[7590-01]

Title 10 - Energy

CHAPTER I - NUCLEAR REGULATORY COMMISSION

PART 35 - HUMAN USES OF BYPRODUCT MATERIAL

Misadministration Reporting Requirements

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

ACTION: Final Rule.

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

EFFECTIVE DATE: (75 days after publication).

> 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 (Phone: 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, to the referring physician and to 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 investigating the incident and 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. Examples of rule changes resulting from misadministrations are: (1) a rule requiring annual calibration of teletherapy units (44 FR 1722), (2) a rule requiring radiation surveys of patients following removal of implants (43 FR 55345), and (3) a proposed rule requiring tests for a radioactive contaminant in Tc-99m radiopharmaceuticals (44 FR 32394).

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 administrered 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, orders to licensees, or through rulemaking.

The Commission recognizes that its misadministration reporting requirement is 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.

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.

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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 to report misadministrations to patients or a responsible relative is important. Patients have a right to know when they are harmed. 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 record-keeping; the Fair Credict 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. The 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 accurracy is of increasing importance because medical information is used to affect employment and collection of insurance and other social benefits....

The Commission recognizes that there is a fine line between having records of misadministrations available to patients and actually informing the patients of the misadministrations. The Commission chooses to cross that line by requiring its licensees to inform the patients directly. This choice is underlined by the recurring theme throughout the public comments - the stated reluctance of many physicians to inform patients of 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.

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 order of the paragraphs in the final rule will be rearranged to emphasize this threshold for reporting diagnostic misadministrations.

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Radiopharmaceuticals can be measured to an accuracy within 10 percent. The definition of a diagnostic misadministration as an error greater than 20 percent is not a normal calibration limit but the point where an error obviously has occurred.

A few commenters objected to the absence of a definition for a "clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations. Some 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.

The Commission believes that "clinically detectable" is a term well understood in medicine. It refers to diagnosis involving direct observation of the patient, and includes such non-invasive testing as: blood pressure, temperature, blood tests, etc. The final rule will not have a definition of "clinically detectable adverse effect." Definitions, such as, a percentage depression in the white blood-cell count, are procedure-specific and patient-specific. 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. Thus, the licensee will determine, based on the diagnosis of a physician, when a diagnostic misadministration causes a clinically detectable adverse effect on the patient.

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, extravasation is not considered a misadministration.

Some commenters questioned whether they would have to measure the activity in a syringes 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.

Summary of Major Changes in the Final Rule

Several commenters' suggestions were incorporated into the final rule. As noted above, the paragraphs in the final rule are rearranged to emphasize the threshold for reporting diagnostic misadministrations. The first paragraph is now the recordkeeping requirement and the second paragraph is the reporting requirement. Also, the term "could cause a clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations was changed to "causes a clinically detectable adverse effect" in the final rule. Several commenters had pointed out the ambiguity of the future tense because any exposure to radiation has the potential to cause an adverse effect.

In the final rule there are two changes regarding notification of the patient or responsible relative in § 35.33(b). First, a parenthetical "(or guardian)" was added to "responsible relative" to cover persons who do not have relatives. Second, now the referring physician can inform patient of the misadministration.

In the final rule the definition of a diagnostic misadministration in § 35.33(d)(4) recognizes the difficulty in scheduling administrations of very short half-life radiopharmaceuticals. These radiopharmaceuticals usually cause a lower radiation dose to the patient. Under the new definition, errors of greater than 50 percent for radioisotopes with half-lives less than three hours are misadministrations.

In the final rule the definition of a therapy misadministration in § 35.33(d)(5) and (6) 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.

In the final rule, licensees will be required to keep records of misadministrations for 50 years because of the long latency period for radiation induced cancers.

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.

A new § 35.33 is added to 10 CFR Part 35 to read as follows:

§ 35.33 Records and reports of misadministrations.

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(a) Each licensee shall maintain for 50 years, 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), a brief description of the event, the effect on the patient, and the action taken to prevent recurrence.

(b) When a misadministration involves a diagnostic procedure that causes a clinically detectable adverse effect on the patient or 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 judgement, 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 patients' 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.)

(c) Within 15 days after the initial 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

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guardian) if either was previously notified by the licensee under paragraph (b) of this section. The written report shall include the licensee's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; and whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. However, the report should not include the names of others involved in the misadministration, such as the patient, physicians, and allied health personnel.

(d) For this section misadministration means the administration of:

(1) A radiopharmaceutical or radiation from a sealed 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 for radioisotopes with a half-life greater than or equal to 3 hours, and 50 percent for radioisotopes with a half-life less than 3 hours;

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

(6) 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.

(3) 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).

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

Dated at Washington, D.C., this _____ day _____1979.

For the Nuclear Regulatory Commission.

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Samuel J. Chilk
Secretary of the Commission

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DRAFT PUBLIC ANNOUNCEMENT

(To be prepared by the Office of Public Affairs)

868 025

Enclosure 2

proposed rules

[7590-01]

NUCLEAR REGULATORY COMMISSION

[10 CFR Part 35]

HUMAN USES OF BYPRODUCT MATERIAL

Misadministration Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations to require licensees to (1) keep records of all misadministrations of radioactive material or radiation from radioactive material, and (2) promptly report potentially dangerous misadministrations to the NRC, to the patient's referring physician, and to the patient or the patient's responsible relative.

DATES: Comment period expires October 5, 1978.

ADDRESSES: Written comments or suggestions for consideration in connection with the proposed amendment should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-5946

SUPPLEMENTARY INFORMATION: Following its organization under the Energy Reorganization Act of 1974 (Pub. L. 93-438), NRC, with a view to possible changes, began reviewing its regulations and procedures about licensing and regulation of nuclear facilities and materials originally promulgated by the Atomic Energy Commission (AEC).

On March 9, 1973, the AEC published a proposed rule in the FEDERAL REGISTER (38 FR 6099) that would have required licensees to report to the AEC and to the patient all misadministrations of byproduct material and also would have required licensees to determine that paramedical (allied health) personnel were adequately trained in the safe use of radioactive materials. Because 5 years have elapsed since the AEC requirement was proposed, it is being withdrawn and a new NRC proposed misadministration recordkeeping and reporting requirement, 10 CFR §35.33, is being offered for public comment. The NRC proposed rule reflects the public comments on the AEC proposal.

One purpose of the misadministration reporting requirements is to allow NRC to investigate the incident; determine if there was a violation of NRC regulations; evaluate the corrective action taken by the licensee to minimize the chance of recurrence; and, if there is a possibility of other licensees making the same error, to allow NRC to begin generic corrective action which, as a minimum, would inform other licensees of the potential problem. Another purpose is to inform the patient or the patient's responsible relative so that corrective action can be taken. On this point, the Commission has expressed concern about the possibility of undue intrusion into the physician-patient relationship. Consequently, the Commission asks that commentors particularly focus on those portions of the proposed amendments which deal with the manner in which referring physicians and their patients are informed of misadministrations.

Specifically, NRC's proposed §35.33 would require licensees to maintain for inspection by the Commission, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy and brachytherapy sources. Licensees would also be required to report promptly all misadministrations that involve a therapy procedure and those diagnostic misadministrations that could cause a clinically detectable adverse effect on the patient: (1) To the NRC, (2) to the patient's referring physician, and (3) to the patient or the patient's responsible relative, unless the referring physician personally informs the licensee that in his medical judgment telling the patient or the patient's responsible relative would be harmful to one or the other, respectively.

It is expected that the licensee would report to the patient's responsible relative rather than the patient when, for example, the referring physician tells the licensee that in his medical judgment informing the patient would be harmful to the patient; the patient is a minor; or the patient is unconscious and incapable of comprehending the information. The licensee would have the discretion of reporting either to the patient or to the patient's responsible relative. The record or report which would be supplied to NRC would contain a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. The names of individuals would be maintained in the licensee's record but not reported to the NRC. A copy of the report to NRC would be furnished by the licensee to the patient or the patient's responsible relative if either had been notified previously.

An example of the follow-up action NRC might take upon receipt of a misadministration report was the NRC investigation of an incident were 400 patients treated for cancer with a cobalt-60 teletherapy unit received radiation doses that exceeded the prescribed doses by as much as 41 percent. This incident occurred because the radiation dose rate from the teletherapy unit had not been properly determined. Soon after its investigation, NRC acted to ensure that all teletherapy units licensed by it were properly calibrated. NRC also published in the FEDERAL REGISTER (42 FR 35743) a proposed amendment to §35.13 requiring teletherapy licensees routinely to calibrate and check their teletherapy devices. The teletherapy calibration proposal also included a specific misadministration reporting requirement that would be replaced by §35.33 (a more general proposal). Comments received in response to the earlier teletherapy misadministration reporting requirement will be considered in conjunction with the proposed rulemaking.

In this newly proposed rule, §35.33(f) (4) and (5) define misadministrations in part as administrations differing from the total prescribed dose or exposure by more than 10 percent for therapeutic procedures or 20 percent from diagnostic procedures. These limits should not be viewed as the normal calibration limits for these procedures but rather the points where an error obviously has occurred. The narrower tolerance for the therapeutic procedures recognizes the greater risk to the patient from therapeutic misadministrations.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United

Enclosure 3

States Code, notice is hereby given that the 1973 AEC proposed rule (38 FR 6309) is withdrawn and adoption of the following new amendments to 10 CFR Part 35 is contemplated.

