the exposure from the licensee pursuant to §19.13(d), "Notifications and reports to individuals."

Under this alternative, notification and recordkeeping requirements of 10 CFR parts 19 and 20 would apply to the medical administration of radiation or radioactive material to the wrong individual that involves a dose to the individual above 1 millisievert (0.1 rem) but less than the threshold definition of a misadministration.

Alternative 2: Part 35 Regulates Doses to Wrong Individuals

In this alternative, the medical administration of radiation or radioactive material to any individual would be the exclusive province of the regulations in 10 CFR part 35. Section 20.1301 would not be applicable. Under this alternative, errors in the administration of radiation or radioactive material to individuals would be subject to the reporting and notification requirements of 10 CFR part 35 rather than the reporting and notification requirements in 10 CFR parts 19 and 20. This alternative is consistent with the Commission's determination, published in the rule on quality management programs and misadministrations (July 25, 1991; 56 FR 34104), that licensees should direct their resources toward preventing the more serious errors in the administration of byproduct material.

However, there would be no requirement in the event of errors in the administration of byproduct material to individuals who were not intended to receive any administration for the medical licensee to notify either the NRC or the individual of the error unless the error meets the threshold definition of a misadministration in § 35.2. In general, standard medical practice is that a physician who becomes aware that a medical procedure has been performed on the wrong individual would notify the individual of the mistake.

Preferred Alternative

Alternative 2 (Part 35 is controlling) is preferable because it maintains the intent of the rulemaking on quality management programs and misadministrations by concentrating 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. Also, this alternative would allow the Commission to treat all medical administrations of licensed material consistently under the regulations in Part 35.

2. Impact of Proposed Action

Licensees. There is no anticipated impact on licensees, except that licensees will more clearly understand the meanings of the regulations.

Individuals. There is no anticipated impact on an individual because this action will not increase or decrease the error rate for administrations of radiation or radioactive material.

NRC Resources. No NRC resources would be required to implement the rule.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, if adopted, this proposed rule would not have a significant economic impact on a substantial number of small entities. The impact of the revised regulation would not be significant because the proposed amendment represents a continuation of current practice and merely clarifies existing requirements.

X. Backfit Analysis

The NRC has determined that the backfit rule, § 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule, because these amendments do not involve any provisions which would impose backfits as defined in § 50.109(a)(1).

List of Subjects

10 CFR Part 20

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

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, 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. 553; the NRC is proposing to adopt 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 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 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, due to any medical administration the individual has received, or due 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.

Occupational dose means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and 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, from any medical administration the individual has received, from voluntary participation in medical research programs, or as a member of the general public.

Public dose means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, or from voluntary participation in medical research programs.

4. In § 20.1301, paragraph (a)(1) is revised to read as follows: