[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 35

Misadministration Reporting Requirements

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final Rule.

SUMMARY: The NRC is amending its regulations to require its licensees to: (1) keep records of all misadministrations of radioactive material; (2) promptly report therapy misadministrations to the NRC, the referring physician, and the patient or the patient's responsible relative (or guardian); and (3) report diagnostic misadministrations quarterly to NRC.

EFFECTIVE DATE: November 10, 1980

Note - NRC has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective reflects inclusion of the 45-day period that the statute allows for this review (44 U.S.C. 3512(c)(2)).

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SUPPLEMENTARY INFORMATION: On July 7, 1978, NRC published in the Federal Register (43 FR 29297) a proposed rule on the misadministration of radioactive material to patients. The proposed § 35.33 would have required medical licensees to do three things:

(1) Keep records of all misadministrations for 5 years;

(2) Promptly report all therapy misadministrations and those diagnostic misadministrations that could cause a clinically detectable adverse effect to: NRC, the referring physician, and the patient or a responsible relative (unless the referring physician stated that the information would harm them); and

(3) Follow the prompt report with a written report to NRC and the patient or responsible relative within 15 days.

In the proposed rule, a misadministration was defined as the administration of:

(1) A radiopharmaceutical or radiation from a source other than the one intended;

(2) A radiopharmaceutical or radiation to the wrong patient;

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 20 percent; or

(5) A therapeutic dose of a radiopharmaceutical or exposure from a radiation source such that the total dose or exposure differs from the prescribed dose or exposure by more than 10 percent.

The public was invited to submit written comments and suggestions on the proposed rule. The proposed rule was mailed to all medical licensees, about 30 professional and public-interest groups, and 2,000 state and county medical societies.

Comments on Proposed Rule

The Commission received 150 letters commenting on the proposed rule. Copies of these letters, a summary and analysis of the comments, and the

value/impact analysis supporting the final rule are available for public inspection at the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C. Single copies of the summary and analysis of the comments or value/impact analysis may be obtained from Edward Podolak at the above address.

Ninety percent of the comments were opposed to the rule, most citing it as an unprecedented intrusion into medical practice. Basically, the commenters were opposed to misadministration reporting to NRC where reports would be open to public scrutiny, and misadministration reporting to patients which they felt would cause "undue alarm" and "unwarranted malpractice suits." Many commenters offered helpful suggestions which were incorporated into the final rule as explained below under "Summary of Major Changes in the Final Rule."

Many commenters questioned the need for a misadministration reporting rule. They cited the low number of reported misadministrations. They stated that misadministrations of radioactive material were less frequent than misadministrations of other drugs or types of therapy. And they noted that there are no similar reporting requirements in medical practice.

The Commission's purpose in requiring misadministration reports to NRC is to identify their causes in order to correct them and prevent their recurrence. The Commission can do this by notifying other licensees if there is a possibility that they could make the same errors. The Commission can also change its regulations to prevent specific errors. The significance of a diagnostic misadministration goes beyond the unnecessary radiation exposure if it results in misdiagnosis. Apparently isolated incidents at individual medical institutions could reveal a generic problem when compared nationally.

Examples of rule changes resulting from misadministrations are: a rule requiring annual calibration of teletherapy units (44 FR 1722), and a rule requiring radiation surveys of patients following removal of implants (43 FR 55345).

The Commission does not know the entire extent of misadministrations of radioactive material. In 1976 NRC investigated an incident where 400 therapy patients had received radiation doses exceeding the prescribed doses by as much as 41 percent. In 1977 NRC received seven reports of misadministrations ranging from minor misadministrations to a serious teletherapy overexposure. In 1978 NRC received eleven reports of misadministrations, one of them a serious misadministration of four Ir-192 seeds that were left in a patient. In 1979 NRC has received a single report of a misadministration; colloidal P-32 was administered instead of soluble P-32. The Commission does not know what fraction of the actual incidence of misadministrations these reports represent. However, whenever there has been a serious misadministration, the Commission has been able to act to help prevent recurrence by issuing notices or orders to licensees or through rulemaking.

The Commission recognizes that its misadministration reporting requirement may be unique to medical practice. The Commission also recognizes that the misadministration of radiopharmaceuticals and radiation from sealed sources may be less frequent than the misadministration of other drugs or forms of therapy, because the radiopharmaceutical doses and radiation doses can be measured before administration to patients. However, the Commission believes that the misadministration recordkeeping and reporting requirement is necessary to protect patients.