A new § 35.33 is added to 10 CFR Part 35 to read as follows:

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves either a diagnostic procedure that could cause a clinically detectable adverse effect or therapy procedure, within 24 hours after the licensee's discovery that the misadministration is likely to have occurred, the licensee shall notify by telephone:

(1) The appropriate NRC Regional Office listed in appendix D of part 20 of this chapter;

(2) The patient's referring physician; and

(3) The patient or the patient's responsible relative, unless the referring physician personally informs the licensee that in his medical judgment telling the patient or the patient's responsible relative would be harmful to one or the other, respectively.

(b) If the referring physician, or the patient's responsible relative is unavailable within 24 hours, the licensee shall make the notification under paragraphs (a)(2) or (a)(3) of this section as soon as practicable after that person becomes available. Attempts to notify the referring physician or the patient's responsible relative shall not defer needed medical care for the patient.

(c) Within 15 days after the licensee's discovery that the misadministration is likely to have occurred, the licensee shall make a written report to the NRC Regional Office initially telephoned, and furnish a copy of the report to the patient or the patient's responsible relative if either has been previously notified under paragraph (a)(3) of this section.

(d) The written report made under paragraph (c) of this section shall include: the licensee's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; and whether the licensee informed the patient or the patient's responsible relative, and if not, why not. However, the report should not include the names of others involved in the misadministration, such as the patient, physicians, and allied health personnel.

(e) Each licensee shall maintain for 5 years for Commission inspection records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of everyone involved in the event (including the licensee, the authorized user(s), allied health personnel, the patient's referring physician, the patient, and, where appropriate, taken to prevent recurrence.

(f) For this section, misadministration means 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 treatment dose or exposure differs from the prescribed dose or exposure by more than 10 percent.

(g) 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.

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

Dated at Washington, D.C., this 7th day of June 1978.

For The Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 78-18735 Filed 7-6-78; 8:45 am]

SUMMARY AND ANALYSIS OF COMMENTS

1. Susan Grant, 66 E. Main Street, Port Norris, N.J. 08349 (July 16, 1978)

COMMENT: In response to your proposal to require medical licensees to report misadministrations of radioactive materials, I would like to make the following comments:

Who is to determine if diagnostic misadministrations cause clinically detectable adverse effects? Leaving this judgment in the hands of a physician or licensee who is liable for suit is a weak proposition. All diagnostic misadministrations should be reported to the NRC, and a hopefully impartial investigator should determine what the effects are, and whether they are adverse or not.

The physician should not be making the decision as to whether the patient should know of a misadministration - I thought we were past the age where it was admirable to consider the physician akin to God. The patient should be notified directly and by written report unless he is unconscious or a juvenile, in which event both direct and written reports should go to the responsible relative.

STAFF RESPONSE: The licensee will determine if the diagnostic misadministration causes a clinically detectable adverse effect based on the diagnosis of a physician. All diagnostic misadministrations are subject to the recordkeeping requirement. If an inspector believes that a misadministration that was not reported should have been reported, NRC will investigate this as a possible violation of the regulation. The staff believes that this procedure, with the people on the spot determining which misadministrations to report, combines speed with efficiency.

COMMENT: Patient or responsible relative should always be the recipient of a confirmatory written report from the NRC as the public agency supposedly safeguarding the public welfare in regards to radioactive materials.

STAFF RESPONSE: The staff does not recommend intruding into the physician-patient relationship to the extent of NRC contacting the patient directly. This recommendation may be changed if licensee compliance with the patient notification provisions of the rule is poor.

COMMENT: Keeping records for misadministrations for 5 years is hardly satisfactory; a fifty year minimum would more accurately reflect both the nature of radioactive materials and their effect on people, and the role of NRC as a "safety" commission.

STAFF RESPONSE: The staff agrees and is recommending a fifty year period for retention of records of misadministrations.

COMMENT: Requiring that paramedical personnel be adequately trained on the safe use of radioactive material seems the least NRC can do.

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STAFF RESPONSE: Present regulations place the responsibility for evaluating the qualifications of paramedical personnel on the licensee and, in particular, on the physicians authorized in the license to use radioactive materials on humans. These physicians are authorized to use the licensed materials and they may delegate certain tasks to paramedical personnel. However, the physicians remain responsible for the use of that material. The staff is studying the possibility of minimum radiation safety qualifications for paramedical personel, but there are no plans to recommend such requirements in the near future.

2. Edward H. Pollaci, Jr., LLM, National Press, Iness Organs Media, 8-19 103rd Avenue, Bond Hill, N.Y. 11419 (July 12, 1978)

COMMENT: Recently the government through one of its agencies representatives Viz Travelers Insurance Companies Railroad Medicare Section have impounded funds claimed due to Railroad Medicare claimants, stating such claims are excessive.

It appears to me that patients would be required to finance the reports and records of doctors arising out of this new regulation. I would like to suggest that the regulations specifically provide that the Federal Government will allow the extra charges be paid in full to the patient and or the persons bearing the expense arising out of the proposed regulation.

STAFF RESPONSE: The licensee will surely pass the cost of this regulation on to the patient. NRC regulations cannot provide for reimbursement by Medicare. Medicare reimbursement is based on the provider's cost which reflects the cost of complying with NRC regulations. This process is not spontaneous.

COMMENT: I do not see any provision for pyramiding of doses administered by different persons unknown to each other; many patients go to more than one doctor. Reports should be made of all administrations of radioactive materials so that the NRC through its computers could evaluate the total doses for different periods throughout significant areas for each patient; and or relative having contact with the patient during the administration.

STAFF RESPONSE: NRC does not plan to keep track of misadministrations on a patient-by-patient basis.

3. Charles D. Teates, M.D., Department of Radiology, School of Medicine, University of Virginia, Charlottesville, Virginia 22901 (July 27, 1978)

COMMENT: When this was originally proposed, I believe that you received a number of comments regarding the implications of misadministration reporting to the NRC and to patients that might result in malpractice litigation. The proposed reporting procedure may stimulate litigation suits and this problem should be considered before it is accepted. The stated reason for informing the patient of the misadministration is so that "corrective action can be taken". I am not sure what corrective action is anticipated. If in fact no corrective action would be envisioned (particularly for the diagnostic tests), what is the reason for inviting litigation by formal notification of patients of misadministration?

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STAFF RESPONSE: NRC did receive many comments about malpractice litigation when the rule was first proposed in 1973. The phase "corrective action" meant medical attention. Under the final rule, serious misadministrations would be reported to the patient or a responsible relative. The staff believes that the patient has a right to be informed of serious misadministrations.

COMMENT: It is suggested that any misadministration that could lead to "clinically detectable adverse effect" be required to be reported immediately to the NRC. In the case of the diagnostic tests, it is difficult to envision a misadministration that would result in clinically detectable adverse effects, particularly with short half life nuclides.

STAFF RESPONSE: The staff agrees that only infrequently would diagnostic misadministrations lead to clinically detectable adverse effects.

COMMENT: I have no quarrel with the requirement that each facility maintain a record of misadministrations, even those with diagnostic tests. However, I think that the definition of misadministration needs clarification. In section 35.33, (F), misadministration is defined to include administration of a radiopharmaceutical by a route of administration other than that intended by the prescribing physician. Would this include the infiltration of a dose intended to be intravenous or intra-arterial? In our experience, some infiltration of the soft tissues occurs in as many as 1/3 of intravenous injections and I doubt that this is intended to be defined as a misadministration.

STAFF RESPONSE: Infiltration of an intra-arterial or intravenous administration (extravasation) is not considered an administration by a route other than the one intended. The preamble of the final rule will make this clear.

4. Don R. Spiegelhoff, M.D., 2900 West Oklahoma Avenue, Milwaukee, Wisconsin 53215 (August 1, 1978)

This proposed rule as written provides no more than another record which must be kept by both your office and our office and will serve no useful purpose. It is presently a standard procedure to inform the appropriate people when a misadministration occurs both as a defense for any malpractice and as a service to all those concerned. This is done whenever it is felt to be in the best interest of all concerned.

Therefore, your proposed rule is merely another step in the U.S. government practicing medicine without knowledge or a license. It will provide for more employment but not be productive in our society as it is after the fact.

STAFF RESPONSE: NRC is not routinely informed of misadministrations. With misadministration reports in hand, NRC can investigate the incident and take steps to prevent recurrence.

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5. Dr. Edward A. Dolan, Chief of Radiology, St. Joseph Mercy Hospital, 2200 East Grand Boulevard, Detroit, Michigan 48211 (August 1, 1978)

COMMENT: It is our opinion that more harm than good comes from informing patients of small misadministrations of diagnostic dosages. If such a misadministration occurs no known harm comes to the patient. In this event the dose cannot be retrieved once it is administered intravenously.

At the time of examination patients are under stress concerning their personal health. Too many facts given to these patients in a heightened anxiety state will not benefit anyone. We urge you to reconsider this regulation.

STAFF RESPONSE: Licensees would not be required to report minor misadministrations of diagnostic dosages. Licensees would be required to report a diagnostic misadministration to NRC, the referring physician and the patient or a responsible relative only if the misadministration caused a clinically detectable adverse effect.

