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

June 14, 1995

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: David L. Morrison, Director
Office of Nuclear Regulatory Research

SUBJECT: FINAL RULE - CRITERIA FOR THE RELEASE OF INDIVIDUALS ADMINISTERED RADIOACTIVE MATERIALS

Attached for your signature is the Commission paper transmitting a final rule amending 10 CFR Parts 20 and 35 on criteria for the release of individuals administered radioactive materials.

Coordination: The Offices of Administration, Nuclear Material Safety and Safeguards, State Programs, Information Resources Management, and Enforcement concur in these amendments. The Office of the General Counsel has no legal objection. No additional resources would be required for its implementation.

Attachment:
Commission Paper w/atts.

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FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: FINAL AMENDMENTS TO 10 CFR PARTS 20 AND 35 ON CRITERIA FOR THE RELEASE OF INDIVIDUALS ADMINISTERED RADIOACTIVE MATERIAL

PURPOSE:

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

BACKGROUND:

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 a dose limit of 1 millisievert (0.1 rem) total effective dose equivalent (TEDE) for members of the public in 10 CFR 20.1301(a). When 10 CFR Part 20 was issued, there was no discussion in the supplemental information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients.

NRC's current patient release criteria are contained in 10 CFR 35.75, "Release of patients or human research subjects containing radiopharmaceuticals or permanent implants." That section states: "(a) A licensee may not authorize release from confinement for medical care any patient or human research subjects 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

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subject administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of 1 meter."

Some licensees were uncertain about what effect the revised 10 CFR Part 20 would have on patient release criteria, and three petitions for rulemaking were received on the issue. To resolve this uncertainty, two steps were taken.

The short-term resolution was to inform licensees of the NRC's position that 10 CFR 35.75 governed patient release. The Commission was informed in SECY-94-01 of the staff's recommendation that 10 CFR 35.75 governs patient release. Information notice No. 94-09 was issued on February 3, 1994, to inform licensees of this position in accordance with a Staff Requirements Memorandum (SRM) dated January 28, 1994. OK,

The longer term resolution was to address this issue through rulemaking, and a proposed rule was published for comment on June 15, 1994 (59 FR 30724). The proposed rule would revise Parts 20 and 35 to make clear that the dose to an individual from a medical administration of radiation or radioactive materials, even an individual not supposed to receive an administration, is regulated by Part 35 of NRC's regulations rather than Part 20.

DISCUSSION:

The rule takes into consideration the recommendations of the ACMUI and the Agreement States, as well as the comment letters received on the proposed rule and the petitions. In all, 232 comment letters were received on the three petitions, and 60 comment letters were received on the proposed rule. The rule was also discussed with the Advisory Committee on Medical Uses of Isotopes (ACMUI) at several public meetings, the last on May 11, 1995.

The final amendments represent a partial granting of the regulatory relief requested by the petitioners. Section VII of the Federal Register notice (Attachment 1) describes in detail each of the petitioner's requests and the staff's proposed disposition. The following summarizes the main features of the final amendments:

1. The amendments make it clear that patient release is governed by 10 CFR 35.75 rather than 10 CFR 20.1301(a). There was very broad agreement with this position in the comment letters, with the ACMUI, and with the Agreement States.

2. The amendments revise the criteria for release of patients administered radioactive material for medical use under 10 CFR 35.75 to permit a maximum likely total effective dose equivalent, excluding background or any occupational exposure, to an individual exposed to the patient of 5 millisieverts (0.5 rem).

   Overall, a substantial majority of all comments supported a dose limit of 0.5 millisieverts (0.5 rem) for individuals exposed to patients

released with radioactive material. In addition, the ACMUI and the Agreement States supported the criterion based on a dose limit. A few commenters opposed the new criterion because they thought that the present criteria were working well and were adequate. These commenters opposed allowing release with quantities of radioactive material greater than permitted under the current regulations.

The NRC staff will provide an acceptable method that relates the quantity of radioactivity administered to the dose in a regulatory guide. A working draft of that guide is attached (Attachment 2). The guide is still under staff review, but will be published in active form before the final rule becomes effective.

The guide provides two methods to relate dose to quantity of radioactivity administered. The first method is through the use of a default table of release quantities and release dose rates based on conservative assumptions. For the radioactive material of greatest significance, iodine-131, the default table is essentially equivalent to the release criteria in the current regulations.

The second method is to perform a case-specific dose calculation using the method described in the guide. The case-specific method can be less conservative than the default table because it permits a more realistic estimate of how quickly the radioactive material leaves the body. Thus, use of this method would, in some cases, permit the release of patients containing several times more radioactive material than the current regulations permit. Under certain circumstances, such as a radionuclide with a long half-life and no biological excretion, the default table and the case-specific dose calculation may be more restrictive than the current release criteria.

3. The proposed rule would have required licensees to maintain, for 3 years, a record of the basis for the patient's release and the total effective dose equivalent if any individual is likely to receive a dose in excess of 1 millisievert (0.1 rem) in a year from a single administration. The purpose of this requirement was to ensure that records would be available to calculate the dose if there were multiple administrations in a year.

This proposed requirement generated a great deal of opposition. Commenters were especially concerned about having to retrieve records of previous administrations, sometimes from another hospital. Upon reconsideration, it was decided to delete this requirement because a review of nuclear medicine procedures indicated that there was not significant likelihood of exceeding a 5 millisieverts (0.5 rem) annual dose because of multiple administrations.

In place of the deleted recordkeeping requirement, the final rule contains a requirement to maintain a record of the basis of the release for a limited number of the more significant administrations. The

requirements (in 10 CFR 35.75(c) and (d)) would only affect about 17,000 of the 8 to 9 million administrations done annually in the roughly 1300 licensed facilities.

4. The amendments require that the patient be given written instructions on how to maintain doses to others as low as reasonably achievable if the dose to an individual is likely to exceed 1 millisievert (0.1 rem). In general, most commenters agreed with this requirement in the proposed rule, although a few did not think that instructions should necessarily have to be written. The staff believes that patients are less likely to remember to follow all of the verbal instructions, and by providing written instructions, family members would also be aware of the necessary precautions to maintain doses as low as is reasonably achievable.

5. The amendments make it clear that the limit on dose in unrestricted areas under 10 CFR 20.1301(a)(2) does not include dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75. The purpose of this change is to clarify that licensees are not responsible for doses outside of their restricted areas from radiation sources not under their control. The comments supported this position.

6. The amendments explicitly include nursing infants as individuals whose dose must be limited. There was relatively little opposition to this, but some commenters wanted information on when instructions would have to be given and what the instructions should say about interruption or cessation of breast feeding. The information requested will be included in the regulatory guide (Attachment 2).

RESOURCES:

Resources needed to implement this rulemaking are included in the FY 1995-1999 Five-Year Plan.

COORDINATION:

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

RECOMMENDATION:

That the Commission:

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

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

3. Note:

a. The final rule will become effective 90 days after publication in the Federal Register;

b. A final regulatory analysis will be available in the Public Document Room (Attachment 3);

c. A final environmental assessment and a finding of no significant impact have been prepared (Attachment 4);

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

e. The rule contains information collection requirements that are subject to review by OMB. Upon Commission approval, the OMB supporting statement (Attachment 7) will be submitted to OMB for approval.

f. The appropriate Congressional Committees will be informed (Attachment 5);

g. A public announcement will be issued (Attachment 6); and

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

James M. Taylor
Executive Director
for Operations

Attachments: As Stated (7)

ATTACHMENT 1

[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 potential dose to other individuals exposed to the patient, including nursing children. 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: _____ (90 days following publication in the Federal Register).

ADDRESSES: Copies of the public record, including the final Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," the final regulatory analysis and the public comments received on the proposed rule, may be examined and copied for a fee in the Commissions's Public Document Room at 2120 L Street, NW. (Lower Level), Washington DC.

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

SUPPLEMENTARY INFORMATION:

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 one 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 is less than 5 millirems per hour at a distance of one 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 20.1301 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), the NRC published a proposed rule on criteria for the release of patients administered radioactive material in response to the first two petitions. 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 a waiting room, 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 to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 millisievert (2 millirems) in any one hour. Patient waiting rooms or hospital rooms would

need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

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 one 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 can be allowed to receive an annual dose up to 5 millisieverts (0.5 rem) in temporary situations where exposure to radiation is not expected to result in 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 one 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 reasonably achievable.

The NRC proposed to adopt a new 10 CFR 35.75(b)(2) to require that licensees maintain, for three 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 control 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 as a conforming change within part 35 on when instructions must be given.

In addition, the NRC issued an associated draft regulatory guide and supporting draft regulatory analysis concurrently for public comment. The draft regulatory guide, DG-8015, "Release of Patients Administered Radioactive Materials," provided 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 provided guidelines on instructions for patients on how to maintain doses to other individuals as low as is reasonably achievable and described recordkeeping requirements. The draft regulatory analysis, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," examined the benefits and impacts of the proposed rule considered by the NRC.

III. Public Comments on the Proposed Rule

A total of 62 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 regulatory agencies in Agreement States, private individuals, and public-interest groups. Overall, the majority of all 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 all commenter letters opposed the proposed recordkeeping requirement. The significant comments are discussed below, arranged by subject.

EXCLUSION OF PATIENT RELEASE FROM § 20.1301(a)

All of 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, 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 previous rulemaking on 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. 10 CFR 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 recommendations of both of these organizations include both a long term objective to be achieved, and short term limitations on the maximum dose for any one year. Both the ICRP and the NCRP recommend that an individual be allowed to receive a dose up to 5 millisieverts (0.5 rem) in a given year in situations where exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) for long periods of time. For 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 1 millisievert (0.1 rem) more than once in a lifetime. 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 millisievert (0.5 rem) is acceptable provided that it is of relatively short duration and that steps are taken to reduce the dose to as low as is reasonably achievable. The NRC reaffirms its previous determination in this rulemaking.

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 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 millirems 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 they 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 with probably no 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 would result in different doses being received from a released patient depending on the radionuclide used. Also, a single dose rate requirement for all radionuclides would not be a uniform indicator of the total dose. 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 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 requisite 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]

The supporting regulatory analysis 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 the default table of activities provided in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." The table of release quantities approach, based on standard conservative assumptions, does not require any personal information from the patient. However, the rule does allow the physician to calculate patient-specific dose estimates allowing 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.

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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.)

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 rate at 1 meter. 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

Going to 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 patient release with more than 1,110 megabecquerels (30 millicuries) of activity. Some commenters were opposed to allowing release with higher activities than 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 due to patient vomiting were not adequately considered.

Response. The concern over contamination is not justified by the radiation doses that are likely to be caused by the contamination. Measurements have shown that a relatively small proportion of the radioactive material administered will appear as contamination. The large majority will

either decay away within the patient's body or will be excreted in the patient's urine and flushed down the toilet. The proportion that will be deposited as contamination on accessible surfaces will be small. Doses to individuals exposed to the patient from pathways other than direct external exposure (e.g., internal exposure due to intake of radionuclides from vomited matter, sweat, etc.) have been measured and have been found to be relatively low compared to direct external exposure. (The intake from the milk in breast-feeding children is dealt with in the regulations as a special case.) These measurements are discussed in the supporting regulatory analysis and Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." In addition, 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]

Comment. One commenter said that the proposed rule did not adequately represent 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, the States did express concerns about releasing patients administered relatively large quantities of

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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.)

iodine-131. However, the Agreement States were generally favorable to the approach that was contained in the proposed rule, and none of the States that commented on the proposed rule indicated that the concerns of the Agreement States 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.

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 it might be beneficial and acceptable to family members in some cases. 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

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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 Pergamom 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.

doses up to 5 millisieverts (0.5 rem) under certain circumstances. Both the ICRP and the NCRP recommend that an individual be allowed to receive a dose up to 5 millisieverts (0.5 rem) in a given year in situations where 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," the NCRP recommended that, in general, a dose limit of 5 millisieverts (0.5 rem) annually for members of the patient's family should apply. 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). 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. However, if special situations arise, exemptions from the regulations in part 35 can be requested by the licensee on a case-by-case basis under § 35.19, "Specific exemptions."

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, it would be necessary for the licensee to 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 are 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 0.1 rem level with all the documentation required.

Another commenter said that it cannot be the licensee's responsibility to know the details of a radionuclide therapy performed by another licensee in terms of which members of the public receive the most radiation dose due to 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 and 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 assure 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, 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 routine 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 and is discussed in detail under the heading, "VI. Discussion of Final Rule Text."

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. 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 states that, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The final rule is consistent with this statement because it does not specify the details of what the physician must say verbally or include in the contents of the written instructions. However, Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," includes recommended contents of the written instructions. Single copies of Regulatory Guide 8.39 are available as indicated in the ADDRESSES heading.

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 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. Following of the instructions is voluntary for the patient.

With regard to compliance with the instructions, surveys of patients and their spouses indicate that most will attempt to follow the instructions faithfully, especially with regard to protecting their children. Some patients and their spouses indicated that they might not keep physically distant from their spouse for prolonged periods of time. In this situation, these couples would be making their own informed decision on what is reasonable or acceptable.

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 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 if the patient were to leave "against medical advice."

Comment. One commenter asked if a patient that 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. 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.

Comment. Several commenters said that the nursing infant should not be considered as an individual exposed to the patient for the purposes of determining if patient release may be authorized. These commenters said that consideration of the nursing infant should be under the jurisdiction of the physician, that the issue is a medical issue rather 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 public health and safety and that responsibility extends to all individuals exposed to a patient administered licensed radioactive materials, including nursing children.

Comment. One commenter said that the proposed rule did not accurately represent the position of the Advisory Committee on Medical Use 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 May 12, 1995, and the ACMUI supported the rule.

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 exists a limit as 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 listed in Table 1 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," for release were calculated using conservative assumptions (for example, by not accounting for biological elimination by using the physical half-life of the radioactive material rather than the more realistic biological 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 flight and would therefore be in close contact with another individual, it may be necessary to authorize release based 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 the draft regulatory guide 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 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 non-voiding 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 but about 12,500 cases (radioiodine therapy for thyroid cancer and permanent implants), release can be authorized based on Table 1 with no calculational effort on the part of the licensee and no additional recordkeeping beyond what is already required. For the 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 hyperthyroidism and 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 specific

patient's release. A review of published information, as described in the regulatory analysis (NUREG-1492), 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 to do case-specific calculations that may be less conservative.

Nevertheless, the NRC agrees that the assumption used in the draft guide of 24-hour non-voiding in the thyroid cancer example was overly conservative. The revised example uses an excretion half-time of 8 hours as recommended by the ICRP in ICRP Publication 53, "Radiation Dose to Patients from Radiopharmaceuticals.[5]

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 be know if other considerations are allowed and if it is acceptable to use values lower than 0.125.

Response. 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. This view is expressed in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." However, lower

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[5]International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53 (March 1987). Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.

values for the occupancy factor are not prohibited by the regulation, but 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. Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," has been appropriately revised. The iodine retention fraction for thyroid cancer was changed to 0.05. The biological half-life for the extrathyroidial fraction was changed to 0.33 day. And the biological half-lives from ICRP Publication No. 53 were used for the thyroid cancer case.

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, "Release of Patients Administered Radioactive Materials." 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 releases 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, "Release of Patients Administered Radioactive Materials," 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, "Release of Patients Administered Radioactive Materials," now provides increased 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 fraction 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.[6]

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.

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[6]Same as footnote 2.

Response. The NRC has expanded the guide to include information on the biological elimination of iodine-131 and when breast-feeding should be interrupted. 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 five 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 nursing of infants should be stopped.

Response. Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," has been greatly expanded with respect to information on the breast-feeding child, including a table on recommendations for the interruption 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 due to graphics limitations, but licensees may add photos if desired.

Comment. Several commenters asked whether multiple individual calculations have to be specifically 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 of the basis 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 some 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 iodine-131-labeled antibodies 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, "Release of Patients Administered Radioactive Materials," 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 Health Physics Society position paper.

Response. The NRC does not believe that the value of $40 per person-rem recommended by the Health Physics Society is appropriate. The NRC continues to believe that for the purposes of this evaluation a value of $1,000 per person-rem is appropriate. Use of this value is standard practice in conducting NRC cost-benefit analyses. The value of $1000 was established in the early 1970's in the 10 CFR part 50, Appendix I, rulemaking for reactor effluents. It was selected as a value that could be considered a conservative upper bound for the value of a rem of dose. The value of $1000 bounded all the values of a rem estimated by a wide variety of different evaluation methods.

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 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), for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, licensees are required to provide a private room with a private sanitary facility. 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 May 12, 1995. The ACMUI was generally supportive of the approach in this rule. 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 Final Rule Text

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).

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 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 be allowed to 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 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 new 10 CFR 35.75(a) explicitly states that the 5-millisievert (0.5-rem) release criteria also applies to breast-feeding children due to radiopharmaceuticals contained in the breast milk of a woman who received an administration. Realistically, a woman would not be denied release because of the potential transmission of radioactive materials in breast milk. Instead, the woman would be given instructions, as required by 10 CFR 35.75(b), to cease or to interrupt breast-feeding. The release could then be authorized on the basis that the woman would cease or interrupt breast-feeding as instructed. It may also be necessary to provide instructions to limit physical contact with children for a period of time.

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 requirement also requires giving instructions to breast-feeding women if the

dose to the child is likely to exceed 1 millisievert (0.1 rem) if there were no interruption of 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 adds approximately 50,000 patients per year who are administered iodine-131 for the treatment of hyperthyroidism and another 27,000 patients who are breast-feeding to whom 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.

In the case of breast-feeding women where the dose to the child is likely to exceed 1 millisievert (0.1 rem), the NRC would find it acceptable to demonstrate compliance with the requirement to provide instructions if the determination of breast-feeding status is made part of the licensee's procedural routine for patient release. However, 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 three years if the calculation of external dose to other individuals, on which the release is based, uses other than the following assumptions: the initial administered activity, a point-source geometry, the physical half-life of the radionuclide, an occupancy factory of 0.25 at 1 meter, and no attenuation of radiation in

tissue. For the convenience of the licensee, the administered activities for which a record would not be required are tabulated and presented in Table 1 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials."

Licensees are already required to retain records of the measurement of the activity of each dosage of radioactive material administered to a patient by 10 CFR 35.53, which is 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, "Release of Patients Administered Radioactive Materials," to demonstrate that patient releases meet the requirements of 10 CFR 35.75(a) if no record is required by 10 CFR 35.75(c). When the licensee determines that the patient must be held and then released, the licensee will need a record of release time to demonstrate that the release criterion has 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, "Release of Patients Administered Radioactive Materials," a record of the thyroid uptake must be retained because it is not one of the standard 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, the basis for the release including the assumptions used for the calculations must also be maintained.

This recordkeeping requirement is a modification of that in 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 other 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 controlling 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 routine practice that would result in exceeding the 5-millisievert (0.5-rem) limit because of multiple administrations in the same year. Without the need to account for the dose from multiple administrations, maintaining records for the tens-of-thousands of patient releases where the dose to an individual is likely to exceed 1 millisievert (0.1 millisievert) becomes an unnecessary burden, and therefore has been deleted. Each patient release is to be treated as a separate event upon which licensee knowledge of previous administrations is unnecessary.

Since a breast-feeding woman is not only a potential source of exposure to members of her family and care givers but also a potential source of exposure to a child through breast milk, the NRC is adopting a new 10 CFR 35.75(d) to require that the licensee also maintain a record of the basis for the release of a breast-feeding woman for three years if the administered activity would be likely to result in a total effective dose equivalent to the breast-feeding child exceeding 5 millisieverts (0.5 rem) if the mother failed

to follow the instructions and did not interrupt breast-feeding for the specified time. Thus, the NRC is requiring records for only the more significant radiopharmaceutical administrations. The record could say that the woman was instructed to cease breast-feeding (e. g. for therapeutic radioiodine administrations) or to interrupt breast-feeding for a specified time (e. g. for some activities of Tc-99m pertechnetate). The activities of radiopharmaceuticals that require this record are described in Regulatory Guide 8.39, "Criteria for the Release of Patients Administered Radioactive Materials."

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)(1) is reworded to clarify the original intent of the paragraph, 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)(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 annual 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." The final rule grants this request and the supporting regulatory guide uses a calculational methodology based on NCRP Report No. 37 to relate the dose to the quantity of activity in the patient.

(3) Delete 10 CFR 20.1301(d) which requires licensees to comply with provisions of 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. 40 CFR part 190 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 apply 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 has no impact on the petitioner, 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.

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 500 millirems. 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. A 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) will be handled as part of another rulemaking, "Medical Administration of Radiation and Radioactive Materials," which was published as a proposed rule on January 25, 1995 (60 FR 4272).

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 states, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The rule is consistent with this statement because 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 states, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." 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 states, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The rule is consistent with this statement because it 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 judgement.

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

IX. Issue of Compatibility for Agreement States

The NRC believes that the definitions contained in § 20.1003 and 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.

10 CFR 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 which are not presented in other sections of part 20. Division 3 levels rules would be appropriate for Agreement States to adopt, but do not require any degree of uniformity between NRC and State rules.

Additionally, § 35.75, is 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.

X. 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 be 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 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.

XI. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (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, gathering and maintaining the data needed, and completing and reviewing the collection of information.

XII. 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 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 under the FOR FURTHER INFORMATION CONTACT heading.

XIII. 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.

XIV. 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 which impose backfits as defined in 10 CFR 50.109(a)(1).

10 CFR part 20

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

10 CFR part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, 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 (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 to individuals administered radioactive material and released in accordance with § 35.75, or to voluntary participation in medical research programs.

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

§ 20.1003 Definitions.

Note to Commission: The definitions of occupational dose and public dose include changes included in SECY-95-140, June 1, 1995.

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* * * * *

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 and/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, as a patient from medical practices, 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 and/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, as a patient from medical practices, 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 mSv) in a year, exclusive of the dose contributions from background radiation, from exposure of individuals to radiation for the purpose of medical diagnosis or therapy, 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 mSv) in any one hour.

* * * * *

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

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

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

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

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.13, 35.50, 35.51, 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, and 35.647.

* * * * *

7. 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, including a breast-feeding child, 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 how to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual for 3 years if the calculation of external dose to other individuals, on which the release is based, uses assumptions other than the following --

(1) The initial administered activity;

(2) A point-source geometry;

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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).

(3) The physical half-life of the radionuclide;

(4) An occupancy factor of 0.25 at 1 meter; and

(5) No attenuation of radiation in tissue.

(d) The licensee shall maintain a record for 3 years that instructions were provided to each patient, who is breast-feeding, prior to release. This record is needed only in cases where, in the absence of the instructions required by paragraph (b) to interrupt breast-feeding, the breast-feeding child could receive a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

§ 35.315 [Amended]

8. In § 35.315, paragraph (a)(6) is deleted.

9. In § 35.415, paragraph (a)(1) is revised and paragraph (a)(5) is deleted:

§ 35.415 Safety precautions.

(a) * * *

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

at 1 meter from the patient or human research subject is less than 2 millirems (0.02 millisieverts) in any 1 hour.

* * * * *

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

For the Nuclear Regulatory Commission.

_____
John C. Hoyle,
Secretary of the Commission.

ATTACHMENT 2

NOTE TO COMMISSION

This guide is a working draft rather than a final draft. It does not have Office concurrence, and it has not yet undergone final editing. It is thus subject to change before publication, but it is expected that the changes will be relatively minor. There should be no difficulty in publishing the final guide at about the same time that the final rule is published.

REGULATORY GUIDE 8.39
(Draft was issued as DG-8015)

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Section 35.75, "Release of individuals containing radiopharmaceuticals or permanent implants," of 10 CFR Part 35, "Medical Use of Byproduct Material," permits licensees to "authorize the release from its control of any individual administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual, including a breast-feeding infant, from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

In addition, 10 CFR 35.75(b) requires that the licensee "provide the released individual with instructions, including written instructions, on how

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

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to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem)."

Section 35.75 also requires that the licensee maintain "a record of the basis for authorizing the release of a individual for 3 years if the calculation of external dose to other individuals, on which the release is based, uses assumptions other than the following -- (1) The initial administered activity; (2) A point-source geometry; (3) The physical half-life of the radionuclide; (4) An occupancy factory of 0.25 at 1 meter; and (5) No attenuation of radiation in tissue."

Hereafter in this guide the individual to whom the radioactive material has been administered will be known as the *patient*.

This guide is being developed to provide guidance on determining the potential doses to an individual likely to receive the highest dose from exposure to the released patient, to establish appropriate activities and dose rates for release, to provide guidance or instructions for patients on how to maintain doses to other individuals as low as reasonably achievable, and to describe recordkeeping requirements.

The information collections contained in this regulatory guide are covered by the requirements in 10 CFR 35.75, which have been approved by the Office of Management and Budget, Approval No. 3150-0010.

B. DISCUSSION

This guide lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

The activities were calculated by using, as a starting point, the method discussed in 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]

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[1] National Council on Radiation Protection and Measurements, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Report No. 37, 1970.

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(1-e^{-0.693t/T_p})}{r^2} \qquad \text{(Equation 1)}$$

Where $D(t)$ = accumulated exposure at time t, in roentgens,
34.6 = conversion factor of 24 hrs/day times the total integration of decay (1.44),
Γ = specific gamma ray constant for a point source, R/mCi·h at 1 cm,
Q_0 = initial activity of the point source in millicuries, at the time of the release,
T_p = physical half-life in days,
r = distance from the point source to the point of interest in centimeters,
t = exposure time in days.

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the *dose to total decay*. Therefore, $(1-e^{-0.693t/T_p})$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 1 rem.

- The doses are calculated using the physical half-life of the radionuclides given in Appendix A and do not account for the biological half-life of the radionuclide.

- The gamma ray constants and half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Appendix A to this guide.

- For radionuclides with half-lives greater than 1 day, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 100 centimeters. Selection of 25 percent of the dose to total decay for estimating the maximal likely exposure is a judgment based on time-distance combinations believed to occur when instructions to spend as little time as possible near the patient are given.

- For radionuclides with half-lives less than 1 day, the factor 1.0 is used in Equation 3 with the assumption that the time that individuals will spend near the patient will be limited. However, this assumption may not be valid when relatively long-term averaging of behavior cannot be assumed.

Thus, for radionuclides with a half-life greater than 1 day:

$$D(\infty) = \frac{34.6\,\Gamma Q_0 T_p (0.25)}{(100\ cm)^2} \qquad \text{(Equation 2)}$$

For radionuclides with a half-life less than 1 day:

$$D(\infty) = \frac{34.6\,\Gamma Q_0 T_p}{(100\ cm)^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. The equations do not account for internal intake by household members and members of the public because the dose from intake by other individuals is normally expected to be small (less than a few percent) relative to the gamma dose (see Section 3.2 of Appendix B). Further, the equations above do not apply to the release of breast-feeding mothers if they continue to breast-feed. Breast-feeding must be considered separately as described below.

C. REGULATORY POSITION

1. ACTIVITY LEVELS

1.1 Activities for Release of Patients

Licensees may demonstrate compliance with the dose limit in 10 CFR 35.75 for release of patients from licensee control if the amount of the radionuclide in the patient's body at the time of release is less than the value in Column 1 of Table 1 or if the dose rate at 1 meter (from the patient centerline) is less than the value in Column 2 of Table 1 for that radionuclide. The release of mothers who might breast-feed after release may also be based on Columns 1 and 2 of Table 1, but Columns 3 and 4 cannot be used to determine when instructions must be given. The instructions that must be given to women who might breast-feed are discussed later in this guide.

1.2 Activities Requiring Instructions

Licensees may use the values in Column 3 or Column 4 of Table 1 to determine when instructions must be given to patients who are not breast-feeding. Column 3 provides activities above which an individual could receive a dose of 1 millisievert (0.1 rem) or more. Column 4 provides corresponding dose rates at 1 meter, based on the activities in Column 3.

If the released patient is a woman who will be breast-feeding after release, licensees may also use Table 2 to determine when additional instructions on the cessation period must be given to the patient to meet the requirements in 10 CFR 35.75(b).

Table 1. Activities and Dose Rates for Authorizing Patient Release and Giving Instructions[2]

Radio-nuclide	Column 1 Activity Below Which Patients May Be Released (mCi)	(GBq)	Column 2 Dose Rate at 1 meter at Which Patients May Be Released (mrem/hr)	Column 3 Activities Requiring Instructions (mCi)	(Gbq)	Column 4 Dose Rates at 1 meter Requiring Instructions (mrem/hr)
Ag-111	500	20	8	100	4	2
Au-198	90	3	20	20	0.7	4
Cr-51	100	4	2	20	0.8	0.4
Cu-64	200	9	30	40	2	5
Ga-67	200	9	20	40	2	4
I-123	160	6	20	30	1	4
I-125 (implant)	8.7	0.32	1	1.7	0.06	0.2
I-125	7	0.2	1	1.4	0.5	0.2
I-131	30	1.2	7	6	0.24	1.4
In-111	60	2	20	10	0.4	4
Ir-192	1.6	0.06	0.8	0.3	0.01	0.1
P-32	100	4	NA	20	0.8	NA
Pd-103 implants	40	1.5	3	7.9	0.29	0.7
Re-186	900	30	10	200	7	2
Re-188	600	20	20	100	4	4
Sc-47	300	10	10	50	2	3
Se-75	2	0.07	.5	.4	0.01	0.1
Sm-153	700	30	30	100	5	6
Sn-117m	30	1	4	6	0.2	0.8
Sr-89	100	4	NA	20	0.8	NA
Tc-99m	700	30	50	100	6	10
Tl-201	400	10	20	80	2	4

[2] Values rounded to one significant figure, except in a few instances where it was considered appropriate to use two significant figures. The details of the calculations are shown in NUREG-1492, *Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material*, 1995.

