRAFT NUREG-1492)

Comment. One commenter said that the value of a person-rem should be $40 rather than $1,000 as used in the draft regulatory analysis for the purpose of evaluating the costs and benefits of the rule. The commenter cited a 1993 Health Physics Society position paper as a reason that the value should be $40 per person-rem.

Response. The Commission recently adopted a value of $2,000 per person-rem as explained in Revision 2 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (November 1995)," Section 4.3.3, "Evaluation of Values and Impacts." (Single copies of

NUREG/BR-0058 are available as indicated in the ADDRESSES heading.) The draft regulatory analysis, which was prepared utilizing $1,000 per person-rem, employed a simple computational model using the physical half-life only of radiopharmaceuticals. The regulatory analysis has been revised to include use of $2,000 per person-rem, as well as a more realistic dose model based on biological retention and elimination of the radiopharmaceuticals. The more realistic model with a value of $2,000 continues to demonstrate the cost-effectiveness of the dose-based limit. Specifically, the savings in hospital costs under the earlier release time allowed are estimated at $14 million, whereas the collective dose of 2,740 person-rem (at a value of $2,000 per person-rem) corresponds to a cost of about $5 million.

NUREG-1492 contains a detailed discussion of the model and the benefits and impacts of the dose-based limit. Single copies of the final regulatory analysis are available as indicated in the ADDRESSES heading.

Comment. One commenter said that the benefits of the rule were overestimated because the length of time that a thyroid patient would have to remain in the hospital was overestimated and the cost of a hospital room was overestimated, being $450 per day rather than $1,000 per day as assumed in the draft regulatory analysis.

Response. The commenter is correct that the benefits of the rule were overestimated. The estimates in the draft regulatory analysis of days of hospitalization required did not include biological elimination of the radioactive material; only radioactive decay was considered. As a consequence, the draft regulatory analysis, in some cases, overestimated the time that patients would need to be retained under licensee control, and

therefore the costs of patient retention were too high. The final regulatory analysis corrects the estimates.

The NRC believes that the current cost of $1,000 per day for a hospital room is not an overestimate. Under 10 CFR 35.315(a)(1), licensees are required to provide a private room with a private sanitary facility for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75. Considering this NRC requirement and the recent reference cited in the final regulatory analysis on the cost of hospitalization, $1,000 per day for a hospital room is a reasonable estimate.

Comment. One commenter said that the description of the measured doses received by family members was not consistent with the reference cited.

Response. The commenter is correct. An incorrect reference was given. The final regulatory analysis provides the correct reference.

IV. Coordination with NRC Agreement States

The NRC staff discussed the status of this rulemaking effort at two public meetings: the Agreement State Managers Workshop held on July 12-14, 1994, and at the All Agreement States Meeting held on October 24-25, 1994. The Agreement States expressed no objections to the approach in this rule.

V. Coordination with the Advisory Committee on Medical Uses of Isotopes

The Advisory Committee on Medical Uses of Isotopes (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 NRC staff presented a summary of the comments on the proposed

rule to the ACMUI during a public meeting held in Rockville, Maryland, on November 17 and 18, 1994.

Drafts of the final rule and regulatory guide were discussed with ACMUI in Rockville, Maryland, on October 18 and 19, 1995. The ACMUI supported the approach in this rule but suggested some clarifying changes. The NRC staff made all but one of the suggested changes. The ACMUI suggested using the term "rationale" instead of "consequences" in the requirement under the revised 10 CFR 35.75(b), to provide "guidance on the interruption or discontinuation of breast-feeding, and information on the consequences of failure to follow the guidance" for cases where failure to follow the instructions could result in a dose to the infant exceeding 1 millisievert (0.1 rem). Since most of the administrations that would be affected by this requirement are technetium-99m administrations, the ACMUI suggested the change because there was concern that the consequences of low doses of radiation cannot always be explained to the patient without causing unjustified alarm. Also, there was concern that physicians cannot explain with certainty the effects of low doses of radiation, such as would be caused by diagnostic administrations of technetium-99m. The staff did not change the rule in response to the ACMUI comment. The requirement to provide information on the consequences is included primarily to protect the breast-feeding infant from therapeutic administrations of radioiodine, which could cause serious thyroid damage. Regulatory Guide 8.39 will contain guidance on the types of information, including expected consequences, to be provided to patients to meet this requirement. Transcripts of the meetings have been placed in and are available for examination at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