6. Thomas A. Gardner, M.D., Chief Radiologist, Franklin Hospital, an Affiliate of Jefferson Medical College, 1 Spruce Street, Franklin, Pa. 16323 (July 31, 1978)

COMMENT: I agree that the implementation of the proposed rules would result in undue intrusion into the physician/patient relationship.

I feel that the incidence of "misadministration" is extremely low.

It appears inappropriate to expect a physician to set the stage for self-incrimination and for malpractice litigation. I know of no similar requirement within the Nuclear Regulatory Commission requiring its officials and/or employees to report similar type errors.

STAFF RESPONSE: The actual incidence of misadministrations is not known. The benefits and the costs of the rule will be proportional to the number of reports. NRC has similar requirements for other licensees but not for its own employees.

7. Daniel J. Price, M.D., Chief Nuclear Medicine, St. Michael Hospital, 2400 West Villard Avenue, Milwaukee, Wisconsin 53209 (July 31, 1978)

COMMENT: We do keep incident records on all misadministrations of radionuclides.

I think prompt reporting of misadministrations to the NRC, to the patient and/or family as well as the attending physician is reasonable only if this misadministration can indeed be considered dangerous. Infrequently, but from time to time either through a physician or nurse ordering errors or errors in our department, a wrong Tc-99m complex will be given or the radionuclide will be given to the wrong patient. The dose of these administrations is low and, although these errors are undesirable, it would appear injudicious to make big issues and conceivable law suit problems out of them.

Basically, the report to the NRC is what we currently maintain in our incident report file. I think it is reasonable for an extensive report, as you suggest in therapeutic procedures, but in low dose diagnostic procedures, proper incident report records within our own files should be adequate. Errors are informally discussed with the patient and the attending physician, as well as action taken to prevent recurrences, but I believe efforts beyond this in low dose diagnostic procedures would represent an over kill.

STAFF RESPONSE: For diagnostic misadministrations, the reporting requirement applies only to those that cause a clinically detectable adverse effect.

8. Edward G. Allen, M.D., Radiation Safety Officer, Emmett Memorial Hospital, Clifton Forge, Va. 24422 (July 27, 1978)

COMMENT: I am against having these procedures reported to the patient or to the patient's responsible relative. The radiation exposure involved in a diagnostic dose of a radiopharmaceutical is so low that I do not feel that the reporting of any misadministration need go further than the radiation safety officer and the referring physician at the institution in question. A record, however, could be kept at the institution to determine if these misadventures would entail a particular technician.

STAFF RESPONSE: All misadministrations are subject to the recordkeeping requirement. All therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect are subject to the reporting requirement.

COMMENT: Since the effects of radiation are so unknown as far as dose-related effect is concerned I feel that a report should not be given to the patient or to the patient's responsible relative as this would simply lead to initiation of malpractice suits in which it would be impossible to determine that a damaging effect resulted. Under this proposal and the freedom of information law, we now have any lawyer that can simply request in the public interest a copy of such a report from any institution and then proceed to contact the patients involved to initiate malpractice procedures.

STAFF RESPONSE: The staff believes that patients should be informed of serious misadministrations. The rule requires that patients be informed of serious misadministrations. The reporting requirement may well increase the cost of malpractice insurance. The amount of this increase is not known.

9a. G. William Whitehurst, 2nd District, Virginia, Congress of the United States, House of Representatives, Washington, D.C. 20515 (August 9, 1978)

COMMENT: Enclosed is a copy of a letter I recently received from Mr. James A. Hancock, Jr., of Norfolk, Virginia. I feel that Mr. Hancock has raised some valid points concerning these proposed regulations and I hope that every consideration will be given to his views.

9b. James A. Hancock, Jr., Radiological Physics Consultant, 1130 Hanover Avenue, Norfolk, Virginia 23508 (August 2, 1978)

868 032

COMMENT: I wish to oppose the adoption of any part of the proposed new part, Section 35.33.

The following reasons are given in support of my position:

This requirement will mean an intrusion of a regulatory agency into the care of a patient without assuming responsibility of the care of the patient.

STAFF RESPONSE: The staff acknowledges that requiring reports to the patient is an intrusion into the physician-patient relationship. The staff believes that this is a necessary intrusion because the patient has a right to know if a serious misadministration has occurred.

COMMENT: I hold that the required reporting will not benefit the patient. The limits in proposed 35.33 (f) (4) do not represent a significant difference in patient dose.

STAFF RESPONSE: The limit of ±20% error in the prescribed dose for diagnostic administrations is not intended to represent a "significant difference in patient dose" but rather a point where a mistake has occurred.

COMMENT: The limit in proposed 35.33 (f) (5) can be adjusted by changing a treatment schedule in external beam treatment, and is well within the biological variation in internal administrations.

STAFF RESPONSE: The therapy limit of ±10% error in the prescribed dose applies to the total treatment dose exposure and accommodates changes in the treatment schedule.

COMMENT: Requirements under the proposed 35.33 (f) (1), (2) and (3) are best reported, as now required, through the local Radioisotopes Committee of the licensee.

STAFF RESPONSE: NRC does not require reports of misadministations to local radioisotopes committees. Individual physician licenses do not include medical isotopes committees. The staff believes that serious misadministrations should be reported directly to NRC so that other licensees can be notified of generic problems.

COMMENT: Requirement of reporting such information under proposed 35.33 (c) would mean an admission of fault on public record. A hospital or physician would be in immediate jeopardy of suit, and such a requirement would add considerably to the cost of liability insurance, if, indeed, it did not actually preclude such insurance. Further, it appears to me to be in violation of the constitutional right against self-incrimination.

STAFF RESPONSE: The constitutional protection applies to criminal action not civil penalties. The reporting requirement of this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

COMMENT: The whole reporting procedure, including the requirement under proposed 35.33 (e) would increase the cost of medical care without adding

to the benefit therefrom, unlike the present requirement of review by the hospital committee.

STAFF RESPONSE: The staff acknowledges that there will be some incremental increase in the cost of medical care which should be offset by the benefits of informing all medical licensees of potential problem areas.

COMMENT: Finally, may I suggest that this requirement will lead, inevitably, to cover up of misadministrations, to avoid the vulnerability to liability suits.

STAFF RESPONSE: The rule is enforceable. I&E has experience with similar reporting requirements for other NRC licensees.

10 John C. Spellmeyer, M.D., Director, Department of Radiology, Reid Memorial Hospital, 1401 Chester Boulevard, Richmond, Indiana 47374 (August 1, 1978)

COMMENT: If I were to participate in the misadministration of a drug or radiopharmaceutical, I would be displeased and unhappy with that occasion. However, I strenuously object to any requirement to notify the NRC of any misadministration.

The doses of radiopharmaceuticals that we are using in clinical practice pose no significant hazard for the intended patient or the inadvertently injected patient if a misadministration should occur.

STAFF RESPONSE: NRC is not requiring reports of diagnostic misadministrations unless there is a clinically detectable adverse effect.

COMMENT: In the current political-legal-medical-malpractice environment, any information provided to the NRC becomes uncontrolled through the Freedom of Information Act. To report a misadministration to a governing authority creates needless legal hazard and jeopardy to the practicing physician.

It is my request that these proposed amendments be defeated at an early date.

STAFF RESPONSE: Only serious misadministrations are required to be reported to NRC, the referring physician and the patient.

11. Ralph G. Robinson, M.D., Head, Division of Nuclear Medicine, The University of Kansas Medical Center, College of Health Sciences and Hospital, Rainbow Boulevard at 39th, Kansas City, Kansas 66103 (August 2, 1978)

COMMENT: I write regarding the Nuclear Regulatory Commission's proposed rule requiring prompt (24 hour) reporting of "misadministrations" of diagnostic radiopharmaceuticals.

If the proposed rule restricted itself to those rare, obvious cases of serious misadministration, such as using the therapeutic quantities of I-131 for a diagnostic procedure, or therapeutic quantities of Phosphorus-32 for a diagnostic procedure (eye), then the rule would perhaps be acceptable. However, the "misadministration" as defined in the

possible rule-making includes all extremely minor administrations which may occur, and which are of no clinical significance to the patients involved. The adoption of this proposed rule would result in scores of instances of notification of patients and relatives, which will most certainly cause alarm in those patients, which would be totally unnecessary in 99.9% of the instances reported.

STAFF RESPONSE: The final rule requires reporting of all therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect.

COMMENT: In addition, whether we are talking about very minor "misadministrations" or the rare serious instance of a wrong dose or radioisotope, the proposed rule dictates who must be notified in terms of the patient and/or his relatives, and how rapidly this notification must take place. This is clearly an intrusion of the Nuclear Regulatory Commission into the practice of medicine. Certainly the physician has a duty to report serious administrations as appropriate, taking into account the patient's clinical diagnosis, prognosis, and his total medical situation at that time. However, that is his prerogative and should not be that of the Nuclear Regulatory Commission's assumed by arbitrary rules and regulations.

STAFF RESPONSE: The staff acknowledges the intrusion but considers that it is necessary to insure that patients are informed of serious misadministrations. The rule permits the physician to not tell the patient or relative, if, in his judgment, the information would harm the patient or relative, respectively.

