May 8, 1996

FOR: The Commissioners

FROM: James M. Taylor /s/
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(1):

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.

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

Some licensees were uncertain about the effect that the revised 10 CFR Part 20 would have on patient release criteria, and three petitions for rulemaking were received on the issue.(2)

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.

The longer term resolution was to address this issue through rulemaking. A proposed rule was transmitted to the Commission in SECY-94-054 and responses to questions raised by the Office of the Inspector General are contained in SECY-94-054A. In an SRM dated May 11, 1994, the Commission directed the staff to proceed with the proposed rule. As a result, a draft rule was published for comment on June 15, 1994 (59 FR 30724), and this paper transmits the final rule for Commission approval.

DISCUSSION:

The final rule (Attachment 1) takes into consideration the recommendations of 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 63 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 October 18 and 19, 1995.

The following summarizes the main features of the amendments:

1. The major changes to the final rulemaking are: (1) significant expansion of the discussion on breast-feeding in the Statement of Considerations and the regulatory analysis and (2) explicit use of the term "breast-feeding" in the final rule text to make it clear that breast-feeding women are a class of patients requiring additional records and instructions to limit the dose to the breast-feeding child. The subject of breast-feeding was mentioned in the Statement of Considerations to the proposed rule but not in the proposed rule text.

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

3. 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 of 5 millisieverts (0.5 rem), excluding background or any occupational exposure, to an individual exposed to the patient.

   Specifying the release criterion in terms of radiation dose requires that the NRC provide an acceptable method that relates the quantity of radioactivity administered to that dose. That relationship will be included in a regulatory guide. A working draft of that guide is attached (Attachment 2); the staff is still reviewing the guide, but will publish it in final form before the final rule becomes effective.

   The guide presents two methods to relate dose to quantity of radioactivity administered. The first method is 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 staff anticipates that nearly all patients will be released based on the default table of activities.

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 patient's 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 or allowed with use of the default table.

The authorization to release a patient is based on the licensee's determination that the total effective dose equivalent to an individual from the released patient is not likely to exceed 5 millisieverts (0.5 rem). The dose to the breast-feeding child from breast-feeding is not necessarily a criterion for release since it can be controlled by giving the woman guidance on the interruption of breast-feeding, as required by the amendments (see No. 5).

Overall, a substantial majority of all comments supported an explicit dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients released with radioactive material in their bodies. In addition, ACMUI and the Agreement States supported the criterion based on a dose limit. A few commenters who thought that the present criteria were working well and were adequate opposed allowing the release of patients with quantities of radioactive material greater than that permitted under the current regulations.

4. 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. This requirement was proposed so that records would be available to calculate the dose if a patient received multiple administrations in a year.

   This proposed recordkeeping requirement met a great deal of opposition. Commenters were especially concerned about having to retrieve records of previous administrations, sometimes from another medical facility. Upon reconsideration, it was decided to delete this requirement because a review of nuclear medicine procedures indicated that there was no significant likelihood of exceeding a 5-millisievert (0.5-rem) annual dose because of multiple administrations.

   In place of the deleted recordkeeping requirement, the final rule contains requirements to maintain: (1) a record for the basis of the release for a limited number of certain radiopharmaceutical administrations (e.g., therapeutic administrations of iodine-131) and (2) a record that instructions were provided to a breast-feeding woman if the administered activity could result in a total effective dose equivalent to the breast-feeding child exceeding 5 millisieverts (0.5 rem) if the woman did not interrupt breast-feeding. The requirements (in 10 CFR 35.75(c) and (d)) would affect about 20,000 of the 8 to 9 million administrations done annually.

5. The amendments require that the patient be given instructions, including written instructions, on how to maintain doses to others as low as is 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, although a few did not think that instructions should necessarily have to be written.

   The proposed rule had a requirement to provide instructions which would include guidance on breast-feeding children, 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 final rule requires that guidance regarding interruption of breast-feeding and consequences be provided if the released individual may be breast-feeding an infant or child and the total effective dose equivalent is likely to exceed 1 millisievert (0.1 rem). The regulatory guide will contain interruption periods that keep the dose from breast-feeding to less than 1 millisievert (0.1 rem). The purpose of describing the consequences is so that women will understand that breast-feeding after an administration of certain radionuclides could cause harm (e.g., iodine-131 could harm the child's thyroid). In other cases, the guidance could simply address avoidance of any unnecessary radiation exposure to the child from breast-feeding. The regulatory analysis indicates the basis for selecting the option of enhancing communications and instructions to breasting-feeding women.

