(ACMUI) has assured the NRC that standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual should and almost always would notify the individual of the mistake. The current quality management program and misadministrations rule does not require the physician to notify the individual if the dose or amount is below the threshold for a misadministration. The NRC is now seeking comment on whether it should continue to rely on standard medical practice below the misadministration threshold or whether it is appropriate to impose an NRC requirement for notification below the misadministration threshold if the administration is to the wrong individual. For example, the NRC would like comments on whether a broader notification requirement would implicitly impose recordkeeping and procedural requirements upon licensees beyond those explicitly set forth in part 35.

# IV. Consistency With the 1979 Medical Policy Statement and Coordination With ACMUI

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 proposed rule is consistent with this statement because it continues to provide for administrations of radioactive materials to be regulated under 10 CFR part 35. The proposed rule further clarifies that additional regulations are not considered necessary.

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." The proposed rule is consistent with the statement because it clarifies that existing requirements concerning misadministrations continue to be concentrated on administrations having the greatest risk significance.

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 proposed rule is consistent with this statement because it limits its specific regulatory requirements for notification to the most serious errors in administration and minimizes requirements on errors in administrations that have less risk significance.

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

The subject of this proposed rule was discussed with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 19, 1994. The ACMUI agreed that medical administrations, including those to an individual not supposed to receive an administration, should be regulated by part 35 rather than part 20. The ACMUI stated that notification of an individual of an error in administration below the misadministration threshold is the current practice and should not be regulated.

# V. Coordination With and Issue of Compatibility for Agreement States

This proposed rulemaking was discussed with representatives of Agreement States at a meeting, "Organization of Agreement State Managers Workshop and Public Meeting on Rulemaking," in Herndon, VA, on July 12, 1994. There was some concern that the NRC approach was different from how State regulations address inadvertent x-ray exposures, but no strong opposition. The proposed rule was revised to address the concerns of the States and then discussed at a subsequent meeting of the Agreement States in Portland, ME, on October 24, 1994. The States were polled on how they regulated an administration to the wrong individual, and it was found that they would regulate the administration the same way as in this proposed rule.

The NRC believes that the proposed modification of part 20 should be a Division 1 matter of compatibility consistent with past practice of requiring basic definitions to be uniform for effective communication of basic radiation concepts. The Commission specifically requests comments on whether the proposed modification to part 20 should be made a Division 1 matter of compatibility.

# VI. Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

The NRC has not prepared a separate environmental assessment. The following discussion constitutes the assessment. The proposed rule would not change the NRC's requirements concerning the administration of radiation and radioactive materials. Those requirements are and would continue to be contained in part 35 of the NRC's regulations. When the potential ambiguity concerning application of part 20 and part 35 requirements was recognized, the Commission specifically informed the staff of its view that the proper interpretation was that the more specific part 35 requirements should govern all medical administrations and directed that action be taken to remove from the regulations any ambiguity on this issue. The staff has, accordingly, not interpreted § 20.1301(a)(1) as applying to any medical administrations, but has proceeded with this rulemaking to remove any ambiguity in the regulations. The proposed rule would merely amend part 20 to make it clear that part 20 does not address medical administrations. Thus, the proposed rule, if adopted, would clarify the NRC's requirements rather than change them, and there would be no environmental impact.

# VII. Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150–0014 and 3150– 0010.

### VIII. Regulatory Analysis

The regulatory analysis for this proposed rulemaking is as follows:

#### 1. Alternatives

# Alternative 1: Part 20 Regulates Doses to Wrong Individuals

In this alternative, a medical administration of radiation or radioactive material to an individual when no administration is intended that results in a total effective dose equivalent greater than 1 millisievert (0.1 rem) would be a violation of § 20.1301. If the event did not meet the threshold definition of a misadministration, NRC would receive a notification of the event from the licensee pursuant to § 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits" and the individual involved would receive notification of