VI. Discussion of Text of Final Rule

This section summarizes the final rule. The NRC is amending 10 CFR 20.1301(a)(1) to state specifically that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensed operation under the provisions of 10 CFR 35.75. This is not a substantive change. It is a clarifying change to make clear that the Commission's policy is that patient release is governed by 10 CFR 35.75, not 10 CFR 20.1301.

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). In addition, the definition of "member of the public," as published in 60 FR 36038 on July 13, 1995, is revised by removing the footnote which read, "Except as delineated in other parts of 10 CFR Chapter 1." With the publication of this rule that footnote is no longer needed.

The NRC is amending 10 CFR 20.1301(a)(2) to state specifically that the limit on dose in unrestricted areas does not include dose contributions from individuals administered radioactive material and released in accordance with 10 CFR 35.75. The purpose of this change is to clarify that after a patient has been released under 10 CFR 35.75, licensees are no longer required to control radiation from the patient. The regulation uses the term "individual" to refer to the individual to whom the radioactive material has been administered rather than "patient" to clarify that the regulation refers to anyone receiving a medical administration.

The NRC is amending 10 CFR 20.1903(b) to use the term "licensee control" rather than "confinement" because the latter term no longer applies to 10 CFR 35.75. The conforming change is necessary since the term "licensee control" more clearly reflects the NRC's intent in 10 CFR 35.75.

The NRC is adopting a new 10 CFR 35.75(a) to change the patient release criteria from 30 millicuries of activity in a patient or a dose rate of 5 millirems per hour at 1 meter from a patient to a dose limit of 5 millisieverts (0.5 rem) total effective dose equivalent to an individual from exposure to a released patient. (The dose from the radionuclide involved is taken to be the dose to total decay.) A dose-based limit provides a single limit that can be used to provide an equivalent level of protection from risks from all radionuclides. Also, the changes are supported by the recommendations of the ICRP and NCRP that an individual can receive an annual dose up to 5 millisieverts (0.5 rem) in temporary situations where exposure to radiation is not expected to result in annual doses above 1 millisievert (0.1 rem) for many years. Usually, the only individuals likely to exceed a dose of 1 millisievert (0.1 rem) will be those who are aware of the patient's condition such as the primary care-giver, a family member, or any other individual who spends significant time close to the patient.

This dose-based rule would, in some instances, permit the release of patients with activities greater than currently allowed. This is especially true when case-specific factors are evaluated to more accurately assess the dose to other individuals. The individuals exposed to the patient could receive higher doses than if the patient had been hospitalized longer. These higher doses are balanced by shorter hospital stays and thus lower health care costs. In addition, shorter hospital stays may provide emotional benefits to patients and their families. Allowing earlier reunion of families can improve the patient's state of mind, which in itself may improve the outcome of the treatment and lead to the delivery of more effective health care.

The release criteria in 10 CFR 35.75(a) could prevent a woman from being released because of the potential transmission of radioactive materials in breast milk. The dose to the breast-feeding child is controlled by giving the woman guidance, as required by 10 CFR 35.75(b), on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The expectation is that the woman would follow the instructions and would interrupt or discontinue breast-feeding.

Finally, 10 CFR 35.75(a) includes a footnote to inform licensees that the NRC has made available guidance on rule implementation. The footnote states that Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem) and describes methods for calculating doses to other individuals.

The NRC is adopting a new 10 CFR 35.75(b) to require that the licensee provide released patients with instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem). This also requires giving instructions to breast-feeding women if the dose to the child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding. The instructions must include guidance on discontinuation or the interruption period for breast-feeding and the consequences of failing to follow the recommendation. Regulatory Guide 8.39 contains tables that show temporary interruption periods for various radiopharmaceuticals or discontinuation. The temporary interruption periods were calculated based on the determination that the dose to a child from breast-feeding is unlikely to exceed 1 millisievert (0.1 rem). However, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption somewhat depending on the woman's concerns about radioactivity or interruption of breast-feeding.