6. The amendments make it clear that the limit on dose in unrestricted areas presented in 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.

The final amendments represent a partial granting of the regulatory relief requested by the petitioners. The request to delete 10 CFR 20.1301(d) was denied because the reference to the Environmental Protection Agency's regulations in 10 CFR 20.1301(d) has nothing to do with the patient release issue. Also, the request to 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, was denied. The staff considers it inadvisable to use a patient's home for the purpose of confinement when the activity in the patient is expected to result in a dose exceeding 5 millisieverts (0.5 rem) to another individual.

At its last meeting, held on October 18 and 19, 1995, the ACMUI passed several motions suggesting changes to three aspects of the rule.

First, the ACMUI suggested using the term "rationale" instead of "consequences" in the requirement, under 10 CFR 35.75 (b), to provide "guidance on the interruption of breast feeding, and information on the consequences of failure to follow the guidance" for cases where failure to follow the instructions could result in a dose to the infant exceeding 1 millisievert (0.1 rem). Since most of the administrations that would be affected by this requirement are technetium-99m administrations, the ACMUI suggested the change because there was concern that the consequences of low doses of radiation cannot always be explained to the patient without causing unjustified alarm. Also, there was concern that physicians cannot explain with certainty the effects of low doses of radiation, such as would be caused by diagnostic administrations of technetium-99m. The staff did not change the rule in response to the ACMUI comment because the requirement to provide information on the consequences is included primarily to protect the breast-feeding infant from therapeutic administrations of radioiodine, which could cause serious thyroid damage. Regulatory Guide 8.39 will contain guidance on the types of information, including expected consequences, to be provided to patients to meet this requirement.

Second, the ACMUI suggested using the phrase "the retained activity rather than the activity administered" instead of "an activity other than the activity administered" in the requirement under 10 CFR 35.75(c), to maintain a record of the basis for authorizing the release of an individual, if the total effective dose equivalent is calculated. The ACMUI was concerned that the meaning was not clear, and in addition, the requirement was already implicit in the remainder of the recordkeeping requirements in 10 CFR 35.75(c). The staff changed the rule in response to the ACMUI comment. This information would be needed for cases where a patient would be held for some time period prior to release. Such cases would not be covered in the default release table that appears in the regulatory guide. In this case, a record is

needed to confirm that the licensee has released the individual in accordance with the limit in Part 35. Regulatory Guide 8.39 will provide guidance on cases where such records will be needed for release.

Third, the ACMUI suggested that the term "discontinuation" should be used in conjunction with "interruption" in the requirement to provide "guidance on the interruption of breast-feeding" if failure to follow the instructions could result in a dose to the infant exceeding 1 millisievert (0.1 rem). The ACMUI suggested the change because they said that there is a distinct difference between the two terms. The staff changed the rule in response to the ACMUI comment. As stated in the Federal Register notice, "the instructions must include guidance on the interruption period for breast-feeding." Table 2 in the guide gives interruption periods for various radiopharmaceuticals which can be temporary (48 hours or less) in some cases, or discontinuation (no resumption) when necessary.

Finally, the ACMUI recommended that the Commission proceed with the rule as promptly as possible.

RESOURCES:

Resources needed to conduct and 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; such certification will satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Notes:
    a. The final rule will become effective 120 days after publication in the Federal Register.
    b. A final regulatory guide will be published, for use, before the final rule becomes effective (Attachment 2).
    c. A final regulatory analysis will be available in the Public Document Room (Attachment 3).
    d. A final environmental assessment and a finding of no significant impact have been prepared (Attachment 4).
    e. 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.
    f. The appropriate Congressional Committees will be informed (Attachment 5);
    g. A public announcement will be issued (Attachment 6).
    h. The rule contains information collection requirements that are subject to review by the Office of Management and Budget. Upon Commission approval, the OMB supporting statement (Attachment 7) will be submitted to OMB for approval.
    i. Copies of the Federal Register notice of final rulemaking and the associated regulatory guide will be distributed to all NRC medical licensees and each Agreement State. The notice will be sent to other interested parties upon request.

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Executive Director for Operations

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Attachments: As Stated (7)

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
April 1996

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 or Human 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 from the patient or the human research subject 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 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, 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 American Medical Association 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 criterion 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 requirements 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.

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, 1996).

