administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than the dose limits in the NRC's regulations concerning standards for protection against radiation. The proposed rule does not represent a change in policy, but is necessary to indicate clearly that this is the NRC's policy and to clarify the relationship of NRC's regulations.

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

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

I. Background

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

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

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

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

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

A question arose about the applicability of those words in a specific case in which an individual mistakenly received an administration of a

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

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

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

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