Many commenters were concerned about the privacy of patients' records when misadministrations are reported to a third party such as NRC.

The final rule states that the patient's name should not be reported to NRC. The reports of misadministrations would be available for public review but without information that would lead to identification of the patient.

The vast majority of the commenters consider the proposed rule as a serious intrusion into the physician-patient relationship. They contend that the proposed rule is an intrusion of a regulatory agency into the care of a patient without assuming responsibility for that care. Many commenters pointed out that the misadministration reporting requirement was unique in medical practice and noted that NRC regulations did not apply to x-rays, accelerator or radium therapy, and accelerator-produced radiopharmaceuticals.

The Commission recognizes the intrusion into the physician-patient relationship in the sense that the rule does affect, to a limited degree, the nature of the physician's obligation to his or her patient--it imposes in certain circumstances an obligation on the physician to report information to the patient and the NRC. For many in the health professions, this limited involvement may be understood, rightly or wrongly, as foreshadowing some greater degree of Governmental involvement or as symbolizing some general movement toward more regulation of the profession.

The Commission does not believe, however, that this limited intrusion warrants abandoning the rule. Some physicians do support the rule--the medical profession is not unanimous that the rule would constitute an unwarranted intrusion into the physician-patient relationship. The "physician-patient" relationship is a concept that was developed to advance

the needs of the patient. The relationship involves duties of reasonable care and skill, confidentiality, and good faith owed by the physician to the patient. Nothing in the rule would detract from these duties. Thus, in a strict sense, the rule would not interfere with the relationship.

It is true that no similar reporting requirements are attached to use of x-rays, accelerator or radium therapy, or accelerator-produced isotopes. However, this is the direct result of limitations in NRC's regulatory authority. At present, unless Congress should expand NRC's authority, the NRC must operate under the presumption that Congress intended that a disproportionate degree of Federal regulatory control be exercised over nuclear materials as opposed to these other sources of radiation.

In many respects the adverse comments track those received by the Food and Drug Administration (FDA) in response to a request for comments to help FDA formulate a policy on labeling of prescription drug products to promote patient understanding of the nature and effects of the drugs prescribed for them. In a notice of proposed rulemaking (44 FR 40016, July 6, 1979), the FDA rejected the assertion that mandatory patient labeling would constitute an unwarranted interference in the physician-patient relationship, pointing out among other things that a patient has a right to know about a drug's benefits, risks, and directions for use.

Also, in a January 1979 report (EMD-79-16), the General Accounting Office (GAO) stated:

> "In our view, requiring medical licensees to report misadministrations to NRC is not an intrusion into medical practice. This is clearly consistent with NRC regulatory responsibilities and a necessary part of an effective nuclear medicine regulatory program. Without this kind of feedback on incidents affecting the public health and safety, NRC cannot be sure it is adequately regulating the possession and use of nuclear materials in medical practice."

Many commenters were concerned that the proposed rule, particularly the patient reporting requirement, would invite unwarranted malpractice suits and thereby boost medical costs. Some of these commenters suggested that the rule would lead to covering up misadministrations to avoid liability.

The Commission believes that the requirement in the final rule to report therapy misadministrations to patients or a responsible relative is important. Patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them. NRC has parallel requirements for licensee reports to workers on occupational overexposures. Also, there is a trend in Federal legislation that recognizes the right of individuals to know information about themselves which is contained in the records of institutions both inside and outside of the Federal sector. Examples are: the Privacy Act of 1974, which set rules for Federal Agencies' recordkeeping; the Fair Credit Reporting Act and related acts, which gave consumers the right to know information abou themselves contained in the records of credit-reporting bureaus; and the Family Education Rights and Privacy Act, which gave students the right to see personal records held by educational institutions. Also, in April 1979, the President sent the proposed "Privacy of Medical Information Act" to Congress, and President said:

> "The 'Privacy of Medical Information Act' is being submitted to you today. It establishes privacy protections for information maintained by almost all medical institutions. The Act will give individuals the right to see their own medical records. If direct access may harm the patient, the Act provides that access may be provided through an intermediary. This legislation allows the individual to ensure that the information maintained as part of his medical care relationship is accurate, timely and relevant to that care. Such accuracy is of increasing importance because medical information is used to affect employment and collection of insurance and other social benefits...."