Y-90	100	4	NA	20	0.8	NA
Yb-169	10	0.4	2	2	0.07	0.4

1.3 Calculations Based on Case-Specific Factors

Licensees may calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis to account for factors specific to a patient. In such cases, licensees may be able to release a patient with radioactive material in excess of the activity listed in Table 1 and still demonstrate compliance with the annual dose limit. Licensees may take into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case.

Appendix B contains procedures for performing case-specific dose calculations, and it describes how various factors may be considered in the calculations.

2. INSTRUCTIONS

2.1 Instructions for Patients To Be Released

If the total effective dose equivalent to an individual exposed to a patient is likely to exceed 1 millisievert (0.1 rem), 10 CFR 35.75(b) requires that the released patient be given instructions, including written instructions, on how to maintain doses to other individuals as low as reasonably achievable.

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, or they may include additional information for individual situations. The instructions should include a contact and phone number in case the patient has any questions. The instructions should include, as appropriate, the need for

- Maintaining distance from other persons, including sleeping arrangements and minimizing use of public transportation,
- Minimizing time in public places (e.g., grocery stores, shopping centers, theaters, restaurants, and sporting events),
- Maintaining good hygiene to reduce contamination, and

- Taking precautions up to a certain given date.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine.[3] This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The NRC considers the instructions in this pamphlet to be acceptable instructions for patients, provided specific information is given to patients regarding any case-specific factors. However, licensees may develop their own instructions, addressing the items discussed above as appropriate.

Sample instructions for patients who have received permanent implants are given in Appendix C.

2.2 Additional Instructions for Release of Women Who Could be Breast-Feeding after Release

If the patient to be released is a woman who could be breast-feeding after release, Table 2 provides information and instructions on the cessation period for the radionuclides currently used in medical diagnosis and treatment. The instructions are appropriate for the normal dosage ranges shown, but if the activity administered is outside this range, the instructions may not be appropriate and may have to be modified.

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[3] "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Note to Commission: The following table, Table 2, "Instructions for Breast-feeding Women," will be replaced by an easier-to-use table that will give threshold quantities for when instructions should be given to breast-feeding women and when records should be kept to meet § 35.75(d).

Table 2

Instructions for Breast-Feeding Women

Radio-pharmaceutical	Administered Activity[4] mCi (MBq)	Dose to infant if no interruption of breast feeding[5] mrem	Instructions Required?[6]	Recommendation on interruption of breast feeding[7]
I-131 NaI	150 (5550)	60,000-40,000,000	yes	Complete cessation is necessary to avoid thyroid ablation in the infant
I-123 NaI	0.4 (14.8)	60	no	None
I-123 OIH	2 (74)	4-30	no	None
I-123 mIBG	10 (370)	300	yes	Interruption for about 24 hours
I-125 OIH	0.01 (0.37)	0.2	no	None
I-131 OIH	0.3 (11.1)	3-20	no	None

[4] Maximum activity normally administered.

[5] Doses are calculated for the maximum administered activities shown in Column 2. If a smaller activity were administered, the doses would be proportionally smaller. The doses are calculated for newborns; doses to a one-year-old would be less than half the doses shown. If a dose range is shown, the range is due to individual variability and measurement variability as indicated by different measurements of concentrations in breast milk. The doses include internal doses only; external doses due to close contact during nursing were found to be small relative to the maximum of the internal dose range. The details of the calculations are shown in NUREG-1492. "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

[6] The decision on whether instructions are required by § 35.75(b) is based on the maximum value of the dose range for the newborn exceeding 0.1 rem.

[7] The duration of interruption is selected to reduce the maximum dose to a newborn infant to less than 0.1 rem. The actual doses that would be received by most infants would be far below 0.1 rem. The physician may use discretion in the recommendation, increasing or decreasing the duration of interruption somewhat depending on the mother's concerns about radioactivity or interruption of breast feeding.

Tc-99m DTPA	20 (740)	0.3-6	no	None
Tc-99m MAA	4 (148)	4-300	yes	Interruption for about 6 hours
Tc-99m pertechnetate	30 (1110)	200-800	yes	Interruption for about 24 hours
Tc-99m DISIDA	8 (300)	4-20	no	None
Tc-99m glucoheptonate	20 (740)	2-5	no	None
Tc-99m HAM	8 (300)	20-50	no	None
Tc-99m MIBI	30 (1110)	1-10	no	None
Tc-99m MDP	20 (740)	4-5	no	None
Tc-99m PYP	20 (740)	5-20	no	None
Tc-99m RBC's in vivo labeling	20 (740)	0.3-100	yes	Interruption for about 6 hours
Tc-99m RBC's in vitro labeling	20 (740)	1-2	no	None
Tc-99m sulfur colloid	12 (444)	9-100	yes	Interruption for about 6 hours
Tc-99m DTPA aerosol	1 (37)	0.02-0.5	no	None
Tc-99m MAG3	10 (370)	0.2-2	no	None
Tc-99m WBC's	5 (185)	20-800	yes	Interruption for about 24 hours
Ga-67 citrate	5 (185)	300-10,000	yes	Complete cessation
Cr-51 EDTA	0.05 (1.85)	<0.01	no	None
In-111 WBC's	0.5 (18.5)	20-100	yes	Interruption for about 6 hours
Tl-201	3 (111)	500-1000	yes	Complete cessation

3. RECORDS

There is no recordkeeping requirement for patient releases based on Table 1. However, if the release of the patient is based on factors other than the standard conservative assumptions on which Table 1 is based, 10 CFR 35.75(c) requires that the licensee maintain, for 3 years, a record of the basis for the release.

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. In those instances for which a case-specific calculation applies to more than one patient release, the calculation need not be performed again.

D. IMPLEMENTATION

The purpose of this section is to provide information about the NRC staff's plans for using this regulatory guide.

Except in those cases in which a licensee uses an acceptable alternative method for complying with 10 CFR 35.75, the method described in this guide will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

APPENDIX A

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide	Half-Life (days)[1]	Exposure Rate Constant[2] ($R \cdot cm^2/mCi \cdot h$)	Radionuclide	Half-Life (days)[1]	Exposure Rate Constant[2] ($R \cdot cm^2/mCi \cdot h$)
Ag-111	7.45	0.150	Pd-103 (implants)	16.97	0.86[4]
Au-198	2.696	2.36	Re-186	3.777	0.168
Cr-51	27.704	0.177	Re-188	0.7075	0.337
Cu-64	0.5292	1.10	Sc-47	3.351	0.626
Ga-67	3.261	0.753	Se-75	119.8	2.60
I-123	0.55	1.61	Sm-153	1.9458	0.425
I-125	60.14	1.42	Sn-117m	13.61	1.48
I-125 (implants)	60.14	1.11[3]	Sr-89	50.5	NA[5]
I-131	8.040	2.20	Tc-99m	0.2508	0.756
In-111	2.83	3.15	Tl-201	3.044	0.447
Ir-192	74.02	4.69	Y-90	0.1329	NA[5]
P-32	14.29	NA[5]	Yb-169	32.01	1.83

[1] Keith F. Eckerman, Anthony B. Wolbarst, and Allan C. B. Richardson, Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion, Report # EPA-520/1-88-020, Office of Radiation Programs, U. S. Environmental Protection Agency, Washington, DC, 1988.

[2] The exposure rate factor includes gamma rays and x-rays with an energy above 11.3 keV. The 11.3 keV cutoff is the one used in NCRP Report No. 41, "Specification of Gamma-Ray Brachytherapy Sources," 1974. The exposure rate constant was calculated from the following equation:

$$\Gamma \frac{mR \cdot cm^2}{mCi \cdot hr} = (1.332 \times 10^{14} \frac{dis}{mCi \cdot hr})(\frac{1}{4\pi (100\ cm)^2}) \sum f_i E_i (\frac{\mu_{a,i}}{\rho}\ \frac{cm^{-1}}{gm \cdot cm^{-3}}) \times$$

$$(\frac{gm \cdot mR}{87.6\ erg})(1.6 \times 10^{-6}\ \frac{erg}{MeV})$$

Where E_i = the energy of the gamma ray or x-ray i in Mev.

f_i = the probability of decay of gamma rays or x-rays with energy E_i per disintegration. Values for E_i and f_i were taken from: Bernard Shleien, The Health Physics and Radiological Health Handbook, Revised Edition, Scinta, Inc., 1992, pages 294-334. For Re-186, Re-188, and Sn-117m the values for E_i and f_i were taken from: Laurie M. Unger and D. K. Trubey, "Specific Gamma-Ray Dose Constants for Nuclides Important to Dosimetry and Radiological Assessment," ORNL/RSIC-45/R1, 1982.

$\mu_{a,i}$ = the linear energy absorption coefficient in air of photons of energy E_i, taken from Radiological Health Handbook, U. S. Department of Health, Education, and Welfare, 1970, page 135.

ρ = the density of air at standard temperature and pressure, taken to be 0.0012929 gm/cm^3.

The details of the calculation of the exposure rate factors are shown in Table A-2, Appendix A to NUREG-1492.

[3] R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and taking into account the attenuation of gamma rays within the implant capsule itself.

[4] Ravinder Nath, Yale University School of Medicine, letter to Dr. U. Hans Behling dated March 31, 1993. The exposure rate constant given is a measured value that takes into account the attenuation of gamma rays within the implant capsule itself.

[5] Not applicable (NA) because release quantities based on beta emission rather than gamma emission.

APPENDIX B

PROCEDURES FOR CALCULATING DOSES BASED ON CASE-SPECIFIC FACTORS

IN certain situations, a licensee may release a patient with an activity higher than the values listed in Table 1 for a specific radionuclide. Licensees may calculate the potential doses to individuals exposed to patients receiving treatment with radioactive material on a case-by-case basis to account for certain factors specific to an individual.

According to 10 CFR 35.75, a record must be kept for 3 years of the basis for the release of the patient if the release of the patient is based on other than standard conservative assumptions. For this requirement, if the individual retains the initial administered activity, standard conservative assumptions are: a point-source geometry, the physical half-life of the radionuclide, an occupancy factor of 0.25 at 1 meter, and no attenuation of radiation in tissue.biological elimination rather than just the physical half-life of the radionuclide or an occupancy factor other than 0.25 at one meter, or includes consideration of the attenuation of radiation by body tissue of the released individual.

The following equation is generally used to calculate doses:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,E}{(r)^2} \qquad \text{(Equation B-1)}$$

Where $D(t)$ = dose to total decay,

34.6 = conversion factor of 24 hrs/day times the total integration of decay (1.44),

Γ = exposure rate constant,

Q_0 = initial activity at the start of the time interval,

T_p = physical half-life,

E = exposure factor that accounts for the different occupancy times and distances when an individual is around a patient. This value is typically 0.25 when the distance is 100 cm.

r = distance. This value is typically 100 cm.

1. EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits to members of the public stated in 10 CFR 35.75. The effective half-life is defined as:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p} \qquad \text{(Equation B-2)}$$

Where T_b = biological half-life of the radionuclide,

T_p = physical half-life of the radionuclide.

Using the effective half-life, Equation B-1 becomes:

$$D(t) = \frac{34.6\,\Gamma Q_0 T_{eff} E}{(r)^2} \qquad \text{(Equation B-3)}$$

with the factors defined as above, T_{eff} is the effective half-life.

For radioiodine, the effective half-life comprises the effective half-life of extrathyroidal iodide (i.e., existing outside of the thyroid) and the effective half-life of iodide following uptake by the thyroid. The

effective half-life for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p} \qquad \text{(Equation B-4)}$$

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p} \qquad \text{(Equation B-5)}$$

Where T_{b1} = biological half-life for extrathyroidal iodide,
T_{b2} = biological half-life of iodide following uptake by the thyroid,
T_p = physical half-life of iodine-131.

Thyroid Cancer Example: **Calculate the maximum likely dose to an individual exposed to a patient who has been administered 100 millicuries (3,700 megabecquerels) of iodine-131, 3 to 4 weeks after thyroid cancer surgery, for the treatment of thyroid remnants and metastases. The occupancy factor is 0.25 at 1 meter.**

Solution: In this example, we will account for the elimination of iodine-131 from the body by using the biological half-lives appropriate for thyroid cancer to calculate the dose. It is generally recognized that, after surgical removal of the thyroid, the uptake of iodine-131 by the thyroidal remnants and metastases does not exceed 5 percent of the administration. It will be necessary to consider the different biological half-lives for thyroidal and extrathyroidal iodine. The following assumptions are made in this example:

IODINE-131 PARAMETERS FOR THYROID CANCER EXAMPLE

Physical half-life of iodine-131, T_p	8.0 days
Extrathyroidal fraction, F_1	0.95[1]
Biological half-life of extrathyroidal fraction, T_{b1}	0.33 day[2]
Effective half-life of extrathyroidal fraction, T_{1eff}	0.3 day
Thyroidal fraction, F_2	0.05[1]
Biological half-life of thyroidal fraction, T_{b2}	80 days[2]
Effective half-life of thyroidal fraction, T_{2eff}	7.3 days
Specific gamma ray constant, Γ	2.2 R·cm²/mCi·h

[1]Personal communication, M. Pollycove, M.D., Visiting Medical Fellow, U.S. Nuclear Regulatory Commission, Rockville, MD, April 1995.
[2]International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987.

The total dose comprises the doses from the extrathyroidal and thyroidal fractions. The equation is:

$$D(t) = \frac{34.6\,\Gamma F_1 Q_0 T_{1eff}(0.25)(1-e^{-0.693t/T_{1eff}})}{(100\text{ cm})^2} + \frac{34.6\,\Gamma F_2 Q_0 T_{2eff}(0.25)(1-e^{-0.693t/T_{2eff}})}{(100\text{ cm})^2} \qquad \text{(Equation B-6)}$$

Substituting the values from above, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2\text{ R·cm}^2/\text{mCi·h})(0.95)(100\text{ mCi})(0.3\text{ d})(0.25)}{(100\text{ cm})^2} + \frac{34.6(2.2\text{ R·cm}^2/\text{mCi·h})(0.05)(100\text{ mCi})(7.3\text{ d})(0.25)}{(100\text{ cm})^2}$$

$$D(\infty) = 0.054 + 0.069$$

$$D(\infty) = 0.124\text{ rem } (1.24\text{ mSv})$$

Therefore, thyroid cancer patients administered 100 millicuries (3,700 megabecquerels) of iodine-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and the patient is given instructions.

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption. For those individuals who have had surgery to remove thyroidal tissue, F_2 is typically smaller and, in some cases, F_2 is known for a specific individual.

Hyperthyroidism Example: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 33 millicuries (1,200 megabecquerels) of iodine-131 for the treatment of hyperthyroidism (i.e., thyroid ablation). The occupancy factor is 0.25 at 1 meter.

Solution: In this example, we will account for elimination of iodine-131 from the body by using the biological half-lives appropriate for hyperthyroidism to calculate the dose. It will be necessary to consider the different biological half-lives for thyroidal and extrathyroidal iodine. The following assumptions are made in this example:

IODINE-131 PARAMETERS FOR HYPERTHYROIDISM EXAMPLE

Physical half-life of iodine-131, T_p	8.0 days
Extrathyroidal fraction, F_1	0.45[1]
Biological half-life of extrathyroidal fraction, T_{b1}	0.33 day[1,2]
Effective half-life of extrathyroidal fraction, T_{1eff}	0.3 day
Thyroidal fraction, F_2	0.55[1]
Biological half-life of thyroidal fraction, T_{b2}	21 days[1]
Effective half-life of thyroidal fraction, T_{2eff}	5.8 days[1]
Specific gamma ray constant, Γ	2.2 $R \cdot cm^2/mCi \cdot h$

[1]Personal communication, M. Pollycove, M.D., Visiting Medical Fellow, U.S. Nuclear Regulatory Commission, Rockville, MD, April 1995.

[2]International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53 (March 1987).

The total dose comprises the doses from the extrathyroidal and thyroidal fractions. The equation is:

$$D(t) = \frac{34.6\,\Gamma F_1 Q_0 T_{1eff}(0.25)(1-e^{-0.693t/T_{1eff}})}{(100\text{ cm})^2} + \frac{34.6\,\Gamma F_2 Q_0 T_{2eff}(0.25)(1-e^{-0.693t/T_{2eff}})}{(100\text{ cm})^2} \qquad \text{(Equation B-6)}$$

Substituting the values from above, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2R\cdot cm^2/mCi\cdot h)(0.45)(33\text{ mCi})(0.3\text{ d})(0.25)}{(100\text{ cm})^2} + \frac{34.6(2.2R\cdot cm^2/mCi\cdot h)(0.55)(33\text{ mCi})(5.8\text{ d})(0.25)}{(100\text{ cm})^2}$$

$$D(\infty) = 0.008 + 0.200$$

$$D(\infty) = 0.208\text{ rem } (2.08\text{ mSv})$$

Therefore, hyperthyroid patients administered 33 millicuries (1,200 megabecquerels) of iodine-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75.

2. EXPOSURE FACTOR

The distance and the time that other individuals will spend in the proximity of the patient may occasionally be taken into account when determining the dose to an individual. If the patient is living alone, will have few if any visits by family or friends, will not be returning to work immediately, and will be generally isolated from other people, the exposure factor can be decreased by a factor of 2 (for example, from the general value

of 0.25 to 0.125). This would allow an individual to be released with an activity that is higher than that specified in Table 1 in the regulatory guide. On the other hand, if the patient needs extensive care at home, the exposure factor will have to be increased to account for the increased exposure of the individual caring for the patient.

In general, the NRC does not believe that the exposure factors should be less than 0.125 because it is not possible to avoid someone being exposed to the patient at all times. Lower values for the exposure factor are not specifically prohibited by the regulation, but must be justified in the record of the calculation, as the record will be subject to inspection.

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received 10 millicuries (370 megabecquerels) of iodine-131. The patient lives alone and will not be working.

Solution: The dose is calculated using Equation B-1:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,E}{r^2}$$

Since the patient lives alone and will not be returning to work, and therefore will not be around the public, the exposure factor can be reduced to 0.125:

$$D(t) = \frac{34.6(2.22\ R\cdot cm^2/mCi\cdot hr)(10\ mCi)(8.05\ d)(0.125)}{(100\ cm)^2}$$

$$D = 0.077\ rem\ (0.77\ mSv)$$

Since the dose is less than 1 millisievert (0.1 rem), the patient may be released and instructions to the patient are not required. Because the administered activity would indicate instructions and a record to be maintained based on the values in Table 1, it is recommended that a record of the calculation be maintained to ensure compliance with the dose limits in 10 CFR 35.75.

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received 10 millicuries (370 megabecquerels) of iodine-131. The patient requires extensive care because of other medical conditions.

Solution: Since the patient needs extensive care, the exposure factor will have to be increased to account for the increased time the primary caregiver will spend near the patient. An exposure factor of 0.5 is used in this example:

$$D = \frac{34.6(2.2\ R \cdot cm^2/mCi \cdot hr)(10\ mCi)(8.04\ d)(0.5)}{(100\ cm)^2}$$

$$D = 0.306\ rem\ (3.06\ mSv)$$

Since the dose exceeds 1 millisievert (0.1 rem), the licensee must provide the patient with written instructions, and a record of the released patient is required.

3. OTHER FACTORS

3.1 Attenuation of the Radiation in the Body

Licensees may take into account attenuation of the radiation by the patient. The fraction of the dose that results after attenuation by the body may be calculated using the following equation:

$$D = D_0 e^{-\mu x} \qquad \text{(Equation B-8)}$$

Where D = dose after attenuation,
D_0 = dose before attenuation,
μ = linear attenuation coefficient of tissue,
x = thickness of tissue covering the implant.

Also, the dose before attenuation is, from Equation 2 in the guide:

$$D_0 = \frac{34.6\,\Gamma\,Q_0\,T_p\,(0.25)}{(100\text{ cm})^2} \qquad \text{(Equation B-9)}$$

Substituting Equation B-9 for D_0 in Equation B-8, the dose after attenuation becomes

$$D = \frac{34.6\,\Gamma\,Q_0\,T_p\,(0.25)(e^{-\mu x})}{(100\text{ cm})^2} \qquad \text{(Equation B-10)}$$

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received a permanent implant of 60 millicuries (2,220 megabecquerels) of iodine-125. The following factors apply:

Γ = 1.11 R·cm²/mCi·hr,
T_p = 60.2 days,
μ = 0.387/cm (Ref. B-1),
5 HVLs = 9 cm (assume 5 Half Value Layers in soft tissue;
1 Half Value Layer for iodine-125 = 1.8 cm).

There is a significant reduction in the exposure rate from the shielding effects of the source capsule. The Γ of 1.11 R·cm²/mCi·h for iodine-125 already accounts for the reduction in exposure rate from attenuation by the source capsule.

Based on empirical assessment involving patients with implants, soft tissue shielding for iodine-125 is likely to exceed 5 or more half value layers (Ref. B-1).

Solution: The dose is calculated using Equation B-10:

$$D = \frac{34.6(1.11\,\text{R·cm}^2/\text{mCi·hr})(60\text{ mCi})(60.2\text{ d})(0.25)(e^{-(0.387/\text{cm})(9\text{ cm})})}{(100\text{ cm})^2}$$

D = 0.107 rem (1.07 mSv)

Therefore, a patient who has received a permanent implant of 60 millicuries (2,220 megabecquerels) of iodine-125 may still be authorized for release. The licensee must provide the patient with instructions and maintain a record that documents the validity of the foregoing assumptions in the individual patient's case.

3.2 Internal Dose

Internal dose may be a consideration with certain radiopharmaceuticals now being developed, such as radiolabeled antibodies, or those that are developed in the future. Many of the radionuclides used in radiolabeled antibodies are predominantly beta or alpha emitters, which emit few gammas.

One way of evaluating the internal dose is to compare the internal dose with the annual limit on intake (ALI) value in 10 CFR Part 20. A rule of thumb is to assume that the individual likely to receive the highest dose from exposure to the patient will receive an internal dose of 1-millionth of the activity that is in the patient. This rule of thumb was developed in Reference B-2 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply for cases of intake by an individual exposed to a patient. However, two studies (Refs. B-3 and B-4) regarding the intakes of individuals exposed to patients administered iodine-131 indicated that internal doses are negligible compared to external doses and that intakes were of the magnitude of one 1-millionth of the quantity in the patient.

In addition, the NCRP 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, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely."(B-5). For additional discussion on the subject, see Reference B-1.

A rough estimate of the effective dose equivalent can be calculated from the following equation:

$$D_i = \frac{Q(5 \text{ rems})(10^{-6})}{ALI} \qquad \text{(Equation B-11)}$$

Where D_i = the internal effective dose equivalent to the individual exposed to the patient in rems,

Q = the activity in the patient at time of release in microcuries,

ALI = the occupational inhalation annual limit on intake from Appendix B of Part 20,

5 rems = the dose from an intake of one ALI,

10^{-6} = the assumed fractional intake.

For example, assume that 30 millicuries (30,000 microcuries) of iodine-131 was administered to a patient. If 1-millionth of the administered activity is taken in by another individual, the activity would be 0.03 microcuries. The stochastic ALI for iodine-131, 200 microcuries, corresponds to an effective dose equivalent of 50 millisieverts (5 rems). Thus, the individual would receive a dose of about 75 microsieverts (0.75 millirem). In this case, the internal dose would be considerably less than 1 percent of the assumed 5 millisieverts (0.5 rem) external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose since they would be significantly less than the uncertainty in the external dose.

REFERENCES FOR APPENDIX B

B-1. Stewart Schneider and Stephen A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, 1995.*

B-2. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (Or 'Is 10^{-6} a Magic Number in Health Physics?')," Health Physics, Volume 39, Number 6, 1980.

B-3. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients - The Contamination Hazard," British Journal of Radiology, Volume 43, 1970.

B-4. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," American Journal of Public Health, Volume 68, Number 3, 1978.

B-5. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

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*Requests for single copies of drafts should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Distribution and Mail Services Section. Requests for drafts will be filled as long as supplies last. Copies of drafts are also available for inspection and copying for a fee from the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

APPENDIX C

SAMPLE INSTRUCTIONS FOR PATIENTS RECEIVING PERMANENT IMPLANTS

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body and to yourself if the source falls out or comes out, you should do the following:

- Stay at a distance of _____ feet from _____ for _____ days/weeks.
- Minimize time with children and pregnant women for _____ days/weeks.
- Do not hold or cuddle children for _____ days/weeks.
- Avoid public transportation for _____ days/weeks.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
    - Take the following action if you find a seed or pellet:
        - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
        - Place the container with the seed/pellet in a location away from people.
        - Notify _____, at (phone number) for further instructions as soon as possible.

If you have any questions, contact the following individual(s):

Name _____ Phone number _____ Beeper number _____
Name _____ Phone number _____ Beeper number _____

REGULATORY ANALYSIS

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, S. Schneider et al., 1995), provides the regulatory basis for this guide and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC.

ATTACHMENT 3

NUREG-1492

Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material

Final Report

Prepared by:

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ABSTRACT

The Nuclear Regulatory Commission (NRC) has received three petitions to amend its regulations in 10 CFR Parts 20 and 35 as they apply to doses received by members of the public exposed to patients released from a hospital after they have been administered radioactive material. While the three petitions are not identical, they all request that the NRC establish a dose limit of 5 millisieverts (0.5 rem) per year for individuals exposed to patients who have been administered radioactive materials. This Regulatory Analysis evaluates three alternatives. Alternative 1 is for the NRC to amend its patient release criteria in 10 CFR 35.75 to use the more stringent dose limit of 1 millisievert (0.1 rem) per year in 10 CFR 20.1301(a) for its patient release criteria. Alternative 2 is for the NRC to continue using the existing patient release criteria in 10 CFR 35.75 of 1,110 megabecquerels (30 millicuries) of activity or a dose rate at one meter from the patient of 0.05 millisievert (5 millirems) per hour. Alternative 3 is for the NRC to amend the patient release criteria in 10 CFR 35.75 to specify a dose limit of 5 millisieverts (0.5 rem) for patient release. The evaluation demonstrates that diagnostic procedures are unaffected by the choice of alternative. Only some therapeutic administrations of radioactive material could be affected by the choice of alternative. The evaluation indicates that Alternative 1 would cause a large increase in the national health care cost from retaining patients in a hospital longer and would cause significant personal and psychological costs to patients and their families. The choice of Alternatives 2 or 3 would affect only thyroid cancer patients treated with iodine-131. For those patients, Alternative 3 would result in less hospitalization than Alternative 2. Alternative 3 has a potential decrease in national health care cost of $10,000,000 per year but would increase the potential collective dose from released therapy patients by about 9,000 person-rem per year, mainly to family members. Alternative 3 would also have personal and psychological benefits for the patients and their families.

CONTENTS

Tables

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1 STATEMENT OF THE PROBLEM

Each year in the U.S., radioactive pharmaceuticals or compounds or radioactive implants are administered to roughly 8 to 9 million patients for the diagnosis or treatment of disease. These people can expose others around them to radiation until the radioactive material has been excreted from their bodies or has decayed away.

NRC's patient release criteria in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants," are as follows: "(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either: (1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of 1 meter; or (2) The activity in the patient is less than 30 millicuries; (b) A licensee may authorize the release of a patient administered a permanent implant only if "the measured dose rate is less than 5 millirems per hour at a distance of 1 meter."

On May 21, 1991, the NRC published a final rule that amended 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360). 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 supplemental information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients, thereby creating the need to address this issue.

Because some licensees were uncertain what effect the revised 10 CFR Part 20 would have on patient release criteria, three petitions for rulemaking were received on this issue. The first petition, submitted by Dr. Carol S. Marcus (PRM-20-20, 56 FR 26945), requested that the NRC:

(1) Raise the annual 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).

(2) Amend 10 CFR 35.75(a)(2) to retain the 1,110-megabecquerel (30-millicurie) limit for iodine-131 (I-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" (NCRP70).

(3) Delete 10 CFR 20.1301(d) which requires licensees to comply with provisions of EPA's environmental regulations in 40 CFR Part 190 in addition to complying with the requirements of 10 CFR Part 20.

The second petition, submitted by the American College of Nuclear Medicine (ACNM) (PRM-35-10, 57 FR 8282, as revised by PRM-35-10A, 57 FR 21043), requested that the NRC:

(1) Adopt a dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients who have been administered radiopharmaceuticals.

(2) Permit licensees to authorize release from hospitalization any patient administered a radiopharmaceutical even if the activity in the patient is greater than 1,110 megabecquerels (30 millicuries) by defining "confinement" to include confinement in a private residence.

A third petition (PRM-35-11, 59 FR 37950) dealing, in part, with these same issues was submitted by the American Medical Association (AMA). The main point of the petition is that the radiation dose limits in 10 CFR 20.1301 should not apply to individuals exposed to the patient.

Since the petitions submitted by Dr. Marcus, the ACNM, and the AMA all address the patient release criteria in 10 CFR 35.75, the NRC decided to resolve these petitions in a single rulemaking.

2 OBJECTIVES OF THE RULEMAKING

The objective of this rulemaking is to respond to the three petitions for rulemaking by amending, as deemed appropriate, the patient release criteria in 10 CFR 35.75.

3 ALTERNATIVES

As the petitions and the public comments that were submitted to the Commission on the petitions made clear, some licensees were uncertain about whether dose limits imposed by 10 CFR 20.1301(a) or the patient release criteria established by 10 CFR 35.75 govern patient release. In the Commission's view, 10 CFR 35.75 governs patient release as explained in the Notice of Proposed Rulemaking (59 FR 30724). The public comments received on the three petitions and the Notice of Proposed Rulemaking also made it clear that the majority of commenters favored an annual dose limit of 5 millisieverts (0.5 rem). Given that 10 CFR Part 35 was deemed to be the controlling regulation, the Commission was faced with the decision regarding the regulatory approach to be pursued in 10 CFR 35.75. To evaluate the issues raised by the petitioners and those who commented on the requests made by the petitioners and the Notice of Proposed Rulemaking, the NRC determined that the following alternatives should be evaluated:

- Alternative 1: 1 millisievert (0.1 rem) total effective dose equivalent

  In this alternative, a 1 millisievert (0.1 rem) dose limit is evaluated as the controlling criteria for determining when a patient may be released from the licensee's control.