The regulatory analysis found that there would be no need to retain patients because of 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 Annual Attributes 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	427,000	427	25.62	0	High
2	29,840	16,000	16	0.96	0	Moderate
3	32,580	0	0	0	2.3	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 $412,000,000 per year, mostly because of increased national health care costs. In view of this, Alternative 1 may be dismissed.
3. Alternative 3 relative to Alternative 2 has a net value of about $9,000,000 per year, mostly due to lower health care costs. Also, Alternative 3 has psychological benefits to patients and their families. Thus, Alternative 3 is 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 occasional cases 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.

IV. ENVIRONMENTAL IMPACTS OF THE PROPOSED ACTION AND THE ALTERNATIVES

Family Members or Other Persons

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 when comparing Alternative 3 to Alternative 2 is an increase of about 27 person-sievert (2,700 person-rem). Most of the increase, about 26 person-sievert (2,600 person-rem), is received by the primary care-providers and family members exposed to released patients (about 10,000) administered iodine-131 sodium iodide for thyroid cancer (see Tables 4.10 and 4.11 of NUREG-1492); whereas, 1 person-sievert (100 person-rem) is associated with exposure to released patients (about 1,000) administered more than 1,110 megabecquerels (30 millicuries) of iodine-131 sodium for thyroid ablation (see Tables 4.10 and 4.11 of NUREG-1492). Based on the assumption that each patient could expose about seven family members and friends (including the primary care-provider), the increase in dose to an affected individual in a year is about 0.00037 sievert (37 millirem) for thyroid cancer and about 0.00014 sievert (14 millirem) for thyroid ablation. The increase in risk to the affected individual could vary from zero (if a dose threshold exists) to 1.8×10^{-5} per year (if the linear no threshold hypotheses is valid and a risk factor of about 5×10^{-4} per person-rem is used). When compared with the incidence of cancer of 0.20 from natural causes, the potential cancer risk for a family member or other person who has close contact with a thyroid cancer or thyroid ablation patient is small. Thus, the environmental impact is not considered significant.

Breast-feeding Infant

There are specific issues associated with the administration of iodine-131 sodium iodide in that following both diagnostic and therapeutic administrations, the dose to a breast-feeding child could exceed 5 millisieverts (0.5 rem) if there was no interruption of breast-feeding. In particular, if the woman does not cease breast-feeding after administration of millicurie quantities of iodine-131 sodium iodide, the internal dose to the breast-feeding infant could be large enough to cause the infant's thyroid to be severely damaged resulting in hypothyroidism. If hypothyroidism were undiagnosed in very young children, severe mental retardation may occur. However, if the patient was provided instructions to discontinue breast-feeding, as well as being advised of the consequences of not following the instructions, the NRC believes that the probability of a woman failing to cease breast-feeding after being administered iodine-131 sodium iodide is small. For example, in 1990 an administered dosage of 185 megabecquerels (5 millicuries) of iodine-131 sodium iodide to a patient resulted in her breast-fed infant receiving an unintended radiation dose of 300 grays (30,000 rads) to the infant's thyroid gland. This dose would result in ablation of the infant's thyroid. This situation was recognized in 2 days which allowed prompt action to be taken thereby reducing potential consequences such as mental retardation. The NRC is aware of two other cases that occurred during 1991 and 1995. In each of these cases, there was a breakdown in communications, rather than lack of intent to prevent breast-feeding.

Although instructions to keep doses to household members and the public as low as is reasonably achievable are currently required for radiopharmaceutical therapy in 10 CFR 35.315(a)(6), there is no requirement specific to the dose from breast-feeding. In some cases, instructions to interrupt or discontinue breast-feeding may not be effectively communicated. To deal with this issue, the NRC considered a range of options which varied from maintaining the status quo to the extreme option of a woman remaining in the hospital for a period of time after administration of millicurie quantities of I-131 sodium iodide to ensure her milk production has stopped. Included within this range of options was the option to enhance communication between the licensee and woman regarding instructions to interrupt or discontinue breast-feeding before the woman is released from the hospital, which is the option adopted in this rulemaking. As discussed in the Regulatory Analysis, the other options were dismissed as ineffective or impractical due to a variety of reasons: the option of a woman remaining in a hospital was dismissed due to psychological impacts to the woman and breast-feeding infants, impacts on the practice of medicine, and health care costs; the option of maintaining status quo was dismissed due to lack of assurance that instructions will be provided to a breast-feeding woman. Therefore, the option to enhance communication is selected as the preferred option.