Regarding the comment that the rule would invite malpractice suits and thereby boost medical costs, this may well be true. The amount of this increase is not known. In response to NRC query, the National Association of Insurance Brokers replied:

> "It is simply beyond our competence to quantify the effect on medical malpractice rates of your proposed rule....that the proposed change would have an adverse effect on rates seems indisputable, since the doctors would be required, in a sense, to prepare testimony against themselves. We frankly doubt that anyone can gauge the likely effect of such a rule...."

Regarding the suggestion that the rule would lead to covering up misadmistrations to avoid liability, the Commission does not believe that physicians would willfully disregard the rule. Moreover, there is nothing in the rule that would in any way modify the legal rules governing malpractice suits arising out of reported misadministrations.

A majority of the commenters who opposed the rule were opposed to the requirement for reporting diagnostic misadministrations to patients. They stated that most misadministrations of diagnostic radiopharmaceuticals would not harm the patient. They also stated that the definition of a diagnostic misadministration as an error greater than 20 percent would unduly alarm the patient because it was too low. They stated that the recommended dosage ranges in the drug labeling spanned factors of two and greater. They further stated that the standard dosages vary between institutions by as much as 100 percent. They also stated that this definition discriminated against short half-life radiopharmaceuticals which give a smaller radiation dose to the patient.

The proposed rule had a threshold for reporting diagnostic misadministrations. The threshold was not clear. The proposed rule required reporting

of all therapy misadministrations and those diagnostic misadministrations that could cause a "clinically detectable" adverse effect on the patient.

The staff agrees that the definition of a diagnostic misadministration as a 20 percent error is too low. That level was chosen originally because it was within the state-of-the-art for radiopharmaceutical measurement and the Commission was concerned that the limit for a diagnostic misadministration would be construed as good practice. The Commission recognizes that there are factors, such as patient scheduling, which are not errors but could cause the patient to receive a dose differing from the prescribed dose by more than 20 percent without affecting the effectiveness of the test. The final rule defines a diagnostic misadministration, in part, as that differing from the prescribed dose by more than 50 percent. At this limit of 50 percent: (1) an error has obviously occurred and (2) 50 percent over or under the prescribed dose can clearly compromise the effectiveness of the diagnostic procedure.

Some commenters objected to the absence of a definition for a "clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations. Others questioned who would make that determination. Others objected to the physician having too much leeway in making the determination. Still others complained that, without guidelines, they would have difficulty in making the determination.

At the proposed rule stage, the Commission believed that "clinically detectable" was a term well understood in medicine. According to some commenters, this is not the case. The Commission recognizes that the diagnosis of an "adverse effect" may in one case be based on a single dramatic symptom, while in another case it may be based on a number of individually minor deviations from the normal for that patient. Because

of this and because adverse effects may be delayed in time, the term "clinically detectable adverse effect" is a moving target. Therefore, the Commission is abandoning this term and the threshold. The final rule will require reporting of all diagnostic misadministrations to NRC.

Several commenters questioned whether extravasation is considered a misadministration.

Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation frequently occurs in otherwise normal intravenous or intraarterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration.

Some commenters questioned whether they would have to measure the activity in a syringe before and after the injection in order to determine if a misadministration has occurred.

Misadministrations of a radiopharmaceutical is defined as a percentage error from the prescribed dose. It is necessary to measure the activity prior to injection and then inject the contents of the syringe. It is not necessary to measure the residual activity in the syringe.

One commenter suggested that licensees be required to keep records of misadministrations for 50 years, instead of the proposed 5 years, because of the long latency period for radiation-induced cancers. For the same reason, another commenter suggested that the records be maintained for 30 years.

The Commission agrees that there are compelling reasons for insuring that the records of misadministrations should be maintained for a period of time longer than the five years as originally proposed. At the same

time it is not yet clear for what specific length of time NRC should require these records to be maintained by the licensee.

As an alternative to requiring licensees to maintain misadministration records for any specific length of time, the final rule requires that licensees shall preserve misadministration records until the Commission authorizes disposition. This approach is consistent with Part 20.401 of NRC's regulations which requires that NRC licensees maintain and preserve radiation exposure records for monitored personnel until the Commission authorizes disposition.