12. Peter B. Schneider, M.D., Professor of Medicine, University of Massachusetts Medical School, Co-Director of Nuclear Medicine, The Memorial Hospital, 119 Belmont Street, Worcester, Massachusetts 01605 (August 1, 1978)

COMMENT: The suggested record keeping and reporting requirements seem an unnecessary bureaucratic burden. The correct action to take in the event of a potentially harmful misadministration of radionuclide is already covered by professional ethics and good judgment. Since misadministration of nuclide is basically the same as any other medical error, it should not be singled out as opposed to say, errors of drug administration. Although it might be argued that the reporting of misadministrations to the NRC might enable the NRC to reduce such events in the future by suggesting remedial actions, I would guess that most errors occur because of carelessness and the remedy is obvious even without tabulations by the NRC.

Even if some reporting requirements are adopted, diagnostic radioisotopes should be excluded. The hazards of such misadministrations are so small that the proposed requirements would be of little value. Since the dosage of diagnostic isotopes in ordinary clinical practice varies within a range of several fold for one procedure, the definition of "misadministration" as a 20% variance is unwarranted. Such variances can occur routinely under good practice. For instance, the prescribed dose of Tc99m-colloid for liver scans may be between 1-4 mCi. Say that a physician prescribes 2 mCi for all liver scans scheduled on a particular day. Several 2 mCi doses are prepared in or delivered to the Nuclear Medicine Unit and calibrated for about noon. A patient may actually be brought to the Unit at

10:00 a.m. because that is when he is available or perhaps, at 2:00 p.m. because he was delayed at another procedure. In either case, the dose, because of decay, will be 20% off the prescribed dose but would still be perfectly adequate for liver scanning. Does your proposal require the physician to represcribe each individual dose to make it match the syringe content? Does a central radiopharmacy have to calibrate each dose for the uncertain time that a patient may be injected? Defining misadministration as you propose would involve us in extra paperwork and engender a burden which would add to costs and lead to confusion and error...and all for the purpose of ensuring that harmless variations in dose agree with some (relatively arbitrary) number written down as a prescription.

STAFF RESPONSE: The definition of misadministration as the administration of a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 20% indicates a point where a mistake was made, rather than a point where the patient is harmed.

COMMENT: Furthermore, labeling something as a "misadministration" carries a perjorative tone which sets a difficult stage for the subsequent determination of "potentially harmful." "Potentially harmful" is such a vague term and so open to nuances of meaning that it might be difficult to defend any dose variation as harmless if it has already been labeled an error.

Although errors in doses of therapeutic isotopes are obviously of great concern, even here a 10% variation may be trivial. In the therapy of thyrotoxicosis with I-131, the prescription of a particular dose is based on estimates and judgements by the physician that far exceed 10% in possible variations.

STAFF RESPONSE: The staff has 10 literature references which indicate that deviations by as little as 5-10% in the therapy dose may result in significant increases in late complications. While this may not be true in treating thyroid disorders, the radiopharmaceutical dosage is readily measured and the unnecessary exposure attendent to therapy misadministrations is not insignificant.

COMMENT: It might be better to define "misadministration" as variation of dose (in amount, form, or route of administration) from the prescribed dose sufficient to cause clinically detectable effects without any explicit reference to permissible quantitative variances from the prescribed dose. That is still rather vague but since notification of the patient is predicated on potential harm anyway, nothing is lost from your original proposal.

STAFF RESPONSE: Patient notification is dependent upon a clinically detectable adverse effect in the patient for diagnostic misadministrations but not in therapy misadministrations. The staff believes that errors greater than 10% for therapy are serious and warrant reporting, even in the absence of clinically detectable adverse effects.

13. Horace W. Scott, M.D., Department of Radiology, Lutheran Medical Center, 2639 Miami, St. Louis, MO 63118 (August 1, 1978)

COMMENT: I am somewhat appalled at the scope of the proposed regulations regarding misadministration of radiation and radiopharmaceuticals. Basically, I agree with the intent of the proposed rules. In our hospital, whenever there is a misadministration of medication of any kind, some notation is made. I think that the best way to avoid such misadministrations, is to prevent them. To this end the Nuclear Regulatory Commission functions well in requiring inspection of the holders of its licenses for the use of radioactive materia..

It is difficult for me to conceive of calling the Nuclear Regulatory Commission every time one of our patients should happen to get a 10% increase or decrease in a radiation treatment. Most of the time this is not a matter of grave concern and is simply adjusted by increasing or decreasing succeeding doses.

STAFF RESPONSE: The 10% error for therapy does not apply to individual treatments but to the total treatment dose.

COMMENT: Would such regulations also apply to radiation generated by standard 200 KVP therapy units or smaller units which do not depend upon byproduct material for the source of their radiation?

In this hospital, as I am sure occurs in other hospitals, occasionally a patient receives an unscheduled or unordered radiographic examination. This may be a chest radiograph or it may be a barium enema. If harm ensues, the matter is noted in the patient's chart and duly reported to our insurance agents. This sometimes is discussed with the patient. It is sometimes not discussed with the patient. These are matters best left to the judgement of the physician. I cannot conceive of calling the Nuclear Regulatory Commission on the telephone and submitting a report and keeping our records for five years every time somebody gets the wrong chest x-ray.

STAFF RESPONSE: NRC does not regulate x-ray machines.

COMMENT: While the intent of the Commission seems admirable, the mechanism that it proposes, it seems to me, is redundant and very expensive.

It is still my feeling that the Nuclear Regulatory Commission's efforts are best spent in the field of prevention.

STAFF RESPONSE: The principle intention of the misadministration rule is to prevent generic type misadministrations that could be controlled by quick communication with all NRC licensees.

14. R. W. Watts, M.D., Chief, Nuclear Medicine, Veterans Administration Hospital, 2100 Ridgecrest Drive, SE, Albuquerque, New Mexico 87108 (July 31, 1978)

COMMENT: Your proposal to keep records of misadministrations of radiation are superfluous since the good practice of medicine already requires records of medications and therapies, and the definition of "misadministration" must be basically a medical judgement rendered in each specific case.

868 037

STAFF RESPONSE: The records of misadministrations that are required by this rule will be maintained for inspection by NRC. The determination of a reportable diagnostic misadministration is basically a medical judgement. However, it is necessary to define misadministrations to have an equitable and enforceable regula

COMMENT: Further, the proposal to inform various parties of these "misadministrations" intrudes a bureaucratic machinery into an area already well overloaded by opportunistic lawyers skyrocketing the cost of medical attention. We must assume at some point that individuals can competently contract with each other for services, and defend their own interests, without imposing ponderous, expensive and ineffectual regulations.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

15. Barbara Y. Croft, Ph.D., Assistant Professor, University of Virginia Medical Center, Charlottesville, Virginia 22908 (July 31, 1978)

COMMENT: In §35.33 (f), (3) misadministration includes the correct radiopharmaceutical by the wrong route. Most of the radiopharmaceutical administrations are intended to be made intravenously. However, because of many circumstances including poor veins and venous collapse during administration, at least part of the dose is administered subcutaneously. I am concerned that labelling all missed injections as misadministrations may needlessly burden an apparatus intended for another purpose and unduly alarm everyone concerned.

STAFF RESPONSE: The staff agrees. The rule was not intended to include extravasation. The preamble to the final rule will make this clear.

COMMENT: In §35.33 (f) (4) and (5), misadministration is defined using limits of ± 10% on therapeutic doses and ± 20% on diagnostic doses. I am concerned that the dose calibrator, the instrument used to measure the doses being administered, cannot itself be controlled to the required tolerance. The standard for dose calibrators is that they read within ± 10% for the standard sources, which should be traceable to the National Bureau of Standards sources. Depending on the design of the calibrator however, the standard source may be read acceptably while other sources, in other geometries, may not be read accurately at all. There have been several comparisons of dose calibrators suggesting that the results may be precise but not accurate. I feel it is thus a mistake to set the tolerance for misadministration too finely. I believe a statistician should be consulted for suggestions on a reasonable level of error.

STAFF RESPONSE: Dose calibrators should be calibrated for the geometry of intended use, i.e., syringe, multidose vial, etc. The American National Standards Institute standard ANSI-N42.13-1978 for dose calibrators states that uses should be able to measure total activity to an accuracy within ±10% and reproducible within ±5%. Therefore, licensees should be able to meet the specification of ±20% error for diagnostic administrations. The specification of ±10% error for therapeutic administrations will require more care, perhaps even the purchase of standards directly from the National Bureau of Standards. The specifications on misadministrations apply to

calculations or to parameters that can be directly measured, e.g., the activity in the syringe before injection or the measured radiation dose or exposure from a Co-60 teletherapy unit, time, etc.

16. Frank L. Iber, M.D., Professor of Medicine, University of Maryland School of Medicine, Chief, Gastroenterology Division, Baltimore VA Hospital, 3900 Loch Raven Boulevard, Baltimore, Maryland 21218 (August 2, 1978)

COMMENT: The biggest difficulty in these two portions is to define precisely misadministration and potentially dangerous misadministration. I would suggest that in misadministration be the administration of an incorrect isotope. Could I suggest an incorrect form of isotope by a dose determined to be at least 100 percent in excess for diagnostic and 25 percent excess for therapeutic. I believe a maximal definition should be defined for potential dangerous misadministration so that there can be no variations for interpretation.