The purpose of describing the consequences is so that women will understand that breast-feeding after an administration of certain radionuclides could cause harm (e.g., iodine-131 could harm the child's thyroid). In other cases, the guidance could simply address avoidance of any unnecessary radiation exposure to the child from breast-feeding.

A requirement for instructions for certain patients was already contained in 10 CFR 35.315(a)(6) and 35.415(a)(5), but the modified requirement for written instructions adds approximately (a) 50,000 patients per year who are administered iodine-131 for the treatment of hyperthyroidism and (b) 27,000 patients per year, among about 8 million administered radiopharmaceuticals, who may be breast-feeding to whom additional written instructions be given. The purpose of the written instructions is to maintain doses to individuals exposed to patients as low as is reasonably achievable. The instructions may be either written only or written plus oral. The NRC believes that written instructions are necessary so that the patient and the patient's family and friends will have a document to refer to rather than having to rely solely on the patient's memory and understanding of the instructions.

The requirement of 10 CFR 35.75(b), requiring a licensee to provide guidance on discontinuation or the interruption period for breast-feeding and the consequences of failing to follow the recommendation, presumes that the licensee will make appropriate inquiry regarding the breast-feeding status of the patient. For breast-feeding women where the dose to the child is likely to exceed 1 millisievert (0.1 rem), the NRC requires that the patient be provided with specific instructions, as described in 10 CFR 35.75(b). There is no specific requirement to maintain a record indicating that breast-feeding status was determined prior to the release of the patient.

The NRC is adopting a new 10 CFR 35.75(c) to require that the licensee maintain a record of the basis for authorizing the release for 3 years if the calculation of the total effective dose equivalent to other individuals uses

the retained activity rather than the activity administered, an occupancy factor less than 0.25 at 1 meter, the biological or effective half-life of the radionuclide, or shielding of radiation by the patient's tissue. Thus, records of release are required when the default assumptions are not used as discussed in Regulatory Guide 8.39. Measurements made in several studies indicate that the default assumptions should generally overpredict the dose even when instructions are not given or are not strictly followed. If a licensee administers an activity no greater than the value in the default table of release quantities provided in the regulatory guide as the basis for release, no record of release is required.

Licensees are already required by 10 CFR 35.53 to retain records of the measurement of the activity of each dosage of radioactive material administered to a patient; these records are typically maintained in a patient dose log. In addition, 10 CFR 35.32 requires licensees to retain a written directive and a record of each administered radiation dose or radiopharmaceutical dosage for therapeutic administrations and diagnostic administrations of iodine-125 or iodine-131 sodium iodide greater than 30 microcuries. These records can be used in conjunction with Regulatory Guide 8.39 to demonstrate that patient releases meet the requirements of 10 CFR 35.75(a) when no record is required by 10 CFR 35.75(c). When the licensee determines that the patient must be held to allow the reduction of radioactivity and then released, the licensee will need a record of release time to demonstrate that the release criteria have been met. A licensee may use any existing record to establish the release time. If biological elimination of radioiodine is a basis for release and the licensee uses the information in Regulatory Guide 8.39, a record of the thyroid uptake may be necessary as part of the basis for release because it is one of the nonstandard conservative assumptions listed in 10 CFR 35.75(c). If other case-specific factors are used as the basis for patient release that are in addition to, or modify, the standard conservative assumptions, a record of the

basis for the release, including the assumptions used for the calculations, must also be maintained.

