UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

(7)

PROPOSED RULE PR 35
45 FR 31701

FEB 0 5 1981

The Honorable George Hansen
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Hansen:

This responds to your January 12, 1981 request for information for your constituent Charles E. Smith, M.D., regarding a recently-concluded NRC rulemaking on reporting requirements for medical misadministration of radioactive materials. Dr. Smith expressed concern that this regulation will be detrimental to the health care profession and to physician/patient relationships.

Throughout this rulemaking, the Commission was very aware of the potential intrusion into the physician/patient relationship. At the proposed rule stage, in July 1978, the Commission expressed concern about the possibility of undue intrusion into the physician/patient relationship and asked commenters to focus on the manner in which referring physicians and their patients were informed of misadministrations.

In that regard, the Commission directed the staff to solicit extensive commentary thereon by distributing the proposed misadministration rule widely to physicians both within and outside of the nuclear medicine community. Accordingly, the proposed rule was mailed to all of NRC's medical licensees, about 30 professional and public interest groups, and about 2,000 local American Medical Association chapters.

Letters from 150 commenters were received and 90 percent of them were opposed to misadministration reporting, with most citing it as a serious intrusion into the physician/patient relationship. The Commission took several steps during the final rulemaking process to mitigate this intrusion. For example, in the final rule the Commission does not require diagnostic misadministrations to be reported to the patient. Also, in the final rule there are provisions for the referring physicians, if they wish, to inform patients of therapy misadministrations, as opposed to a strict requirement for the licensee to inform the patient.

The possibility of an undue intrusion into the physician/patient relationship by the NRC, was unquestionably the issue of greatest concern when the Commission considered the final rulemaking. In reaching its decision, the Commission concluded that the benefit of identifying the causes of misadministrations and thereby enabling measures to be taken to prevent recurrence, coupled with specific steps to minimize the intrusion into the physician/patient relationship, outweighed the possible detriment to that relationship resulting from the reporting of misadministrations.

In his correspondence with you, Dr. Smith erroneously stated that NRC had not prepared a value/impact analysis for the subject medical misadministration reporting requirements. A value/impact analysis supporting the rulemaking was prepared and was used by the Commission when it decided to promulgate the final rule. The notice of final rulemaking which was published in the Federal Register on May 14, 1980 (45 FR 31701), copy enclosed, also gave notice of the availability of that value/impact analysis for public scrutiny. A copy of the value/impact analysis is enclosed. Additionally, copies of two Commission papers, which provide an analysis of the public comments on the rulemaking are enclosed.

At this time the NRC does not intend to reopen the rulemaking on misadministration reporting unless there is substantial pertinent information that was not available to the Commission when they approved the final rule. However, when they approved the final rule, the Commission instructed the staff to reexamine the rule after it had been in place for three years.

I trust that this information is sufficient for your office to prepare a reply to Dr. Smith. If there are any further questions, please contact me or Edward Podolak in our Office of Standards Development (Telephone: 301-443-5860).

Sincerely,

(Signed) T. A. Rehm

William J. Dircks, Executive Director
for Operations

Enclosures: (3)
1. Federal Register Notice
2. Value/Impact Analysis
3. Commission Papers (SECY80-26) and SECY 80-26A

TASK # RH 025-4

DISTRIBUTION:
Central File
SD RDG/ALPHA
RHSB RDG/Subject
Smith
Goller
Guibert
Parsont
Podolak
WJDircks
G. Ertter (G.T. 10043)
SECY and LUnderwood, MPA

OFFICE	RHSB/RHSS/SD	AD/RHSS/SD	D/SHSS/SD	D/SD	EDO		
SURNAME	EPodolak/JG MParsont	JCGuibert	KRGoller KRG	RGSmith	WJDircks		
DATE	1/27/81	1/30/81	1/30/81	1/ /81	1/ /81		

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)).

FOR FURTHER INFORMATION CONTACT: Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–443–5860).

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 misadminstrations. 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 55385).

The Commission does not know the entire extent of misadministrations of radioactive material. In 1978 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 40018, 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 about 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 provide 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 misadministrations 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 commenter's 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 retake 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:

Sec.
35.41 Definition of a misadministration.
35.42 Reports of therapy misadministrations.
35.43 Reports of diagnostic misadministrations.
35.44 Records of all misadministrations.
35.45 Rights and duties of licensees.

Authority: Sections 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.; Section 201, Pub. L. 93-438, 88 Stat. 1242, 42 U.S.C. 5841.

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 radiopharmaceuted 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) *Immediate 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 also 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 judgment, 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, patient 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 is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, 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 refering 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 refering 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, patient or responsible relatives (or guardians).

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

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 80-14623 Filed 5-13-80; 8:45 am]

BILLING CODE 7590-01-M

REPORT JUSTIFICATION ANALYSIS FOR GAO

AND

VALUE-IMPACT ANALYSIS

I. Type of Recordkeeping and Report

Under the misadministration rule, licensees will be required to: (1) keep records of all misadministrations, (2) promptly report to NRC, the referring physician, and the patient or responsible relative (or guardian) all therapy misadministrations and (3) report diagnostic misadministrations quarterly to NRC. The prompt report is a telephone report within 24 hours of the event. The telephone report will be followed by a written report to those previously notified within 15 days. The record will include the names of individuals and a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. The follow-on written report of the therapy misadministration and the quarterly report of the diagnostic misadministration will contain the same information.