STAFF RESPONSE: The definition of a misadministration is intended to reveal mistakes. Serious misadministrations which will be promptly reported to NRC, the referring physician and the patient are intended to flag instances where the patient is harmed.

COMMENT: I believe that these rules will create the factual basis for fairly expensive malpractice settlements since by definition a recorded misadministration is a compensatable tort.

However, I would suggest the following: Potentially dangerous misadministrations be defined in terms of a radiation exposure that includes exceeding the diagnostic amount for diagnostic radiation by a certain number of rads; or an increased therapeutic dose of the order of 25 percent. Once these two levels of danger are described and defined, then it could be made the regulation to require the licensee to both keep a record and to report this to the referring physician.

STAFF RESPONSE: The staff believes that it is better to define a misadministration with parameters that can be readily measured, such as activity or source strength.

COMMENT: I personally have great difficulty with requiring by regulation that this also be reported to the patient for it simply will boost the cost of medical care and only serve to regulate this unfortunate occurrence when a given physician or technician is repeatedly involved in the same action. I repeat, the problem is with definition.

STAFF RESPONSE: The final rule will clearly show a threshold where only serious misadministrations will be required to be reported to the patient, i.e., all therapy misadministrations and those diagnostic misadministrations having a clinically detectable adverse effect on the patient.

17. Henry C. Gorman, M.D., Department of Radiology, Lakeview Medical Center, 812 North Logan Avenue, Danville, Illinois 61832 (July 31, 1978)

COMMENT: I am highly in favor of NRC control of radioactive material.

With some limitations I also favor the prompt reporting of misadministration of radioactive material. I could see, however, that this could become cumbersome and unreasonable. If I inavertently injected a patient with radioactive material for a liver scan on Tuesday instead of Wednesday, that still would fall under the category of misadministration of radioactive material, but would seem unreasonable in the practical sense.

I think the real dangerous misadministration ought to be reported to the attending physician, the patient, and/or relatives, and to the NRC as is suggested.

STAFF RESPONSE: There is a clear threshold in the final rule. Only dangerous misadministrations will be reported to NRC. The example given does not appear to be a misadministration under the definition in the rule.

18. Frederick N. Cushmore, M.D., St. Joseph's Hospital and Medical Center, 703 Main Street, Paterson, N.J. 07503 (August 4, 1978)

COMMENT: I believe that this proposed rule while having merit, is in general, irresponsible. I take particular exception for the definition of misadministration where it refers to a diagnostic dose greater than 20% of the prescribed dose. To the best of my knowledge, notifying the patient, the patient's physician, and everyone in general is totally unnecessary. There is no proof that a dose of more than 20% of that usually given is in any way damaging. Furthermore, there are many Isotope Departments who administer 50 to 100% more of a particular isotope than other departments.

I suggest that the NRC submit to a department, during an inspection period, an "unknown" to place in their dose calibrator for testing. If the calibrator is functioning correctly then I think we will have to assume that the technicians are giving the "usual prescribed dose". I would suggest that a dose of 5 to 10 times the usual diagnostic amount should be reported to the patient's physician but certainly not 20%.

STAFF RESPONSE: All therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect will be reportable to NRC, the referring physician and the patient or a responsible relative.

The quality control check suggested by the commenter would not fulfill the primary purpose of the rule which is to ensure that NRC and the patient are promptly informed of serious misadministrations. NRC does not plan to equip inspectors with check sources but will encourage the Society of Nuclear Medicine to develop such a program in conjunction with the National Bureau of Standards. The Atomic Industrial Forum has a similar program with NBS which is aimed at the radiopharmaceutical manufacturers.

COMMENT: The therapeutic dose range probably should be raised to about 25% rather than 10%. Again, there are many variations in the amount given for a specific illness depending on the radiation therapist. I also believe if a misadministration is discovered this should be reported to the patient's physician and perhaps to the patient if the overdose could result in tissue necrosis.

STAFF RESPONSE: The limit for misadministration will remain at ±10% for therapy doses. Errors greater than 10% in therapy can be assumed to be harmful to the patient. The staff has 10 references which indicate that deviations by as little as 5-10% in the therapy dose may result in significant increases in late complications.

COMMENT. The proposed rules, while important in attempting to correct misadministrations, would prove to be a bonanza for malpractice lawyers. At the very least they would cause excessive concern on the part of the patient if we assume that all cases of misadministration would even be admitted.

STAFF RESPONSE: Licensees would be required to report all therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect.

19. David L. Yuille, M.D., Associate Director, Nuclear Medicine, St. Luke's Hospital, 2900 West Oklahoma Ave., Milwaukee, Wisconsin 53215 (August 3, 1978)

COMMENT: I most strongly object to the proposed regulation. My objections are based on the following points:

The Regulation of Pharmaceuticals should not be performed by the NRC but more properly by the FDA, which at least has some familiarity with regulating pharmaceuticals.

STAFF RESPONSE: FDA receives voluntary reports of "adverse reactions", not reports of misadministrations. FDA and NRC regulatory authority differ in many respects. NRC has more authority over how radiopharmaceuticals are used by physicians than does FDA.

COMMENT: The proposed rule is an example of gross over-regulation proposed by persons who apparently have little understanding of the processes they are attempting to regulate.

a. There have been no large scale studies performed which demonstrate a serious problem in need of regulation.

b. In the absence of hard data, reasonable and logical rules cannot be properly proposed.

STAFF RESPONSE: Data on medical misadministrations is hard to collect on a voluntary basis. NRC does have some reports of misadministrations but not enough to profile the true incidence. The misadministrations that NRC does know about have led to changes in licensing procedures or regulations.

COMMENT: The regulations proposed are illogical at face value.

a. The proposed 20% tolerance on drug dosage is incredibly restrictive for example: In the nuclear medicine literature you will find acceptable Gallium-67 Citrate doses described from 3MCi to 10MCi for patients. It is incredible that with such a broad dosage range, you would require a report for dosage variance of 20%. Furthermore, patients vary in size, shape, weight and height. They also vary

markedly with respect to localization and excretion patterns for a given pharmaceutical. These individual variations alone could easily account for a 100 to 300% change in absorbed radiation dosage for a given dose administration.

STAFF RESPONSE: The dosage variance of 20% for diagnostic procedures is not based on the effect of the misadministration but on the fact that a mistake has been made from the intended administration. Only diagnostic misadministrations that cause a clinically detectable adverse effect need be reported.

COMMENT:

b. The proposed 10% tolerance on therapeutic radiation pharmaceutical dosage is even more incredible and again reflects the total lack of knowledge and understanding of clinical problems by the people involved in promulgating this regulation. As an example, the accepted dosage for I-131 therapy for hyperthyroidism is between 80 and 120 uCi per gram of estimated weight of thyroid (a 50% variation). Besides this broad therapeutic range, the I-131 dose calculation depends upon the estimated weight of the thyroid gland which is often in error by at least 20%. Additional patient factors including varying thyroidal iodine turnover rate may cause an additional 100-300% variation in the therapeutic dose delivered to the patient. Thus, the proposed rule regarding a 10% tolerance for therapeutic doses is grossly over restrictive and unnecessary.

c. Studies of patients who have received therapy I-131 for hyper thyroidism have not yet revealed any detectable long term radiation effects. Since the radiation exposure from diagnostic procedures are at least 1 - 2 orders of magnitude less than for a therapeutic procedure, there is no demonstrated need for this NRC regulation.

STAFF RESPONSE: The limit of ±10% for therapy errors indicates a mistake and is based on a measurable quantity; in this example, Iodine-131 activity. In therapy, the staff assumes that the ±10% misadministration is harmful to the patient and should be reported. The staff has 10 literature references which indicate that deviations by as little as 5-10% in the therapy dose may result in significant increases in late complications. While this may not be true for treatment of thyroid disorders, the radiopharmaceutical dosage is readily measured before administration and the unnecessary exposure attendant to therapy misadministrations is not insignificant.

COMMENT: Nuclear Medicine Diagnostic procedures are among the safest of all diagnostic procedures that a patient can undergo as no radiation effects have been observed and because allergic and idiosyncreatic reactions to these materials are extremely rare. To propose a regulation which requires a telephone report within 24 hours to the NRC for inconsequential errors in dosage and to further require a follow-up written report to be made available both to the NRC and to patients is indeed making Mount Everest out of an ant hill. Furthermore, written notification to the patient will most certainly induce groundless fears of nuclear medicine procedure and may also result in needless law suits which are trouble enough in these litigious times.

STAFF RESPONSE: The reporting requirement in the final rule will apply to all therapy misadministrations and only those diagnostic misadministrations having a clinically detectable adverse effect.

20. S. V. Hilts, M.D., F.A.C.P., Nuclear Medicine, P. O. Box 6607, Tucson, Arizona 85733 (August 3, 1978)

COMMENT: The requirement that records be kept of misadministrations is reasonable, and these could be reviewed by the state or federal inspection agency. To place the records of such administration in the NRC files is to invite "browsing" of those files by hungry attorneys. It would be quite easy to relate such a report to the patient in a small or moderate-size hospital and to proceed with inciting the patient to lawsuit. Despite the fact that this practice is unethical, it is common knowledge that it is very frequent.

It is difficult to see any benefit that would accrue from this, other than providing employment to several more individuals in NRC; before such a rule is promulgated there should be clear evidence that such situations are frequent enough to provide a hazard. I firmly believe that such is not the case.

The language referring to "a diagnostic procedure that could cause a clinically detectable adverse effect" places the burden of proof on the practitioner that it could not produce an effect, despite the almost total safety of nuclear medicine diagnostic procedures. This is not reasonable.

STAFF RESPONSE: The language of the final rule is changed to read "a diagnostic procedure that causes a clinically detectable adverse effect." The staff believes that the word "could cause" is inexact and open ended.

COMMENT: It is my opinion that existing national and state laws provide more than adequate protection against misadministrations, which are much less likely to produce adverse effects in nuclear medicine than they are in administration of ordinary drugs. It is no more appropriate to have reporting of errors in nuclear medicine to a federal agency than it is to provide such reporting in each case of digitalis overdosage.

STAFF RESPONSE: When they approved the proposed rule the Commission was aware that the misadministration reporting requirement was unique in the practice of medicine. The misadministration reporting requirement is, however, similar to reporting requirements for other NRC licensees.

21. D. P. Shreiner, M.D., Chief, Nuclear Medicine Service, Veterans Administration Hospital, Pittsburgh, Pa. 15240 (August 3, 1978)

COMMENT: In most such cases the administration of the wrong radiopharmaceutical or the radiopharmaceutical administered with a 20 percent error in the dose will not cause clinically detectable adverse effects. Most diagnostic procedures, in contrast to therapeutic procedures, will not result in detectable adverse effects on the patient. According to the definition of misadministration in paragraph (f), misadministrations of diagnostic doses are to be reported even when no clinically detectable adverse effects are likely to occur. I would suggest that item (4)(f) be

excluded from the rule and that emphasis be given to the point that misadministrations to be reported include only those that could cause a clinically detectable adverse effect.

STAFF RESPONSE: The final rule will clearly state that only diagnostic misadministrations causing a clinically detectable adverse effect need be reported. All diagnostic misadministration would be subject to the record-keeping requirement.

COMMENT: Furthermore, it might be well to define what is meant by a clinically detectable adverse effect.

STAFF RESPONSE: At the proposed rule stage, the staff recommended against trying to define a "clinically detectable adverse effect," leaving this judgement up to a physician on the scene. 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). The staff still believes that the final rule should refrain from attempting to define a "clinically detectable adverse effect."

22. Frank A. Raila, M.D., Chief, Radiology Service, Veterans Administration Center, Dublin, Georgia 31021 (August 3, 1978)

COMMENT: First, find out how many misadministrations there have been. I doubt if the number is significant enough to warrant the amount of paper work that would be needed to keep the proposed records.

STAFF RESPONSE: The staff does not know the frequency of misadministrations of radioactive material. The rule will supply this information.

COMMENT:

2. Records are being kept at the present time on all administration of radioactive materials, and this would be sufficient enough to include any misadministration. Any episode of misadministration would be followed by a note stating that this was reported to the Health Physicist, referring physician, patient, and other responsible persons.

STAFF RESPONSE: The rule would require that records of misadministrations be maintained for NRC inspection. Regular patient records would be virtually impossible to inspect for misadministrations.

COMMENT:

3. There should be a definition regarding what is misadministration of a particular radioactive material in relation to a particular disease process or examination. This, in itself, would be a formidable task, as many world authorities have quite different opinions as to when administration becomes dangerous.

STAFF RESPONSE: The staff agrees that this would be a formidable, if not impossible, task.

COMMENT:

4. Certain nuclear medicine laboratories have a greater potentiality for misadministration of radioactive materials.

5. I believe that simply requesting that any radioactive misadministration be reported to the Nuclear Regulatory Commission would suffice.

STAFF RESPONSE: The staff believes that reporting all misadministrations to NRC would be unnecessarily burdensome to the licensees and would result in a large number of reports that would not warrant any NRC action.

23. Thomas R. Duncan, M.D., Columbia Radiology Associates, 1224 Trotwood Avenue, Columbia, Tennessee 38401 (August 9, 1978)

COMMENT: This is a request that you rescind the proposed rule.

First of all, there is ambiguity in the term "misadministration." Is a 14 millicurie dose instead of a 12 millicurie dose a misadministration? Is a subcutaneous injection instead of an intravenous injection a misadministration?

STAFF RESPONSE: If a 12 millicurie dose of a diagnostic radiopharmaceutical is prescribed or intended, then an administration of greater than 14.4 millicuries or less than 9.6 millicuries is a misadministration, i.e., differences of greater than ±20% of that intended for diagnostic radiopharmaceutical. Extravasation is not a misadministration and the preamble to the final rule will state this clearly.

COMMENT: The reporting procedure would unduly alarm patients and many would be suspicious that any disease they contracted in the future would be caused by the radionuclide.

The added bureaucracy would cause the taxpayers more money with questionable gain.

Malpractice liabilities for radionuclide studies would undoubtedly go up. This cost would also be passed on to the patient.

For these reasons I emphatically urge you not to adopt the new regulations and not to consider other similar regulations for the future.

STAFF RESPONSE: Only serious misadministrations would be required to be reported to the patient, i.e., all therapy misadministrations and those diagnostic misadministrations causing a clinically detectable adverse effect.

24. Nicholas Kutka, M.D., Ph.D., Nuclear Medicine Physician, P. O. Box 20183, Houston, Texas 77025 (August 1, 1978)

COMMENT: The positive consequences of the proposed rule are, that if there is a misadministration with no clinically detectable adverse effect, there is no need to notify anyone.

The definition in 35.33 (a) is vague: I feel that the word "could" should be replaced by "did". Word "could" means a possibility of occurrence of an event, with a probability higher than 0%. There is no way to predict reliably any outcome of a misadministration, or rather, a possibility of a clinically detectable adverse effect that most likely would be Nil. Word "did" would stress that the adverse effect, if any, actually had occurred.

STAFF RESPONSE: The staff agrees with the commenter and the words "could cause" are replaced with the word "causes."

COMMENT: The misadministration in fact did not need to occur at all ("is likely to have occurred"), or if misadministration is only likely to have occurred, we are requested to report such a likelihood. I feel it should be clearly stated that you require to report only such misadministration that positively occurred. The phrase "is likely to have occurred" is not in the final rule.

STAFF RESPONSE: The staff agrees.

COMMENT: Furthermore, in addition to the above, your rules for written reporting do not clarify that the clinically detectable adverse effect had to occur too, as specified in 35.33 (a) in case of a telephone reporting. I feel this paragraph should be completed with the statement that only if a misadministration positively took place and an adverse reaction did occur, a written report is requested by you and to you.

STAFF RESPONSE: The staff agrees. The threshold for reporting diagnostic misadministrations is clear in the final rule.

COMMENT: Since in many instances, the "licensee" is a hospital or an institution, the reporting to you and maintaining of records for 5 years, etc., should be delegated to the Radioisotope Committee, that each licensee (hospital or institution) should have appointed.

STAFF RESPONSE: The requirements are placed on the licensee because NRC has direct regulatory control over the licensee. Also, private practice licensees do not have medical isotopes committees.

COMMENT: The definitions of misadministration is 35.33 (f) should include the statement: "and clinically detectable adverse effect did occur."

STAFF RESPONSE: The definitions for a misadministration are intended to reveal when a mistake has occurred, not just an adverse effect on the patient.

COMMENT: Despite some suggestions given above, I have objections against the rules as a whole. The proposed rules try to add further administrative task to the Nuclear Medicine Service's reporting and quality control obligations. We already report any adverse reaction to the Food and Drug Administration and the U.S. Pharmacopeia. Your proposed rule is something very close to it, since you request reporting if "clinically detectable adverse effect could occur." Hence, a duplication.

868 046

STAFF RESPONSE: Adverse reactions are idiosyncratic reactions to properly administered drugs and are voluntarily reported to FDA. Misadministrations are not usually reported to FDA.

COMMENT: Misadministrations in a Nuclear Medicine Laboratory occur seldom, and such ones which cause "clinically detectable adverse effect" are even less frequent, since most radiopharmaceuticals have few side effects. What, however, such reporting may cause, is an unnecessary scaring of the patient, and creating of an unnecessary basis for initiating malpractice problems.

STAFF RESPONSE: All therapy misadministrations and only those diagnostic misadministrations causing a clinically detectable adverse effect are subject to the reporting requirement.

COMMENT: There is little hazard to the diagnostic use of radiopharmaceutical, given the margin for error for excessive dosage. In fact, the tolerance for error is such that most errors lead to little, if any, physical consequence to the patient. (E. R. Eisenhardt: "Risk of Professional Liability in the Practice of Nuclear Medicine," in "Financial Operation and Management Concepts in Nuclear Medicine," University Park Press, 1977; and J. Shani, H. L. Atkins, W. Wolf: "Adverse Reaction to Radiopharmaceuticals," in "Seminars in Nuclear Medicine," Vol. 6, #3, 1976.)

Although there is little physical risk to the patient from the performance of an improper diagnostic nuclear medicine procedure, there may be extreme emotional reaction in the patient, when he is advised of the error. The loss or damage occasioned by this reaction would be recoverable by a law suit, particularly in a society moderately hostile to proliferate use of radioactive materials.

Because of the above aspect, the proposed rules are not favorable.

STAFF RESPONSE: Only diagnostic misadministrations having a clinically detectable adverse effect on the patient and all therapy misadministrations are required to be reported to the patient.

COMMENT: Assuming a low probability of occurrence of "misadministration and adverse reaction," then in a middle size hospital with approximately 5,000 nuclear medicine procedures per year, such incident might involve 1 to 2 or less, if at all any.

On the other hand, however, for comparison, it is claimed that heparin and digoxin, both non-radioactive pharmaceuticals, are responsible for many causes of morbidity and even mortality in the hospitals. Heparin was the leading cause of adverse drug reactions in hospitalized patients (22%).

With given probability of occurrence of "misadministration and adverse reaction," in case of heparin and digoxin with their widespread use, the number of affected patients per year comparing to radiopharmaceuticals, is substantially higher, but is usually undetected and not reported, although having much more dangerous consequences. No 5 years maintaining of records is required.

The problem of misadministration of radiopharmaceuticals, if at all considered so serious, may be well handled by the nuclear medicine physician in charge of the patient, with the patient's referring physician and with the Radioisotope Committee of the institution as a consultant, if at all necessary. In case of an adverse reaction, the incident is anyway reported to the Food and Drug Administration or to US Pharmacopeia, as a problem with radiopharmaceuticals. Additional interference by NRC is unnecessary.

STAFF RESPONSE: The FDA and U.S. Pharmacopeia and Society of Nuclear Medicine "Adverse Reaction Registry" is voluntary and covers drug defects and adverse reactions to properly administered drugs. This system does not cover misadministrations.

25. Carl P. Wisoff, M.D., Chief of Nuclear Medicine, Medical Center Radiologists, Norfolk General Hospital, Norfolk, Virginia 23507 (August 8, 1978)

COMMENT: I am opposed to the adoption of any part of the proposed rules concerning the human uses of bi-product material.

Although on occasion a misadministration of radioactive material may or has occurred, I feel that there is adequate policing and safeguards by virtue of the structure of the medical institutions involved. The intrusion of a regulatory agency into the care of a patient without assuming the responsibility of his or her care is deplorable.

The paragraph of limitations proposed in 35.33 (F) (4) (5) is not considered clinically significant and regulations of these amounts would not benefit the patient.

STAFF RESPONSE: These limits are intended to reveal where a mistake has been made and not clinical significance.

COMMENT: The result of reporting these incidents would certainly multiply the already large problem of malpractice insurance.

The costs for the government of monitoring all of these regulations will be horrendous and certainly unjustified for the benefit the government hopes to obtain.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known. The cost to NRC should be proportional to the benefit to patients and both the cost and the benefit proportional to the number of reports.

26. Michael S. Cunningham, R.T.N., Imaging Supervisor, Trinity Lutheran Hospital, 31st and Wyandotte Streets, Kansas City, Missouri 64108 (August 8, 1978)

COMMENT: You are essentially discussing three classes of misadministrations: 1) misadministrations of radiation from teletherapy and brachytherapy sources, 2) misadministration of a radiopharmaceutical involving a therapy procedure, and 3) misadministration of a radiopharmaceutical involving a diagnostic procedure. I feel that the first two classes certainly need to be controlled, but the third class should not be. You

state that "those diagnostic misadministrations that could cause a clinically detectable adverse effect on the patient" must be reported. I don't believe that there are any diagnostic administrations that cause a detectable adverse effect. Even if the wrong patient was administered a radiopharmaceutical, it would be difficult to state that this caused any detectable adverse effect.

Another problem that you are going to get into with this proposed rule is where you state that a misadministration includes any administration of a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 20 percent. This is not possible to detect with the present state-of-art of dose calibrators. There is at this time no uniformity from one dose calibrator company to another. Our radiopharmaceutical doses are received from a commercial radiopharmacy. We routinely measure them in our dose calibrator, and it is not uncommon at all to find our readings differing from the radiopharmacy's by 20 percent or more.

I respectfully submit that the Nuclear Regulatory Commission should not at this time require the reporting of misadministrations of radiopharmaceuticals involving a diagnostic procedure.

STAFF RESPONSE: As noted in the staff response to comment #15, the licensees should be able to measure doses of radiopharmaceuticals to an accuracy within ±10% if they follow the ANSI standard and calibrate their instruments. An example of a diagnostic misadministration causing a clinically detectable adverse effect, is the accidental administration of millicuries of I-131 instead of microcuries.

27. A. G. Howell, Administrator, Louise Obici Memorial Hospital, Suffolk, Virginia 23434 (August 8, 1978)

COMMENT: I wish to oppose the adoption of any part of the proposed new part, Section 35.33.

The following reasons are given in support of my position:

1. This requirement will mean an intrusion of a regulatory agency into the care of a patient without assuming responsibility of the care of the patient.

STAFF RESPONSE: This is the crux of one of the strongest arguments against the rule. Basically the physicians feel that they are being required to do certain things by Federal regulation and then they will be stuck with the results. The staff recognizes the strength of this argument but recommends proceeding with the rule because it is our best tool to prevent future misadministrations.

COMMENT:

2. I hold that the required reporting will not benefit the patient. The limits in proposed 35.33 (f) (4) do not represent a significant difference in patient dose. The limit in proposed 35.33 (f) (5) can

be adjusted by changing a treatment schedule in external beam treatment, and is well within the biological variation in internal administrations. Requirements under the proposed 35.33 (f) (1), (2) and (3) are best reported, as now required, through the local Radioisotopes Committee of the licensee.

3. Requirement of reporting such information under proposed 35.33 (c) would mean an admission of fault on public record. A hospital or physician would be in immediate jeopardy of suit, and such a requirement would add considerably to the cost of liability insurance, if, indeed, it did not actually preclude such insurance. Further, it appears to me to be in violation of the constitutional right against self-incrimination.

4. The whole reporting procedure, including the requirement under proposed 35.33 (e) would increase the cost of medical care without adding to the benefit therefrom, unlike the present requirement of review by the hospital committee.

Finally, may I suggest that this requirement will lead, inevitably, to cover up of misadministrations, to avoid the vulnerability to liability suits.

Thank you for the privilege of submitting this statement.

STAFF RESPONSE: See comment #9.

28. G. William Bretz, M.D., Good Samaritan Hospital and Health Center, 2222 Philadelphia Drive, Dayton, Ohio 45406 (August 7, 1978)

COMMENT: In my opinion the definition of misadministration for diagnostic procedures in Paragraph 35.33/10 CFR, Part 35, Section f 3 and 4 is unreasonably restrictive.

For example in our department, uptakes are performed with a 5 mCi dose of I-123 or I-131. Such capsules of the radiopharmaceutical may not be available, however, in the department on certain days. If a 6 to 10 mCi capsule of I-123 is administered for convenience to patient, hospital or both, the patient's thyroid received a dose of .2 rads instead of the usual .1 rad at maximum.

The difference is biologically negligible and it appears to me as a grand Hocus-Pocus establishing requirement to report such incidences to the patient, physician and to the government. The additional dose contributed by a 100% overdosing for thyroid uptake would be equivalent to the radiation dose attained by anteroposterior cervical spine radiography. Nobody has yet required to report the retake of a single cervical spine x-ray to the government, physician, or to the patient. Such retake may be necessitated by factors totally out of the control of the technologist, physician or manufacturing companies.

Gentlemen, let's not overregulate medicine and require voluminous reports on insignificant, ridiculous Mickey-Mouse stuff. The money that is spent on such unnecessary functions is yours and mine.

STAFF RESPONSE: The definitions of a misadministration in the regulation are intended to reveal when a mistake has been made and not clinical significance. The reporting requirement applies to all therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect and thus does address clinical significance. If I-131 is prescribed and I-131 is accidently administered, then it is a misadministration. If I-123 is prescribed and administered, then it is not a misadministration.

29. Charles L. Rogers, Administrator, Cushing Memorial Hospital, 623 Marshall, Leavenworth, Kansas 66048 (August 7, 1978)

COMMENT: The proposed rule changes in our view intrude unnecessarily into the physician patient relationship.

In other fields of medicine misadministration of therapy with serious potential consequences are not handled in this manner. Most such acts when they do occur have no consequences. To require these reports to be a part of the public record is equally objectionable and unnecessary.

Mistakes which cannot be resolved should be handled by the courts. Another layer of regulations will not accomplish anything useful.

STAFF RESPONSE: At the proposed rule stage, the Commission was aware that this regulation would be unique in the practice of medicine. The misadministration reporting requirement is, however, similar to reporting requirements for other NRC licensees.

30. James L. Males, M.D., Thyroid Laboratory, Presbyterian Hospital, Northeast 13th Street at Lincoln Boulevard, Oklahoma City, Oklahoma 78104 (August 9, 1978)

COMMENT: From my perspective, it seems to me that your proposed regulations are reasonable and are in the best interest of safety for our patients. The recordkeeping and reporting seems to be adequate, and yet not excessive or overly demanding.