This recordkeeping requirement is a modification of the proposed rule. The proposed rule would have required that a record be maintained of the basis for the patient's release, including all calculations performed, if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration. Under the proposed rule, the major purpose of the record was to provide the basis for limiting the dose to 5 millisieverts (0.5 rem) to individuals exposed to a patient who may receive more than one administration in a year. Upon reconsideration, based on public comments and consultation with the ACMUI, an NRC medical consultant, and the NRC Visiting Medical Fellow, the NRC has decided to delete this requirement. A review of medical treatment practices revealed no common practice that would result in doses exceeding the 5 millisievert (0.5 rem) limit because of multiple administrations in the same year to the same patient. Without the need to account for the dose from multiple administrations, maintaining records for the many tens of thousands of patients released when their dose to an individual is likely to exceed 1 millisievert (0.1 millisievert) becomes an unnecessary burden. The requirement to retain these records has therefore been deleted. Each patient release is to be treated as a separate event, and licensee knowledge of previous administrations is unnecessary.

The NRC is also adopting a new 10 CFR 35.75(d) to require that the licensee maintain a record that instructions were provided to a breast-feeding woman if the administered activity could result in a total effective dose equivalent to the breast-feeding child exceeding 5 millisieverts (0.5 rem) if the mother did not interrupt or discontinue breast-feeding. Thus, the NRC is requiring records for certain radiopharmaceutical administrations (e.g., therapeutic administrations of iodine-131). The activities of

radiopharmaceuticals that require this record are described in Regulatory Guide 8.39.

Finally, the NRC is deleting its requirements on written instructions in 10 CFR 35.315(a)(6) and 35.415(a)(5) because those paragraphs are redundant now that 10 CFR 35.75 has requirements for instructions. In addition, 10 CFR 35.415(a) and a(1) are reworded to clarify the original intent of the paragraphs, which was to limit the dose rate at 1 meter from the patient. The ambiguity was introduced when Part 20 was revised and a conforming change was made in 10 CFR 35.415. The conforming change that was made was not fully consistent with the original intended meaning of 10 CFR 35.415(a) and (a)(1).

VII. Disposition of the Petitions for Rulemaking

The three petitions for rulemaking submitted by Dr. Marcus (PRM-20-20), the ACNM (PRM-35-10 and PRM-35-10A), and the AMA (PRM-35-11) requested that the NRC amend the revised 10 CFR part 20 and 10 CFR part 35. These requests and their disposition by this rulemaking are discussed below.

The requests made by Dr. Marcus and their disposition may be summarized as follows:

(1) Raise the radiation dose limit in 10 CFR 20.1301(a) for individuals exposed to radiation from patients receiving radiopharmaceuticals for diagnosis or therapy from 1 millisievert (0.1 rem) to 5 millisieverts (0.5 rem). The final rule grants this request.

(2) Amend 10 CFR 35.75(a)(2) to retain the 1,110-megabecquerel (30-millicurie) limit for iodine-131, but provide an activity limit for other radionuclides consistent with the calculational methodology employed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."[1] The final rule does not contain activity limits, but Regulatory Guide 8.39 uses a calculational methodology

based on NCRP Report No. 37 to relate the dose to the quantity of activity in the patient. Therefore, the wish of the petitioner to have an easy method to determine when the patient may be released is granted in Regulatory Guide 8.39.

(3) Delete 10 CFR 20.1301(d), which requires licensees to comply with provisions of the Environmental Protection Agency's environmental regulations in 40 CFR Part 190 in addition to complying with the requirements of 10 CFR Part 20. The EPA regulations referenced in 10 CFR 20.1301(d) are contained in 40 CFR Part 190, which deals only with doses and airborne emissions from uranium fuel cycle facilities. Part 190 of Title 40 of the Code of Federal Regulations does not apply to hospitals or to the release of patients.

Furthermore, 10 CFR 20.1301(d) does not incorporate the EPA's Clean Air Act standards in 40 CFR Part 61 that applies to hospitals. The NRC is separately pursuing actions with the EPA to minimize the impact of dual regulation under the Clean Air Act and to take agreed upon actions that will lead to EPA recision of 40 CFR Part 61 for NRC and Agreement State licensees. Because the reference to EPA regulations in 10 CFR 20.1301(d) has nothing to do with the patient release issue, and therefore is outside the scope of this rulemaking, the final rule denies this request.