To enhance communications and reduce the probability of a mother breast-feeding after administration of large quantities of iodine-131, amended 10 CFR 35.75(b) will require licensees to provide guidance on the interruption or discontinuation of breast-feeding and information on the rationale for following the guidance. Compliance with the regulation provides NRC with confidence that the licensee will give the instructions to breast-feeding women and it is expected that almost all women will follow instructions to interrupt or discontinue breast-feeding to protect their children from potentially harmful effects. The NRC is not aware of any instances where instructions were given to the woman but she ignored the warning and continued breast-feeding a child.

The decision to require instructions as shown in column 5 of Table B.5 of the Regulatory Analysis (NUREG-1492) is based on both the external and internal dose to the nursing infant. It can be seen from column 4 that for some radiopharmaceuticals the external dose from breast-feeding can be a significant part of the total dose. The duration of the interruption shown in column 6 is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem). However, 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) due to the conservatism of the analysis. The conservative factors are based on: (1) the maximum measured level of activity in breast milk, (2) the longest biological half-life, and (3) the lowest body weight (i.e., the newborn).

It is expected that there will be no effect from breast-feeding on collective dose due to therapeutic administrations, although there may be a small effect from more infants having an opportunity to have contact with a woman sent home from hospital (i.e., cancer patients). However, instructions providing guidance, such as to maintain distance from other persons, should aid in minimizing this effect. In the case of diagnostic administrations of iodine-131 sodium iodide, it is currently normal practice to recommend interruption of breast-feeding. Thus, this rule is expected to have little or no effect on collective dose due to diagnostic administrations. In sum, the environmental impact is not considered significant.

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 amendments establish new criteria for patient release that are based on the potential radiation dose to other individuals exposed to the patient. Furthermore, the amendments require the licensee to provide written instructions to patients on how to maintain the doses to others as low as is reasonably achievable. It is expected that there will be no significant impact to the environment.

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	Atlanta, GA
	Agreement States: AL, AR, AZ, CA, CO, FL, 07/16/92 GA, IL, KS, KY, LA, MD, NC, ND, NE, NH, NV, NY, OR, SC, TX, UT, WA, and NY City
10/24/92	Tempe, AZ
10/25/92 10/26/92 10/27/92	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	Portland, ME
10/25/94	Agreement States: AL, AR, IL, KS, LA, NH, NV, NY, PA, RI, TX, UT, WA, and NY City
10/22/92	Rockville, MD
10/23/92	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
05/03/93	Bethesda, MD
05/04/93	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
11/01/93	Reston, VA
	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
11/18/94	Rockville, MD
	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
05/12/95	Rockville, MD
	Advisory Committee on the Medical Uses of Isotopes (ACMUI)
10/18/95	Rockville, MD
10/19/95	Advisory Committee on the Medical Uses of Isotopes (ACMUI)

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, Ph.D., Radiation and Cellular Oncology Department, University of Chicago, Chicago, IL

K. Behling, S. Cohen and Associates, McLean, VA

U. H. Behling, S. Cohen and Associates, McLean, VA

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

D. Goldin, S. Cohen and Associates, McLean, VA

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

P. Holahan, Ph.D., U.S. Nuclear Regulatory Commission, Washington, DC

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, Ph.D., Professor of Yale University, School of Medicine, and past President of the American Association of Physicists in Medicine, New Haven, CT

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

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

M. Pollycove, M.D., Visiting Medical Fellow, U.S. Nuclear Regulatory Commission, Washington, DC

G.E. Powers, Ph.D., Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC

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

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

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

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

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

J. Stubbs, Ph.D., Radiation Internal Dose Information Center, Oak Ridge Institute for Science and Education, Oak Ridge, TN

K. Suphanpharian, Ph.D., President, Best Industries, Springfield, VA

R.E. Toohey, Ph.D., 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 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 anyone in contact with the patient, would be greater than 500 millirems. (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 and the National Council on Radiation Protection and Measurements.

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.

The final rule amends the NRC's 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 minimize exposures to others. If the released individual may be breast-feeding an infant or child, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance.

The 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 _____ (120 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 or discontinuation 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: 17,126 hours (includes NRC and Agreement State licensees).
8. The average annual burden per respondent: 13 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 is reasonably achievable if the dose to an individual exposed to the patient is likely to exceed 0.1 rem. In those cases where the released individual may be a breast-feeding woman, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The amendment also requires the licensee to maintain a record of the basis for the release if the release is authorized using other than standard assumptions or that instructions were provided to a breast-feeding woman if the dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.5 rem. These requirements are necessary to ensure adequate protection of the public health and safety and that doses to other individuals are maintained as low as 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:

Peter Francis
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 , 1996.