- Alternative 2: ≤ 1,110 megabecquerels (30 millicuries) or ≤ 0.05 millisievert (5 millirems)/hr at 1 meter

  In this alternative, the current patient release criteria in 10 CFR 35.75 is evaluated as the controlling requirement for determining when a patient may be released from the licensee's control.

- Alternative 3: 5 millisieverts (0.5 rem) total effective dose equivalent)

  This alternative evaluates a dose limit of 5 millisieverts (0.5 rem) to an individual exposed to a patient as the limiting factor for determining when a patient may be released from the licensee's control.

4 CONSEQUENCES

To evaluate the impacts of the three alternatives, it is necessary to determine which current procedures involving the administration of radiopharmaceuticals or permanent implants might be affected by the imposition of a 1-millisievert (0.1-rem) total effective dose equivalent dose limit for individuals exposed to released patients. For convenience, procedures involving the administration of radioactive materials to patients may be classified as: 1) diagnostic procedures involving administration of radiopharmaceuticals to obtain information about normal and pathological processes in the patient; or, 2) therapeutic procedures involving administration of radiopharmaceuticals or implantation of a radioactive source to destroy diseased tissue in the patient.

4.1 Current Uses of Radiopharmaceuticals

Radiopharmaceuticals can be defined as "drugs" that are radioactive. Although radiopharmaceuticals, diagnostic or therapeutic, may be classified as drugs, it should be noted that radiopharmaceuticals are not given for the purpose to exert any pharmacological action.

Radiopharmaceuticals are generated from two sources: nuclear reactors and accelerators. Nuclear reactors can produce radionuclides through neutron capture reactions (e.g., (n, γ), (n, p), and (n, α)), as well as by nuclear fission (n, f). Other radiopharmaceuticals are accelerator

produced, in which a highly pure target material is bombarded with protons, deuterons, or alpha particles. Many have relatively short half-lives. Some radiopharmaceuticals may be produced by either reactor or accelerator (e.g., palladium-103 and Iodine-125). The choice in production method is dictated by cost considerations and vendor access to a high neutron flux reactor facility. While most iodine-125 has in the past and continues to be produced by reactors, the production of palladium-103 has shifted from reactor to accelerator (personal communication, C. Jacobs, August 1993).

4.1.1 Diagnostic Administrations

4.1.1.1 Estimates of the Number of Diagnostic Procedures Performed

Estimates regarding the frequency and total number of diagnostic nuclear medicine procedures have been reported over the years in several studies reviewed and analyzed by Mettler, et al. (ME85). Among the earliest data reported was a study supported by the American College of Radiology (ACR75), which reflects data collected in 1972 by J. Lloyd Johnson Associates. Additional data for the years 1973 and 1975 were obtained in a similar fashion and also published in the American College of Radiology Manpower Survey (ACR82).

In 1975, the Bureau of Radiological Health (BRH; now the Center for Medical Devices and Radiological Health, CDRH) of the U.S. Food and Drug Administration initiated a pilot study that surveyed information reported by six hospitals to the Medically Oriented Data System (MODS). This project was later expanded to include 26 stratified hospitals that provided data for 1977 and 1978 (FDA85).

Comprehensive data on 1980 diagnostic imaging procedures were obtained by J. Lloyd Johnson Associates by mail questionnaire using a stratified random sample of general hospitals and selected office practices in the U.S. (JO83). The sample included 6,109 hospitals and was estimated to reflect about 90 percent of the total diagnostic imaging examinations. Additional studies were conducted by the BRH for the years 1980, 1981, and 1982. The hospital-based survey was called the Radiation Experience Data (RED 1 and RED 2 studies) (ME85). The RED 1 study examined the computer billing records of 81 hospitals. Data for the subsequent RED 2 study reflect information obtained by mail survey from 500 hospitals.

Data for 1982 were also provided by Parker, et al. (PA84) in which a randomized sample of 10 percent of the U.S. hospitals was surveyed. Although his survey was specifically directed to thyroid examinations, survey data also provided estimates of total examinations.

All of the studies mentioned above are summarized in Table 4.1 and represent hospital data only. However, the exclusion of non-hospital facilities should not significantly affect the accuracy of estimates since less than 1 percent of all nuclear medicine procedures are performed out-side hospitals (JO83). Inspection of Table 4.1 reveals several important trends. While the total number of diagnostic procedures has shown a general increase, the number of specific procedures has in some cases dramatically increased or decreased. By 1982, there were fewer radionuclide brain imaging examinations than in 1972, undoubtedly due to replacement by computerized tomography (ME85). For the same period, liver imaging increased tenfold. The largest percent increase involves cardiovascular imaging, which increased from an estimated 25,000 procedures in 1972 to about 950,000 in 1982. Other procedures such as renal, lung, and tumor imaging have experienced only modest increases in numbers.

A search of the open literature revealed no recent comprehensive studies to assess more current U.S. use of radiopharmaceuticals. It is generally thought, however, that the frequency and usage of radiopharmaceuticals have stabilized because of the competing technologies of computerized tomography, magnetic resonance imaging, and gray-scale ultrasound (personal communication, F.A. Mettler, March 1993). For this report, the most recent RED 2 frequency distribution and the cumulative frequency of 16 diagnostic nuclear medicine procedures per one-thousand population will be used to estimate current usage. Table 4.2 provides frequency estimates of diagnostic procedures adjusted to reflect the 1993 U.S. population, which is projected at 256,466,000 by the U.S. Bureau of the Census.

Table 4.1 Estimated Number of Diagnostic Radiopharmaceutical Procedures Performed in the U.S. between 1972 and 1982

	Year								
	1972	1973	1975	1978	1980	1980	1981	1982	1982
	Source								
Examination Type	ACR	ACR	ACR	MODS	Johnson	RED 1	RED 2	RED 2	Parker
Brain	1260[1]	1510	2120	1546	870	1176	1038	812	---
Hepatobiliary	26	---	---	---	---	---	109	179	---
Liver	455	535	676	1302	1180	1399	1445	1424	---
Bone	81	125	220	1160	1270	1307	1613	1811	---
Respiratory	332	417	597	1053	830	898	1095	1191	---
Thyroid	356	460	627	699	650	506	664	677	533
Urinary	108	122	154	205	200	164	402	236	---
Tumor	10	14	22	166	130	---	125	121	---
Cardiovascular	25	33	49	160	580	558	708	950	---
Other	686	294	338	120	120	368	---	---	---
Total	3339	3510	4803	6411	5830	6374	7199	7401	7690
	(16)[2]	(17)	(22)	(29)	(26)	(28)	(31)	(32)	(33)

Source: ME85.
[1] Numbers not in parenthesis indicate number of examinations x 1,000.
[2] Numbers in parenthesis indicate number of examinations/1,000 population.

The identity, chemical form, and average quantity of radionuclides used for diagnostic in-vivo procedures are cited in Table 4.2 and reflect values cited by Mettler, et. al. (ME86). It can be assumed that the average quantity per examination has not significantly changed since the time of original publication (personal communication, F.A. Mettler, March 1993).

As the results in Table 4.2 indicate, there are approximately 8.2 million diagnostic examinations employing radiopharmaceuticals performed annually in the U.S. Of these, more than 85 percent use technetium-99m (Tc-99m) as the label, about 5 percent use xenon-133 (Xe-133), bout 5 percent use thallium-201 (Tl-201), about 3 percent use iodine-131 or iodine-123 (I-123), and about 2 percent use gallium-67 (Ga-67).

4.1.1.2 Age and Sex Distribution of Patients

The age and sex distribution of the U.S. population that underwent nuclear medicine examinations in 1980, as cited by Mettler, et. al. (ME86), is shown in Table 4.3. For the period of observation, more than three-fourths of all nuclear medicine examinations were performed on persons over the age of 45; nearly 40 percent of these patients were 64 years and older. With the exception of the youngest age category, the percentage of females exceeded males.

Table 4.2 Estimated Radiopharmaceutical Use for Diagnostic Procedures in the U.S. in 1993[1]

Examination Type (Radiopharmaceutical)	Average Activity per Examination (MBq)	(mCi)	Total No. of Examinations (x 1,000)
Brain			
- Tc-99m DTPA	740	(20)	450
- Tc-99m O_4	740	(20)	450
Hepatobiliary			
- Tc-99m IDA	185	(5)	198
Liver			
- Tc-99m sulfur colloid	185	(5)	1,578
Bone			
- Tc-99m phosphate	740	(20)	2,007
Lung Perfusion			
- Tc-99m MAA	185	(5)	871
Lung Ventilation			
- Xe-133	370	(10)	449
Thyroid			
- Tc-99m O_4	185	(5)	600
- I-131	3.7	(0.1)	75
- I-123	11.1	(0.3)	75
Renal			
- Tc-99m DTPA	740	(20)	157
- I-131 hippuran	9.3	(0.25)	105
Cardiovascular			
- Tc-99m RBC	740	(20)	421
- Tc-99m phosphate	740	(20)	211
- Tl-201 chloride	111	(3)	421
Tumor			
- Ga-67 citrate	111	(3)	134
Total			8,202

[1] Based on ME86; and personal communication, F. A. Mettler, March 1993, but adjusted for the 1993 U.S. population.

Table 4.3 Age and Sex Distribution of Patients Having Nuclear Medicine Examinations

Age	Male (%)	Female (%)	Total (%)
< 15	0.9	0.7	1.6
15 - 29	3.3	4.9	8.2
30 - 44	5.2	8.7	13.9
45 - 64	15.8	21.6	37.4
> 64	17.0	21.9	38.9

Source: ME86.

4.1.2 Therapeutic Administrations

Therapeutic use of radioactive materials involves two distinct approaches. The first involves the oral, intravenous, or intracavity administration of a radiopharmaceutical that may subsequently be distributed, concentrated, retained, and eliminated by physical, chemical, and metabolic actions occurring within the body. The second approach involves the implantation of radioactive sources (i.e., seeds) directly into a solid tumor. While both temporary and permanent implants are performed, all patients receiving temporary implants are hospitalized until the implants are removed. Thus, only permanent implants are potentially affected by this rulemaking.

4.1.2.1 Radiopharmaceuticals Used in Therapy

The in-vivo use of radiopharmaceuticals in therapy is based on the ability to differentially deliver lethal radiation doses to the selected target tissue. Most desirable are beta emitters that can deliver intense irradiation of target cells while sparing the surrounding tissues. In contrast to diagnostic procedures for which the gamma emission is essential, the emission of energetic gammas is undesirable for therapeutic purposes since it results in unwanted irradiation of surrounding healthy tissues and doses to individuals in close proximity to the patient. The more significant therapeutic applications are described below.

Hyperthyroidism

Hyperthyroidism is characterized by an increased production of thyroid hormone. Hyperthyroidism is most commonly associated with Graves' Disease. Graves' Disease is an autoimmune disease in which the body's own immune system is directed against cellular and secretary products of the thyroid gland. Hyperthyroidism can also be the result of excessive hormone production by a single "toxic" nodule, thyroid carcinomas, and medications inclusive of potassium iodide.

Hyperthyroidism is not a condition reportable to public health agencies. As a result, data on rates of occurrence and treatment must be inferred. Incidence of hyperthyroidism is reported at 3 per 10,000 adults per year, with peak incidence occurring between 30 and 50 years of age (DG79).

From the most recent data (1990) available from the U.S. Bureau of the Census, it can be assumed that about 75 percent of the U.S. population (approximately 191,500,000 persons) is 18 years of age or older. Thus, it can be estimated that about 57,500 individuals per year require medical treatment for hyperthyroidism.

Although medical treatment may in some cases involve the use of anti-thyroid drugs or surgery, it may be assumed that about 85 percent of the cases of hyperthyroidism are treated with therapeutic doses of iodine-131 (personal communication, M. Pollycove, November 1993). The resulting estimate is about 50,000 treatments per year.

In the past, therapeutic quantities of iodine-131 for treatment of hyperthyroidism tended to be of a magnitude that would reduce the hormone production of the hyperactive thyroid gland to

normal levels. However, experience demonstrated that over a period of years the therapy-induced euthyroidal (normal or healthy thyroid) condition deteriorated to one of hypothyroidism requiring thyroid hormone replacement therapy. As a result, hyperthyroid therapy today involves ablation of the thyroid using doses of iodine-131 in the range of 550 to 1,100 megabecquerels (15 to 30 millicuries). Such doses quickly result in the total loss of thyroid function and the patient is given hormone replacement therapy from the onset (personal communication, F.A. Mettler, March 1993).

Thyroid Nodules

Single or multiple nodules of sufficient size may cause obvious enlargement of the thyroid. A nodule(s) refers to a replacement of the normal homogeneous cytostructure of the thyroid with a histologic pattern ranging from colloid-filled cysts and colloid adenomas to follicular adenomas. Since the incidence is 4 to 5 times as great in women as in men, and since it develops and progressively increases in size during life, it is most frequently found in females 50 to 70 years of age. It is not uncommon for nodules to remain undetected until a post-mortem examination.

Small nodules in euthyroid subjects require no therapy. If the gland is grossly enlarged and causes a cosmetic problem or tracheal compression, treatment may be indicated along with thyroid hormone replacement therapy.

A small percentage of thyroid nodules tend to produce thyroid hormones uncontrollably and in excess (i.e., the nodule is not under the regulatory control of the pituitary gland and is clinically referred to as toxic nodular goiter). The presence of these autonomously functioning thyroid nodules leads to hyperthyroidism (thyrotoxicosis).

Toxic nodular goiter, like Graves' Disease, may be treated surgically (thyroidectomy) or by therapeutic dose(s) with radioactive iodine. Estimates of the frequency of radioactive iodine treatment for this condition are included under the estimates for hyperthyroid treatment above.

Thyroid Cancer

There is no nationwide cancer registry that accurately defines the number of new cases of cancer diagnosed each year. However, the American Cancer Society (ACS) annually publishes data on cancer incidence and patient survival based on information provided by the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program.

The ACS estimates of U.S. cancer cases diagnosed for 1992, are based on age-specific incidence rates from the SEER program for 1986-1988 applied to the Census Bureau's population projections for 1992. The ACS's estimate of new thyroid cancers in 1992, is 12,500 (ACS93). This report assumes that about 10,000 cases per year will be treated with therapeutic doses of iodine-131.

The quantities of iodine-131 used in thyroid cancer therapy depend upon the type of cancer, the status of the cancer, and the degree of uptake and retention of iodine-131 by residual cancerous thyroid tissue. As a result, current therapeutic doses range from 1,850 to 11,100 megabecquerels (50 to 300 millicuries) (personal communications, F.A. Mettler and K.L. Miller, March 1993).

Therapy for Polycythemia Vera

Since the introduction of radiophosphorus in 1936, patients with polycythemia vera have been treated successfully with this radioisotope to control rather than cure this disease. Polycythemia vera is a relatively rare disease that is characterized by an autonomous proliferation of marrow cells leading to an over production of red blood cells, white blood cells, and platelets. Typically, phosphorous-32 (P-32) is administered intravenously in doses of 110 to 185 megabecquerels (3 to 5 millicuries) per treatment over a period of time with average cumulative quantities of 740 megabecquerels (20 millicuries) per patient.

Bone Therapy

Since the use of radioactive strontium for the treatment of bone metastases was first described in early 1942 (PE42), bone therapy has included other radionuclides. Bone therapy may involve the treatment of primary bone tumors such as osteosarcoma (BL87) in which bone-seeking radiopharmaceuticals are in fact tumor seeking. Bone therapy may also be the treatment of painful skeletal metastases, which may be palliated by

bone-seeking radionuclides. Although the literature references the palliative and tumor therapeutic use of these radionuclides (phosphorous-32: CH80, RO77; strontium-89 (Sr-89): BL88, KL87, RO87, ROE90, SI85; rhenium-186 (Re-186): KE87, MA88, SC90; samarium-153 (Sm-153): LA90, TU89), there are no data bases and no studies have been performed that would allow quantitative estimates regarding the number of patients given bone therapy with radiopharmaceuticals. These other therapies are performed so seldom that they have negligible impact in comparison with the radioiodines.

Therapy with Radiolabelled Cells

For lymphoid cell malignancies, the tumor cells (i.e., lymphocytes) may retain their ability to migrate and recirculate into the lymphoreticular tissues (i.e., spleen, liver, bone marrow, and lymph nodes). The harvesting, labelling, and reinjection of lymphocytes has been demonstrated to deliver therapeutic levels of radiation doses to tumors of the lymphoreticular system (CO87). Indium-114-labelled lymphocytes have a potential therapeutic role in the management of lymphoma, and clinical studies are underway. Because use of this new therapy is not widespread, its impact may be omitted in the analysis, but it should be noted that use of a dose-based methodology provides a means to determine the quantities for which release may be authorized.

Intra-Arterial Therapy

Some primary tumors as well as metastatic lesions are highly vascularized. Direct arterial injection with insoluble radiolabelled particulates that lodge in arterioles and capillaries of the tumor is the basis of this form of therapy (EH87, ZI84). Insoluble carriers of radionuclides that have been clinically tested include iodine-131-labelled oil contrast medium, iodine-131-lipoidal or -ethiodol (PA87), yttrium-90-glass microspheres (HE88), and yttrium-90 (Y-90) resin particles (ROE90). Since these therapies are so seldom used, their impact may be ignored in this analysis.

Intracavitary Tumor Therapy

For tumors that are spread over the serosal linings of the body cavities or for ascites tumors, one approach to delivering therapeutic doses of radiation is to inject the radiopharmaceutical directly into the body cavity. For this approach, colloids, chelates, and, more recently, monoclonal antibodies labelled with gold-198 (Au-198), phosphorous-32, yttrium-90, or iodine-131 can be used.

Initially, gold-198 colloids were used, but phosphorous-32 is now preferred due to its longer half-life, more energetic beta particles, and the absence of gamma radiation. Intracavitary radionuclide therapy with phosphorous-32 in quantities of 185 to 370 megabecquerels (5 to 10 millicuries) has been applied to malignancies involving the pleural, pericardial, and peritoneal cavities (JA81, KA81, MA78).

More recently, iodine-131- or yttrium-90-labelled tumor-associated monoclonal antibodies have been used in intracavitary therapy (FI89, PE86, RI90) in doses of 740 to 2,220 megabecquerels (20 to 60 millicuries). Superiority of monoclonal antibodies over colloids is expected due to the enhanced affinity of the labelled antibody for the target cells. At present, these therapies are rarely used and thus have no impact in comparison with radioiodines.

Radioimmunotherapy

Radioimmunotherapy involves the use of radiolabelled antibodies directed against tumor-specific antigens such as the carcinoembryonic antigen (CEA) and ferritin. Only a very limited number of cancer patients have been treated experimentally with radiolabelled antibodies in combination with chemotherapy and external beam irradiation. Among cancers treated are hepatomas, Hodgkin's disease, and non-Hodgkin's lymphoma (LE85, NE90, OR85). In the past, radioimmunotherapy involved the use of iodine-131- and yttrium-90-labelled polyclonal antibodies raised against tumor-associated antigens in a variety of animal species. Based on avidity of tumor cells and exposure considerations of the bone marrow, single doses of 370 to 1,110 megabecquerels (10 to 30 millicuries) have been used.

The development of the hybridoma technique by Kohler and Milstein (KO75) has caused significant shift in radioimmunotherapy. The hybridoma technique allows the development of monoclonal antibodies against tumor-associated antigens. At

this time, however, the use of radiolabelled monoclonal antibodies for therapeutic applications has been limited to experimental treatments. At present, these therapies are rarely used and thus have no impact in comparison with radioiodines.

4.1.2.2 Radioactive Materials Used in Permanent Implants (Brachytherapy)

In-situ radiotherapy may involve permanent implants or brachytherapy. Brachytherapy has been around almost since the discovery of X rays. Brachytherapy can be divided into temporary implantation using high activity sources or permanent brachytherapy using the interstitial implantation of encapsulated radioactivity. In 1911, Pasteau reported the first treatment of prostate cancer by brachytherapy using radium inserted through a urethral catheter (PA11). Currently, iridium-192 (Ir-192) is the radionuclide of choice for temporary implantation. For temporary implantation, patients may be retained in the hospital for reasons that are independent of radiological considerations. Radionuclides used for temporary implants are, therefore, of no concern to this report and will not be discussed further.

Over the past 20 years, several radionuclides have been introduced to brachytherapy, allowing for the permanent implantation of radioactive "seeds." Seeds are miniature capsules that are strategically inserted within a solid tumor and over the period of their decay deliver a lethal dose of radiation to tumor cells within a short distance of the implant. The major advantage of brachytherapy over external irradiation in the treatment of solid tumors is the favorable ratio of dose delivered to tumor cells versus normal tissue. This is particularly true of prostate cancer where the surrounding normal tissue includes the bladder, rectum, and urethra. The presence of these normal tissues limits the dose of external beam radiation therapy that can be administered safely to the prostate.

The radionuclides primarily used in permanent implants are iodine-125 (I-125) and palladium-103 (Pd-103). Less frequently used radionuclides include gold-198 and ytterbium-169 (Yb-169).

The most frequently used radionuclide in permanent implants is iodine-125, which has the advantage of an extremely low energy (27 keV) photon and a half-life of 60 days. Besides minimizing dose to surrounding healthy tissue, the low photon energy also limits doses to hospital personnel and others when compared to temporary implants with iridium-192 or permanent implants with gold-198 (CL89, RU92). Although iodine-125 implants are most commonly used to treat cancer of the prostate (DE86, FU91, HE82, MO88, PR92, WH88), they have also been used on a very limited basis for brain tumors (AG92, OS92, SC92), carcinomas of the pancreas (MO92), non-oat cell lung carcinomas (FL92), breast cancers (RU92), and tumors of the head, neck, and eye.

Palladium-103 seeds were developed for use in brachytherapy to reduce some of the problems associated with iodine-125. Its average photon energy of 21 keV is lower than iodine-125, but, given its shorter 17 day half-life, it has a higher initial dose rate. Recently, palladium-103 seeds have been developed with the same physical parameters as iodine-125 seeds to ensure compatibility with the brachytherapy tubes and templates used for iodine implantation (ME90).

Ytterbium-169 has been hailed as a replacement for iodine-125 in brachytherapy. Compared to iodine-125 and palladium-103, it has a slightly higher initial dose rate, and its average 93 keV beta energy allows for a more favorable dose distribution and negligible tissue self-attenuation (PO90). However, its use as a permanent implant is nominal due to the presence of a small (less than 3 percent) average photon peak at 300 keV, that can significantly impact radiation doses to individuals in proximity to the patient.

Gold-198 implants have been used in a few instances of prostate cancer (CA88, FR88). The potential advantage of delivering a high dose within a relatively short time, however, is offset by its energetic gamma emissions, which has caused its use in recent years to fall into disfavor and be used only rarely (CA87).

A thorough search of the literature and personal communications with several prominent members of the medical and scientific community (see Acknowledgements) indicates that there is no published data available to quantify the annual number of cancer patients receiving permanent implants. However, the scientific literature and consensus opinion among the experts identified in

the acknowledgments to this report does support the following:

1. permanent implants are currently considered an appropriate treatment for only a few sites of solid tumors;

2. among the cancer sites for which permanent implants are currently employed, prostate cancer represents the overwhelming majority;

3. among the 132,000 annual new cases of prostate cancer (ACS93), only a small fraction is treated with permanent implants; and,

4. for the purposes of this analysis, implants involving gold-198 (largely discontinued) and ytterbium-169 (isolated use only) may be ignored.

In the absence of documented clinical data, information was sought from the implant vendors on numbers of administrations and typical activities of radioactive material used per administration. Currently, there are only three vendor sources. Vendor supplied data suggests that approximately 2,000 implants involving iodine-125 are performed annually, at activities ranging from 1,110 to 1,850 megabecquerels (30 to 50 millicuries). For palladium-103, approximately 1,500 implants are performed annually, at activities ranging from 2,775 to 4,625 megabecquerels (75 to 125 millicuries).

4.1.2.3 Summary of Therapeutic Administrations

Table 4.4 summarizes the estimates of the quantities of gamma-emitting radioactive materials used in therapeutic administrations and the numbers of each therapy currently performed annually.

4.2 Assessment of Doses to Individuals Exposed to Patients Administered Radioactive Materials

To identify the potential impacts associated with each of the alternatives, it is necessary to know the magnitude of doses that could be received by an individual exposed to a patient who has been administered radioactive materials. While exposure can occur via any of the elimination pathways by which radionuclides are removed from the body (e.g., exhalation, feces, saliva, sweat, urine, and possibly vomit), experience indicates that for iodine-131 and other gamma emitters, these pathways will generally be insignificant in relation to the doses that can result from exposure to the direct gamma radiation from the patient, with the exception of intake from the milk in breast-feeding infants. This section of the report assesses the external and internal doses to individuals, including a breast-feeding infant, exposed to patients who have been administered radioactive materials.

4.2.1 Methodology for Calculating External Gamma Dose

The methodology for calculating the external gamma dose from exposure to the released patient is fully described in the associated regulatory guide for the final rule (NRC95). The methodology is based on the one 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" (NCRP70).

To calculate the dose to total decay $D(\infty)$, the regulatory guide uses for radionuclides with a half-life greater than 1 day

Table 4.4 Number of Annual Therapeutic Administrations in the U.S. (significant gamma-emitting radionuclides only)

Therapeutic Procedure	Radionuclide Employed	Activity per Administration (MBq (mCi))	Estimated No. of Administrations (per year)
Thyroid Ablation for Hyperthyroidism	I-131	370 - 1,110[1] (10 - 30)	50,000
Thyroid Cancer	I-131	1,850 - 11,100[2] (50 - 300)	10,000
Permanent Implant	I-125	1,110 - 1,850[3] (30 - 50)	2,000
Permanent Implant	Pd-103	2,775 - 4,625[3] (75 - 125)	1,500
Total			63,500

[1] Based on personal communication, F. A. Mettler, March 1993.
[2] Based on personal communications, F. A. Mettler and K.L. Miller, March 1993.
[3] Based on information supplied by implant vendors, August 1993.

$$D(\infty) = \frac{34.6\Gamma Q_o T_p (0.25)}{(100\,cm)^2}, \qquad (1)$$

and for radionuclides with a half-life less than 1 day

$$D(\infty) = \frac{34.6\Gamma Q_o T_p}{(100\,cm)^2}, \qquad (2)$$

where Γ = exposure rate constant for a point source, R/mCi-h at 1 cm,

Q_o = initial activity of the point source in millicuries, at the time of release,

T_p = physical half-life in days.

4.2.1.1 Occupancy Factor

Equation 1 assumes, for radionuclides with half-lives greater than 1 day, that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the total dose to decay (0.25 in Equation 1) at a distance of 100 cm (1 m). For radionuclides with half-lives less than 1 day, the factor 1.0 is used in Equation 2 because the assumption that the time that individuals will spend near the patient will be limited is not valid when most of the dose is delivered in a relatively short time.

Doses among individuals who may come in contact with a released patient are highly variable and reflect the crucial, but difficult to define, parameters of time, distance, and shielding. Based on time and distance considerations, it is reasonable to conclude that for the overwhelming majority of released patients, the maximally exposed individual is likely to be the primary care-provider, the family, or any other individual who spends significant time close to the patient.

Based on time, distance, and shielding factors, which describe normal lifestyles of the U.S. population, it is highly unlikely that doses equal to spending 100 percent of time at a distance of 1 meter from a patient would result to any individual including a patient's spouse. As a standard medical practice, patients undergoing therapeutic treatments with radiopharmaceuticals are given firm instructions, both verbally and in writing, regarding basic principles on how to minimize doses to other individuals.

Given all considerations, a realistic estimate of the maximal likely dose to an individual exposed to a patient is 25 percent of the dose-to-total decay at a distance of 1 meter. The selection of an occupancy factor of 25 percent at 1 meter for estimating maximal likely exposure is based on the authors' professional judgment of time-distance combinations that are believed likely to occur when instructions to minimize time spent close to the patient are given.

The occupancy factor of 0.25 at 1 meter is also supported by empirical data. Harbert and Wells (HA74) monitored the external dose of 8 family members of 3 patients treated for thyroid carcinoma using iodine-131. All doses to family members were far below 5 millisieverts (0.5 rem) as shown in Table 4.5. The last column of Table 4.5 provides dose estimates based on the 25 percent occupancy factor in Equation 1. The actual doses are far below the calculated doses for an occupancy factor of 25 percent, indicating that the model generally provides a conservative estimate of the dose.

Harbart and Wells (HA74) also measured the external doses to 11 family members of seven hyperthyroid patients. All doses to family members were far below 5 millisieverts (0.5 rem). Also, in each case the measured doses were at least a factor of 10 below the doses predicted by Equation 1 using an occupancy factor of 0.25 at 1 meter.

Jacobson et al. (JA78) measured the external doses to 10 family members of 7 iodine therapy patients. In each case except one, the external dose to the family member was below that predicted by Equation 1 using an occupancy factor of 0.25 at 1 meter and well below 5 millisieverts (0.5 rem). In the case of the exception, the family went on a extended vacation spending much of the time together in an automobile. This demonstrates that if reasonable efforts to maintain distance are not made doses can be higher than predicted by Equation 1.

Buchan and Brindle (BU71) monitored the doses of 54 family members of patients who underwent iodine therapy for hyperthyroidism. This study is interesting because no instructions on minimizing dose were given. Thus, the results can be taken to represent the doses that would be received if no instructions were given or if instructions were totally disregarded. The highest measured dose to a family member was 2.7 millisieverts (0.27 rem), below the 5-millisievert (0.5-rem) limit. The effective occupancy factor at 1 meter was less than or equal to 0.25 in 45 of the 54 cases (83%). Thus, even in the complete absence of instructions, the occupancy factor at 1 meter was usually less than 0.25.