II. Need for the Report

In 1972, the General Accounting Office recommended that NRC require licensees to report misadministrations of byproduct material. The GAO stated that the information would help NRC to alert other licensees to generic misadministration problems. The records or reports will permit Inspection and Enforcement to investigate the incidents where warranted. Nuclear Materials Safety and Safeguards and State Programs will use the information to alert other medical licensees. Standards Development will use the information for

rulemaking actions, if indicated. GAO reaffirmed it 1972 recommendation in a January 1979 report (EMD-79-16).

The misadministration recordkeeping and reporting requirement should save lives.

III. GAO Report Justification Analysis

Misadministration data are very sparse, and what data do exist, are suspect. The frequency of misadministrations of radioactive material is not known. Food and Drug Administration (FDA) receives voluntary reports of adverse drug reactions (not misadministrations). Approximately 2500 NRC licensees and most of the 3000 Agreement State licensees will be affected by the proposed recordkeeping and reporting requirement. The estimates in this report can be multiplied by a factor of two to account for the potential burden on the Agreement States and their licensees. Assuming that, on the average, each NRC licensee has diagnostic misadministration (as defined in the final rule) per year there will be 2,500 records and reports to NRC.

GAO is concerned about the cost, in man-hours, of actually producing the record or report and the cost of reviewing them. The analysis of the incident and other associated costs are considered costs of complying with the regulation and not costs of recordkeeping or reporting. Both the recordkeeping and reporting requirements can be fulfilled by extracting pertinent facts from the patient's medical records.

The estimated cost to the licensees of preparing a record is one man-hour per misadministration. The estimated cost to the licensee of telephone reporting is one-half man-hour each for the NRC report, the referring physician report, and the patient report. The estimated cost to the licensee for a written report

is 2.5 man-hours. The total cost to the licensee for the reporting to NRC, the referring physician and the patient is therefore 4 man-hours per therapy incident.

Where they exist, misadministration reports are currently reviewed by NRC inspectors during scheduled inspections. The estimated cost of reviewing a licensee record is one man-hour per misadministration. Each telephone report of a therapy misadministration is estimated to require one man-hour to receive and write up. Each written report is estimated to require one man-hour to review and enter into the central registry. The total cost to the NRC is estimated to be 2 man-hours per diagnostic misadministration and 3 man-hours per therapy misadministration. With these assumptions the following calculations apply:

(1) 1 man-hour per record x 2,600 records = 2,600 man-hours annually for licensee recordkeeping; and 2,600 man-hours annually for NRC review.

(2) 4 man-hours per therapy report x 100 therapy misadministrations = 400 man-hours annually for licensee reporting; and half that or 200 man-hours annually to NRC (for therapy misadministrations).

(3) 2.5 man-hours per diagnostic report x 2,500 diagnostic misadministrations = 6250 man-hours annually for licensee reporting; and 2,500 man-hours annually to NRC (for diagnostic misadministrations).

(4) (2,600 + 400 + 6250) man-hours = 9250 man-hours annually to licensees for recordkeeping and reporting.

(5) (2,600 + 200 + 2500) man-hours = 5,300 man-hours annually to NRC for reviewing records and receiving and reviewing reports.

IV. Evaluation of Alternatives

There are no alternative data sources. Voluntary reporting was not satisfactory to GAO in 1972, and is probably an unworkable alternative. Adverse drug reactions voluntarily reported to FDA usually do not include reports of misadministrations.

Several commenters suggested alternatives to the rule. All of these alternatives were remedial measures to prevent misadministrations which are by now familiar, such as, requiring a written prescription. NRC has taken steps to prevent future misadministrations of the type that are presently known such as the one in the example. However, the purpose of misadministration reporting is to uncover novel types of misadministrations and to evaluate the effectiveness of steps taken to prevent the recurrence of misadministrations.

V. Value/Impact Assessment

It is difficult to place a dollar value on a human life. In the case of a fatality through malpractice, the courts have awarded judgments on the order of magnitude of 1 million dollars per death. The cost of illness and loss of productivity associated with misadministrations is more difficult to assess. An additional difficulty is that many of the patients, particularly therapy patients, may have a terminal cancer.

The actual, annual cost in dollars to licensees for preparing and maintaining (for 5 years) records of all misadministrations misadministrations is estimated to $50 for each of the 2,600 misadministrations or $130,000. The actual cost in dollars to licensees for reporting misadministrations is estimated to be $750 for each of 100 reportable misadministrations or $75,000. The annual cost for reporting the diagnostic misadministrations to NRC would be $500,000 at $200 per report. This $705,000 total annual cost to licensees does not include the cost of investigating the incidents, followup medical care, or malpractice.

The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known. All of the increases in medical costs due to this rule will certainly be passed on to patients.

The Office of Inspection and Enforcement estimates the cost of investigating 100 reports of therapy misadministrations to be 7.5 additional persons (3 man-weeks per investigation x 100 investigations ÷ 40 man-weeks/person). They estimate that an additional 2.5 persons are required for reviewing the 2,600 licensee records of misadministrations, preparing preliminary notifications, preparing Abnormal Occurrence reports, etc. The Office of Standards Development estimates that one additional person will be needed to prepare regulations and standards to prevent future misadministrations. The Office of Nuclear Materials Safety and Safeguards estimates that two additional persons will be needed to plan corrective actions, prepare orders to licensees review new regulations, and maintain the central registry. The remainder of the NRC offices will need a total of 2 additional persons to handle the work load generated by the misadministrations reports. The estimated, total annual cost to NRC is 16 persons at $30,000 per person or $480,000.

The estimated, total annual cost of the misadministration rule is $1,185,000 ($480,000 + $705,000). If the misadministration rule can prevent the death of a single individual annually, its value is established. The value of the rule should be proportional to the number of misadministrations and, hence, the cost, since the purpose of the rule is to identify the causes of misadministrations in order to prevent their recurrence.