The requests made by the ACNM and their disposition may be summarized as follows:

(1) Adopt a dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients who have been administered radiopharmaceuticals. The final rule grants this request.

(2) 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 final rule denies this request for the reasons described in the discussion on this issue.

Finally, the requests made by the AMA did not all pertain to the issue of patient release. The final rule grants the request pertaining to patient release, i.e., that the radiation dose limits in 10 CFR 20.1301 should not apply to individuals exposed to the patient and that the dose limit to the individuals should be 5 millisieverts (0.5 rem). The request to change the term "hospitalized" in 10 CFR 35.310(a) and 35.315(a) to the term "confined" was denied for the reasons discussed above. The request not related to the subject of patient release (that it should be clear in Part 20 that Part 20 does not limit the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy) was addressed in another rulemaking, "Medical Administration of Radiation and Radioactive Materials," which was published as a final rule on September 20, 1995 (60 FR 48623), and became effective on October 20, 1995.

VIII. Consistency with 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 reads "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 its purpose is to provide for the safety of individual members of the public exposed to patients administered radioactive materials.

The second statement of the policy is "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." This statement is not relevant to the rule because the rule does not affect the safety of patients themselves. The rule instead affects the safety of individuals exposed to patients.

The third statement of the policy reads "The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The rule is consistent with this statement because it places no requirements on the administration of radioactive materials to patients and because the release of patients administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public rather than solely a matter of medical judgment.

Thus, the final rule is considered to be consistent with the 1979 Medical Policy Statement.

IX. Issue of Compatibility for Agreement States

The NRC considers the definitions contained in § 20.1003 and the text in § 20.1301(a) that are modified by this rulemaking are Division 1 levels of compatibility. The definitions and text in these sections must be the same for all NRC and Agreement State licensees so that national consistency can be maintained.

Section 20.1002, "Scope," is a Division 3 level of compatibility because this section by nature is not a regulatory requirement and many States are prohibited by their administrative procedures act from including such sections in their rules. The scope section is a general statement of scope of the rule and does not contain specific requirements that are not presented in other sections of Part 20. Rules at the Division 3 level would be appropriate for Agreement States to adopt, but they do not require any degree of uniformity between NRC and State rules.

Additionally, §§ 35.75(a) and (b) are a Division 2 level of compatibility because the patient release criteria required by the rule are the minimum requirements necessary to ensure adequate protection of the public health and safety. The Agreement States will be allowed to establish

requirements that are more stringent than the NRC's requirements, but not less stringent. The recordkeeping requirements in §§ 35.75(c) and (d) are a Division 3 level of compatibility because uniformity in recordkeeping is not considered essential for this rule.

X. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

XI. Finding of No Significant Environmental Impact: Availability

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR part 51, that the amendments are not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The final amendments clarify the pertinent regulatory language to reflect explicitly the relationship between 10 CFR part 20 and part 35 with respect to release of patients, and the amendments revise the release criteria for patients receiving radioactive material for medical use from an activity-based standard to a dose basis. It is expected that there will be relatively little change in radiation dose to the public or to the environment as a result of the revised regulation.

The final environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and the finding of no significant

impact are available as indicated in the FOR FURTHER INFORMATION CONTACT heading.

XII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0010.

The public reporting burden for this collection of information is estimated to average 13 hours per licensee per year, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XIII. Regulatory Analysis

The NRC has prepared a final regulatory analysis (NUREG-1492) on this regulation. The analysis examines the benefits and impacts considered by the

NRC. The NRC has received public comments regarding the draft regulatory analysis and has addressed the comments (see Comments on the Draft Regulatory Analysis in Section III. Public Comments on the Proposed Rule). The final regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available as indicated in the ADDRESSES heading.

XIV. 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. This rule affects medical use of byproduct material licensees. The impact of the final rule will not be significant because the final rule basically represents a continuation of current practice.

XV. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 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 that impose backfits as defined in 10 CFR 50.109(a)(1).

Lists of Subjects in 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.

Lists of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Incorporation by reference, 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. 552 and 553; the NRC is adopting 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, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), 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, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with § 35.75, or to exposure from voluntary participation in medical research programs.