In conclusion, both empirical measurements and professional judgement support an occupancy factor of 0.25 at 1 meter as a generally conservative value. Using this value in Equation 1 should generally overpredict the dose even if instructions are not given or are to strictly followed. However, higher occupancy factors are certainly possible in situations where instructions are disregarded. The possibility of higher doses than predicted by Equation 1 is not considered a problem for this rulemaking. The NRC's rulemaking based on Alternative 3 provides an adequate level of protection with a significant margin of safety for those families that make a reasonable effort to follow the instructions. The NRC considers that to be sufficient.

4.2.1.2 Exposure Rate Constant

The exposure rate constant Γ expresses the dose rate per hour at 1 cm in air for a 37-megabecquerel (1-millicurie) point source of a given radionuclide. The exposure rate constants and the physical half-lives of radionuclides used in medicine are shown in Table A-1 of Appendix A.

For permanent implants, a significant reduction in the dose and dose rate occurs from the shielding effects of the source capsule. For iodine-125 and palladium-103 implants, the dose to total decay at 1 meter was calculated using an exposure rate constant corrected for capsule shielding as shown in Table A-1 of Appendix A. The physical characteristics of other radionuclides used in permanent implants (e.g., gold-198 and ytterbium-169) are given in Appendix A.

4.2.1.3 Effective Half-Life

A licensee may replace T_p in Equations (1) and (2) with the effective half-life T_{eff} of the radioactive material to demonstrate compliance with the dose limit in the revised 10 CFR 35.75. T_{eff} is characterized by T_p and the biological half-life T_b of the radionuclide according to the equation:

$$T_{eff} = \frac{T_p \times T_b}{T_p + T_b} \qquad (3)$$

The biological retention and elimination (i.e., biological half-life) of the radiopharmaceutical by the patient following administration is generally not considered for the

purposes of this analysis. However, under the final rule a licensee could authorize release on a case-by-case basis based on the biological half-life rather than only the physical half-life of the radiopharmaceutical.

4.2.1.4 Internal Exposure

Upon oral administration or direct injection into the circulating blood, the normal processes of absorption, distribution, and excretion take place. Removal of radionuclides from the body may follow the pathways of breast milk, exhaled air, feces, saliva, sweat, urine and vomitus.

Breast Milk. Radionuclide excretion via the mammary gland constitutes a potential exposure pathway to the breast-fed infant or child. This can be a very important pathway after the administration of radioiodines. Relatively small administrations of radioiodine to a breast-feeding mother can cause very large doses to the thyroid of the infant. Thus, precautions must be taken against breast-feeding after the administration of radioiodines.

Exhaled Air. Exhalation is the principal pathway for the elimination of radioactive gases such as xenon-133, which is used for lung ventilation tests. Through passive diffusion, unbound iodide in the circulating blood may also be exhaled.

Feces. Radiopharmaceuticals retained or catabolized by the liver may be secreted into the gastrointestinal lumen via the bile. Biliary secretion of a radionuclide may be followed by intestinal reabsorption.

Saliva. Salivary excretion of radionuclides is also proportional to the unbound or diffusible fraction in the plasma. However, salivary excretion is seldom an important elimination route, since nearly all saliva is swallowed rather than expectorated.

Sweat. Radionuclides present in the extracellular fluid will tend to be excreted in the sweat in accordance with the fraction that is unbound in the plasma.

Urine. Radionuclide excretion in the urine is the dominant and almost universal elimination pathway.

Vomitus. Radionuclide excretion by vomiting is seldom an important elimination route, since orally administered radiopharmaceuticals such as iodine-131 are rapidly absorbed, within a half hour, by the gastrointestinal system. However, a significant portion of the administered radionuclide could be excreted if vomiting occurs immediately following the administration. In this case the patient typically would not have been released, and the licensee would be able to limit exposure and cleanup contamination.

4.2.1.5 Measurements of Internal Exposure

The potential for contamination by patients treated with radioiodine which may serve as a source for internal exposures to others have been assessed for various excreta pathways (BL71, MA73, NI80). Maximum excretion rates are observed shortly after an administered dose. Excretion rates decline rapidly thereafter due to renal clearance and thyroidal uptake. Almost all the excreted activity is excreted in the urine. Contamination through urinary excretion may be readily controlled by cautious but reasonable hygiene practices.

In a thorough study of two patients treated for thyroid carcinomas, Nishizawa, et.al. (NI80) observed maximum excretion rates of iodine in exhalation, perspiration, and saliva of 3.2×10^{-6}/hr, 2.4×10^{-6}/hr, and 6.3×10^{-3}/hr of the administered dose, respectively. Thus, the amounts in exhalation and perspiration were very small. The amount in saliva is larger, but transfer of saliva to other people is likely to be limited.

A British study (BU70) estimated thyroid radioiodine activity in 39 subjects who, as family members, were associated with patients treated for hyperthyroidism. Administered quantities ranged from 148 to 740 megabecquerels (4 to 20 millicuries) per patient. Of the 39 patients, 28 were instructed to take precautionary measures to minimize exposure to family members. Eleven patients volunteered to disregard special precautions against contamination and minimizing spousal and family exposure. On the basis of one measurement per family, subject thyroid burdens ranged from less than 37 to 1,110 becquerels (1 to 30 nanocuries) with an average of 259 becquerels (7 nanocuries). Thus, the uptake of radioiodine by family members was only about 1 one-millionth

Table 4.5 Family Doses from Patients Treated with Iodine-131 for Thyroid Carcinoma

Patient	Total Activity Administered (mCi)	Body Burden at Time of Discharge (mCi)	Measured Doses to Family Member (mrem)	Predicted Dose Based on Occupancy Factor of 25% at 1 meter (mrem)
1	210	25.2	80, 70, 30	386
2	311	26.4	50, 20, 20	404
3	209	18.4	80, 40	282

Source: HA74.

of the administered quantity, and the dose from the uptake was less than 0.01 millisievert (1 millirem) committed effective dose equivalent. This internal dose is negligible compared to the external dose. The authors concluded that contamination is not important and "except where young children are involved, precautions to minimize contamination should be abandoned."

In a 1978 study by Jacobson, et.al. (JA78), seven families were studied in which one family member had been treated with iodine-131 doses ranging from 296 to 5,500 megabecquerels (8 to 150 millicuries). Non-patient family members were assessed for external exposures by means of thermoluminescent dosimeters (TLDs) worn at the wrist for the full duration of exposure. Internal exposure (i.e., thyroid burden) was determined at discrete time intervals by means of a pair of 30-inch NaI crystals. Although all family members proximal to the patient had measurable thyroid burdens, dose estimates in nearly all cases indicate that internal committed effective dose equivalents were always less than 10 percent of the 5-millisievert (.5-rem) dose limit, even when no precautions were taken, and the external dose substantially exceeded the internal dose.

The investigators also concluded that it " . . . appears certain from our study of these subjects that for spouses, there is a relation between thyroid activity and intimacy. Of the 12 husbands and wives questioned, . . . none were willing to adjust living habits with their spouses because of the radiation therapy. Most, however, are concerned for their children and are willing to listen to suggestions which minimize exposure to their children." While the authors are vague about what they mean by "adjust living habits," it appears that couples are often unwilling to abstain from brief periods of close intimate contact for prolonged periods of time. This should not be a problem because the brief times will be too short to add significant external dose and transfer of contamination is not a significant contributor to internal dose.

Thus, the studies on internal exposures suggest that internal doses from intake of contamination are likely to be much smaller than doses from external radiation and much smaller than the public dose limit. Therefore, internal exposures will not be considered in this analysis.

..2.1.6 Tissue Shielding for Permanent Implants

In addition to the shielding effects of the source capsule (see 4.2.1.2 Exposure Rate Constant), a significant reduction in the dose and dose rate also occurs from the tissue surrounding the implant. For a prostate implant, tissues that serve to reduce photon flux about the patient include the soft and bone tissues of the thighs, pelvis, buttocks, abdomen, etc. The linear attenuation coefficient and corresponding soft tissue half-value layer for the 27 keV photon of iodine-125 are 0.387 cm^{-1} and 1.8 cm, and for the 21 keV photon of palladium-103, 0.770 cm^{-1} and 0.9 cm, respectively (JOH83).

To assess the impact of tissue shielding by the patient, the medical health physicist of the Memorial Sloan Kettering Cancer Center was consulted (personal communication, J. St.

Germain, March 1993). Based on empirical assessment involving patients with prostate implants, tissue shielding for iodine-125 is likely to exceed 5 or more half-value layers (HVLs), which would reduce the dose and dose rate by a factor of at least 32. For palladium-103 implants, in which the HVL in tissue is less than one centimeter, the shielding afforded by the patient's tissue is even more extensive. For other implants involving the lungs, brain, pancreas, etc., tissue shielding values of similar magnitude can be assumed for an adult male and female. For certain implants involving primary cancers of the neck and head, overlying tissues may provide less than 5 HVLs of attenuation. In such instances, it is standard practice to provide the patient with a small portable "shield" which effectively attenuates all emissions (personal communications, C. Jacobs, August 1993, and R. Nath, J. St. Germain and K. Suphanpharian, March 1993). A shield consists of a vinyl sheet impregnated with lead and molded to fit the anatomical surface over the implant.

For the purposes of this analysis, implants will be evaluated considering shielding by tissue equivalent to 5 half value layers.

4.2.2 Estimate of Maximum Likely Doses to Individuals Exposed to Patients

Assessments were made of the doses that could result from exposure to a patient treated with each of the radionuclides used.

4.2.2.1 Diagnostic Procedures

The results of the calculations for diagnostic procedures are summarized in Table 4.6. Table 4.6 indicates that, except for some procedures using iodine-131 to detect thyroid cancer, none of the other diagnostic procedures currently being performed have the potential to deliver a 1 millisievert (0.1 rem) dose to an individual exposed to a patient. However, in the case of iodine-131, the effective half-life of the extrathroidal component is much shorter than the physical life used to calculate doses. Therefore, the dose would be much lower than the value shown in Table 4.6. Since the doses in all cases are much below 1 millisievert (0.1 rem), diagnostic procedures will not be considered any further in this analysis.

4.2.2.2 Therapeutic Procedures

Table 4.7 provides the maximum likely doses to individuals from current therapeutic procedures based on physical half-life only and assuming immediate release of the patient by the licensee (i.e., no hospitalization). Only the therapies involving radioiodine would be affected by any of the alternatives under consideration.

4.2.3 Assessment of Doses to Breast-Feeding Infants

If a radiopharmaceutical is administered to a woman who is breast feeding, a fraction of the quantity administered will be deposited in the breast milk and will be transferred to the breast-feeding infant. In considering the dose to the individual likely to receive the highest dose from exposure to a patient who has been administered a radiopharmaceutical, it is necessary to consider both the internal and external dose to a breast-feeding infant.

4.2.3.1 Internal Dose

The potential internal dose to the breast-feeding infant was calculated for the maximum normally administered quantities of commonly used diagnostic and therapeutic radiopharmaceuticals assuming no interruption in breast feeding. The results of the calculations are shown in Appendix B.

The doses can be represented as a range where the range covers the minimum and the maximum transfer of radioactive material from published data. The range is due to individual variability and measurement variability as indicated by concentrations measured in breast milk. The doses were calculated for newborn and one-year-old infants. Since the doses for newborn infants are the highest, those doses were used in the analysis. The dose ranges for commonly used radiopharmaceuticals assuming no interruption of breast feeding are shown in Table B-1 (see Appendix B). The radionuclides in the table that are not regulated by the NRC (e.g., Ga-67) are omitted from further consideration in this analysis.

Table 4.6. Maximum Likely Doses to Total Decay to Exposed Individuals from Diagnostic Procedures

Examination Type (Radiopharmaceutical)	Activity per Examination[1] (MBq (mCi))		Gamma Dose[2] (mSv (rem))	
Brain				
- Tc-99m DTPA	740	(20)	0.13	(0.013)
- Tc-99m O_4	740	(20)	0.13	(0.013)
Hepatobiliary				
- Tc-99m IDA	185	(5)	0.03	(0.003)
Liver				
- Tc-99m sulfur colloid	185	(5)	0.03	(0.003)
Bone				
- Tc-99m phosphate	740	(20)	0.13	(0.013)
Lung Perfusion				
- Tc-99m MAA	185	(5)	0.03	(0.003)
Thyroid				
- Tc-99m O_4	185	(5)	0.03	(0.003)
- I-131	3.7	(0.1)	0.02	(0.002)
- I-131 (maximum)	370	(10)	1.5	(0.15)
Cardiovascular				
- Tc-99m RBC	740	(20)	0.13	(0.013)
Tc-99m phosphate	740	(20)	0.13	(0.013)
- Tl-201 chloride	111	(3)	0.04	(0.004)
Renal				
- Tc-99m DTPA	740	(20)	0.13	(0.013)
- I-131 hippuran	9.3	(0.25)	0.04	(0.004)

[1] The activity is the average per administration (see Table 4.2). The maximum diagnostic activity of I-131 is shown because it yields gamma doses exceeding 1 millisievert (0.1 rem).

[2] Calculations assume no biological elimination and no attenuation of gamma rays in air or body of patient.

Table 4.7 Maximum Likely Doses to Total Decay to Exposed Individuals from Therapeutic Procedures Assuming No Hospitalization

Therapeutic Procedure (Radionuclide)	Activity Administered (MBq (mCi))		Maximum Likely Dose[1] (mSv (rem))	
Thyroid Ablation (Hyperthyroidism)				
- iodine-131	370	(10)	1.5	(0.15)
	740	(20)	3.0	(0.30)
	1,110	(30)	4.6	(0.46)
Thyroid Cancer				
- iodine-131	1,850	(50)	7.6	(0.76)
	3,700	(100)	15.3	(1.53)
	7,400	(200)	30.6	(3.06)
Permanent Implant[2]				
- iodine-125	1,110	(30)	0.54	(0.054)
	1,480	(40)	0.72	(0.072)
	1,850	(50)	0.90	(0.090)
- palladium-103	2,775	(75)	0.29	(0.029)
	3,700	(100)	0.39	(0.039)
	4,625	(125)	0.49	(0.049)

[1] Maximum likely dose based on physical half-life only.

[2] These dose values account for the 5 HVLs of tissue shielding by the patient and, therefore, are equal to the point source dose in air divided by 32.

The proposed rule would require that instructions on maintaining the doses to other individuals as low as reasonably achievable be given to the released patient if the dose to another individual is likely to exceed 1 millisievert (0.1 rem). Therefore, the decision to require instructions, as shown in Table B-1, is based on the maximum value in the dose range for the newborn infant exceeding 1 millisievert (0.1 rem). The duration of the interruption shown in Table B-1 is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem). The actual doses that would be received by most infants for the recommended interruption periods shown should be a small fraction of 1 millisievert (0.1 rem).

In reviewing Table B-1, it was concluded that the recommendations on interruption of breast feeding to reduce the dose to the infant to less than 1 millisievert (0.1 rem) are practical and prudent, that the overwhelming majority of women would follow instructions, and that there is no reason for doses to nursing infants exceeding 1 millisievert (0.1 rem). For example, the internal dose to the breast-feeding infant from iodine-131 sodium iodide diagnostic and therapeutic procedures could exceed 5 millisieverts (0.5 rem) with no cessation of breast-feeding. However, in these cases the licensee would instruct the woman to cease breast feeding as a condition for authorizing release. Consequently, it is reasonable to assume that there would be no internal dose to the infant. Therefore, the issue of internal dose to breast-feeding infants does not affect the choice of alternatives and it can be eliminated from further consideration.

4.2.3.2 External Dose

To determine a realistic estimate of the external dose to total decay to the infant during breast feeding, an occupancy factor must be selected that specifically reflects the variables involved. It can be assumed that the average infant feeds for a period lasting 30 minutes every 3 hours, resulting in an occupancy factor of 16 percent. Since breast feeding requires close contact, the analysis uses 20 centimeters as the distance between the infant and the source. For permanent implants, capsule shielding and tissue attenuation by the woman's body are considered. Also, since only

the physical half-life is considered, the analysis is conservative. The results are shown in Table B-2. It can be seen that in some cases, external dose can be significant. Thus, for some radiopharmaceuticals, the recommended interruption period in Table B-1 had to be adjusted to take external dose into consideration.

4.2.4 Collective Dose

To evaluate each alternative, it is also necessary to estimate not only the dose to the maximally exposed individual, but also the collective dose to other individuals who may be exposed to patients administered radioactive materials. To calculate precisely the collective dose that would be received under any of the alternatives would require detailed information of a highly diverse group of patients relative to lifestyles, living arrangements, work environments, social activities, etc. This information does not exist and is essentially impossible to precisely determine. In place of a precise estimate we have made a rough estimate of the collective dose per procedure which we believe is adequate for the purposes of this rulemaking.

Based on considerations of the written instructions provided patients, the demographics of the patient population (see Table 4.3), and time, distance, and shielding factors, we estimate that the collective dose per procedure is 3 times the maximal dose. This 3 times factor could occur in the following manner, based upon intuitive assumptions about a typical family and friends. In addition to the person receiving the maximal dose, who is likely to be the primary care-provider, there could be 2 other people who will average about half as much time near the patient. There might also be about 4 other people who will average about a quarter as much time near the patient as the maximally exposed individual. The sum of the collective dose to all these people is 3 times the dose to the maximally exposed individual. This situation could represent a typical family and friends. Of course some patients will spend more time near other people, but other patients will spend less. A collective dose of 3 times the dose to the maximally exposed individual is thus a reasonable average representation.

Finally, as data are not available on the distribution of the quantities of radionuclides administered for each procedure, the estimates of collective dose for each alternative are based on the mid-point values within the ranges of the activities administered.

Tables 4.8, 4.9, and 4.10 present the estimates of the collective doses for Alternatives 1, 2, and 3, respectively for therapeutic administrations that could be affected by choice of alternative. Implants using palladium-103 are not included because doses to exposed individuals are always less than 1 millisievert (0.1 rem).

In Table 4.8, the collective dose per procedure was determined in the following manner. For all types of procedures in the table, the average activity administered was used. It was assumed that all patients would remain hospitalized until the dose dropped to 1 millisievert (0.1 rem) or less for iodine-125 implants. Thus, the dose to the most exposed individual would be 1 millisievert (0.1 rem). The collective dose per procedure is then assumed to be 3 times the dose to the most exposed individual.

In Table 4.9, the collective dose per procedure was calculated in the following manner. For thyroid ablation, no hospitalization is required because the administered activity is less than 1,110 mega-becquerels (30 millicuries). From Table 4.7, the dose to the most exposed individual from an administration of 740 megabecquerels (20 millicuries) is 3 millisieverts (0.3 rem). The collective dose is 3 times the individual dose or 9 millisieverts (0.9 rem). The collective dose per procedure for iodine-125 implants was calculated in the same manner assuming no hospitalization. For thyroid cancer, hospitalization is assumed until the activity remaining in the patient's body is 1,110 megabecquerels (30 millicuries). The estimated total effective dose equivalent to the maximally exposed individuals from a patient leaving the hospital after 2 days who has been released with 1,110 megabecquerels (30 millicuries) is estimated to be 2 millisieverts (0.2 rem) considering biological excretion. In Table 4.10, the collective dose per procedure for thyroid cancer is estimated by assuming hospitalization for one day until the maximum dose to an individual would be 5 millisieverts (0.5 rem).

Table 4.8 Estimates of Collective Dose from Therapeutic Radioiodine Procedures for Alternative 1: Annual Limit of 1 millisievert (0.1 rem)

Therapeutic Procedure	Average Activity Administered (MBq (mCi))		Collective Dose/Procedure (mSv (rem))		Estimated Procedures per Year	Total Collective Dose (person-Sv (rem))	
Thyroid Ablation							
- iodine-131	740	(20)	3.0	(0.3)	50,000	150	(15,000)
Thyroid Cancer							
- iodine-131	3,700	(100)	3.0	(0.3)	10,000	30	(3,000)
Permanent Implant							
- iodine-125	1,480	(40)	2.2	(0.22)	2,000	4.4	(440)
All Therapeutic Procedures					62,000	184.4	(18,440)

Table 4.9 Estimates of Collective Dose from Therapeutic Radioiodine Procedures for Alternative 2: Limits of 1,110 megabecquerels (30 millicuries) or 0.05 millisievert (5 millirems)/hr

Therapeutic Procedure	Average Activity Administered (MBq (mCi))		Collective Dose/Procedure (mSv (rem))		Estimated Procedures per Year	Total Collective Dose (person-Sv (rem))	
Thyroid Ablation							
- iodine-131	740	(20)	9.0	(0.9)	50,000	450	(45,000)
Thyroid Cancer							
- iodine-131	3,700	(100)	6.0	(0.6)	10,000	60	(6,000)
Permanent Implant							
- iodine-125	1,480	(40)	2.2	(0.22)	2,000	4.4	(440)
All Therapeutic Procedures					62,000	514	(51,400)

Table 4.10 Estimates of Collective Dose from Therapeutic Radioiodine Procedures for Alternative 3: Annual Limit of 5 millisieverts (0.5 rem)

Therapeutic Procedure	Average Activity Administered (MBq (mCi))		Collective Dose/Procedure (mSv (rem))		Estimated Procedures per Year	Total Collective Dose (person-Sv (rem))	
Thyroid Ablation							
- iodine-131	740	(20)	9.0	(0.9)	50,000	450	(45,000)
Thyroid Cancer							
- iodine-131	3,700	(100)	15	(1.5)	10,000	150	(15,000)
Permanent Implant							
- iodine-125	1,480	(40)	2.2	(0.22)	2,000	4.4	(440)
All Therapeutic Procedures					62,000	604	(60,440)

The collective dose is therefore 15 millisieverts (1.5 rems), using the previously described assumption that the collective dose will be 3 times the dose to the maximally exposed individual.

4.3 Value Impact Analysis

4.3.1 Estimates of the Potential Costs

The analysis in Section 4.2 indicates that the 1 millisievert (0.1 rem) per year dose limit imposed by Alternative 1 would result in the smallest collective dose to individuals exposed to released patients. The benefit of smaller doses estimated for Alternative 1 will only be achieved if the patients to whom the radioactive materials have been administered are retained under the control of licensees for longer periods of time. The impact of retaining patients must be assessed in terms of the patient, family, and society as a whole. At a minimum, the economic cost must consider the direct cost of medical resources required to retain the patient in a hospital and the indirect cost resulting from the loss of human resources. Additional consideration should be given to the psychological impact of retention on the affected individual and family members. Hospitalization will also cause an increase in the dose to the hospital staff and other patients in the hospital. However, the increase in dose to the hospital staff is expected to be low relative to a patient going home earlier because of the precautions taken during hospitalization; e.g., patients are isolated and the hospital staff rarely enters the patient's room.

In the analysis that follows, these costs are calculated assuming that all retained patients will be hospitalized. While retention costs might be less for non-hospital locations, no attempt is made in this analysis to quantify the potential costs.

4.3.1.1 Estimates of the Direct Costs of Patient Retention

Durations of Patient Retention

Estimates of the periods of time that patients would need to be retained under licensee control for each of the alternatives are presented in Table 4.11. These estimates employ the midpoint activities used for a given medical procedure and are based on realistic estimates of the retention in the body using the effective half-life rather than the physical half-life.

Cost of Patient Retention

To estimate the annual dollar costs for these periods of retention, one needs only multiply the number days required for each procedure by the number of procedures per year and the average cost per day of hospitalization. In 1990, the average cost per day in a community hospital was $687 (SA92). The per diem cost at the beginning of 1995 is estimated to be $800.

However, as the current regulations require that patients who are hospitalized from a therapeutic administration of radiopharmaceuticals to be placed in a private room, the $800 per day estimate is adjusted to $1,000 per day. Using this figure, the potential costs of retaining patients under Alternative 1 are estimated to be $402 million. Under Alternative 2, the estimated cost is $60 million. And, under Alternative 3, the estimated cost is $30 million.

Costs of Providing Recordkeeping

The currently envisioned proposed rule associated with Alternative 3 imposes additional paperwork and recordkeeping requirements on the estimated 1,350 licensees (NRC- and Agreement State-licensed) that provide therapeutic administrations of radiopharmaceuticals or permanent radioactive implants. For therapeutic administrations where releases are not based on the default table in Regualtory Guide 8.39, a record must be maintained for three years.

It is estimated that approximately 17,200 procedures per year would be subject to these requirements (i.e., (1) 10,000 iodine treatment for thyroid cancer patients and (2) 6,800 technetium-99m pertechnetate plus 400 iodine administrations to breast-feeding mothers). This results in an annual estimated cost of approximately $0.3 million.

Costs of Providing Instructions

The rule associated with Alternative 3 imposes additional costs for providing instructions, including written instructions, on the estimated 1,350 licensees. In the case in which the administered activity could cause a dose from direct radiation exceeding 0.1 rem (1 millisievert), instructions, instructions would have to be given to 62,000 patients per year at a cost of $1.4 million per year. In addition, instructions would have to be given to approximately 27,000 breast-feeding mothers at a cost of $0.6 million per year. The total cost of instructions is $2 million per year.

4.3.1.2 Derivation of Indirect Costs

Loss of Time

Indirect costs principally reflect the time and output lost or forfeited by the patient while retained in a controlled environment. Indirect costs may also be incurred by individuals other than the patient who may forego economic activities to accommodate a family member's hospital retention. Economic activities include occupational work that is lost to either the patient or his or her employer as well as non-occupational (e.g., domestic) work which must be performed by someone else at the expense of the patient.

The conversion of time lost from economic activities to equivalent dollars is most fairly achieved by means of the gross national product (GNP). The GNP is considered the most comprehensive measure of the country's economic activity and includes the market value of all goods and services that have been bought for final use during a year. From the GNP of about $5,600 billion in 1991, the gross average annual per capita income of about $22,000 is derived. The value of $22,000 per year corresponds to $60 per day and can be used to determine the equivalent dollar value for the number of days lost due to retention of an individual. The value of the days lost is shown in Table 4.12.

4.3.1.3 Evaluation of Psychological Costs

Retention of patients in a hospital by design necessitates that the patient be "isolated" and that human contact, inclusive of family members, is either avoided or minimized. Such isolation may bring about numerous changes and impositions in the lives of the patient and family members that may in part be linked to, but are not reflected in, the direct and indirect economic costs identified above. The wide variety of deterioration in the quality of life brought on by illness are frequently referred to as psychological costs. For thyroid cancer or dysfunction requiring therapeutic doses of iodine-131 for example, a deterioration in the quality of life may be precipitated by the loss of bodily function, a lifetime dependence on medication, hormonal instability, uncertainty of normal life-expectancy, disruption of normal daily routines, and reduced financial security related to employment, lost earnings, and medical expenses.

While some of these elements of psychological costs are the result of the disease itself, others such as disruption of normal routines, social isolation, and enhanced financial strain are clearly elements of psychological costs that are directly related to patient retention. In characterizing

Table 4.11 Duration of Retention per Therapeutic Procedure (to the nearest day)

Therapeutic Procedure	Midpoint Activity Administered (MBq (mCi))	Alternative 1 (days) per procedure	Alternative 1 (days) Σ procedures (x 1000)	Alternative 2 (days) per procedure	Alternative 2 (days) Σ procedures (x 1000)	Alternative 3 (days) per procedure	Alternative 3 (days) Σ procedures (x 1000)
Thyroid Ablation I-131, 50,000 procedures/year							
	740 (20)	2	100	0	0	0	0
Thyroid Cancer I-131, 10,000 procedures/year							
	3,700 (100)	4	40	2	20	1	10
Permanent Implant, I-125, 2,000 procedures/year							
	1,480 (40)	0	0	0	0	0	0
Total for All Therapeutic Procedures			140		20		10

2. Alternative 1 is considerably more expensive to the public compared to Alternative 2 (the status quo) or Alternative 3. Even neglecting the psychological costs, which have not been expressed in dollar terms, the additional cost of Alternative 1 relative to Alternative 2 is about $126,000,000 per year, mostly in increased national health care costs. The value of the dose savings at a value of $1,000 per person rem is $33,000,000 per year. In view of this, Alternative 1 may be dismissed.

3. Alternative 3 relative to Alternative 2 has a value of $9,400,000 per year, mostly in lower health care costs at a collective dose cost of $9,000,000 per year. Alternative 3 also has psychological benefits to patients and their families. Thus, Alternative 3 appears cost effective in comparison with Alternative 2.

4. Basing the patient release criteria in 10 CFR 35.75 on the dose to individuals exposed to a patient provides a consistent, scientific basis for such decisions that treats all radionuclides on a risk-equivalent basis. The dose delivered by an initial activity of 30 millicuries or a dose rate at 1 meter of 5 millirems per hour varies greatly from one radionuclide to another. Thus, while the values in the current 10 CFR 35.75 may be appropriate for iodine-131, they are too high for some other radionuclides and too low for others.

5. A dose-based rule no longer restricts patient release to a specific activity, and therefore would permit the release of patients with activities that are greater than currently allowed. This is especially true when case-specific factors are evaluated to more accurately assess the dose to other individuals. For the case of thyroid cancer, in those cases occasional where multiple administrations in a year of 1,110 millisieverts (30 millicuries) or less of iodine-131 are now administered to a patient, it may be possible to give all of the activity in a single administration. This would reduce the potential for repeated exposures to hospital staff and to those providing care to the released patient. Additionally, this would provide physicians with the flexibility to not have to fractionate doses to avoid hospitalization to meet the current requirements, which may lead to a more effective treatment.

6. Shorter hospital stays 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.

6 IMPLEMENTATION

No impediments to implementation of the recommended alternative have been identified. The staff is preparing a Regulatory Guide for licensees which will provide, in part, simple methods to evaluate the dose to the individual member of the public likely to receive the highest dose from the released patient. This will enable licensees to determine when a patient may be released from their control.

