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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Parts 20 and 35

**RIN 3150–AF10**

### Medical Administration of Radiation and Radioactive Materials

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Nuclear Regulatory Commission is amending 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 by the dose limits in the NRC's regulations concerning standards for protection against radiation. The 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:** Effective date: October 20, 1995.

**ADDRESSES:** Examine comments received at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555–0001.

**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 to an individual for whom it is not intended.

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 to the wrong individual in excess of certain specified quantities (''30 microcuries of either sodium iodide I–125 or I–131'') or doses (''5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ''). The practical effect of the definition of a misadministration is that some diagnostic administrations of radiopharmaceuticals to individuals for whom they were not intended are not misadministrations as defined in § 35.2 because the specified quantities or doses are not exceeded, and therefore 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 particular 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. The question that arose was whether § 20.1301(a)(1) had been violated or did 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?

This same issue was raised in a Petition for Rulemaking (PRM–35–11) filed by the American Medical Association (59 FR 37950; July 26, 1994). That petition requested, in part, that Part 20 specifically exclude all medical administrations.

Because of these concerns, the Commission proposed an amendment to 10 CFR Part 20 to clarify the regulations (60 FR 4872, January 25, 1995). The proposed rule explained that the Commission believed that, in general, the administration of radiopharmaceuticals should be regulated by Part 35 rather than by Part 20. The medical administration of radioactive materials is a special use of radioactive materials that is best dealt with by specific regulations covering those administrations. In particular, the Commission believed that an administration to any individual is and should be subject to the regulations in Part 35. That was the Commission's intent when the current misadministration requirements were adopted in the final rule, ''Quality Management Programs and Misadministrations,'' (56 FR 34104; July 25, 1991). Further explanation of the Commission's rationale is contained in the Federal Register notice for the proposed rule (60 FR 4872; January 25, 1995).

II. Comments on the Proposed Rule and Petition for Rulemaking PRM–35–11

Four comment letters were received on the proposed rule, three from Agreement States and one from a medical health physicist. All supported the proposed rule. Three comment letters were received on PRM–35–11. Each of the letters supported the petition.

The Federal Register notice on the proposed rule specifically asked for comment on whether to adopt a requirement to inform an individual of the error in the case of administration of a radiopharmaceutical to the wrong individual, but in a quantity below the misadministration threshold. 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 error be notified of the error. The NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI), an advisory committee on rulemakings and other initiatives related to the medical use of byproduct materials, 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.

Two comments addressed this question. One, from an employee at a medical facility, favored an NRC regulation requiring notification of the individual regardless of the dose because sometimes an attempt might be made to keep this information from the individual. The other, from an Agreement State, opposed such a requirement because it would be inconsistent with the NRC's medical policy statement, ''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 NRC has decided to retain the notification requirements that it established in the misadministration rulemaking and thus not amend the notification requirements. Therefore, the NRC will require notification only for the more serious errors. Notification requirements for less serious errors are left to the medical profession and to State and local regulations. The NRC sees no need to interject itself into medical judgements or to override State and local regulations for the less serious errors.

III. Summary of the Changes

Neither the comments received nor any other information available to the Commission give any reasons for not adopting the amendments substantially as proposed, which would regulate administrations to individuals under Part 35 and not Part 20. Therefore, the NRC is adopting the amendments as described below.

To clarify the meaning and intent of Part 20, the NRC is amending 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 to 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 changes in Part 20 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'' clarifies that the statement refers to anyone receiving a medical administration.

In § 20.1002, the phrase ''for the purpose of medical diagnosis and therapy'' is 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 new wording makes 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 are 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 are added to § 20.1301(a).

A proposed rule published on 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 Part 20.

In Part 35, for consistency in terminology between parts, the phrase ''patient or human research subject'' in the definition of misadministration in § 35.2, ''Definitions,'' and in the misadministration reporting requirements in § 35.33, ''Notifications, reports, and records of misadministrations,'' is replaced by the word ''individual.'' Note that § 35.33(a)(3) also requires the licensee to notify the referring physician of a misadministration. If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33.

The changes made by these amendments have the effect of granting the request in PRM–35–11 that Part 20 specifically exclude all medical administrations.

IV. Consistency With the 1979 Medical Policy Statement

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

V. Coordination With the Advisory Committee on Medical Uses of Isotopes

The subject of this final rule was discussed with the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 11, 1995. The ACMUI is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. 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 by Part 20. The ACMUI stated that notification

of an individual of an error in administration below the misadministration threshold is the current medical practice and should not be regulated. A transcript of the meeting is available for examination at the NRC Public Document Room, 2120 L St., NW. (Lower Level), Washington, DC.

VI. Coordination With and Issue of Compatibility for Agreement States

This rulemaking was discussed with representatives of Agreement States at a meeting 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 appear to regulate such administrations consistent with this rule. Two States commented on the rule, and both fully supported the rule.

The NRC believes that the modification of Part 20 should be a Division 1 matter of compatibility consistent with past practice of requiring basic definitions to be essentially identical for effective communication of basic radiation concepts. One Agreement State commenting on the compatibility issue supported a Division 1 level. Another Agreement State supported Division 1 compatibility ''*provided* that Division 1 compatibility means the intent, but not the language must be identical.''

VII. 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 is not a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

The NRC prepared an environmental assessment for the proposed rule, which was contained within the Federal Register notice for that rule. That assessment continues to stand for the final rule.

VIII. Paperwork Reduction Act Statement

This 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.

IX. Regulatory Analysis

The regulatory analysis prepared for the proposed rule and published as part of the Federal Register notice on the proposed rule is still valid for this final rule.

X. Regulatory Flexibility Certification

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

XI. Backfit Analysis

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

XII. 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 recording 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. 552 and 553; the NRC is adopting 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, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), 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 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 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 the course of employment in which the individual's assigned duties involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses 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 public.

* * * * *

*Public dose* means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of the licensee. Public dose 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 millisievert) 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.

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## PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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).

### § 35.2 [Amended]

6. In § 35.2, the definition for *misadministration* is amended in paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) by removing the term ''patient or human research subject'' and inserting the word ''individual.''

7. In § 35.33, paragraphs (a)(2), (a)(3), (a)(4), (b), and (c) are 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 who received the misadministration; 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), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

Dated at Rockville, Maryland, this 14th day of September, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

*Secretary of the Commission.*

[FR Doc. 95–23288 Filed 9–19–95; 8:45 am]

BILLING CODE 7590–01–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

[Docket No. 95–NM–148–AD; Amendment 39–9364; AD 95–19–03]

## Airworthiness Directives; Aerospatiale Model ATR 42–300 and 42–320 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42–300 and -320 series airplanes. This action requires modification of the electrical wire bundle associated with the smoke detection system. This amendment is prompted by a report of a short circuit in this electrical wire bundle, which was caused by chafing of the wire against a smoke detection pipe. The actions specified in this AD are intended to prevent such chafing, which could result in short circuits of the electrical wire bundle and a potential fire hazard.

**DATES:** Effective October 5, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 5, 1995.

Comments for inclusion in the Rules Docket must be received on or before November 20, 1995.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–148–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Gary Lium, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–1112; fax (206) 227–1149.

**SUPPLEMENTARY INFORMATION:** The Direction Générale de l'Aviation Civile