farms; (3) apportioning reserves for use in (a) establishing allotments for new farms, and (b) making corrections and adjusting inequities in old farm allotments; and (4) holding referenda.

Request for Comments

This rule proposes to amend 7 CFR part 723, subpart A to include 1995-crop national marketing quotas for fire-cured (type 21), fire-cured (types 22 & 23), Maryland (type 32), dark air-cured (types 35 & 36), Virginia sun-cured (type 37), cigar-filler (type 41), cigar-filler (type 46), cigar-filler and cigar-binder (types 42–44 & 53–55) and cigar binder (types 51 & 52) tobaccos. These nine kinds of tobacco account for about 6 percent of total U.S. tobacco production.

Accordingly, comments are requested concerning the proposed establishment of the national marketing quotas for the subject tobaccos at the following levels:

(1) Fire-Cured (Type 21) Tobacco

The 1995-crop national marketing quota for fire-cured (type 21) tobacco will range from 1.5 to 2.0 million pounds. This range reflects the assumption that the national acreage factor will range from 0.75 to 1.0.

(2) Fire-Cured (Types 22 & 23) Tobacco

The 1995-crop national marketing quota for fire-cured (types 22 & 23) tobacco will range from 32.0 to 40.0 million pounds. This range reflects the assumption that the national acreage will range from 0.8 to 1.0.

(3) Dark Air-Cured (Types 35 & 36) Tobacco

The 1995-crop national marketing quota for dark air-cured (types 35 & 36) tobacco will range from 8.0 to 10.0 million pounds. This range reflects the assumption that the national acreage factor will range from 0.8 to 1.0.

(4) Virginia Sun-Cured (Type 37) Tobacco

The 1995-crop national marketing quota for Virginia sun-cured (type 37) tobacco will range from 80,000 to 100,000 pounds. This range reflects the assumption that the national acreage factor will range from 0.8 to 1.0.

(5) Cigar-Filler and Cigar-Binder (Types 42–44 & 53–55) Tobacco

The 1995-crop national marketing quota for cigar-filler and cigar-binder (types 42–44 & 53–55) tobacco will range from 8.0 to 10.0 million pounds. This range reflects the assumption that the national acreage factor will range from 0.8 to 1.0.

(6) Cigar Filler (Type 46) Tobacco

The 1995-crop national marketing quota for cigar-filler (type 46) tobacco will be zero.

(7) Maryland (Type 32) Tobacco

The national acreage factor will be 1.0 and the national marketing quota will be 5.8 million pounds.

(8) Pennsylvania Filler (Type 41) Tobacco

The national acreage factor will be 1.0 and the national marketing quota will be 1.5 million pounds.

(9) Cigar Binder (Types 51 & 52) Tobacco

The national acreage factor will be 1.0 and the national marketing quota will be 670,000 pounds.

List of Subjects in 7 CFR Part 723

Acreage allotments, Marketing quotas, Penalties, Reporting recordkeeping requirements, Tobacco.

Accordingly, it is proposed that 7 CFR part 723, subpart A be amended as follows:

PART 723—TOBACCO

1. The authority citation for 7 CFR part 723 continues to read as follows:

Authority: 7 U.S.C. 1301, 1311–1314, 1314–1, 1314b, 1314b–1, 1314b–2, 1314c, 1314d, 1413e, 1314f, 1314i, 1315, 1316, 1362, 1363, 1372–75, 1377–1379, 1421, 1445–1, and 1445–2.

2. Sections 723.113 is amended by adding paragraph (c) to read follows:

§ 723.113 Fire-cured (type 21) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota will range from 1.5 million pounds to 2.0 million pounds.

3. Section 723.114 is amended by adding paragraph (c) to read a follows:

§ 723.114 Fire-cured (types 22–23) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota will range from 32.0 million pounds to 40.0 million pounds.

4. Section 723.115 is amended by adding paragraph (c) to read as follows:

§ 723.115 Dark air-cured (types 35–36) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota will range from 8.0 million pounds to 10.0 million pounds.

5. Section 723.116 is amended by adding paragraph (c) to read as follows:

§ 723.116 Sun-cured (type 37) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota will range from 80,000 to 100,000 pounds.

6. Section 723.117 is amended by adding paragraph (c) to read as follows:

§ 723.117 Cigar-filler and Cigar binder (types 42–44; 53–55) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota will range from 8.0 million pounds to 10.0 million pounds.

7. Section 723.118 is amended by adding paragraph (c) to read as follows:

§ 723.118 Cigar filler (type 46) tobacco.

(a) * * *

(b) * * *

(c) The 1995-crop national marketing quota is 0.0 million pounds.

8. Section 723.119 is added to read as follows:

§ 723.119 Maryland (type 32) tobacco.

The 1995-crop national marketing quota is 5.8 million pounds.