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APPENDIX A. PARAMETERS AND CALCULATIONS FOR DETERMINING RELEASE QUANTITIES AND DOSE RATES FOR RADIONUCLIDES USED IN MEDICINE.

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radio-nuclide	Half-Life (days)[1]	Exposure Rate Constant[2] ($R \cdot cm^2/mCi \cdot h$)	Radio-nuclide	Half-Life (days)[1]	Exposure Rate Constant[2] ($R \cdot cm^2/mCi \cdot h$)
Ag-111	7.45	0.150	Pd-103 implant	16.97	0.86[4]
Au-198	2.696	2.36	Re-186	3.777	0.168
Cr-51	27.704	0.177	Re-188	0.7075	0.337
Cu-64	0.5292	1.10	Sc-47	3.351	0.626
Ga-67	3.261	0.753	Se-75	119.8	2.60
I-123	0.55	1.61	Sm-153	1.9458	0.425
I-125	60.14	1.42	Sn-117m	13.61	1.48
I-125 implant	60.14	1.11[3]	Sr-89	50.5	NA[5]
I-131	8.040	2.20	Tc-99m	0.2508	0.756
In-111	2.83	3.15	Tl-201	3.044	0.447
Ir-192	74.02	4.69	Y-90	0.1329	NA[5]
P-32	14.29	NA[5]	Yb-169	32.01	1.83

[1] Keith F. Eckerman, Anthony B. Wolbarst, and Allan C. B. Richardson, Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion, Report # EPA-520/1-88-020, Office of Radiation Programs, U. S. Environmental Protection Agency, Washington, DC, 1988.

[2] The exposure rate factor includes gamma rays and x rays with an energy above 11.3 keV. The 11.3 keV cutoff is the one used in NCRP Report No. 41, "Specification of Gamma-Ray Brachytherapy Sources," 1974. The exposure rate constant was calculated from the following equation (as shown in Table A-2):

$$\Gamma \left(\frac{mR \cdot cm^2}{mCi \cdot hr}\right) = (1.332 \times 10^{14} \frac{dis}{mCi \cdot hr})\left(\frac{1}{4\pi (100\ cm)^2}\right) \sum f_i E_i \left(\frac{\mu_{a,i}\ cm^{-1}}{\rho\ gm \cdot cm^{-3}}\right) \times$$

$$\left(\frac{gm \cdot mR}{87.6\ erg}\right)(1.6 \times 10^{-6}\ \frac{erg}{MeV})$$

Where E_i = the energy of the gamma ray or x ray i in Mev.

f_i = the probability of decay of gamma rays or x rays with energy E_i per disintegration. Values for E_i and f_i were taken from: Bernard Shleien, The Health Physics and Radiological Health Handbook, Revised Edition, Scinta, Inc., 1992, pages 294-334. For Re-186, Re-188, and Sn-117m the values for E_i and f_i were taken from: Laurie M. Unger and D. K. Trubey, Specific Gamma-Ray Dose Constants for Nuclides Important to Dosimetry and Radiological Assessment, ORNL/RSIC-45/R1, 1982.

$\mu_{a,i}$ = the linear energy absorption coefficient in air of photons of energy E_i, taken from Radiological Health Handbook, U. S. Department of Health, Education, and Welfare, 1970, page 135.

ρ = the density of air at standard temperature and pressure, taken to be 0.0012929 gm/cm^3.

The details of the calculation of the exposure rate factors are shown in Table A-2.

[3] R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and taking into account the attenuation of gamma rays within the implant capsule itself.

[4] Ravinder Nath, Yale University School of Medicine, letter to Dr. U. Hans Behling dated March 31, 1993. The exposure rate constant given is a measured value that takes into account the attenuation of gamma rays within the implant capsule itself.

[5] Not applicable (NA) because the release quantity is based beta emissions.

Table A-2. Calculations of Exposure Rate Factors, Release Quantities, and Release Dose Rates

Gamma Dose Factor Calculations										
half-life in days		linear absorption coeff					Q_o based on .5 rem			
Isotope $T_{1/2}$	fraction/dis	E(Mev)	U_{en}(1/m)	Mev/cm/dis	R/hr-Ci @ 1 m	R/hr-mCi @ 1 cm	Q_o(mCi)	Q_o(MBq)	Q_o(GBq)	mrem/hr @ 1 m for Q_o
Ag-111	0.000245	0.022984	4.30E-02	2.42E-09	3.63E-05	3.63E-04				
	0.000462	0.023174	4.00E-02	4.28E-09	6.42E-05	6.42E-04				
	0.000151	0.0261	2.80E-02	1.10E-09	1.65E-05	1.65E-04				
	0.001202	0.09675	3.00E-03	3.49E-09	5.23E-05	5.23E-04				
	0.012291	0.24539	3.60E-03	1.09E-07	1.63E-03	1.63E-02				
	0.0668	0.34213	3.80E-03	8.68E-07	1.30E-02	1.30E-01				
	0.000559	0.65472	3.80E-03	1.39E-08	2.09E-04	2.09E-03				
7.45				TOTAL	1.50E-02	1.50E-01	5.16E+02	1.91E+04	1.91E+01	7.76E+00
Au-198	0.008053	0.068895	3.50E-03	1.94E-08	2.91E-04	2.91E-03				
	0.013695	0.0708	3.45E-03	3.35E-08	5.02E-04	5.02E-03				
	0.006024	0.080	E-03	1.57E-08	2.36E-04	2.36E-03				
	0.9551	0.411	E-03	1.53E-05	2.30E-01	2.30E+00				
	0.010602	0.675	E-03	2.72E-07	4.08E-03	4.08E-02				
	0.002292	1.0877	E-03	8.85E-08	1.33E-03	1.33E-02				
2.696				TOTAL	2.36E-01	2.36E+00	9.07E+01	3.36E+03	3.36E+00	2.14E+01
Cr-51	0.0983	0.32008	3.75E-03	1.18E-06	1.77E-02	1.77E-01				
27.704				TOTAL	1.77E-02	1.77E-01	1.18E+02	4.36E+03	4.36E+00	2.09E+00
Cu-64	0.004898	1.3459	3.35E-03	2.21E-07	3.31E-03	3.31E-02		Occupancy Factor = 1		
	0.3574	0.511	3.90E-03	7.12E-06	1.07E-01	1.07E+00				
0.52920833				TOTAL	1.10E-01	1.10E+00	2.48E+02	9.18E+03	9.18E+00	2.73E+01
Ga-67	0.02856	0.091266	3.00E-03	7.82E-08	1.17E-03	1.17E-02				
	0.357	0.093311	2.95E-03	9.83E-07	1.47E-02	1.47E-01				
	0.19706	0.18458	3.40E-03	1.24E-06	1.85E-02	1.85E-01				
	0.02242	0.20895	3.50E-03	1.64E-07	2.46E-03	2.46E-02				
	0.15994	0.30022	3.75E-03	1.80E-06	2.70E-02	2.70E-01				
	0.044768	0.39353	3.90E-03	6.87E-07	1.03E-02	1.03E-01				
	0.001385	0.88769	3.65E-03	4.49E-08	6.73E-04	6.73E-03				
	0.001247	0.62941	3.85E-03	3.02E-08	4.53E-04	4.53E-03				
3.26083333				TOTAL	7.53E-02	7.53E-01	2.35E+02	8.71E+03	8.71E+00	1.77E+01
I-123	0.24631	0.027202	2.60E-02	1.74E-06	2.61E-02	2.61E-01				
	0.45954	0.027472	2.50E-02	3.16E-06	4.73E-02	4.73E-01				
	0.15952	0.031	1.73E-02	8.56E-07	1.28E-02	1.28E-01				
	0.834	0.159	3.30E-03	4.38E-06	6.56E-02	6.56E-01				
	0.001259	0.34635	3.80E-03	1.66E-08	2.48E-04	2.48E-03				
	0.004287	0.44002	3.90E-03	7.36E-08	1.10E-03	1.10E-02				
	0.003161	0.50533	3.85E-03	6.15E-08	9.22E-04	9.22E-03				
	0.013928	0.52896	3.85E-03	2.84E-07	4.25E-03	4.25E-02				
	0.00382	0.53854	3.85E-03	7.92E-08	1.19E-03	1.19E-02		Occupancy Factor = 1		
	0.004763	0.49444	3.90E-03	9.18E-08	1.38E-03	1.38E-02				
0.55				TOTAL	1.61E-01	1.61E+00	1.63E+02	6.04E+03	6.04E+00	2.63E+01

Table A-2 Calculations of Exposure Rate Factors, Release Quantities, and Release Dose Rates

Gamma Dose Factor Calculations										
half-life in days		linear absorption coeff					Q_o based on .5 rem			
Isotope $T_{1/2}$	fraction/dis	E(Mev)	U_{en}(1/m)	Mev/cm/dis	R/hr-Ci @ 1 m	R/hr-mCi @ 1 cm	Q_o(mCi)	Q_o(MBq)	Q_o(GBq)	mrem/hr @ 1 m for Q_o
I-125	0.39233	0.027202	2.60E-02	2.77E-06	4.16E-02	4.16E-01				
	0.73196	0.027472	2.50E-02	5.03E-06	7.54E-02	7.54E-01				
	0.25409	0.031	1.73E-02	1.36E-06	2.04E-02	2.04E-01				
	0.0649	0.035492	1.20E-02	2.76E-07	4.14E-03	4.14E-02				
60.14				TOTAL	1.42E-01	1.42E+00	6.79E+00	2.51E+02	2.51E-01	9.61E-01
I-131	0.013468	0.029458	1.95E-02	7.74E-08	1.16E-03	1.16E-02				
	0.024987	0.029779	1.90E-02	1.41E-07	2.12E-03	2.12E-02				
	0.008883	0.0336	1.30E-02	3.88E-08	5.82E-04	5.82E-03				
	0.026182	0.080183	3.25E-03	6.82E-08	1.02E-03	1.02E-02				
	0.002648	0.17721	3.35E-03	1.57E-08	2.36E-04	2.36E-03				
	0.060521	0.2843	3.68E-03	6.33E-07	9.49E-03	9.49E-02				
	0.002507	0.32578	3.75E-03	3.06E-08	4.59E-04	4.59E-03				
	0.81164	0.36448	3.80E-03	1.12E-05	1.69E-01	1.69E+00				
	0.003605	0.50299	3.85E-03	6.98E-08	1.05E-03	1.05E-02				
	0.072605	0.63697	3.80E-03	1.76E-06	2.64E-02	2.64E-01				
	0.002195	0.6427	3.80E-03	5.36E-08	8.04E-04	8.04E-03				
	0.018025	0.72289	3.75E-03	4.89E-07	7.33E-03	7.33E-02				
	0.002304	0.32939	3.75E-03	2.85E-08	4.27E-04	4.27E-03				
8.04				TOTAL	2.20E-01	2.20E+00	3.27E+01	1.21E+03	1.21E+00	7.19E+00
In-111	0.23628	0.022984	4.30E-02	2.34E-06	3.50E-02	3.50E-01				
	0.44581	0.023174	4.00E-02	4.13E-06	6.20E-02	6.20E-01				
	0.14597	0.0261	2.80E-02	1.07E-06	1.60E-02	1.60E-01				
	0.9024	0.17128	3.35E-03	5.18E-06	7.76E-02	7.76E-01				
	0.94	0.24539	3.60E-03	8.30E-06	1.25E-01	1.25E+00				
	0.000028	0.15081	3.25E-03	1.37E-10	2.06E-06	2.06E-05				
2.83				TOTAL	3.15E-01	3.15E+00	6.48E+01	2.40E+03	2.40E+00	2.04E+01
Ir-192	0.011323	0.061487	3.90E-03	2.72E-08	4.07E-04	4.07E-03				
	0.019555	0.063001	3.85E-03	4.74E-08	7.11E-04	7.11E-03				
	0.008399	0.0714	3.45E-03	2.07E-08	3.10E-04	3.10E-03				
	0.004674	0.20131	3.45E-03	3.25E-08	4.87E-04	4.87E-03				
	0.032873	0.2058	3.50E-03	2.37E-07	3.55E-03	3.55E-02				
	0.002615	0.28326	3.70E-03	2.74E-08	4.11E-04	4.11E-03				
	0.007264	0.37448	3.80E-03	1.03E-07	1.55E-03	1.55E-02				
	0.031628	0.48458	3.90E-03	5.98E-07	8.96E-03	8.96E-02				
	0.003989	0.48906	3.90E-03	7.61E-08	1.14E-03	1.14E-02				
	0.000797	0.42307	3.90E-03	1.32E-08	1.97E-04	1.97E-03				
	0.02635	0.065122	3.70E-03	6.35E-08	9.52E-04	9.52E-03				
	0.045197	0.066832	3.60E-03	1.09E-07	1.63E-03	1.63E-02				
	0.019675	0.0757	3.35E-03	4.99E-08	7.48E-04	7.48E-03				
	0.001806	0.13635	3.20E-03	7.88E-09	1.18E-04	1.18E-03				
	0.29015	0.29596	3.75E-03	3.22E-06	4.83E-02	4.83E-01				
	0.29678	0.30846	3.80E-03	3.48E-06	5.22E-02	5.22E-01				
	0.82853	0.31651	3.80E-03	9.97E-06	1.49E-01	1.49E+00				
	0.006645	0.41646	3.90E-03	1.08E-07	1.62E-03	1.62E-02				
	0.48055	0.46807	3.90E-03	8.77E-06	1.32E-01	1.32E+00				

Table A-2. Calculations of Exposure Rate Factors, Release Quantities, and Release Dose Rates

Gamma Dose Factor Calculations										
half-life in days		linear absorption coeff					Q_o based on .5 rem			
Isotope $T_{1/2}$	fraction/dis	E(Mev)	U_{en}(1/m)	Mev/cm/dis	R/hr-Ci @ 1 m	R/hr-mCi @ 1 cm	Q_o(mCi)	Q_o(MBq)	Q_o(GBq)	mrem/hr @ 1 m for Q_o
	0.045735	0.58858	3.85E-03	1.04E-06	1.55E-02	1.55E-01				
	0.082024	0.60441	3.85E-03	1.91E-06	2.86E-02	2.86E-01				
	0.053357	0.61246	3.85E-03	1.26E-06	1.89E-02	1.89E-01				
	0.003016	0.88451	3.65E-03	9.74E-08	1.46E-03	1.46E-02				
	0.000986	0.87173	3.60E-03	3.09E-08	4.64E-04	4.64E-03				
74.02				TOTAL	4.69E-01	4.69E+00	1.00E+00	6.16E+01	6.16E-02	7.81E-01
Re-186	0.016	0.058	4.20E-03	3.90E-08	5.84E-04	5.84E-03				
	0.0278	0.0593	4.00E-03	6.59E-08	9.89E-04	9.89E-03				
	0.0118	0.0672	3.60E-03	2.85E-08	4.28E-04	4.28E-03				
	0.007	0.1223	3.10E-03	2.65E-08	3.98E-04	3.98E-03				
	0.0116	0.0615	3.90E-03	2.78E-08	4.17E-04	4.17E-03				
	0.2	0.063	3.85E-03	4.85E-07	7.27E-03	7.27E-02				
	0.0086	0.0714	3.45E-03	2.12E-08	3.18E-04	3.18E-03				
	0.0952	0.1372	3.15E-03	4.11E-07	6.17E-03	6.17E-02				
	0.0006	0.7022	3.80E-03	1.60E-08	2.40E-04	2.40E-03				
3.77666667				TOTAL	1.68E-02	1.68E-01	9.10E+02	3.37E+04	3.37E+01	1.53E+01
Re-188	0.0136	0.0615	3.90E-03	3.26E-08	4.89E-04	4.89E-03				
	0.235	0.063	3.85E-03	5.70E-07	8.55E-03	8.55E-02				
	0.0101	0.0714	3.45E-03	2.49E-08	3.73E-04	3.73E-03				
	0.1497	0.155	3.25E-03	7.54E-07	1.13E-02	1.13E-01				
	0.0105	0.478	3.90E-03	1.96E-07	2.93E-03	2.93E-02				
	0.0015	0.6331	3.80E-03	3.61E-08	5.41E-04	5.41E-03				
	0.0011	0.6725	3.80E-03	2.81E-08	4.21E-04	4.21E-03				
	0.0041	0.8295	3.70E-03	1.26E-07	1.89E-03	1.89E-02				
	0.0056	0.9313	3.70E-03	1.93E-07	2.89E-03	2.89E-02		Occupancy Factor = 1		
	0.0072	1.134	3.55E-03	2.90E-07	4.35E-03	4.35E-02				
0.7075				TOTAL	3.37E-02	3.37E-01	6.05E+02	2.24E+04	2.24E+01	2.04E+01
Sc-47	0.68	0.15939	3.85E-03	4.17E-06	6.26E-02	6.26E-01				
3.351				TOTAL	6.26E-02	6.26E-01	2.76E+02	1.02E+04	1.02E+01	1.72E+01
Se-75	0.07269	0.0117	4.25E-01	3.61E-06	5.42E-02	5.42E-01				
	0.010226	0.06605	3.65E-03	2.47E-08	3.70E-04	3.70E-03				
	0.034086	0.096733	3.00E-03	9.89E-08	1.48E-03	1.48E-02				
	0.16744	0.12112	3.10E-03	6.29E-07	9.43E-03	9.43E-02				
	0.59202	0.136	3.20E-03	2.58E-06	3.86E-02	3.86E-01				
	0.014472	0.1986	3.50E-03	1.01E-07	1.51E-03	1.51E-02				
	0.598	0.26465	3.65E-03	5.78E-06	8.66E-02	8.66E-01				
	0.25236	0.27953	3.70E-03	2.61E-06	3.91E-02	3.91E-01				
	0.013216	0.30391	3.75E-03	1.51E-07	2.26E-03	2.26E-02				
	0.11422	0.40065	3.90E-03	1.78E-06	2.68E-02	2.68E-01				
119.8				TOTAL	2.60E-01	2.60E+00	1.85E+00	6.86E+01	6.86E-02	4.82E-01

Table A-2 Calculations of Exposure Rate Factors, Release Quantities, and Release Dose Rates

Gamma Dose Factor Calculations										
half-life in days		linear absorption coeff					Q_o based on .5 rem			
Isotope $T_{1/2}$	fraction/dis	E(Mev)	U_{en}(1/m)	Mev/cm/dis	R/hr-Ci @ 1 m	R/hr-mCi @ 1 cm	Q_o(mCi)	Q_o(MBq)	Q_o(GBq)	mrem/hr @ 1 m for Q_o
Sm-153	0.17263	0.040902	7.70E-03	5.44E-07	8.15E-03	8.15E-02				
	0.31218	0.041542	7.30E-03	9.47E-07	1.42E-02	1.42E-01				
	0.12217	0.047	4.60E-03	2.64E-07	3.96E-03	3.96E-02				
	0.0517	0.069672	3.45E-03	1.24E-07	1.86E-03	1.86E-02				
	0.00194	0.075422	3.35E-03	4.90E-09	7.35E-05	7.35E-04				
	0.002	0.083366	3.20E-03	5.34E-09	8.00E-05	8.00E-04				
	0.00158	0.089484	3.00E-03	4.24E-09	6.36E-05	6.36E-04				
	0.00718	0.09743	3.00E-03	2.10E-08	3.15E-04	3.15E-03				
	0.283	0.10318	3.00E-03	8.76E-07	1.31E-02	1.31E-01				
	0.002775	0.42266	3.85E-03	4.52E-08	6.77E-04	6.77E-03				
1.94583333				TOTAL	4.25E-02	4.25E-01	6.99E+02	2.59E+04	2.59E+01	2.97E+01
Sn-117m	0.1873	0.025	3.35E-02	1.57E-06	2.35E-02	2.35E-01				
	0.3514	0.0253	3.30E-02	2.93E-06	4.40E-02	4.40E-01				
	0.1185	0.0285	2.25E-02	7.60E-07	1.14E-02	1.14E-01				
	0.0211	0.156	3.25E-03	1.07E-07	1.60E-03	1.60E-02				
	0.864	0.1586	3.30E-03	4.52E-06	6.78E-02	6.78E-01				
13.61				TOTAL	1.48E-01	1.48E+00	2.86E+01	1.06E+03	1.06E+00	4.25E+00
Sr-89	0.00015	0.9091	3.65E-03	4.98E-09	7.46E-05	7.46E-04				
50.5				TOTAL	7.46E-05	7.46E-04	1.53E+04	5.67E+05	5.67E+02	1.14E+00
Tc-99m	0.021021	0.018251	7.90E-02	3.03E-07	4.54E-03	4.54E-02				
	0.040194	0.018367	7.90E-02	5.83E-07	8.74E-03	8.74E-02				
	0.012059	0.0206	5.90E-02	1.47E-07	2.20E-03	2.20E-02				
	0.8907	0.14051	3.20E-03	4.00E-06	6.00E-02	6.00E-01		Occupancy Factor = 1		
	0.000214	0.14263	3.20E-03	9.77E-10	1.46E-05	1.46E-04				
0.25083333				TOTAL	7.56E-02	7.56E-01	7.63E+02	2.82E+04	2.82E+01	5.76E+01
Tl-201	0.0022	0.0206	1.80E-02	1.21E-08	1.82E-04	1.82E-03				
	0.27357	0.068895	3.45E-03	6.50E-07	9.75E-03	9.75E-02				
	0.46525	0.070819	3.40E-03	1.12E-06	1.68E-02	1.68E-01				
	0.20465	0.0803	3.20E-03	5.26E-07	7.88E-03	7.88E-02				
	0.0265	0.13534	3.20E-03	1.15E-07	1.72E-03	1.72E-02				
	0.0016	0.16588	3.30E-03	8.76E-09	1.31E-04	1.31E-03				
	0.1	0.16743	3.30E-03	5.53E-07	8.28E-03	8.28E-02				
3.044				TOTAL	4.47E-02	4.47E-01	4.24E+02	1.57E+04	1.57E+01	1.90E+01

Table A-2. Calculations of Exposure Rate Factors, Release Quantities, and Release Dose Rates.

Gamma Dose Factor Calculations										
half-life in days		linear absorption coeff					Q_o based on .5 rem			
Isotope $T_{1/2}$	fraction/dis	E(Mev)	U_{en}(1/m)	Mev/cm/dis	R/hr-Ci @ 1 m	R/hr-mCi @ 1 cm	Q_o(mCi)	Q_o(MBq)	Q_o(GBq)	mrem/hr @ 1 m for Q_o
Yb-169	0.002134	0.02075	6.00E-02	2.66E-08	3.98E-04	3.98E-03				
	0.52777	0.049773	5.25E-03	1.38E-06	2.07E-02	2.07E-01				
	0.93411	0.050742	5.05E-03	2.39E-06	3.59E-02	3.59E-01				
	0.38301	0.0575	4.25E-03	9.36E-07	1.40E-02	1.40E-01				
	0.43747	0.063119	3.75E-03	1.04E-06	1.55E-02	1.55E-01				
	0.026578	0.093613	3.05E-03	7.59E-08	1.14E-03	1.14E-02				
	0.17363	0.10978	3.05E-03	5.81E-07	8.72E-03	8.72E-02				
	0.018818	0.11819	3.10E-03	6.89E-08	1.03E-03	1.03E-02				
	0.11058	0.13052	3.20E-03	4.62E-07	6.92E-03	6.92E-02				
	0.21437	0.17721	3.40E-03	1.29E-06	1.94E-02	1.94E-01				
	0.3492	0.19795	3.60E-03	2.49E-06	3.73E-02	3.73E-01				
	0.001222	0.2403	3.60E-03	1.06E-08	1.59E-04	1.59E-03				
	0.017654	0.26107	3.65E-03	1.68E-07	2.52E-03	2.52E-02				
	0.10806	0.307..	3.75E-03	1.25E-06	1.87E-02	1.87E-01				
	0.001843	0.34406	3.80E-03	2.41E-08	3.61E-04	3.61E-03				
32.01				TOTAL	1.83E-01	1.83E+00	9.88E+00	3.66E+02	3.66E-01	1.81E+00

APPENDIX B. PARAMETERS AND CALCULATIONS FOR DETERMINING INSTRUCTIONS TO BREAST FEEDING WOMEN.

Table B-1. Potential Doses to Breast Feeding Infants from Radiopharmaceuticals Administered to the Mother if No Interruption of Breast Feeding.

Radio-pharmaceutical	Maximum Administered Activity[1] mCi (MBq)	Dose to infant if no interruption of breast feeding[2] mrem	Instructions Required?[3]	Recommendation on interruption of breast feeding[4]
I-131 NaI	150 (5550)	60,000-40,000,000	yes	Complete cessation is necessary to avoid thyroid ablation in the infant
I-123 NaI	0.4 (14.8)	60	no	None
I-123 OIH	2 (74)	4-30	yes	Interruption for about 6 hours[5]
I-123 mIBG	10 (370)	300	yes	Interruption for about 24 hours
I-125 OIH	0.01 (0.37)	0.2	no	None
I-131 OIH	0.3 (11.1)	3-20	no	None
Tc-99m DTPA	20 (740)	0.3-6	no	None
Tc-99m MAA	4 (148)	4-300	yes	Interruption for about 6 hours

[1] Maximum activity normally administered.

[2] Doses are calculated in Table B-4 for the maximum administered activities shown in Column 2. If a smaller activity were administered, the doses would be proportionally smaller. The doses are calculated for newborn infants; doses to one-year-old infants would be less than half the doses shown. If a dose range is shown, the range is due to individual variability and measurement variability as indicated by different measurements of concentrations in breast milk as shown in Table B-3. The doses include internal doses only; external doses due to close contact during nursing were found to be small relative to the maximum of the internal dose range as shown in Table B-2.

[3] The decision on whether instructions are required by § 35.75(b) is based on the maximum value of the dose range for the newborn infant exceeding 0.1 rem.

[4] The duration of interruption is selected to reduce the maximum dose to a newborn infant to less than 0.1 rem. The actual doses that would be received by most infants would be far below 0.1 rem. The physician may use discretion in the recommendation, increasing or decreasing the duration of interruption somewhat depending on the mother's concerns about radioactivity or interruption of breast feeding.

[5] Dose from external radiation during breast feeding, as shown in Table B-2, was considered in developing the recommendation.

Tc-99m pertechnetate	30 (1110)	200-800	yes	Interruption for about 24 hours
Tc-99m DISIDA	8 (300)	4-20	no	None
Tc-99m glucoheptonate	20 (740)	2-5	no	None
Tc-99m HAM	8 (300)	20-50	no	None
Tc-99m MIBI	30 (1110)	1-10	no	None
Tc-99m MDP	20 (740)	4-5	no	None
Tc-99m PYP	20 (740)	5-20	no	None
Tc-99m RBC's in vivo labeling	20 (740)	0.3-100	yes	Interruption for about 6 hours
Tc-99m RBC's in vitro labeling	20 (740)	1-2	no	None
Tc-99m sulfur colloid	12 (444)	9-100	yes	Interruption for about 6 hours
Tc-99m DTPA aerosol	1 (37)	0.02-0.5	no	None
Tc-99m MAG3	10 (370)	0.2-2	no	None
Tc-99m WBC's	5 (185)		yes	Interruption for about 24? hours
Ga-67 citrate	5 (185)	300-10,000	yes	Complete cessation
Cr-51 EDTA	0.05 (1.85)	<0.01	no	None
In-111 WBC's	0.5 (18.5)	20-100	yes	Interruption for about 12 hours[5]
Tl-201	3 (111)			

Table B-2. Maximum Likely External Doses to an Infant During Breast Feeding with Administered Activity and Interruption as Specified in Table B-1

Radio-pharmaceutical	Administerd Activity[1] (mCi (MBq))	Interruption of Breast Feeding	Dose to Infant with Interruption of Breast Feeding[2] (rem (mSv))
I-123 OIH	2 (74)	6 hours	0.123 (1.23)
I-125 OIH	0.01 (0.37)	None	0.012 (0.12)
I-131 OIH	0.3 (11.1)	6 hours	0.073 (0.73)
Tc-99m pertechnetate	30 (1,110)	6 hours	0.01 (0.1)
Cr-51 EDTA	0.05 (1.85)	None	0.003 (0.03)
In-111 WBC's	0.5 (18.5)	6 hours	0.06 (0.6)
Tl-201	3 (111)	None	0.056 (0.56)

[1] From Table B-1.

[2] Based on an occupancy factor of 0.16 and an effective distance from source to receptor tissue of 0.2 meter.

Table B-3. Biokinetic Parameters for Radiopharmaceuticals Excreted in Breast milk.