Under the provisions of section 208 of the Energy Reorganization Act of 1974, the Commission reports each quarter to the Congress on any abnormal occurrences involving facilities and activities regulated by the NRC. An abnormal occurrence is defined in section 208 as an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. The Commission published a policy statement on abnormal occurrence reporting in the Federal Register (42 FR 10950). Those misadministrations which the Commission determines meet the criteria for abnormal occurrence reporting will be published in the quarterly "Report to Congress on Abnormal Occurrences." In the past, teletherapy overexposures have been reported to Congress in this manner.

Summary of Major Changes in the Final Rule

The final rule was organized into separate sections, specifically §§ 35.41 through 35.45, to make the requirements easier to understand.

Several commenters' suggestions were incorporated into the final rule. As noted above, the term "could cause a clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations has been

abandoned in the final rule. Instead, all diagnostic misadministrations will be reported quarterly to NRC only. These reports of diagnostic misadministrations are to be in letter format and postmarked not later than 10 days following the calendar quarters ending in March, June, September, and December.

The Commission encourages licensees to report diagnostic misadministrations to patients but does not believe that the risk of a diagnostic misadministration warrants Federal intervention in this decision. Therefore, the Commission will not require licensees to report diagnostic misadministrations to the patient or relative (or guardian).

In the final rule, only therapy misadministrations are required to be reported to the referring physician and the patient or responsible relative. There are two changes regarding notification of the patient or responsible relative in § 35.42(a). First, a parenthetical "(or guardian)" was added to "responsible relative" to cover persons who do not have relatives. Second, now the referring physicians, if they wish, may inform the patient of the misadministration.

In the final rule, the limit for a diagnostic misadministration in § 35.41 has been raised to errors greater than 50 percent. Many commenters pointed out that the recommended dosages in radiopharmaceutical labeling cover ranges of up to a factor of 10 and that, comparing nuclear medicine departments, there is often a 100% or greater difference in the standard dosages for the same procedure. The Commission did not raise the limit of error for a diagnostic misadministration above the 50% level because this level begins to affect the quality of the diagnostic procedures. A poor quality diagnostic procedure could require a re-take or could result in a misdiagnosis.

In the final rule, the definition of a therapy misadministration in § 35.41 (e) and (f) distinguishes between radiopharmaceutical therapy and sealed source therapy. For sealed source therapy, the new definition recognizes that the therapist often adjusts the dose during treatment. Also, the new definition recognizes that the radiation dose in sealed source therapy is calculated as a function of dose rate, time, and treatment geometry, and is not usually measured directly. These changes resulted from several comments from radiation therapists.

Final Rule

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35, are published as a document subject to codification.

Part 35 - HUMAN USES OF BYPRODUCT MATERIAL

New §§ 35.41 through 35.45 are added to 10 CFR Part 35 to read as follows:

MISADMINISTRATION REPORTS AND RECORDS

§ 35.41 Definition of a misadministration.

For this part, misadministration means the administration of:

(a) A radiopharmaceutical or radiation from a sealed source other than the one intended;

(b) A radiopharmaceutical or radiation to the wrong patient;

(c) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(d) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

(e) A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or

(f) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

§ 35.42 Reports of therapy misadministrations.

(a) diate telephone report. When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall a'so notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient or that, in his medical judg ment, telling the patient or the patient's responsible relative (or guardian) would be

harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. (If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of this.)

(b) Written report. Within 15 days after the initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report shall not include the patient's name, or other information which could lead to identification of the patient.

§ 35.43 Reports of diagnostic misadministrations.

When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September, and December) in which they occur. These written reports shall include the licensee's name; the referring physician's name, a description of the event;

the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information which could lead to identification of the patient.

§ 35.44 Records of all misadministrations.

Each licensee shall maintain for Commission inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. These records shall be preserved until the Commission authorizes their disposition.

§ 35.45 Rights and duties of licensees.

Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees and physicians in relation to each other, patients or responsible relatives (or guardians).

(Secs. 81, 161 b. and o., Pub. L. 83-703, 68 Stat. 935, 948 b. and o. (42 U.S.C. 2111, 2201 b. and o.); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C 5841).)

Dated at Washington, D.C., this 7th day May 1979.

For the Nuclear Regulatory Commission.

Samuel J. Chilk
Secretary of the Commission