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 others as low as is reasonably achievable if the dose to an individual exposed to a released patient is likely to exceed 1 millisievert (0.1 rem). In those cases where the released individual may be a breast-feeding woman, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The amendment also establishes recordkeeping requirements when the release is authorized using other than standard assumptions or when instructions were provided to a breast-feeding woman because the dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

1. Need for the Collection of Information

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

§ 35.75 Release of individuals containing radiopharmaceuticals or permanent implants.

Paragraph (b) of this section requires licensees to provide, upon release, the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem). In those cases where the released individual may be a breast-feeding woman, paragraph (b) also requires the instructions to include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance. The instructions should be specific to the type of treatment given and may include additional information regarding individual situations. The instructions should include a contact and phone number in case the patient has any questions. Instructions should include, as appropriate: (1) maintaining distance from other individuals, including

sleeping arrangements and the need to minimize use of public transportation; (2) the interruption period for breast-feeding and the consequences to the breast-feeding child upon failure to follow the guidance, if applicable; (3) minimizing time in public places (such as grocery stores, shopping centers, restaurants, and sporting events); (4) hygiene; and (5) the length of time precautions should be taken. Written instructions are needed to provide a reference available after the patient's release, if questions regarding patient care arise, and to reduce the chance of misunderstanding the licensee's instructions as 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 3 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 that instructions were provided to a breast-feeding woman if the administered activity could result in a total effective dose equivalent to the breast-feeding infant exceeding 5 millisieverts (0.5 rem) if the woman did not interrupt or discontinue breast-feeding. The records are necessary so that the NRC inspector can verify that instructions were given to the breast-feeding woman to inform her of the need to interrupt or discontinue breast-feeding.

2. Agency Use of Information

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

3. Reduction of Burden Through Information Technology

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

4. Effort to Identify Duplication and Use Similar Information

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

5. Effort to Reduce Small Business Burden

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

6. Consequences 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, May 1995, and October 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.

In addition, the estimated burden on the Agreement States to review records is estimated to be 1 hour per Agreement State licensee per year, or 900 hours for all Agreement State licensees. At a cost of $133 per hour, the annual cost to Agreement States is $119,700 annually.

12. Estimate of Burden

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

13. 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 13 hours per licensee. The proposed rule required records for releases if the total effective dose equivalent to any individual other than the released patient exceeded 0.1 rem. The final rule requires records only for exceptions to standard assumptions and when instructions were provided to a breast-feeding woman if the dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

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 Burden Hours**
35.75(b) exceeding 0.1 rem breast-feeding mothers	62,000[3] 27,000[4]	1/6 1/6	10,333 4,500

Recordkeeping Requirements			
Section	**No. of Procedures Requiring Records Per Year**	**Hours Per Licensee**	**Total Burden Hours**
35.75(c) 35.75(d)	10,000[5] 7,200[6]	2/15 2/15	1,333 960
Total burden = 17,126 hours or 13 hours per licensee (17,126 ÷ 1,350) at a cost of $2,277,758 ($133 x 17,126).			

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1. The subject paper was submitted to the Commission on November 30, 1995 (SECY-95-286). Subsequently, the staff requested withdrawal of the paper to revise the regulatory analysis (RA) to conform with the new RA guidelines. In a Staff Requirements Memorandum dated December 21, 1995, the Commission granted the request. The staff revised the RA (a summary of major changes is attached to the RA) and made conforming changes to the Federal Register Notice (FRN) and the Environmental Assessment (EA). These revisions did not affect the content of this staff paper except in Items 1 and 5 of the DISCUSSION in which the staff mentioned the expanded discussions of breast-feeding women in the RA.

2. One commenter raised an issue about contacts allegedly relating to this rulemaking between one of the petitioners and the Office of the Chairman. The staff notes that the final rule is based on the public record associated with the rulemaking and that the NRC decision maker with whom contact was made is no longer with the Commission. The staff has not included any further comment with respect to this issue in the final rulemaking package.

3. 50,000 iodine administrations for thyroid ablation + 10,000 iodine administrations for thyroid cancer + 2,000 iodine permanent implants = 62,000.

4. 8,000,000 administrations x 0.5 fraction of the administrations potentially requiring instructions x 0.135 fraction of females of child bearing age (from Table 4.3 of NUREG-1492) x 0.05 breast-feeding = 27,000.

5. Iodine treatment for thyroid cancer patients.

6. (60,000 iodine + 1,000,000 technetium-99m pertechnetate) x 0.135 fraction of females of child bearing age x 0.05 breast feeding = 7,200.