9. Section 723.120 is added to read as follows:

§ 723.120 Pennsylvania filler (type 41) tobacco.

The 1995-crop national marketing quota is 1.5 million pounds.

10. Section 723.121 is added to read as follows:

§ 723.121 Cigar binder (types 51 & 52) tobacco.

The 1995-crop national marketing quota is 670,000 pounds.

Signed at Washington, DC on January 19, 1995.

Bruce R. Weber,

Acting Administrator, Consolidated Farm Service Agency.

[FR Doc. 95–1852 Filed 1–24–95; 8:45 am]

BILLING CODE 3510–05–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 35

RIN 3150–AF10

Medical Administration of Radiation and Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to clarify that the medical

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

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 rule).

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

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 right time.

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 § 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

(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

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:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, any medical administration the individual has received, voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

* * * * *

5. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

6. In § 35.2, the definition for *misadministration* is revised at paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) by removing the word ''patient'' and inserting the word ''individual.''

7. In § 35.33, paragraph (a)(2) is revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, or the individual's responsible relative or guardian (this person will be subsequently referred to as ''the patient'' in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

* * * * *

Dated at Rockville, Maryland, this 19th day of January, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

[FR Doc. 95–1817 Filed 1–24–95; 8:45 am]

BILLING CODE 7590–01–P

10 CFR Part 52

RIN 3150–AE42

Combined Licenses; Conforming Amendments; Post-Promulgation Comment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; comment response.

SUMMARY: The Nuclear Regulatory Commission (Commission) is addressing the one comment that it received in response to a supplementary post-promulgation comment opportunity on a portion of its final rule amending its regulations to conform to the provisions of Title XXVIII of Public Law 102–486, the ''Energy Policy Act of 1992,'' signed into law on October 24, 1992. This notice is necessary to inform the public of the Commission's response to that post-promulgation comment.

DATES: The final rule became effective January 22, 1993. Comments to the supplementary comment opportunity were due by July 11, 1994.

FOR FURTHER INFORMATION CONTACT: Grace H. Kim, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–415–3605.

SUPPLEMENTARY INFORMATION:

Background

By Federal Register notice published on June 10, 1994 (59 FR 29965), the Commission offered a supplementary 30-day opportunity for ''post-promulgation'' comment on a portion of the final rule revising 10 CFR part 52 in light of Title XXVIII of the Energy Policy Act of 1992 (Pub. L. 102–486, 106 Stat. 2776), which amended the Atomic Energy Act to authorize explicitly the issuance of combined construction and operating licenses for nuclear power plants.[1] As the Commission explained in its **Federal Register** notice, this supplementary comment opportunity, limited to the so-called ''Sholly'' portion of the final part 52 rule,[2] was provided by the Commission in conjunction with an agreement for the voluntary withdrawal of a petition for review of the final part 52 rule that had been filed by the Nuclear Information and Resource Service in the Court of Appeals for the District of Columbia Circuit. See *id.* The Commission received only one comment in response, which was submitted on July 8, 1994 by the Nuclear Energy Institute (NEI) (the successor organization to NUMARC). In its submittal NEI essentially mirrors NUMARC's previous comments with respect to the ''Sholly'' provisions of the final rule, expressing its support for the Commission's amendment of 10 CFR 52.97 to make the ''Sholly'' procedure applicable to combined licenses and reiterating NUMARC's earlier request that the Commission modify certain language in the final rule's statement of considerations to clarify the Commission's intent regarding the implementation of § 52.97. *See* 58 FR at 69220, 69221. Because NEI merely reiterates NUMARC's comments, which have already been fully considered and addressed by the Commission (*id.*), no further response is necessary.

List of Subjects in 10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

Dated at Rockville, Maryland this 19th day of January, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

[FR Doc. 95–1816 Filed 1–24–95; 8:45 am]

BILLING CODE 7590–01–M

[1] As required by 10 CFR 2.804(f), the Commission had also invited post-promulgation comment at the time it promulgated the final part 52 rule. See 57 FR 60975 (December 30, 1992). In response to this comment opportunity, the Commission received comments only from the Nuclear Management and Resources Council (NUMARC). The Commission responded to this comment in a Federal Register notice published on December 30, 1993 (58 FR 69220).

[2] The ''Sholly'' procedure, which the Commission made applicable to combined licenses in the final rule in accordance with the Energy Policy Act (see 57 FR at 60976; 10 CFR 52.97(b)(2)(ii)), allows the Commission to make an amendment to a combined license immediately effective (*i.e.*, prior to a hearing if it makes a finding that there are no significant hazards considerations.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 2, 57, 85, 86, 122, 123, 145, 233, 260, 270, 271, 281, 350, 403, 704, 707, 710, 712, 716, 717, 720, 723, 750 and 790

[FRL–5143–6]
RIN 2020–AA21

Public Information and Confidentiality Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period.