Class A	Excretion Fraction* Lowest	Highest	T_B (h)	Reference
Ga-67 Citrate		9.5E-5 (72)	226	Tobin
	2.7E-5 (36)	3.7E-5 (58)	82-385	Rubow
		5.6E-5 (96)		Larson
		1.0E-4 (88)		Greener
		4.3E-5 (43)		Wellner
	3.16E-2§§	9.9E-2§§	20-390	Rubow94
Tc-99m DTPA		7.2E-7 (2.2)	15	Mount84
		6.0E-7 (2.8)	15	Mount85
	5.0E-4§§	2.4E-3§§	6.5-30	Rubow94
		~5.0E-7 (~3)	9.6	Ahlgren
Tc-99m MAA		1.4E-4 (2.2)	20	Mount84
	7.1E-6 (5)	3.1E-4 (7)	5.2-45	Marsson
		2.4E-5 (4)	5.3	Berke
		1.4E-4 (3.5)	12**	Cranage
		7.0E-6 (6)	~12	Heaton
	4.0E-3§§	5.2E-2§§	7.3-18	Ahlgren
Tc-99m pertechnetate		~5.7E-6 (8.5)		Rumble
	2.6E-5 (10)	6.4E-5 (2)	4-66	Wyburn
		1.4E-4 (20)	20	Vagenakis
		~1.3E-5 (3)		Pittard
	7.19E-3 (2.4)	1.7E-2 (2)		Ogunleye†
		~5.0E-4 (~5)	6.9	Ahlgren
		1.7E-4 (6.2)	6	Mount87
		1.4E-4 (~3)	5.2	Hedrick86
I-131 NaI	1.4E-5 (24)	4.0E-5 (6)	~9.9	Nurnberger
		6.7E-4 (6)		Weaver
		6.6E-4	12	Dydek (2 comp
		+ 1.6E-5	526	model)
		3.0E-2 (18)	~5.4	Rubow
		~5.0E-4	14	Robinson
			11	Robinson (2 comp
			235	model
		2.3E-1§§	117	Rubow94
	2.5E-1§§	4.6E-1§§	7.6-12	Mount89

Class B	Excretion Fraction* Lowest	Highest	Biological T1/2 T_B (h)	Reference (see ref)
Cr-51 EDTA	1.5E-4§§	6.5E-4§§	5.0-7.0	Ahlgren
Tc-99m DISIDA	1.0E-3§§	2.8E-3§§	10-(9.1)††	Rubow94
Tc-99m glucoheptonate		1.4E-3§§	9.0	Rubow94
		2.6E-6	12	Mount87
Tc-99m HAM	8.8E-3§§	1.1E-2§§	6.0-(7.0)††	Rubow94
Tc-99m MIBI		1.4E-6 (3.3)	43	Rubow91
	1.0E-4§§	3.0E-4§§	18-(6.7)††	Rubow94
Tc-99m MDP/HDP		~1.6E-6 (~4)	8.4-34	Ahlgren

Table B-4. Calculated Doses to Newborn and 1-Year-Old Infants from Maximum Administered Dosages of Radiopharmaceuticals as a Function of Breast Feeding Interruption Time.

Tc-99m PYP	1.5E-3§§	4.4E-3§§	8.4 (6.0)††	Rubow94
Tc-99m RBC - in vivo	6.0E-3§§	1.0E-2§§	(7.7)††	Rose90
		4.5E-5 (5)	(6.8)††	Rose89
		1.0E-7 (4)	(7)††	Ahlgren
Tc-99m RBC - in vitro	2.1E-4§§	3.0E-4§§	(7.8-9.0)††	Rubow94
Tc-99m Sulphur Colloid	1.6E-3§§	1.5E-2§§	35-(8.3)†*	Rubow94
In-111 WBC		3.3E-7 (13)	(85.3)†*	Mount85
		7.3E-7 (16)	(140)††	Hesselewood88
		2.4E-7 (20)		Butt
I-123 NaI		2.6E-2§§	10.4	Hedrick
		6.5E-5	10.4	Hedrick
I-123 OIH *		6.0E-5	4.8	Mount89
	1.2E-02§§	3.5E-2§§	8.1-10.2	Rose
		1.5E-4 (4)	8.3	Rose
I-123 mIBG*		7.2E-6 (8)	85	Kettle
I-125 OIH		2.1E-3§§	4.8	Ahlgren
I-131 OIH	1.8E-2§§	4.9E-2§§	2.2-6.0	Ahlgren
Tl-201 Chloride		2.2E-6	43	Murphy89 (2 compartment model)
		* 1.9E-7	(352)††	
		5.9E-7	13	Johnston (2 compartment model)
		* 1.1E-6	(164)††	

Class C

Tc-99m DTPA Aerosol	Fraction of administered aerosol assumed to reach bloodstream (0.406) treated as Tc-99m DTPA
Tc-99m MAG3	Treated as Tc-99m DTPA (renal agent for which data exist)
Tc-99m WBC	Treated as Tc-99m pertechnetate, as fraction of free Tc-99m is highly variable
Xe-133 gas	See text

* Peak fraction per ml of milk. All values corrected to the time of activity administration. The number in parenthesis is the time (h) at which this maximum was observed. "Lowest" is the lowest concentration observed at peak, and "Highest" is the highest concentration observed at peak, in an individual patient. If data from only one patient are reported, they are given under the "Highest" column.

** Pooled data from 4 patients

† Patient admitted for study of enlarged thyroid.

‡ Conservative value chosen due to anecdotal report (n=1)

§ Conservative value chosen due to irregularities in reported (n=1) data

§§ Total fraction excreted - milk concentrations not given

(t)†† Effective half-time > T_p indicates continued activity accumulation

* Speciation tests indicated that the activity excreted was most likely in the form of NaI, not mIBG.

Table B-4. Calculated Doses to Newborn and 1-Year-Old Infants from Maximum Administered Dosages of Radiopharmaceuticals as a Function of Breast Feeding Interruption Time.

Ga-67 Citrate,	A(c) = 5	mCi, min concentration, t1/2:								
INTERR. TIME =	3 hr,	INTAKE =	4.09E-02 mCi	=	8.17E-01% of inj	DOSE(0) =	2.72E+02 mrem	DOSE(1) =	1.04E+02 mrem	
INTERR. TIME =	24 hr,	INTAKE =	1.64E-02 mCi	=	3.28E-01% of inj	DOSE(0) =	1.09E+02 mrem	DOSE(1) =	4.18E+01 mrem	
INTERR. TIME =	48 hr,	INTAKE =	5.77E-03 mCi	=	1.15E-01% of inj	DOSE(0) =	3.84E+01 mrem	DOSE(1) =	1.47E+01 mrem	
INTERR. TIME =	96 hr,	INTAKE =	7.14E-04 mCi	=	1.43E-02% of inj	DOSE(0) =	4.76E+00 mrem	DOSE(1) =	1.82E+00 mrem	
INTERR. TIME =	120 hr,	INTAKE =	2.51E-04 mCi	=	5.03E-03% of inj	DOSE(0) =	1.67E+00 mrem	DOSE(1) =	6.42E-01 mrem	
INTERR. TIME =	168 hr,	INTAKE =	3.11E-05 mCi	=	6.23E-04% of inj	DOSE(0) =	2.07E-01 mrem	DOSE(1) =	7.95E-02 mrem	
INTERR. TIME =	336 hr,	INTAKE =	2.08E-08 mCi	=	4.17E-07% of inj	DOSE(0) =	1.39E-04 mrem	DOSE(1) =	5.32E-05 mrem	
INTERR. TIME =	672 hr,	INTAKE =	9.27E-15 mCi	=	1.85E-13% of inj	DOSE(0) =	6.17E-11 mrem	DOSE(1) =	2.37E-11 mrem	
Ga-67 Citrate,	A(c) = 5	mCi, max concentration, t1/2:								
INTERR. TIME =	3 hr,	INTAKE =	1.99E+00 mCi	=	3.98E+01% of inj	DOSE(0) =	1.33E+04 mrem	DOSE(1) =	5.08E+03 mrem	
INTERR. TIME =	24 hr,	INTAKE =	1.59E+00 mCi	=	3.18E+01% of inj	DOSE(0) =	1.06E+04 mrem	DOSE(1) =	4.06E+03 mrem	
INTERR. TIME =	48 hr,	INTAKE =	1.23E+00 mCi	=	2.47E+01% of inj	DOSE(0) =	8.21E+03 mrem	DOSE(1) =	3.15E+03 mrem	
INTERR. TIME =	96 hr,	INTAKE =	7.40E-01 mCi	=	1.48E+01% of inj	DOSE(0) =	4.93E+03 mrem	DOSE(1) =	1.89E+03 mrem	
INTERR. TIME =	120 hr,	INTAKE =	5.73E-01 mCi	=	1.15E+01% of inj	DOSE(0) =	3.82E+03 mrem	DOSE(1) =	1.46E+03 mrem	
INTERR. TIME =	168 hr,	INTAKE =	3.44E-01 mCi	=	6.88E+00% of inj	DOSE(0) =	2.29E+03 mrem	DOSE(1) =	8.78E+02 mrem	
INTERR. TIME =	336 hr,	INTAKE =	5.76E-02 mCi	=	1.15E+00% of inj	DOSE(0) =	3.83E+02 mrem	DOSE(1) =	1.47E+02 mrem	
INTERR. TIME =	672 hr,	INTAKE =	1.61E-03 mCi	=	3.23E-02% of inj	DOSE(0) =	1.07E+01 mrem	DOSE(1) =	4.12E+00 mrem	
Tc-99m DTPA,	A(o) = 20	mCi, min concentration, t1/2:								
INTERR. TIME =	3 hr,	INTAKE =	2.57E-03 mCi	=	1.29E-02% of inj	DOSE(0) =	3.23E-01 mrem	DOSE(1) =	1.43E-01 mrem	
INTERR. TIME =	24 hr,	INTAKE =	2.43E-05 mCi	=	1.22E-04% of inj	DOSE(0) =	3.06E-03 mrem	DOSE(1) =	1.35E-03 mrem	
INTERR. TIME =	48 hr,	INTAKE =	1.18E-07 mCi	=	5.92E-07% of inj	DOSE(0) =	1.49E-05 mrem	DOSE(1) =	6.57E-06 mrem	
INTERR. TIME =	96 hr,	INTAKE =	2.80E-12 mCi	=	1.40E-11% of inj	DOSE(0) =	3.52E-10 mrem	DOSE(1) =	1.55E-10 mrem	
INTERR. TIME =	120 hr,	INTAKE =	1.36E-14 mCi	=	6.80E-14% of inj	DOSE(0) =	1.71E-12 mrem	DOSE(1) =	7.55E-13 mrem	
INTERR. TIME =	168 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem	
INTERR. TIME =	336 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem	
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem	
Tc-99m DTPA,	A(o) = 20	mCi, max concentration, t1/2:								
INTERR. TIME =	3 hr,	INTAKE =	4.78E-02 mCi	=	2.39E-01% of inj	DOSE(0) =	6.02E+00 mrem	DOSE(1) =	2.65E+00 mrem	
INTERR. TIME =	24 hr,	INTAKE =	2.61E-03 mCi	=	1.31E-02% of inj	DOSE(0) =	3.29E-01 mrem	DOSE(1) =	1.45E-01 mrem	
INTERR. TIME =	48 hr,	INTAKE =	9.43E-05 mCi	=	4.72E-04% of inj	DOSE(0) =	1.19E-02 mrem	DOSE(1) =	5.24E-03 mrem	
INTERR. TIME =	96 hr,	INTAKE =	1.23E-07 mCi	=	6.14E-07% of inj	DOSE(0) =	1.55E-05 mrem	DOSE(1) =	6.82E-06 mrem	
INTERR. TIME =	120 hr,	INTAKE =	4.43E-09 mCi	=	2.22E-08% of inj	DOSE(0) =	5.58E-07 mrem	DOSE(1) =	2.46E-07 mrem	
INTERR. TIME =	168 hr,	INTAKE =	5.77E-12 mCi	=	2.89E-11% of inj	DOSE(0) =	7.26E-10 mrem	DOSE(1) =	3.20E-10 mrem	
INTERR. TIME =	336 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem	
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem	
Tc-99m MAA	A(o) = 4	mCi, min concentration, t1/2:								
INTERR. TIME =	3 hr,	INTAKE =	6.66E-03 mCi	=	1.66E-01% of inj	DOSE(0) =	4.19E+00 mrem	DOSE(1) =	1.70E+00 mrem	
INTERR. TIME =	24 hr,	INTAKE =	3.60E-05 mCi	=	9.00E-04% of inj	DOSE(0) =	2.26E-02 mrem	DOSE(1) =	9.19E-03 mrem	
INTERR. TIME =	48 hr,	INTAKE =	9.23E-08 mCi	=	2.31E-06% of inj	DOSE(0) =	5.81E-05 mrem	DOSE(1) =	2.36E-05 mrem	
INTERR. TIME =	96 hr,	INTAKE =	6.07E-13 mCi	=	1.52E-11% of inj	DOSE(0) =	3.82E-10 mrem	DOSE(1) =	1.55E-10 mrem	
INTERR. TIME =	120 hr,	INTAKE =	1.54E-15 mCi	=	3.85E-14% of inj	DOSE(0) =	9.69E-13 mrem	DOSE(1) =	3.93E-13 mrem	

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INTERR. TIME =  168 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m MAA,  A(o) =  4 mCi, max concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  4.78E-01 mCi  =  1.19E+01% of inj  DOSE(0) =  3.01E+02 mrem  DOSE(1) =  1.22E+02 mrem
INTERR. TIME =   24 hr,  INTAKE =  3.07E-02 mCi  =  7.68E-01% of inj  DOSE(0) =  1.93E+01 mrem  DOSE(1) =  7.84E+00 mrem
INTERR. TIME =   48 hr,  INTAKE =  1.33E-03 mCi  =  3.33E-02% of inj  DOSE(0) =  8.38E-01 mrem  DOSE(1) =  3.40E-01 mrem
INTERR. TIME =   96 hr,  INTAKE =  2.51E-06 mCi  =  6.28E-05% of inj  DOSE(0) =  1.58E-03 mrem  DOSE(1) =  6.41E-04 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.09E-07 mCi  =  2.73E-06% of inj  DOSE(0) =  6.86E-05 mrem  DOSE(1) =  2.78E-05 mrem
INTERR. TIME =  168 hr,  INTAKE =  2.06E-10 mCi  =  5.14E-09% of inj  DOSE(0) =  1.29E-07 mrem  DOSE(1) =  5.25E-08 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m O4,  A(o) =  30 mCi, min concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  4.78E-02 mCi  =  1.59E-01% of inj  DOSE(0) =  1.95E+01 mrem  DOSE(1) =  7.92E+00 mrem
INTERR. TIME =   24 hr,  INTAKE =  2.58E-04 mCi  =  8.61E-04% of inj  DOSE(0) =  1.05E-01 mrem  DOSE(1) =  4.28E-02 mrem
INTERR. TIME =   48 hr,  INTAKE =  6.63E-07 mCi  =  2.21E-06% of inj  DOSE(0) =  2.70E-04 mrem  DOSE(1) =  1.10E-04 mrem
INTERR. TIME =   96 hr,  INTAKE =  4.36E-12 mCi  =  1.45E-11% of inj  DOSE(0) =  1.77E-09 mrem  DOSE(1) =  7.23E-10 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.11E-14 mCi  =  3.69E-14% of inj  DOSE(0) =  4.50E-12 mrem  DOSE(1) =  2.09E-12 mrem
INTERR. TIME =  168 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m O4,  A(o) =  30 mCi, max concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  2.03E+00 mCi  =  6.76E+00% of inj  DOSE(0) =  8.25E+02 mrem  DOSE(1) =  3.38E+02 mrem
INTERR. TIME =   24 hr,  INTAKE =  1.44E-01 mCi  =  4.81E-01% of inj  DOSE(0) =  5.88E+01 mrem  DOSE(1) =  2.73E+01 mrem
INTERR. TIME =   48 hr,  INTAKE =  7.05E-03 mCi  =  2.35E-02% of inj  DOSE(0) =  2.87E+00 mrem  DOSE(1) =  1.33E+00 mrem
INTERR. TIME =   96 hr,  INTAKE =  1.68E-05 mCi  =  5.61E-05% of inj  DOSE(0) =  6.84E-03 mrem  DOSE(1) =  3.17E-03 mrem
INTERR. TIME =  120 hr,  INTAKE =  8.21E-07 mCi  =  2.74E-06% of inj  DOSE(0) =  3.34E-04 mrem  DOSE(1) =  1.55E-04 mrem
INTERR. TIME =  168 hr,  INTAKE =  1.96E-09 mCi  =  6.53E-09% of inj  DOSE(0) =  7.97E-07 mrem  DOSE(1) =  3.69E-07 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-131 NaI,  A(o) =  150 mCi, min concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  1.06E+00 mCi  =  7.07E-01% of inj  DOSE(0) =  6.28E+05 mrem  DOSE(1) =  4.71E+05 mrem
INTERR. TIME =   24 hr,  INTAKE =  1.45E-01 mCi  =  9.66E-02% of inj  DOSE(0) =  8.58E+04 mrem  DOSE(1) =  6.44E+04 mrem
INTERR. TIME =   48 hr,  INTAKE =  1.49E-02 mCi  =  9.94E-03% of inj  DOSE(0) =  8.82E+03 mrem  DOSE(1) =  6.62E+03 mrem
INTERR. TIME =   96 hr,  INTAKE =  1.58E-04 mCi  =  1.05E-04% of inj  DOSE(0) =  9.33E+01 mrem  DOSE(1) =  7.00E+01 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.62E-05 mCi  =  1.08E-05% of inj  DOSE(0) =  9.60E+00 mrem  DOSE(1) =  7.20E+00 mrem
INTERR. TIME =  168 hr,  INTAKE =  1.71E-07 mCi  =  1.14E-07% of inj  DOSE(0) =  1.02E-01 mrem  DOSE(1) =  7.61E-02 mrem
INTERR. TIME =  336 hr,  INTAKE =  1.92E-14 mCi  =  1.28E-14% of inj  DOSE(0) =  1.14E-08 mrem  DOSE(1) =  8.54E-09 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-131 NaI,  A(o) =  150 mCi, max concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  7.50E+01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
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 INTERR. TIME =   24 hr,  INTAKE =  7.50E-01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
 INTERR. TIME =   48 hr,  INTAKE =  7.50E-01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
 INTERR. TIME =   96 hr,  INTAKE =  7.50E-01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
 INTERR. TIME =  120 hr,  INTAKE =  7.50E-01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
 INTERR. TIME =  168 hr,  INTAKE =  7.50E-01 mCi  =  5.00E+01% of inj  DOSE(0) =  4.44E+07 mrem  DOSE(1) =  3.33E+07 mrem
 INTERR. TIME =  336 hr,  INTAKE =  1.88E-01 mCi  =  1.25E+01% of inj  DOSE(0) =  1.11E+07 mrem  DOSE(1) =  3.34E+06 mrem
 INTERR. TIME =  672 hr,  INTAKE =  7.68E-01 mCi  =  5.12E-01% of inj  DOSE(0) =  4.55E+05 mrem  DOSE(1) =  3.41E+05 mrem

Cr-51 EDTA,  A(o) =  .05  mCi, min concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  7.71E-06 mCi  =  1.54E-02% of inj  DOSE(0) =  8.85E-04 mrem  DOSE(1) =  3.71E-04 mrem
 INTERR. TIME =   24 hr,  INTAKE =  9.44E-07 mCi  =  1.89E-03% of inj  DOSE(0) =  1.08E-04 mrem  DOSE(1) =  4.54E-05 mrem
 INTERR. TIME =   48 hr,  INTAKE =  8.55E-08 mCi  =  1.71E-04% of inj  DOSE(0) =  9.81E-06 mrem  DOSE(1) =  4.11E-06 mrem
 INTERR. TIME =   96 hr,  INTAKE =  7.02E-10 mCi  =  1.40E-06% of inj  DOSE(0) =  8.06E-08 mrem  DOSE(1) =  3.38E-08 mrem
 INTERR. TIME =  120 hr,  INTAKE =  6.37E-11 mCi  =  1.27E-07% of inj  DOSE(0) =  7.30E-09 mrem  DOSE(1) =  3.06E-09 mrem
 INTERR. TIME =  168 hr,  INTAKE =  5.23E-13 mCi  =  1.05E-09% of inj  DOSE(0) =  6.00E-11 mrem  DOSE(1) =  2.51E-11 mrem
 INTERR. TIME =  336 hr,  INTAKE =  1.56E-20 mCi  =  3.12E-17% of inj  DOSE(0) =  1.79E-18 mrem  DOSE(1) =  7.50E-19 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Cr-51 EDTA,  A(o) =  .05  mCi, max concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  3.27E-05 mCi  =  6.75E-02% of inj  DOSE(0) =  3.87E-03 mrem  DOSE(1) =  1.62E-03 mrem
 INTERR. TIME =   24 hr,  INTAKE =  4.13E-06 mCi  =  8.26E-03% of inj  DOSE(0) =  4.74E-04 mrem  DOSE(1) =  1.99E-04 mrem
 INTERR. TIME =   48 hr,  INTAKE =  3.74E-07 mCi  =  7.48E-04% of inj  DOSE(0) =  4.29E-05 mrem  DOSE(1) =  1.80E-05 mrem
 INTERR. TIME =   96 hr,  INTAKE =  3.07E-09 mCi  =  6.15E-06% of inj  DOSE(0) =  3.53E-07 mrem  DOSE(1) =  1.48E-07 mrem
 INTERR. TIME =  120 hr,  INTAKE =  2.79E-10 mCi  =  5.57E-07% of inj  DOSE(0) =  3.19E-08 mrem  DOSE(1) =  1.34E-08 mrem
 INTERR. TIME =  168 hr,  INTAKE =  2.29E-12 mCi  =  4.58E-09% of inj  DOSE(0) =  2.62E-10 mrem  DOSE(1) =  1.10E-10 mrem
 INTERR. TIME =  336 hr,  INTAKE =  6.82E-20 mCi  =  1.36E-16% of inj  DOSE(0) =  7.82E-18 mrem  DOSE(1) =  3.28E-18 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m DISIDA,  A(o) =  8  mCi, min concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  5.64E-03 mCi  =  7.05E-02% of inj  DOSE(0) =  4.30E+00 mrem  DOSE(1) =  2.30E+00 mrem
 INTERR. TIME =   24 hr,  INTAKE =  1.17E-04 mCi  =  1.46E-03% of inj  DOSE(0) =  9.95E-02 mrem  DOSE(1) =  4.76E-02 mrem
 INTERR. TIME =   48 hr,  INTAKE =  1.39E-06 mCi  =  1.74E-05% of inj  DOSE(0) =  1.18E-03 mrem  DOSE(1) =  5.67E-04 mrem
 INTERR. TIME =   96 hr,  INTAKE =  1.97E-10 mCi  =  2.47E-09% of inj  DOSE(0) =  1.68E-07 mrem  DOSE(1) =  8.03E-08 mrem
 INTERR. TIME =  120 hr,  INTAKE =  2.35E-12 mCi  =  2.94E-11% of inj  DOSE(0) =  2.00E-09 mrem  DOSE(1) =  9.57E-10 mrem
 INTERR. TIME =  168 hr,  INTAKE =  3.21E-16 mCi  =  4.02E-15% of inj  DOSE(0) =  2.73E-13 mrem  DOSE(1) =  1.31E-13 mrem
 INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m DISIDA,  A(o) =  8  mCi, max concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  2.25E-02 mCi  =  2.82E-01% of inj  DOSE(0) =  1.92E+01 mrem  DOSE(1) =  9.17E+00 mrem
 INTERR. TIME =   24 hr,  INTAKE =  4.55E-03 mCi  =  5.69E-02% of inj  DOSE(0) =  3.87E+00 mrem  DOSE(1) =  1.85E+00 mrem
 INTERR. TIME =   48 hr,  INTAKE =  7.32E-04 mCi  =  9.15E-03% of inj  DOSE(0) =  6.23E-01 mrem  DOSE(1) =  2.98E-01 mrem
 INTERR. TIME =   96 hr,  INTAKE =  1.89E-05 mCi  =  2.36E-04% of inj  DOSE(0) =  1.61E-02 mrem  DOSE(1) =  7.70E-03 mrem
 INTERR. TIME =  120 hr,  INTAKE =  3.04E-06 mCi  =  3.80E-05% of inj  DOSE(0) =  2.59E-03 mrem  DOSE(1) =  1.24E-03 mrem
 INTERR. TIME =  168 hr,  INTAKE =  7.86E-08 mCi  =  9.83E-07% of inj  DOSE(0) =  6.69E-05 mrem  DOSE(1) =  3.20E-05 mrem
 INTERR. TIME =  336 hr,  INTAKE =  2.18E-13 mCi  =  2.73E-12% of inj  DOSE(0) =  1.86E-10 mrem  DOSE(1) =  8.89E-11 mrem
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 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m gluco,  A(o) =  20  mCi, min concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  1.48E-02 mCi  =  7.41E-02% of inj  DOSE(0) =  2.20E+00 mrem  DOSE(1) =  5.38E+00 mrem
 INTERR. TIME =   24 hr,  INTAKE =  2.61E-04 mCi  =  1.31E-03% of inj  DOSE(0) =  4.06E-02 mrem  DOSE(1) =  9.48E-02 mrem
 INTERR. TIME =   48 hr,  INTAKE =  2.59E-06 mCi  =  1.29E-05% of inj  DOSE(0) =  4.02E-04 mrem  DOSE(1) =  9.38E-04 mrem
 INTERR. TIME =   96 hr,  INTAKE =  2.53E-10 mCi  =  1.27E-09% of inj  DOSE(0) =  3.94E-08 mrem  DOSE(1) =  9.19E-08 mrem
 INTERR. TIME =  120 hr,  INTAKE =  2.51E-12 mCi  =  1.25E-11% of inj  DOSE(0) =  3.90E-10 mrem  DOSE(1) =  9.10E-10 mrem
 INTERR. TIME =  168 hr,  INTAKE =  2.21E-16 mCi  =  1.11E-15% of inj  DOSE(0) =  3.44E-14 mrem  DOSE(1) =  8.03E-14 mrem
 INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m gluco,  A(o) =  20  mCi, max concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  3.02E-02 mCi  =  1.51E-01% of inj  DOSE(0) =  4.70E+00 mrem  DOSE(1) =  1.10E+01 mrem
 INTERR. TIME =   24 hr,  INTAKE =  7.99E-04 mCi  =  3.99E-03% of inj  DOSE(0) =  1.24E-01 mrem  DOSE(1) =  2.90E-01 mrem
 INTERR. TIME =   48 hr,  INTAKE =  1.25E-05 mCi  =  6.27E-05% of inj  DOSE(0) =  1.95E-03 mrem  DOSE(1) =  4.55E-03 mrem
 INTERR. TIME =   96 hr,  INTAKE =  3.10E-09 mCi  =  1.55E-08% of inj  DOSE(0) =  4.81E-07 mrem  DOSE(1) =  1.12E-06 mrem
 INTERR. TIME =  120 hr,  INTAKE =  4.87E-11 mCi  =  2.43E-10% of inj  DOSE(0) =  7.56E-09 mrem  DOSE(1) =  1.76E-08 mrem
 INTERR. TIME =  168 hr,  INTAKE =  1.19E-14 mCi  =  5.97E-14% of inj  DOSE(0) =  1.86E-12 mrem  DOSE(1) =  4.33E-12 mrem
 INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m HAM,  A(o) =  8  mCi, min concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  3.60E-02 mCi  =  4.50E-01% of inj  DOSE(0) =  2.00E+01 mrem  DOSE(1) =  8.13E+00 mrem
 INTERR. TIME =   24 hr,  INTAKE =  2.83E-04 mCi  =  3.54E-03% of inj  DOSE(0) =  1.57E-01 mrem  DOSE(1) =  6.38E-02 mrem
 INTERR. TIME =   48 hr,  INTAKE =  1.11E-06 mCi  =  1.39E-05% of inj  DOSE(0) =  6.17E-04 mrem  DOSE(1) =  2.51E-04 mrem
 INTERR. TIME =   96 hr,  INTAKE =  1.72E-11 mCi  =  2.14E-10% of inj  DOSE(0) =  9.52E-09 mrem  DOSE(1) =  3.87E-09 mrem
 INTERR. TIME =  120 hr,  INTAKE =  6.73E-14 mCi  =  8.42E-13% of inj  DOSE(0) =  3.74E-11 mrem  DOSE(1) =  1.52E-11 mrem
 INTERR. TIME =  168 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
 INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m HAM,  A(o) =  8  mCi, max concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  8.95E-02 mCi  =  1.12E+00% of inj  DOSE(0) =  4.97E+01 mrem  DOSE(1) =  2.02E+01 mrem
 INTERR. TIME =   24 hr,  INTAKE =  1.12E-02 mCi  =  1.40E-01% of inj  DOSE(0) =  6.21E+00 mrem  DOSE(1) =  2.53E+00 mrem
 INTERR. TIME =   48 hr,  INTAKE =  1.04E-03 mCi  =  1.30E-02% of inj  DOSE(0) =  5.77E-01 mrem  DOSE(1) =  2.35E-01 mrem
 INTERR. TIME =   96 hr,  INTAKE =  8.98E-06 mCi  =  1.12E-04% of inj  DOSE(0) =  4.98E-03 mrem  DOSE(1) =  2.03E-03 mrem
 INTERR. TIME =  120 hr,  INTAKE =  8.35E-07 mCi  =  1.04E-05% of inj  DOSE(0) =  4.63E-04 mrem  DOSE(1) =  1.88E-04 mrem
 INTERR. TIME =  168 hr,  INTAKE =  7.21E-09 mCi  =  9.01E-08% of inj  DOSE(0) =  4.00E-06 mrem  DOSE(1) =  1.63E-06 mrem
 INTERR. TIME =  336 hr,  INTAKE =  3.00E-16 mCi  =  3.75E-15% of inj  DOSE(0) =  1.66E-13 mrem  DOSE(1) =  6.76E-14 mrem
 INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m MIBI,  A(o) =  30  mCi, min concentration, t1/2:
 INTERR. TIME =    3 hr,  INTAKE =  2.23E-03 mCi  =  7.44E-03% of inj  DOSE(0) =  1.16E-00 mrem  DOSE(1) =  5.37E-01 mrem
 INTERR. TIME =   24 hr,  INTAKE =  8.83E-05 mCi  =  2.94E-04% of inj  DOSE(0) =  4.57E-02 mrem  DOSE(1) =  2.13E-02 mrem
 INTERR. TIME =   48 hr,  INTAKE =  2.20E-06 mCi  =  7.34E-06% of inj  DOSE(0) =  1.14E-03 mrem  DOSE(1) =  5.30E-04 mrem
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INTERR. TIME =   96 hr,  INTAKE =  1.37E-09 mCi  =  4.56E-09% of inj  DOSE(0) =  7.09E-07 mrem  DOSE(1) =  3.29E-07 mrem
INTERR. TIME =  120 hr,  INTAKE =  3.41E-11 mCi  =  1.14E-10% of inj  DOSE(0) =  1.77E-08 mrem  DOSE(1) =  8.21E-09 mrem
INTERR. TIME =  168 hr,  INTAKE =  2.12E-14 mCi  =  7.08E-14% of inj  DOSE(0) =  1.10E-11 mrem  DOSE(1) =  5.11E-12 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m MIBI,  A(o) =  30  mCi, max concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  1.97E-02 mCi  =  6.56E-02% of inj  DOSE(0) =  1.02E+01 mrem  DOSE(1) =  4.73E+00 mrem
INTERR. TIME =   24 hr,  INTAKE =  2.24E-03 mCi  =  7.47E-03% of inj  DOSE(0) =  1.16E+00 mrem  DOSE(1) =  5.39E-01 mrem
INTERR. TIME =   48 hr,  INTAKE =  1.87E-04 mCi  =  6.24E-04% of inj  DOSE(0) =  9.70E-02 mrem  DOSE(1) =  4.51E-02 mrem
INTERR. TIME =   96 hr,  INTAKE =  1.31E-06 mCi  =  4.36E-06% of inj  DOSE(0) =  6.77E-04 mrem  DOSE(1) =  3.14E-04 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.09E-07 mCi  =  3.64E-07% of inj  DOSE(0) =  5.66E-05 mrem  DOSE(1) =  2.63E-05 mrem
INTRRR. TIME =  168 hr,  INTAKE =  7.62E-10 mCi  =  2.54E-09% of inj  DOSE(0) =  3.95E-07 mrem  DOSE(1) =  1.83E-07 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m MDP,  A(o) =  20  mCi, min concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  8.94E-03 mCi  =  4.47E-02% of inj  DOSE(0) =  3.64E+00 mrem  DOSE(1) =  1.39E+00 mrem
INTERR. TIME =   24 hr,  INTAKE =  1.40E-04 mCi  =  7.02E-04% of inj  DOSE(0) =  5.71E-02 mrem  DOSE(1) =  2.18E-02 mrem
INTERR. TIME =   48 hr,  INTAKE =  1.22E-06 mCi  =  6.09E-06% of inj  DOSE(0) =  4.95E-04 mrem  DOSE(1) =  1.89E-04 mrem
INTERR. TIME =   96 hr,  INTAKE =  9.16E-11 mCi  =  4.58E-10% of inj  DOSE(0) =  3.73E-08 mrem  DOSE(1) =  1.42E-08 mrem
INTERR. TIME =  120 hr,  INTAKE =  7.94E-13 mCi  =  3.97E-12% of inj  DOSE(0) =  3.23E-10 mrem  DOSE(1) =  1.23E-10 mrem
INTERR. TIME =  168 hr,  INTAKE =  4.15E-17 mCi  =  2.08E-16% of inj  DOSE(0) =  1.69E-14 mrem  DOSE(1) =  6.45E-15 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc-99m MDP,  A(o) =  20  mCi, max concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  1.20E-02 mCi  =  5.98E-02% of inj  DOSE(0) =  4.87E+00 mrem  DOSE(1) =  1.86E+00 mrem
INTERR. TIME =   24 hr,  INTAKE =  6.92E-04 mCi  =  3.46E-03% of inj  DOSE(0) =  2.82E-01 mrem  DOSE(1) =  1.08E-01 mrem
INTERR. TIME =   48 hr,  INTAKE =  2.67E-05 mCi  =  1.33E-04% of inj  DOSE(0) =  1.09E-02 mrem  DOSE(1) =  4.14E-03 mrem
INTERR. TIME =   96 hr,  INTAKE =  3.96E-08 mCi  =  1.98E-07% of inj  DOSE(0) =  1.61E-05 mrem  DOSE(1) =  6.15E-06 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.52E-09 mCi  =  7.62E-09% of inj  DOSE(0) =  6.20E-07 mrem  DOSE(1) =  2.37E-07 mrem
INTERR. TIME =  168 hr,  INTAKE =  2.26E-12 mCi  =  1.13E-11% of inj  DOSE(0) =  9.20E-10 mrem  DOSE(1) =  3.51E-10 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