3. In § 20.1003, the footnote to the definition of *member of the public* is removed and 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 the course of employment in which the individual's assigned duties involve exposure to radiation or 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 exposure to individuals administered radioactive material and released in accordance with § 35.75, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in

accordance with § 35.75, or from voluntary participation in medical research programs.

* * * * *

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

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that--

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

* * * * *

5. In § 20.1903, paragraph (b) is revised to read as follows:

§ 20.1903 Exceptions to posting requirements.

* * * * *

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to § 20.1902 provided that the patient could be released from licensee control pursuant to § 35.75 of this chapter.

* * * * *

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

6. 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).

7. In Section 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

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(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.20, 35.21, 35.22, 35.23, 35.29, 35.13, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.75, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, 35.980 and 35.981.

* * * * *

8. Section 35.75 is revised to read as follows:

§ 35.75 Release of individuals containing radiopharmaceuticals or permanent implants.

(a) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose

equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).[1]

(b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include: (1) guidance on the interruption or discontinuation of breast-feeding and (2) information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less than 0.25 at 1 meter, (3) using the biological or effective half-life, or (4) considering the shielding by tissue.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

§ 35.315 [Amended]

9. In § 35.315, paragraph (a)(6) is removed and reserved.

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[1]Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).

§ 35.315 Safety precautions.

(a) * * *

(6) [Reserved]

* * * * *

10. In § 35.415, the introductory text to paragraph (a) and paragraph (a)(1) are revised and paragraph (a)(5) is removed.

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to § 35.75 of this part, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____, 1997.

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,
Secretary of the Commission.

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* User name:    DON (181)                      Queue:  TW9/HP3SI-TW9-9E57       *
* File name:    SOURCE.SEL                     Server: HP3SI-TW9-9E57           *
* Directory:                                                                    *
* Description:                                                                  *
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Attachment 3

SOURCE SELECTION JUSTIFICATION

TITLE: Continued Evaluation of Testing and Quality Control Procedures for Electronic Personnel Dosimeters (EPDs)

SELECTED SOURCE: Kenneth L. Swinth; Swinth Associates
2177 Cascade
Richland, WA 99352

ORGANIZATION: RES/DRA/RPHEB

TYPED NAME-PROJECT MANAGER: Donald O.Nellis **DATE:** 10/08/96

BASIS FOR SELECTION:

Proposals from other sources were not considered, in part because of the urgency to now move forward on this project, and in part because of the limited experience and knowledge of the current state-of-the-art in electronic personnel dosimetry by both the electronics and dosimetry communities. EPDs are essentially electronic instruments, much like radiation survey instruments. They also contain a small computer and a software program, referred to as an algorithm, which converts the electronic pulses received in the detector into radiation dose and/or dose rates. Like other electronic devices they are subject to interference from electric, magnetic, and high frequency electromagnetic fields and some models can be disabled with a small magnet. Also, changes made to the algorithm will alter the calibration of the EPD.

The individual chosen as the selected source is unique in that he has several years of hands-on experience in both type and performance testing of EPDs and was project manager on the project that was the immediate predecessor to this

work, a review of the present status of EPDs, which culminated in the report NUREG/CR-6354," Performance Testing of Electronic Personal Dosimeters." In addition, this individual is knowlegeable in the operation and functioning of both the Siemens-Plessy (British) and Merlin Gerin (French) EPD systems that constitute the majority of the EPDs in use in the United States. Furthermore, the individual is knowledgeable of the type-testing and manufacturing quality control procedures stipulated by these manufacturers to ensure continued quality operation of the EPD systems. An understanding of how the regulatory controls exercised in Europe work to ensure acceptable EPD performance, is essential to developing controls in this country, that will ensure EPDs performance such that it will qualify them for use as alternatives to the currently used TLD and film dosimeters. It is believed that the individual chosen as the selected source has the capability to evaluate and respond responsibly to the comments received on NUREG/CR-6354 and also to evaluate the European EPD systems and develop a similar or parallel system for use in this country.

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