an administration to the wrong individual; what corrective actions should be taken if the mistake occurs; and what regulatory response is appropriate if such a mistake occurs?

Each of these questions was dealt with in developing the rule on quality management programs and misadministrations. The Commission considered, in the rulemaking on quality management program and misadministrations, what steps should be taken to avoid the administration of radioactive materials to an individual not supposed to receive the administration. Those steps are contained in § 35.32, "Quality management program." In adopting those requirements, the Commission decided to apply the requirements in § 35.32 only to administrations with the potential for relatively high doses and to exclude most diagnostic administrations from the requirements. For those diagnostic administrations not covered by § 35.32, it was considered adequate to rely on the normal and traditional methods and techniques that medical care providers use to ensure that medications are given to the right individual in the right amount at the

Similarly, the NRC's requirements that licensees take appropriate corrective actions in response to a misadministration are contained in § 35.32. The specific requirements dealing with corrective actions apply to any administration requiring a quality management program.

With regard to the appropriate regulatory response to mistakes in administrations, the Commission decided that violation of the quality management program requirements, which apply to the more significant administrations, were significant enough that they may result in a civil penalty.

Thus, in the quality management program and misadministrations rulemaking, the Commission clearly addressed the issue of when the administration of a radioactive material to the wrong individual was sufficiently significant to warrant certain actions. Specific thresholds were established and codified to reflect the Commission's view of a reasonable balance between harm and burden. In particular, the Commission concluded that lower thresholds would not significantly reduce risk and would divert resources that should be directed toward reducing the more serious of those errors. The Commission continues to endorse the judgement that it made in that rulemaking.

II. Summary of the Proposed Changes

To clarify the meaning and intent of part 20, the NRC is proposing to amend the scope of part 20, the definitions of public dose and occupational dose, and the wording in § 20.1301(a)(1) on public dose limit to clarify that the dose limit for individual members of the public does not apply to dose contributions from any medical administration the individual has received. Thus, the medical administration of radioactive materials or radiation to any individual, even an individual not supposed to receive an administration, is not subject to the public dose limit in $\S 20.1301(a)(1)$, but is within the scope of part 35.

The proposed changes in part 20 would replace the word "patient" with the word "individual." The word "patient" has sometimes been taken to mean only the individual intended to receive the administration. At other times, the view has been that anyone who receives a medical procedure is a "patient." Replacing "patient" with "individual" would clarify that the statement refers to anyone receiving a medical administration. For consistency, in terminology between parts, the word "patient" in the definition of misadministration in § 35.2, "Definitions," and in certain locations in paragraph (a)(2) of § 35.33 would be replaced by the word 'individual.

In § 20.1002, the phrase "for the purpose of medical diagnosis and therapy" would be replaced by the phrase "any medical administration the individual has received." The existing wording raised the question of whether an administration was within the scope of part 20 if the administration had no valid medical purpose. The proposed wording would make it clear that regardless of the purpose or lack of purpose, dose to an individual from any medical administration the individual has received is not within the scope of part 20, but is within the scope of part 35.

For the sake of consistency and clarity, the same words would be 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 would be added to § 20.1301(a).

The existing § 20.1301(a) also excludes dose contributions from the

licensee's disposal of radioactive material into sanitary sewerage. That exclusion would not be added to \$\\$ 20.1002 and 20.1003 because the question of dose from sewer disposal of radioactive material is now under consideration by the NRC. When that issue is resolved, it is intended that the wording concerning dose from sewer disposal will be made consistent in \$\\$ 20.1002, 20.1003, and 20.1301(a).

Another recently published proposed rule (June 15, 1994; 59 FR 30724), which deals with criteria for the release of individuals administered radioactive material, would also amend § 20.1301(a)(1). When that amendment of § 20.1301(a)(1) is published in final form, the wording on what is excluded from the dose limit will be inserted in §§ 20.1002 and 20.1003 (in the definitions of public dose and occupational dose) so that the same parallelism will exist throughout.

In addition, another proposed rule (February 3, 1994; 59 FR 5132) would amend the definitions of public dose and occupational dose in 10 CFR part 20. However, that proposed rule would only amend the first sentence in the definitions and would not change the wording associated with what is excluded from public dose. Therefore, this proposed rule and that proposed rule do not conflict.

III. Request for Comment on Notification

Another question related to the administration of radioactive materials to the wrong individual concerns informing the individual of the error. Section 35.33 generally requires notification of the individual in the case of a misadministration. However, if the dose or the amount is less than the misadministration threshold, § 35.33 does not require that the individual who received an administration of a radiopharmaceutical by mistake be notified of the error. One fundamental difference in the case in which the wrong individual receives the administration is that, unlike the intended patient, who it may be argued may have been informed that he or she will be exposed to radiation and has thereby implicitly or explicitly consented to the procedure, the wrong individual has generally not consented to any radiation dose at all. The question then becomes, should part 35 require that the individual be notified of the error regardless of the dose that would be received?

The Commission was divided on whether the individual should be notified. The NRC's Advisory Committee on Medical Uses of Isotopes