Tc 99m PYP   A(o) =  23  mCi, min concentration, t1/2:
INTERR. TIME =    3 hr,  INTAKE =  1.73E-02 mCi  =  8.66E-02% of inj  DOSE(0) =  4.81E+00 mrem  DOSE(1) =  2.05E+00 mrem
INTERR. TIME =   24 hr,  INTAKE =  2.72E-04 mCi  =  1.36E-03% of inj  DOSE(0) =  7.55E-02 mrem  DOSE(1) =  3.22E-02 mrem
INTERR. TIME =   48 hr,  INTAKE =  2.36E-06 mCi  =  1.18E-05% of inj  DOSE(0) =  6.54E-04 mrem  DOSE(1) =  2.79E-04 mrem
INTERR. TIME =   96 hr,  INTAKE =  1.77E-10 mCi  =  8.87E-10% of inj  DOSE(0) =  4.92E-08 mrem  DOSE(1) =  2.10E-08 mrem
INTERR. TIME =  120 hr,  INTAKE =  1.54E-12 mCi  =  7.70E-12% of inj  DOSE(0) =  4.27E-10 mrem  DOSE(1) =  1.82E-10 mrem
INTERR. TIME =  168 hr,  INTAKE =  8.05E-17 mCi  =  4.02E-16% of inj  DOSE(0) =  2.23E-14 mrem  DOSE(1) =  9.53E-15 mrem
INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
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Tc-99m PYP, A(o) = 20 mCi, max concentration, t1/2:

INTERR. TIME =	3 hr,	INTAKE =	8.73E-02 mCi	=	4.37E-01% of inj	DOSE(0) =	2.42E+01 mrem	DOSE(1) =	1.03E+01 mrem
INTERR. TIME =	24 hr,	INTAKE =	1.03E-02 mCi	=	5.14E-02% of inj	DOSE(0) =	2.85E+00 mrem	DOSE(1) =	1.22E+00 mrem
INTERR. TIME =	48 hr,	INTAKE =	8.90E-04 mCi	=	4.45E-03% of inj	DOSE(0) =	2.47E-01 mrem	DOSE(1) =	1.05E-01 mrem
INTERR. TIME =	96 hr,	INTAKE =	6.68E-06 mCi	=	3.34E-05% of inj	DOSE(0) =	1.85E-03 mrem	DOSE(1) =	7.91E-04 mrem
INTERR. TIME =	120 hr,	INTAKE =	5.79E-07 mCi	=	2.90E-06% of inj	DOSE(0) =	1.61E-04 mrem	DOSE(1) =	6.86E-05 mrem
INTERR. TIME =	168 hr,	INTAKE =	4.35E-09 mCi	=	2.17E-08% of inj	DOSE(0) =	1.21E-06 mrem	DOSE(1) =	5.15E-07 mrem
INTERR. TIME =	336 hr,	INTAKE =	4.20E-17 mCi	=	2.10E-16% of inj	DOSE(0) =	1.17E-14 mrem	DOSE(1) =	4.97E-15 mrem
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem

Tc-99m RBC vivo, A(o) = 20 mCi, min concentration, t1/2:

INTERR. TIME =	3 hr,	INTAKE =	9.49E-04 mCi	=	4.75E-03% of inj	DOSE(0) =	2.88E-01 mrem	DOSE(1) =	1.30E-01 mrem
INTERR. TIME =	24 hr,	INTAKE =	1.12E-04 mCi	=	5.58E-04% of inj	DOSE(0) =	3.39E-02 mrem	DOSE(1) =	1.53E-02 mrem
INTERR. TIME =	48 hr,	INTAKE =	9.67E-06 mCi	=	4.84E-05% of inj	DOSE(0) =	2.94E-03 mrem	DOSE(1) =	1.32E-03 mrem
INTERR. TIME =	96 hr,	INTAKE =	7.26E-08 mCi	=	3.63E-07% of inj	DOSE(0) =	2.20E-05 mrem	DOSE(1) =	9.94E-06 mrem
INTERR. TIME =	120 hr,	INTAKE =	6.29E-09 mCi	=	3.15E-08% of inj	DOSE(0) =	1.91E-06 mrem	DOSE(1) =	8.62E-07 mrem
INTERR. TIME =	168 hr,	INTAKE =	4.73E-11 mCi	=	2.36E-10% of inj	DOSE(0) =	1.43E-08 mrem	DOSE(1) =	6.47E-09 mrem
INTERR. TIME =	336 hr,	INTAKE =	4.57E-19 mCi	=	2.28E-18% of inj	DOSE(0) =	1.39E-16 mrem	DOSE(1) =	6.25E-17 mrem
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem

Tc-99m RBC vivo, A(o) = 20 mCi, max concentration, t1/2:

INTERR. TIME =	3 hr,	INTAKE =	4.38E-01 mCi	=	2.19E+00% of inj	DOSE(0) =	1.33E+02 mrem	DOSE(1) =	5.99E+01 mrem
INTERR. TIME =	24 hr,	INTAKE =	5.48E-02 mCi	=	2.74E-01% of inj	DOSE(0) =	1.66E+01 mrem	DOSE(1) =	7.50E+00 mrem
INTERR. TIME =	48 hr,	INTAKE =	5.09E-03 mCi	=	2.54E-02% of inj	DOSE(0) =	1.54E+00 mrem	DOSE(1) =	6.96E-01 mrem
INTERR. TIME =	96 hr,	INTAKE =	4.39E-05 mCi	=	2.20E-04% of inj	DOSE(0) =	1.33E-02 mrem	DOSE(1) =	6.01E-03 mrem
INTERR. TIME =	120 hr,	INTAKE =	4.08E-06 mCi	=	2.04E-05% of inj	DOSE(0) =	1.24E-03 mrem	DOSE(1) =	5.59E-04 mrem
INTERR. TIME =	168 hr,	INTAKE =	3.52E-08 mCi	=	1.76E-07% of inj	DOSE(0) =	1.07E-05 mrem	DOSE(1) =	4.82E-06 mrem
INTERR. TIME =	336 hr,	INTAKE =	1.47E-15 mCi	=	7.33E-15% of inj	DOSE(0) =	4.45E-13 mrem	DOSE(1) =	2.01E-13 mrem
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem

Tc-99m RBC vitro, A(o) = 20 mCi, min concentration, t1/2:

INTERR. TIME =	3 hr,	INTAKE =	3.53E-03 mCi	=	1.76E-02% of inj	DOSE(0) =	1.10E+00 mrem	DOSE(1) =	1.83E-01 mrem
INTERR. TIME =	24 hr,	INTAKE =	5.46E-04 mCi	=	2.73E-03% of inj	DOSE(0) =	1.70E-01 mrem	DOSE(1) =	2.47E-02 mrem
INTERR. TIME =	48 hr,	INTAKE =	6.47E-05 mCi	=	3.24E-04% of inj	DOSE(0) =	2.01E-02 mrem	DOSE(1) =	3.86E-03 mrem
INTERR. TIME =	96 hr,	INTAKE =	9.10E-07 mCi	=	4.55E-06% of inj	DOSE(0) =	2.83E-04 mrem	DOSE(1) =	1.25E-04 mrem
INTERR. TIME =	120 hr,	INTAKE =	1.08E-07 mCi	=	5.39E-07% of inj	DOSE(0) =	3.35E-05 mrem	DOSE(1) =	1.48E-05 mrem
INTERR. TIME =	168 hr,	INTAKE =	1.52E-09 mCi	=	7.58E-09% of inj	DOSE(0) =	4.71E-07 mrem	DOSE(1) =	2.08E-07 mrem
INTERR. TIME =	336 hr,	INTAKE =	4.95E-16 mCi	=	2.48E-15% of inj	DOSE(0) =	1.54E-13 mrem	DOSE(1) =	6.78E-14 mrem
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem

Tc-99m RBC vitro, A(o) = 20 mCi, max concentration, t1/2:

INTERR. TIME =	3 hr,	INTAKE =	6.06E-03 mCi	=	3.03E-02% of inj	DOSE(0) =	1.88E+00 mrem	DOSE(1) =	8.30E-01 mrem
INTERR. TIME =	24 hr,	INTAKE =	1.20E-03 mCi	=	6.01E-03% of inj	DOSE(0) =	3.74E-01 mrem	DOSE(1) =	1.65E-01 mrem
INTERR. TIME =	48 hr,	INTAKE =	1.90E-04 mCi	=	9.48E-04% of inj	DOSE(0) =	5.89E-02 mrem	DOSE(1) =	2.59E-02 mrem
INTERR. TIME =	96 hr,	INTAKE =	4.70E-06 mCi	=	2.35E-05% of inj	DOSE(0) =	1.46E-03 mrem	DOSE(1) =	6.44E-04 mrem
INTERR. TIME =	120 hr,	INTAKE =	7.41E-07 mCi	=	3.71E-06% of inj	DOSE(0) =	2.30E-04 mrem	DOSE(1) =	1.01E-04 mrem

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  INTERR. TIME =  168 hr,  INTAKE =  1.84E-08 mCi  =  9.20E-08% of inj  DOSE(C) =  5.72E-06 mrem  DOSE(1)   2.52E-06 mrem
  INTERR. TIME =  336 hr,  INTAKE =  4.43E-14 mCi  =  2.22E-13% of inj  DOSE(C) =  1.38E-11 mrem  DOSE(1)   6.07E-12 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E-00 mCi  =  2.00E+00% of inj  DOSE(C) =  0.00E+00 mrem  DOSE(1)   0.00E+00 mrem

Tc-99m SC,  A(o) =  12  mCi, min concentration  t1/2=
  INTERR. TIME =    3 hr,  INTAKE =  1.26E-02 mCi  =  1.05E-01% of inj  DOSE(C) =  9.13E+00 mrem  DOSE(1)   4.57E+00 mrem
  INTERR. TIME =   24 hr,  INTAKE =  7.38E-04 mCi  =  5.15E-03% of inj  DOSE(C) =  5.46E-01 mrem  DOSE(1)   2.68E-01 mrem
  INTERR. TIME =   48 hr,  INTAKE =  2.88E-05 mCi  =  2.40E-04% of inj  DOSE(C) =  2.13E-02 mrem  DOSE(1)   1.05E-02 mrem
  INTERR. TIME =   96 hr,  INTAKE =  4.40E-08 mCi  =  3.67E-07% of inj  DOSE(C) =  3.26E-05 mrem  DOSE(1)   1.60E-05 mrem
  INTERR. TIME =  120 hr,  INTAKE =  1.72E-09 mCi  =  1.43E-08% of inj  DOSE(C) =  1.27E-06 mrem  DOSE(1)   5.23E-07 mrem
  INTERR. TIME =  168 hr,  INTAKE =  2.62E-12 mCi  =  2.19E-11% of inj  DOSE(C) =  1.94E-09 mrem  DOSE(1)   9.51E-10 mrem
  INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(C) =  0.00E+00 mrem  DOSE(1)   0.00E+00 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(C) =  0.00E+00 mrem  DOSE(1)   0.00E+00 mrem

Tc-99m SC,  A(c) =  12  mCi, max concentration, t1/2=
  INTERR. TIME =    3 hr,  INTAKE =  1.76E-01 mCi  =  1.47E+00% of inj  DOSE(C) =  1.30E+02 mrem  DOSE(1)   5.38E+01 mrem
  INTERR. TIME =   24 hr,  INTAKE =  3.05E-02 mCi  =  2.54E-01% of inj  DOSE(C) =  2.26E+01 mrem  DOSE(1)   1.11E+01 mrem
  INTERR. TIME =   48 hr,  INTAKE =  4.11E-03 mCi  =  3.42E-02% of inj  DOSE(C)    3.04E+00 mrem  DOSE(1)   1.49E+00 mrem
  INTERR. TIME =   96 hr,  INTAKE =  7.47E-05 mCi  =  6.22E-04% of inj  DOSE(C) =  5.53E-02 mrem  DOSE(1)   2.71E-02 mrem
  INTERR. TIME =  120 hr,  INTAKE =  1.01E-05 mCi  =  8.39E-05% of inj  DOSE(C) =  7.45E-03 mrem  DOSE(1)   3.65E-03 mrem
  INTERR. TIME =  168 hr,  INTAKE =  1.83E-07 mCi  =  1.53E-06% of inj  DOSE(C) =  1.35E-04 mrem  DOSE(1)   6.64E-05 mrem
  INTERR. TIME =  336 hr,  INTAKE =  1.48E-13 mCi  =  1.23E-12% of inj  DOSE(C) =  1.09E-10 mrem  DOSE(1)   5.36E-11 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(C) =  0.00E+00 mrem  DOSE(1)   0.00E+00 mrem

In-111 WBC,  A(o) =  .5  mCi, min concentration, t1/2=
  INTERR. TIME =    3 hr,  INTAKE =  6.21E-04 mCi  =  1.24E-03% of inj  DOSE(C) =  2.04E+01 mrem  DOSE(1)   8.04E+00 mrem
  INTERR. TIME =   24 hr,  INTAKE =  5.23E-04 mCi  =  1.05E-03% of inj  DOSE(C) =  1.72E+01 mrem  DOSE(1)   6.77E+00 mrem
  INTERR. TIME =   48 hr,  INTAKE =  4.30E-04 mCi  =  8.60E-04% of inj  DOSE(C) =  1.42E+01 mrem  DOSE(1)   5.57E+00 mrem
  INTERR. TIME =   96 hr,  INTAKE =  2.91E-04 mCi  =  5.82E-04% of inj  DOSE(C) =  9.58E+00 mrem  DOSE(1)   3.77E+00 mrem
  INTERR. TIME =  120 hr,  INTAKE =  2.39E-04 mCi  =  4.78E-04% of inj  DOSE(C) =  7.88E+00 mrem  DOSE(1)   3.10E+00 mrem
  INTERR. TIME =  168 hr,  INTAKE =  1.62E-04 mCi  =  3.23E-04% of inj  DOSE(C) =  5.32E+00 mrem  DOSE(1)   2.09E+00 mrem
  INTERR. TIME =  336 hr,  INTAKE =  4.11E-05 mCi  =  8.22E-05% of inj  DOSE(C) =  1.35E+00 mrem  DOSE(1)   5.32E-01 mrem
  INTERR. TIME =  672 hr,  INTAKE =  2.66E-06 mCi  =  5.31E-06% of inj  DOSE(C) =  8.75E-02 mrem  DOSE(1)   3.44E-02 mrem

In-111 WBC  A(c) =  .5  mCi, max concentration, t1/2=
  INTERR. TIME =    3 hr,  INTAKE =  3.10E-03 mCi  =  6.19E-03% of inj  DOSE(C) =  1.02E+02 mrem  DOSE(1)   4.01E+01 mrem
  INTERR. TIME =   24 hr,  INTAKE =  2.79E-03 mCi  =  5.58E-03% of inj  DOSE(C) =  9.19E+01 mrem  DOSE(1)   3.62E+01 mrem
  INTERR. TIME =   48 hr,  INTAKE =  2.48E-03 mCi  =  4.95E-03% of inj  DOSE(C) =  8.16E+01 mrem  DOSE(1)   3.21E+01 mrem
  INTERR. TIME =   96 hr,  INTAKE =  1.95E-03 mCi  =  3.91E-03% of inj  DOSE(C) =  6.43E+01 mrem  DOSE(1)   2.53E+01 mrem
  INTERR. TIME =  120 hr,  INTAKE =  1.73E-03 mCi  =  3.47E-03% of inj  DOSE(C) =  5.71E+01 mrem  DOSE(1)   2.25E+01 mrem
  INTERR. TIME =  168 hr,  INTAKE =  1.37E-03 mCi  =  2.74E-03% of inj  DOSE(C) =  4.50E+01 mrem  DOSE(1)   1.77E+01 mrem
  INTERR. TIME =  336 hr,  INTAKE =  5.95E-04 mCi  =  1.19E-03% of inj  DOSE(C) =  1.96E+01 mrem  DOSE(1)   7.71E+00 mrem
  INTERR. TIME =  672 hr,  INTAKE =  1.13E-04 mCi  =  2.26E-03% of inj  DOSE(C) =  3.72E+00 mrem  DOSE(1)   1.46E+00 mrem

I-123 NaI,  A(o) =  .4  mCi, min concentration, t1/2=
  INTERR. TIME =    3 hr,  INTAKE =  1.03E-02 mCi  =  2.58E+00% of inj  DOSE(C) =  6.11E+01 mrem  DOSE(1)   2.20E+01 mrem
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INTERR. TIME =	24 hr,	INTAKE =	8.45E-04 mCi	=	2.11E-01% of inj	DOSE(0) =	5.00E+00 mrem	DOSE(1) =	3.44E+00 mrem		
INTERR. TIME =	48 hr,	INTAKE =	4.84E-05 mCi	=	1.21E-02% of inj	DOSE(0) =	2.87E-01 mrem	DOSE(1) =	1.97E-01 mrem		
INTERR. TIME =	96 hr,	INTAKE =	1.59E-07 mCi	=	3.98E-05% of inj	DOSE(0) =	9.42E-04 mrem	DOSE(1) =	6.48E-04 mrem		
INTERR. TIME =	120 hr,	INTAKE =	9.12E-09 mCi	=	2.28E-06% of inj	DOSE(0) =	5.40E-05 mrem	DOSE(1) =	3.71E-05 mrem		
INTERR. TIME =	168 hr,	INTAKE =	3.00E-11 mCi	=	7.49E-09% of inj	DOSE(0) =	1.77E-07 mrem	DOSE(1) =	1.22E-07 mrem		
INTERR. TIME =	336 hr,	INTAKE =	0.00E-00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
INTERR. TIME =	672 hr,	INTAKE =	0.00E-00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
I-123 NaI, A(o) =	.4 mCi, max concentration, t1/2:										
INTERR. TIME =	3 hr,	INTAKE =	1.08E-02 mCi	=	2.70E+00% of inj	DOSE(0) =	6.40E+01 mrem	DOSE(1) =	4.40E+01 mrem		
INTERR. TIME =	24 hr,	INTAKE =	8.86E-04 mCi	=	2.22E-01% of inj	DOSE(0) =	5.25E+00 mrem	DOSE(1) =	3.61E+00 mrem		
INTERR. TIME =	48 hr,	INTAKE =	5.08E-05 mCi	=	1.27E-02% of inj	DOSE(0) =	3.01E-01 mrem	DOSE(1) =	2.07E-01 mrem		
INTERR. TIME =	96 hr,	INTAKE =	1.67E-07 mCi	=	4.17E-05% of inj	DOSE(0) =	9.88E-04 mrem	DOSE(1) =	6.79E-04 mrem		
INTERR. TIME =	120 hr,	INTAKE =	9.56E-09 mCi	=	2.39E-06% of inj	DOSE(0) =	5.66E-05 mrem	DOSE(1) =	3.89E-05 mrem		
INTERR. TIME =	168 hr,	INTAKE =	3.14E-11 mCi	=	7.85E-09% of inj	DOSE(0) =	1.86E-07 mrem	DOSE(1) =	1.28E-07 mrem		
INTERR. TIME =	336 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
I-123 OIH, A(o) =	2 mCi, min concentration, t1/2:										
INTERR. TIME =	3 hr,	INTAKE =	1.63E-02 mCi	=	8.13E-01% of inj	DOSE(0) =	3.85E+00 mrem	DOSE(1) =	1.62E+00 mrem		
INTERR. TIME =	24 hr,	INTAKE =	2.60E-04 mCi	=	1.30E-02% of inj	DOSE(0) =	6.16E-02 mrem	DOSE(1) =	2.60E-02 mrem		
INTERR. TIME =	48 hr,	INTAKE =	2.31E-06 mCi	=	1.15E-04% of inj	DOSE(0) =	5.47E-04 mrem	DOSE(1) =	2.31E-04 mrem		
INTERR. TIME =	96 hr,	INTAKE =	1.82E-10 mCi	=	9.08E-09% of inj	DOSE(0) =	4.30E-08 mrem	DOSE(1) =	1.82E-08 mrem		
INTERR. TIME =	120 hr,	INTAKE =	1.61E-12 mCi	=	8.06E-11% of inj	DOSE(0) =	3.82E-10 mrem	DOSE(1) =	1.61E-10 mrem		
INTERR. TIME =	168 hr,	INTAKE =	8.79E-17 mCi	=	4.40E-15% of inj	DOSE(0) =	2.08E-14 mrem	DOSE(1) =	8.78E-15 mrem		
INTERR. TIME =	336 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
I-123 OIH, A(o) =	2 mCi, max concentration, t1/2:										
INTERR. TIME =	3 hr,	INTAKE =	1.24E-01 mCi	=	6.18E+00% of inj	DOSE(0) =	2.93E+01 mrem	DOSE(1) =	1.24E+01 mrem		
INTERR. TIME =	24 hr,	INTAKE =	9.86E-03 mCi	=	4.93E-01% of inj	DOSE(0) =	2.33E+00 mrem	DOSE(1) =	9.85E-01 mrem		
INTERR. TIME =	48 hr,	INTAKE =	5.48E-04 mCi	=	2.74E-02% of inj	DOSE(0) =	1.30E-01 mrem	DOSE(1) =	5.47E-02 mrem		
INTERR. TIME =	96 hr,	INTAKE =	1.69E-06 mCi	=	8.45E-05% of inj	DOSE(0) =	4.00E-04 mrem	DOSE(1) =	1.69E-04 mrem		
INTERR. TIME =	120 hr,	INTAKE =	9.38E-08 mCi	=	4.69E-06% of inj	DOSE(0) =	2.22E-05 mrem	DOSE(1) =	9.37E-06 mrem		
INTERR. TIME =	168 hr,	INTAKE =	2.89E-10 mCi	=	1.45E-08% of inj	DOSE(0) =	6.85E-08 mrem	DOSE(1) =	2.89E-08 mrem		
INTERR. TIME =	336 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
INTERR. TIME =	672 hr,	INTAKE =	0.00E+00 mCi	=	0.00E+00% of inj	DOSE(0) =	0.00E+00 mrem	DOSE(1) =	0.00E+00 mrem		
I-123 mIBG, A(o) =	10 mCi, min concentration, t1/2:										
INTERR. TIME =	3 hr,	INTAKE =	5.41E-02 mCi	=	5.41E-01% of inj	DOSE(0) =	3.20E+02 mrem	DOSE(1) =	2.20E+02 mrem		
INTERR. TIME =	24 hr,	INTAKE =	1.51E-02 mCi	=	1.51E-01% of inj	DOSE(0) =	8.96E+01 mrem	DOSE(1) =	6.16E+01 mrem		
INTERR. TIME =	48 hr,	INTAKE =	3.53E-03 mCi	=	3.53E-02% of inj	DOSE(0) =	2.09E+01 mrem	DOSE(1) =	1.44E+01 mrem		
INTERR. TIME =	96 hr,	INTAKE =	1.92E-04 mCi	=	1.92E-03% of inj	DOSE(0) =	1.14E+00 mrem	DOSE(1) =	7.82E-01 mrem		
INTERR. TIME =	120 hr,	INTAKE =	4.48E-05 mCi	=	4.48E-04% of inj	DOSE(0) =	2.65E-01 mrem	DOSE(1) =	1.82E-01 mrem		
INTERR. TIME =	168 hr,	INTAKE =	2.44E-06 mCi	=	2.44E-05% of inj	DOSE(0) =	1.44E-02 mrem	DOSE(1) =	9.92E-03 mrem		
INTERR. TIME =	336 hr,	INTAKE =	9.15E-11 mCi	=	9.15E-10% of inj	DOSE(0) =	5.42E-07 mrem	DOSE(1) =	3.73E-07 mrem		

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  INTERR. TIME =  672 hr,  INTAKE =  0.00E-00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-123 mIBG,  A(o) =  10  mCi, max concentration, t1/2:
  INTERR. TIME =    3 hr,  INTAKE =  5.41E-02 mCi  =  5.41E-01% of inj  DOSE(0) =  3.20E+02 mrem  DOSE(1) =  3.20E+02 mrem
  INTERR. TIME =   24 hr,  INTAKE =  1.51E-02 mCi  =  1.51E-01% of inj  DOSE(0) =  8.96E+01 mrem  DOSE(1) =  6.16E+01 mrem
  INTERR. TIME =   48 hr,  INTAKE =  3.53E-03 mCi  =  3.53E-02% of inj  DOSE(0) =  2.09E+01 mrem  DOSE(1) =  1.44E+01 mrem
  INTERR. TIME =   96 hr,  INTAKE =  1.92E-04 mCi  =  1.92E-03% of inj  DOSE(0) =  1.14E+00 mrem  DOSE(1) =  7.82E-01 mrem
  INTERR. TIME =  120 hr,  INTAKE =  4.48E-05 mCi  =  4.48E-04% of inj  DOSE(0) =  2.65E-01 mrem  DOSE(1) =  1.82E-01 mrem
  INTERR. TIME =  168 hr,  INTAKE =  2.44E-06 mCi  =  2.44E-05% of inj  DOSE(0) =  1.44E-02 mrem  DOSE(1) =  9.92E-03 mrem
  INTERR. TIME =  336 hr,  INTAKE =  9.15E-11 mCi  =  9.15E-10% of inj  DOSE(0) =  5.42E-07 mrem  DOSE(1) =  3.73E-07 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-125 OIH,  A(o) =  .01  mCi, min concentration, t1/2:
  INTERR. TIME =    3 hr,  INTAKE =  2.52E-04 mCi  =  2.52E+00% of inj  DOSE(0) =  2.24E-01 mrem  DOSE(1) =  9.94E-02 mrem
  INTERR. TIME =   24 hr,  INTAKE =  1.20E-05 mCi  =  1.20E-01% of inj  DOSE(0) =  1.07E-02 mrem  DOSE(1) =  4.31E-03 mrem
  INTERR. TIME =   48 hr,  INTAKE =  3.72E-07 mCi  =  3.72E-03% of inj  DOSE(0) =  3.30E-04 mrem  DOSE(1) =  1.33E-04 mrem
  INTERR. TIME =   96 hr,  INTAKE =  3.55E-10 mCi  =  3.55E-06% of inj  DOSE(0) =  3.15E-07 mrem  DOSE(1) =  1.27E-07 mrem
  INTERR. TIME =  120 hr,  INTAKE =  1.10E-11 mCi  =  1.10E-07% of inj  DOSE(0) =  9.75E-09 mrem  DOSE(1) =  3.94E-09 mrem
  INTERR. TIME =  168 hr,  INTAKE =  1.05E-14 mCi  =  1.05E-10% of inj  DOSE(0) =  9.32E-12 mrem  DOSE(1) =  3.77E-12 mrem
  INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-125 OIH,  A(o) =  .0_  mCi, max concentration, t1/2:
  INTERR. TIME =    3 hr,  INTAKE =  2.52E-04 mCi  =  2.52E+00% of inj  DOSE(0) =  2.24E-01 mrem  DOSE(1) =  9.04E-02 mrem
  INTERR. TIME =   24 hr,  INTAKE =  1.20E-05 mCi  =  1.20E-01% of inj  DOSE(0) =  1.07E-02 mrem  DOSE(1) =  4.31E-03 mrem
  INTERR. TIME =   48 hr,  INTAKE =  3.72E-07 mCi  =  3.72E-03% of inj  DOSE(0) =  3.30E-04 mrem  DOSE(1) =  1.33E-04 mrem
  INTERR. TIME =   96 hr,  INTAKE =  3.55E-10 mCi  =  3.55E-06% of inj  DOSE(0) =  3.15E-07 mrem  DOSE(1) =  1.27E-07 mrem
  INTERR. TIME =  120 hr,  INTAKE =  1.10E-11 mCi  =  1.10E-07% of inj  DOSE(0) =  9.75E-09 mrem  DOSE(1) =  3.94E-09 mrem
  INTERR. TIME =  168 hr,  INTAKE =  1.05E-14 mCi  =  1.05E-10% of inj  DOSE(0) =  9.32E-12 mrem  DOSE(1) =  3.77E-12 mrem
  INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-131 OIH,  A(o) =  .3  mCi, min concentration, t1/2:
  INTERR. TIME =    3 hr,  INTAKE =  2.62E-03 mCi  =  8.73E-01% of inj  DOSE(0) =  2.91E+00 mrem  DOSE(1) =  1.16E+00 mrem
  INTERR. TIME =   24 hr,  INTAKE =  3.26E-06 mCi  =  1.09E-03% of inj  DOSE(0) =  3.61E-03 mrem  DOSE(1) =  1.45E-03 mrem
  INTERR. TIME =   48 hr,  INTAKE =  1.56E-09 mCi  =  5.19E-07% of inj  DOSE(0) =  1.73E-06 mrem  DOSE(1) =  6.91E-07 mrem
  INTERR. TIME =   96 hr,  INTAKE =  3.48E-16 mCi  =  1.16E-13% of inj  DOSE(0) =  3.86E-13 mrem  DOSE(1) =  1.54E-13 mrem
  INTERR. TIME =  120 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
  INTERR. TIME =  168 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
  INTERR. TIME =  336 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem
  INTERR. TIME =  672 hr,  INTAKE =  0.00E+00 mCi  =  0.00E+00% of inj  DOSE(0) =  0.00E+00 mrem  DOSE(1) =  0.00E+00 mrem

I-131 OIH,  A(o) =  .3  mCi, max concentration, t1/2:
  INTERR. TIME =    3 hr,  INTAKE =  1.50E-02 mCi  =  4.99E+00% of inj  DOSE(0) =  1.66E+01 mrem  DOSE(1) =  6.65E+00 mrem
  INTERR. TIME =   24 hr,  INTAKE =  1.23E-03 mCi  =  4.09E-01% of inj  DOSE(0) =  1.36E+00 mrem  DOSE(1) =  5.45E-01 mrem
  INTERR. TIME =   48 hr,  INTAKE =  7.05E-05 mCi  =  2.35E-02% of inj  DOSE(0) =  7.82E-02 mrem  DOSE(1) =  3.13E-02 mrem
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INTERR. TIME = 96 hr,	INTAKE = 2.32E-07 mCi = 7.73E-05% of inj	DOSE(0) = 2.58E-04 mrem	DOSE(1) = [illegible] mrem
INTERR. TIME = 120 hr,	INTAKE = 1.33E-08 mCi = 4.44E-06% of inj	DOSE(0) = 1.48E-05 mrem	DOSE(1) = 5.91E-06 mrem
INTERR. TIME = 168 hr,	INTAKE = 4.38E-11 mCi = 1.46E-08% of inj	DOSE(0) = 4.86E-08 mrem	DOSE(1) = [illegible] mrem
INTERR. TIME = 336 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 672 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem

Tc-99m DTPA Aer, A(o) = 1 mCi, min concentration, t1/2:

INTERR. TIME = 3 hr,	INTAKE = 9.00E-05 mCi = 9.00E-03% of inj	DOSE(0) = 2.50E-02 mrem	DOSE(1) = 1.07E-02 mrem
INTERR. TIME = 24 hr,	INTAKE = 8.52E-07 mCi = 8.52E-05% of inj	DOSE(0) = 2.36E-04 mrem	DOSE(1) = 1.01E-04 mrem
INTERR. TIME = 48 hr,	INTAKE = 1.14E-09 mCi = 1.14E-07% of inj	DOSE(0) = 3.15E-06 mrem	DOSE(1) = 4.90E-07 mrem
INTERR. TIME = 96 hr,	INTAKE = 9.79E-14 mCi = 9.79E-12% of inj	DOSE(0) = 2.72E-11 mrem	DOSE(1) = 1.16E-11 mrem
INTERR. TIME = 120 hr,	INTAKE = 4.76E-16 mCi = 4.76E-14% of inj	DOSE(0) = 1.32E-13 mrem	DOSE(1) = 5.64E-14 mrem
INTERR. TIME = 168 hr,	INTAKE = 0.00E-00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 336 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 672 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem

Tc-99m DTPA Aer, A(o) = 1 mCi, max concentration, t1/2:

INTERR. TIME = 3 hr,	INTAKE = 1.69E-03 mCi = 1.69E-01% of inj	DOSE(0) = 4.70E-01 mrem	DOSE(1) = 2.00E-01 mrem
INTERR. TIME = 24 hr,	INTAKE = 9.25E-05 mCi = 9.25E-03% of inj	DOSE(0) = 2.57E-02 mrem	DOSE(1) = 1.10E-02 mrem
INTERR. TIME = 48 hr,	INTAKE = 3.34E-06 mCi = 3.34E-04% of inj	DOSE(0) = 9.26E-04 mrem	DOSE(1) = 3.95E-04 mrem
INTERR. TIME = 96 hr,	INTAKE = 4.35E-09 mCi = 4.35E-07% of inj	DOSE(0) = 1.21E-06 mrem	DOSE(1) = 5.15E-07 mrem
INTERR. TIME = 120 hr,	INTAKE = 1.57E-10 mCi = 1.57E-08% of inj	DOSE(0) = 4.35E-08 mrem	DOSE(1) = 1.86E-08 mrem
INTERR. TIME = 168 hr,	INTAKE = 2.04E-13 mCi = 2.04E-11% of inj	DOSE(0) = 5.67E-11 mrem	DOSE(1) = 2.42E-11 mrem
INTERR. TIME = 336 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 672 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem

Tc-99m MAG3, A(o) = 10 mCi, min concentration, t1/2:

INTERR. TIME = 3 hr,	INTAKE = 1.29E-03 mCi = 1.29E-02% of inj	DOSE(0) = 1.52E-01 mrem	DOSE(1) = 6.66E-02 mrem
INTERR. TIME = 24 hr,	INTAKE = 1.22E-05 mCi = 1.22E-04% of inj	DOSE(0) = 1.44E-03 mrem	DOSE(1) = 6.30E-04 mrem
INTERR. TIME = 48 hr,	INTAKE = 5.92E-08 mCi = 5.92E-07% of inj	DOSE(0) = 7.00E-06 mrem	DOSE(1) = 3.06E-06 mrem
INTERR. TIME = 96 hr,	INTAKE = 1.40E-12 mCi = 1.40E-11% of inj	DOSE(0) = 1.66E-10 mrem	DOSE(1) = 7.25E-11 mrem
INTERR. TIME = 120 hr,	INTAKE = 6.80E-15 mCi = 6.80E-14% of inj	DOSE(0) = 8.05E-13 mrem	DOSE(1) = 3.52E-13 mrem
INTERR. TIME = 168 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 336 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 672 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem

Tc-99m MAG3, A(o) = 10 mCi, max concentration, t1/2:

INTERR. TIME = 3 hr,	INTAKE = 2.39E-02 mCi = 2.39E-01% of inj	DOSE(0) = 2.83E+00 mrem	DOSE(1) = 1.24E+00 mrem
INTERR. TIME = 24 hr,	INTAKE = 1.31E-03 mCi = 1.31E-02% of inj	DOSE(0) = 1.55E-01 mrem	DOSE(1) = 6.77E-02 mrem
INTERR. TIME = 48 hr,	INTAKE = 4.72E-05 mCi = 4.72E-04% of inj	DOSE(0) = 5.58E-03 mrem	DOSE(1) = 2.44E-03 mrem
INTERR. TIME = 96 hr,	INTAKE = 6.14E-08 mCi = 6.14E-07% of inj	DOSE(0) = 7.27E-06 mrem	DOSE(1) = 3.18E-06 mrem
INTERR. TIME = 120 hr,	INTAKE = 2.22E-09 mCi = 2.22E-08% of inj	DOSE(0) = 2.62E-07 mrem	DOSE(1) = 1.15E-07 mrem
INTERR. TIME = 168 hr,	INTAKE = 2.89E-12 mCi = 2.89E-11% of inj	DOSE(0) = 3.42E-10 mrem	DOSE(1) = 1.50E-10 mrem
INTERR. TIME = 336 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem
INTERR. TIME = 672 hr,	INTAKE = 0.00E+00 mCi = 0.00E+00% of inj	DOSE(0) = 0.00E+00 mrem	DOSE(1) = 0.00E+00 mrem

ATTACHMENT 4

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

ON

AMENDMENTS OF 10 CFR PARTS 20 AND 35 ON "CRITERIA FOR THE RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL"

Stewart Schneider and Stephen A. McGuire
Office of Nuclear Regulatory Research
U. S. Nuclear Regulatory Commission
June, 1995

I. THE PROPOSED ACTION

The Nuclear Regulatory Commission (NRC) is amending its regulations in 10 CFR Parts 20 and 35 concerning criteria for the release of patients administered radioactive material. The amendments permit licensees to authorize the release from licensee control of patients administered radiopharmaceuticals or permanent implants only if the dose to total decay to an individual exposed to the released patient is not likely to exceed 5 millisieverts (0.5 rem).

II. NEED FOR THE RULEMAKING ACTION

This action is necessary to respond to three petitions for rulemaking. The petitions were submitted by Dr. Carol S. Marcus, by the American College of Nuclear Medicine (ACNM), and by the American Medical Association (AMA).

NRC's current patient release criteria in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants," are as follows: "(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either: (1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or (2) The activity in the patient is less than 30 millicuries; (b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of one 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 a dose limit of 1 millisievert (0.1 rem) (total effective dose equivalent) for members of the public in 10 CFR 20.1301(a). When 10 CFR part 20 was issued, there was no discussion in the supplemental information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients.

Because some licensees were uncertain about what effect the revised 10 CFR part 20 would have on patient release criteria, three petitions 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. The petition requested the NRC to amend the revised part 20 and 10 CFR 35.75 to raise the annual radiation dose limits to members of the public from 1 millisievert (0.1 rem) to 5 millisieverts (0.5 rem) from patients administered radioactive materials. 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 for a similar petition for rulemaking (PRM-35-10) from the 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, the ACNM submitted two letters dated September 24, 1991, and October 8, 1991, on the issues in their petition. On July 26, 1994 (59 FR 37950) the NRC published in the Federal Register a petition from the AMA requesting that patient release be regulated by Part 35 rather than Part 20.

On June 15, 1994, the NRC published a proposed rule on criteria for the release of patients administered radioactive material in response to the petitions (59 FR 30724). The Federal Register Notice for the proposed rule discussed the public comment letters received on the first two petitions. Three comment letters, each supporting the petition, were received on the third petition (PRM-35-11), but these letters 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.

III. ALTERNATIVES CONSIDERED

To evaluate the issues raised by the petitioners and the members of the public who commented on the requests made by the petitioners and the proposed rule, the NRC has determined that the following alternatives merit evaluation:

- Alternative 1: 1 millisievert (0.1 rem) total effective dose equivalent

  In this alternative, the 1 millisievert (0.1 rem) per year dose limit in 10 CFR 20.1301(a) is evaluated as the controlling criteria for determining when a patient may be released from the licensee's control.

- Alternative 2: < 1,110 megabecquerels (30 millicuries) or < 0.05 millisievert (5 millirems)/hr at 1 meter

  In this alternative, the existing patient release criteria in

10 CFR 35.75 are evaluated as the controlling requirement for determining when a patient may be released.

- Alternative 3: 5 millisieverts (0.5 rem) total effective dose equivalent)

In this alternative, a dose limit of 5 millisieverts (0.5 rem) for determining when a patient may be released is evaluated.

IV. ENVIRONMENTAL IMPACTS OF THE PROPOSED ACTION AND THE ALTERNATIVES

The alternatives were evaluated in the regulatory analysis done for the rulemaking (*Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Materials, Final Report*, Stewart Schneider and Stephen A. McGuire, NRC report NUREG-1492, 1995).

The regulatory analysis found that there would be no need to retain patients due to any diagnostic procedure under any of the alternatives. Only about 62,000 therapeutic procedures per year, mostly using iodine-131, would be potentially affected. The costs of the alternatives for the affected therapeutic procedures are presented in Table 1. For details of how the results were calculated, the regulatory analysis should be consulted.

Table 1 Impacts of Alternatives 1, 2, and 3

			Cost Estimates			
Alternative	Collective Dose (person-rem)	Hospital Retention (days)	Hospitalization cost $ (millions)	Value of lost time $ (millions)	Records & Instructions $ (millions)	Psychological cost (relative)
1	18,400	140,000	140	8.4	0	High
2	51,400	20,000	20	1.2	0	Moderate
3	60,400	10,000	10	0.6	0.3	Low

As set forth in more detail in the Regulatory Analysis, Alternative 3 is favored for the following reasons:

1. All of the Alternatives are acceptable according to generally accepted radiation protection principles, as those expressed by NRC, NCRP, and ICRP, as discussed in Section 4.4 of the Regulatory Analysis.

2. Alternative 1 is considerably more expensive to the public compared to Alternative 2 (the status quo) or Alternative 3. Even neglecting the psychological costs, which have not been expressed in dollar terms, the additional cost of Alternative 1 relative to Alternative 2 is about $126,000,000 per year, mostly in increased national health care costs. The value of the dose savings at a value of $1,000 per person rem is

$33,000,000 per year. In view of this, Alternative 1 may be dismissed.

3. Alternative 3 relative to Alternative 2 has a value of $10,300,000 per year, mostly in lower health care costs at a collective dose cost of $9,00,000 per year. Alternative 3 also has psychological benefits to patients and their families. Thus, Alternative 3 appears cost effective in comparison with Alternative 2.

4. Basing the patient release criteria in 10 CFR 35.75 on the dose to individuals exposed to a patient provides a consistent, scientific basis for such decisions that treats all radionuclides on a risk-equivalent basis. The dose delivered by an initial activity of 30 millicuries or a dose rate at 1 meter of 5 millirems per hour varies greatly from one radionuclide to another. Thus, while the values in the current 10 CFR 35.75 may be appropriate for iodine-131, they are too high for some other radionuclides and too low for others.

5. A dose-based rule no longer restricts patient release to a specific activity, and therefore would permit the release of patients with activities that are greater than currently allowed. This is especially true when case-specific factors are evaluated to more accurately assess the dose to other individuals. For the case of thyroid cancer, in those cases occasional where multiple administrations in a year of 1,110 millisieverts (30 millicuries) or less of iodine-131 are now administered to a patient, it may be possible to give all of the activity in a single administration. This would reduce the potential for repeated exposures to hospital staff and to those providing care to the released patient. Additionally, this would provide physicians with the flexibility to not have to fractionate doses to avoid hospitalization to meet the current requirements, which may lead to a more effective treatment.

6. Shorter hospital stays provide emotional benefits to patients and their families. Allow-ing 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.

For the purpose of evaluating the environmental impact of the proposed action, the proposed action (Alternative 3) is compared to the impact of the existing patient release criteria, the status quo (Alternative 2). The impacts can be seen in Table 1 above. The estimated change in the collective dose is balanced by decreased hospitalization costs and psychological benefits to the patient and the patient's family. The environmental impact of the preferred Alternative 3 is not considered significant because the change is small relative to the existing impact (under Alternative 2) and the change is balanced by the benefits.

V. FINDING OF NO SIGNIFICANT IMPACT

The Commission 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 Commission believes these amendments would result in benefits for patient care while continuing to adequately protect public health and safety. As can be seen in Table 1, there will be no significant change in radiation exposure to the public or to the environment due to the proposed Alternative 3 beyond the exposures currently resulting from the medical use of radioactive material (Alternative 2).

VI. LIST OF AGENCIES AND PERSONS CONSULTED

The NRC has held public meetings concerning the release criteria for patients receiving radioactive material for medical use. Appropriate suggestions from the meetings have been incorporated in the proposed amendments. The following table lists the date, location, and the groups represented at each meeting.

Public Meetings Held

Date	Location	Groups Represented
07/15/92 07/16/92	Atlanta, GA	Agreement States: AL, AR, AZ, CA, CO, FL, GA, IL, KS, KY, LA, MD, NC, ND, NE, NH, NV, NY, OR, SC, TX, UT, WA, and NY City
10/24/92 10/25/92 10/26/92 10/27/92	Tempe, AZ	Agreement States: AL, AR, AZ, CA, CO, FL, GA, IA, IL, KY, LA, MD, MS, NC, ND, NE, NH, NV, OR, RI, SC, TN, TX, UT, WA, and NY City
10/24/94 10/25/94	Portland, ME	Agreement States: AL, AR, IL, KS, LA, NH, NV, NY, PA, RI, TX, UT, WA, and NY City
10/22/92 10/23/92	Rockville, MD	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
05/03/93 05/04/93	Bethesda, MD	
11/01/93	Reston, VA	
11/18/94	Rockville, MD	
05/12/95	Rockville, MD	

Much of the statistical and technical information required for this assessment is not available in the open literature. In such instances, information was obtained directly from technical experts. The following individuals are acknowledged for their cooperation and contribution of technical information and data:

R. Atcher, PhD, Radiation and Cellular Oncology Department., University of Chicago, Chicago, IL

D. Flynn, M.D., (NRC Advisory Committee on Medical Use of Isotopes) Massachusetts General Hospital, Boston, MA

W.R. Hendee, PhD, Dean of Research, Medical College of Wisconsin, Milwaukee, WI

C. Jacobs, President, Theragenics, Norcross, GA

F.A. Mettler, M.D., Department of Radiology, University of New Mexico, School of Medicine, Albuquerque, NM

K.L. Miller, CHP, Professor of Radiology and Director, Division of Health Physics, Milton Hershey Medical Center, Hershey, PA

R. Nath, PhD, Professor of Yale University, School of Medicine, and President of the American Association of Nuclear Physics, New Haven, CT

M.P. Nunno, PhD, CHP, Cooper Hospital, University Medical Center, Camden, NJ

P. Paras, PhD, Food and Drug Administration, Center for Devices and Radiology Health, Rockville, MD

M. Pollycove, M.D., Visiting Medical Fellow, U.S. Nuclear Regulatory Commission, Rockville, MD

G.E. Powers, PhD, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Rockville, MD

M. Rosenstein, PhD, Food and Drug Administration, Center for Devices and Radiology Health, Rockville, MD

B.A. Siegel, M.D., (Chairman, NRC Advisory Committee on Medical Use of Isotopes) Director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology, Washington University Medical Center, St. Louis, MO

J. St.Germain, Radiation Safety Officer, Memorial Sloan Kettering, New York City, NY

M.G. Stabin, PhD, CHP, Radiation Internal Dose Information Center, Oak Ridge Institute for Science and Education, Oak Ridge, TN

D. Steidley, PhD, CHP, Medical Health Physicist, Department of Oncology, St. Barnabas Medical Center, Livingston, NJ

J. Stubb, PhD, Radiation Internal Dose Information Center, Oak Ridge Institute for Science and Education, Oak Ridge, TN

K. Suphanpharian, PhD, President, Best Industries, Springfield, VA

R.E. Toohey, PhD, Director, Radiation Internal Dose Information Center, Oak Ridge Institute for Science and Education, Oak Ridge, TN

ATTACHMENT 5

DRAFT CONGRESSIONAL LETTER

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a final amendment to 10 CFR Parts 20 and 35 dealing with criteria for the release of patients administered radioactive materials. Roughly 8 to 9 million medical diagnostic and therapeutic administrations of radioactive material are performed in the United States each year.

The rule is largely in response to three petitions for rulemaking that were submitted by the medical community because of concerns that the NRC's recent amendments of its regulations in Part 20, "Standards for Protection Against Radiation," would require medically unnecessary hospitalization of patients administered radioactive materials for the treatment of disease and would thus increase national health care costs.

The rule makes it clear that the release of patients administered radioactive materials continues to be regulated by the requirements in NRC's Part 35, "Medical Use of Byproduct Material." While the comments of the medical community on the proposed rule were generally supportive, they objected strongly to one of the recordkeeping requirements contained in the proposed rule. Upon reconsideration, the NRC has deleted the recordkeeping requirement in question after concluding that the records were not necessary to provide for adequate protection of public health and safety.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Representative _____

Attachment 5

ATTACHMENT 6

NRC REVISES REGULATIONS ON RELEASE

OF PATIENTS ADMINISTERED BYPRODUCT MATERIAL

The Nuclear Regulatory Commission is amending its regulations governing the release of patients from a hospital or other licensed medical facility after they have received radioactive material for treatment or diagnostic purposes. The revisions respond to three petitions received on this subject.

Radioactive pharmaceuticals or radioactive implants are administered to approximately 8 to 9 million patients in the United States each year for diagnosis or treatment of disease. These patients can expose other persons around them to radiation until the radioactive material has been excreted from their bodies or has become less intense due to radioactive decay.

Under the final rule, licensees may not authorize the release of patients if the estimated dose, to the individual likely to receive the highest dose from exposure to the patient, would be greater than 500 millirems in any one year. (Typical natural background radiation in the United States is 300 millirems per year.) The new criteria are consistent with recommendations of the International Commission on Radiological Protection.

Under current NRC medical use regulations, licensees are not permitted to authorize the release of patients to whom nuclear material has been administered until either (1) the measured dose rate from the patient is less than 5 millirems per hour at a distance of 1 meter or (2) the radiopharmaceutical content of the patient is less than 30 millicuries.

In addition, the Commission's radiation protection standards limit the dose to individual members of the public from an NRC-licensed operation to 100 millirems per year. However, when these were issued, there was no

consideration of how they would be applied to the release of patients.

In adopting the radiation protection standards, the Commission did not intend them to supersede the medical use regulations. The final rule therefore amends the general radiation protection regulations to exclude doses to individuals exposed to released patients. Release of patients containing radioactivity is instead governed by the more explicit requirements of revised medical use regulations, which include, in addition to the 500-millirem per year limit, a requirement that, if the annual dose to an individual exposed to the patient is likely to exceed 100 millirems, the licensee must provide the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable.

The revisions partially grant three petitions for rulemaking on criteria for release of patients who have been administered radioactive material. On June 12, 1991, March 9, 1992, May 18, 1992, and July 26, 1994, the NRC published Federal Register notices concerning receipt of the petitions from Dr. Carol S. Marcus, the American College of Nuclear Medicine and the American Medical Association.

A proposed rule on this subject was published in the Federal Register on June 15, 1994. The final rule reflects public comments received.

The rule will be effective _____ (90 days after publication of a Federal Register notice on _____).

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ATTACHMENT 7

[7590-01]

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35).

1. Type of submission, new, revised, or extension: Revision.

2. The title of the information collection: Final amendments to 10 CFR 35.75, "Criteria for the Release of Individuals Administered Radioactive Material."

3. The form number if applicable: Not applicable.

4. How often is the collection required: On occasion; when the release of a patient is based on other than standard assumptions or requires interruption of breast feeding to meet the 5-millisievert (0.5 rem) dose limit.

5. Who will be required or asked to report: Medical licensees administering radiopharmaceuticals and permanent implants and releasing patients under the provisions of 10 CFR 35.75.

6. An estimate of the number of respondents: Approximately 1,350 NRC and Agreement State licensees.

7. An estimate of the number of hours annually needed to complete the requirement or request: 21,723 hours (includes NRC and Agreement State licensees).

8. The average annual burden per respondent: 16 hours.

9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable.

10. Abstract: The Nuclear Regulatory Commission (NRC) is amending the criteria for release of individuals administered radioactive material under 10 CFR Part 35. The amendment requires the licensee to provide the patient with written instructions on how to maintain doses to other

individuals as low as reasonably achievable if the dose to an individual exposed to the patient is likely to exceed 0.1 rem and to maintain a record of the basis for the release if the release is authorized using other than standard assumptions or requires interruption of breast feeding. These requirements are necessary to ensure adequate protection of the public health and safety and that doses to other individuals are maintained as low a reasonably achievable.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Comments and questions can be directed by mail to the OMB reviewer:

Troy Hillier
Office of Information and Regulatory Affairs
(3150-0010)
NEOB-10202
Office of Management and Budget
Washington, DC 20503

Comments may also be communicated by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415-7230.

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

For the Nuclear Regulatory Commission.

_____

Gerald F. Cranford, Designated Senior Official for Information Resources Management.

OMB SUPPORTING STATEMENT FOR 10 CFR PART 35,
"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 annual dose of 5 millisieverts (0.5 rem) to an individual member of the public, requires written instruction on how to maintain doses to other as low as is reasonably achievable if the dose to an individual exposed to a released patient is likely to exceed 0.1 rem, and establishes recordkeeping requirements when the release is authorized using other than standard assumptions or requires interruption of breast feeding.

1. Need for 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). 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 need to interrupt breast-feeding, 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 verbal 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 three years, a record of the basis for the release if the release is authorized using other than standard assumptions. 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 in paragraph (a) were met.

Paragraph (d) of this section requires licensees to maintain for 3 years, a record of the basis for the release of a breast-feeding woman if the administered activity would be likely to result in a total effective dose equivalent to the breast-feeding child exceeding 5 millisieverts (0.5 rem), assuming no interruption of breast feeding. The record would generally state that instructions were given to interrupt breast-feeding. The records are necessary so that the NRC inspector can verify either that a woman was not breast-feeding or that instructions were given to the breast-feeding woman to inform her of the need to interrupt or cease 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 of Less Frequent Collection

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. Consultation 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 and May, 1995. The Agreement States and the ACMUI were generally supportive of the approach in the rule.

9. Confidentiality of Information

No information normally considered confidential is requested.

10. Justification of Sensitive Information

No sensitive information is requested under these regulations.

11. Estimated Annual 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 $133 per hour, the annual cost to NRC is $59,850 annually. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Part 171.

12. Estimate of Burden

The total burden to provide instructions and maintain release records is estimated to be about 16 hours per licensee annually, or a total of approximately 21,723 hours annually for all 1,350 NRC and Agreement State medical use of byproduct material licensees. See attached table for details.

13. Reasons for Change in Burden

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 16 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.

14. Publication for Statistical Use

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

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 Burder Hours
35.75(b)			
exceeding 0.1 rem	10,000	0.17	10,333
breast-feeding mothers	27,000[1]	0.17	4,590

Recordkeeping Requirements

Section	No. of Procedures Reguiring Records Per Year	Hours Per Licensee	Total Burden Hours
35.75(c)	10,000[2]	0.50	5,000
35.75(d)	7,200[3]	0.25	1,800

Total burden = 21,723 hours or 16 hours per licensee (21,723 ÷ 1,350) at a cost of $2,889,159 ($133 x 21,723).

[1]8,000,000 administrations x 0.5 fraction of the administrations potentially requiring instructions x 0.136 fraction of females of child bearing age (from Table 4.3 of NUREG-1492) x 0.05 breast-feeding = 27,000.

[2]Iodine treatment for thyroid cancer patients.

[3](60,000 iodine + 1,000,000 Tc-99m pertechnetate) x 0.136 fraction of females of child bearing age x 0.05 breast feeding = 7,200.

b. A final regulatory analysis will be available in the Public Document Room (Attachment 3);

c. A final environmental assessment and a finding of no significant impact have been prepared (Attachment 4);

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

e. The rule contains information collection requirements that are subject to review by OMB. Upon Commission approval, the OMB supporting statement (Attachment 7) will be submitted to OMB for approval.

f. The appropriate Congressional Committees will be informed (Attachment 5);

g. A public announcement will be issued (Attachment 6); and

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

James M. Taylor
Executive Director
for Operations

Attachments: As Stated (7)

RECORD NOTE: A draft of the final rule was sent to OIG for information on May 31, 1995.

Offc:	RPHEB:DRA	RPHEB:DRA	RPHEB:DRA	D:DRA:RES	D:NMSS	D:SP	ADM
Name:	SSchneider	SMcGuire	JGlenn	BMorris	CPaperiello	RBangart	WOliu
Date:	6/8/95	6/18/95	6/19/95	6/14/95	6/13/95	6/13/95	6/15/95
				attached	attached		attached

Offc:	D:IRM	GC	OGC	D:OE	D:RES	EDO
Name:	GCranford	PScroggins	MMalsch	JLieberman	DMorrison	JMTaylor
Date:	6/17/95	6/18/95	6/18/95	6/16/95	6/14/95	/95
	attached	attached	attached	attached		

OFFICIAL RECORD COPY