31. Andrew W. Goodwin II, M.D., Chairman, Department of Radiology/Nuclear Medicine, Memorial Division, 3200 MacCorkle Avenue, S.E., Charleston, West Virginia 25304 (August 9, 1978)

COMMENT: I am particularly concerned about the propriety of 35.33 records and reports of misadministrations, item number 3 where the licensee is directly reporting the misadministration to the patient or patients responsible relative. All clinical information concerning the patient should be channeled through the referring physician. The licensee should not become involved in the direct conveyance of clinical information to the patient without the approval of the referring physician. This does not exclude further explanations regarding the misadministration and its effect after the referring physician or his agent has made initial contact and discussed the matter with the patient.

I feel that the aforementioned suggestion would minimize the intrusion into the physician patient relationship that is otherwise evident in the proposed amendment.

STAFF RESPONSE: The staff agrees with this comment to an extent, and the final rule will not require the licensee to inform the patient or the patient's relative if the referring physician states that he will inform the patient or relative. Both the proposed and final rule provide for not informing the patient or relative if the referring physician states that such informing would be harmful to the patient or relative.

32. Malcolm R. Powell, M.D., and Andrea S. Blum, M.D., 350 Parnassus Ave., Suite 908, San Francisco, California 94117 (August 7, 1978)

COMMENT: I am writing to express my concern about loss of patient confidentiality involved in the proposed rule published 7/6/78. The rule requires that the NRC be notified of any potentially dangerous misadministrations of radioactivity. Since information provided to NRC is available for public review, it is inappropriate that such a reporting mechanism should be used. I recommend that the proposed rule be changed to provide for reporting in a way that would preserve patient confidentiality. In other respects the proposed rule should receive generally strong support from individuals using radiation in medical diagnosis and therapy.

STAFF RESPONSE: The proposed reporting system provides for patient confidentiality. Medical files and files containing the names of individuals who have received exposure to radiation are exempt from disclosure under the NRC Freedom of Information Act Regulations (see § 9.5(a)(6)). The reports of misadministrations would be available for public review but without information which would lead to identification of the individuals involved.

33. L. A. McKinnis, M.D., Radiology, 715 N. St. Joseph Ave., Hastings, Nebraska 68901 (August 8, 1978)

COMMENT: I have deep concern that the proposed regulations represent an intrusion of the federal government into the private practice of medicine in a way which was not intended by legislative mandate. I am fearful that in the long run there will be more potential harm from this type of regulation to medicine and therefore to the patient than whatever beneficial results might be achieved by these rules.

In regard to the proposed regulation requiring reporting of a difference in the prescribed dose by more than 20%, I believe this is most unrealistic. There is often a 100% or greater difference in standard dosages of many radionuclides administered when comparing institution to institution. I believe this would serve no useful purpose. The radiation dosage from the minute amount administered is usually far less than many standard x-ray studies would deliver to the patient. I cannot see the real purpose in such a regulation.

STAFF RESPONSE: The definition of misadministration is intended to reveal mistakes, not clinical significance.

COMMENT: I believe the rule requiring reporting to the patient or relative of any misadministration is also improper as a federal regulation. I feel it is totally proper for the physician to so report to the patient or a responsible relative in most instances where a significant misadministration has occurred. However, I cannot see any purpose in federally mandating this.

In the occasional instance of administration of a radiopharmaceutical to the wrong patient, any potential ill effects would be almost nil, and radiation dosage again would normally be less than if a radiograph were obtained on the wrong patient. I again cannot see any purpose in requiring reporting of such an instance.

STAFF RESPONSE: The rule requires reporting of all therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect.

COMMENT: I can appreciate the interest of the NRC in compiling statistics on possible misadministrations, but I cannot see that this would accomplish any significant good when seen in perspective of many years of medical practice. I sincerely hope real consideration will be given toward withdrawing these proposed regulations.

STAFF RESPONSE: The purpose of the rule is not to compile statistics but to try to prevent future misadministrations by notifying all licensees of potential generic problems. There are other longer-term remedies that can be pursued, such as changes in NRC regulations and licensing procedures that will help mitigate future misadministrations.

34. Richard M. Butler, M.D,. Radiologist, Reid Memorial Hospital, 1401 Chester Boulevard, Richmond, Indiana 47374 (August 2, 1978)

COMMENT: I would like to bring attention to two points regarding this rule.

1. The dose of radiopharmaceuticals that we are using in clinical practice pose no significant hazard for the intended patient or a patient inadvertently injected if a misadministration should occur.

2. I feel that much undue medical-legal-malpractice question could be raised and would be stimulated by notifying multiple people including relatives and patients that they have been misinjected or drugs had been misadministered, in light of the fact they would be of no significant hazard to the patient. I feel this is especially true in today's environment of escalating medical-legal encounters and discussions. I feel the reporting of these incidents places an undue stress on practicing physicians.

STAFF RESPONSE: All therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect are required to be reported to NRC, the referring physician and the patient or a responsible relative. Licensees will be required to keep records of all misadministrations.

868 053

35. Frank H. DeLand, M.D., Chief, Nuclear Medicine, University of Kentucky, Lexington, Kentucky 40506 (August 8, 1978)

COMMENT: Although the concept in principle is good, the degree is too minimal and the enforcement would be unattainable.

If the error is relative to therapy, patient and/or physician should be informed.

If the error is relative to diagnosis, need for reporting not indicated unless maximal permissible dose is exceeded.

Intra-institutional records of misadministration adequate except as indicated above.

STAFF RESPONSE: This is essentially the way the final rule is composed, with the exception that a clinically detectable adverse effect is the trigger for reporting diagnostic misadministrations, rather than "maximal permissible dose" as suggested by the commenter.

36. Robert A. Nebesar, M.D., Director, Nuclear Medicine, Cardinal Cushing General Hospital, 235 North Pearl Street, Brockton, Massachusetts 02401 (August 9, 1978)

COMMENT: I believe that this proposed regulation is an excessive step beyond the bounds of rational need and prudent responsibility. It is my opinion that it is the physician administering and prescribing the radionuclide who is primarily responsible to the patient and additional bureaucratic burdens will not improve upon this responsibility or the efficacy of care delivery. There is no question that misadminstrations may occur with any medication administered by physicians and nurses within the hospital. I do not believe it practical or in the best interests to report each and every one of these misadministrations, some of which may be potentially much more hazardous than the misadministration of a tracer dose of radionuclides. Furthermore it is virtually impossible to report any misadministrations of x-rays obtained on patients. Consequently I see no practical import on reporting such misadministrations to the bureaucracy which will only have to increase its size at increased cost to the public at large. It is such intrusions upon the doctor-patient relationship that cause an increase in the delivery of medical care and do not in fact guarantee better care because the event has already occurred and its reporting will in no way rectify a misadministration. The only way to prevent such misadministrations are through educational means and conscientious exercise of each health care deliverer's duties and responsibilities.

In summary, I would urge you to withdraw the proposed rule.

STAFF RESPONSE: The primary purpose of the misadministration reporting requirement is to make information available to all licensees on generic type misadministrations. This will not improve on the physician's responsibility to the patient but will make NRC licensees aware of potential pitfalls in their use of radioactive material on humans. The threshold for reporting, as opposed to recordkeeping, is sufficiently high that the increased cost of reporting will be balanced by the utility of the information gained.

37. Yale M. Wolk, Administrator, Community Hospital of Ottawa, 1100 East Norris Drive, Ottawa, Illinois 61350 (August 9, 1978)

COMMENT: I would like to convey this hospital's feeling that the regulations as proposed are not appropriate or necessary at this particular time.

1. The rules as they are proposed constitute a major breach in the patient/physician relationship in the caring for a patient. The rules specify that a hospital must report misadministration of a radioactive material directly to the patient, which does breach this confidentiality and this relationship as established for the care of a patient. It is our feeling that this places the hospital in a very precarious situation in dealing with the relationship of the physician and the patient; and with this breach existing, it would be a nonpractical application of a reporting mechanism.

STAFF RESPONSE: The rule does not specify which representative of the licensee must inform the patient. The physician who performed the procedure or the physician designated as the authorized user on the license could inform the patient.

COMMENT:

2. This hospital also feels that the necessity of keeping records of this type of activity would not only be a needless addition to a cost of an already overburdened reporting system but also, per our own review process, find that the type of cases this reporting mechanism is to detect constitutes less than 1/10 of 1% of all doses given. Consequently, we feel this would become nothing more than a paper exercise without meaningful or valuable information being gathered.

STAFF RESPONSE: Under the rule, records of all misadministrations will be maintained for inspection by NRC. NRC inspectors will review the records during routine inspections to determine if there are trends of minor misadministrations that indicate lax administrative controls or violations of NRC regulations.

COMMENT:

3. The next item would be the exposure of this institution to liability. With the notification of patients directly as well as physicians directly, this would constitute a major increase of liability suits being filed in the area of misadministration of radioactive materials where potentially little harm might exist. With everyone's concern over the use of radioactive materials at this time, just the notification to a patient of a misadministration in itself would cause an expensive liability suit to be filed whether or not it was justified and the major expense of having to defend this liability suit would be incurred. In conclusion, we would again like to recommend that this proposed rule not be adopted for the above-named reasons.

STAFF RESPONSE: The threshold for reporting misadministrations to NRC, the referring physician and the patient or relative puts them in the category of potentially harmful or serious misadministrations.

38. S. Lon Conner, Executive Director, The Medical Association of The State of Alabama, 19 South Jackson Street, P. O. Box 1900-C, Montgomery, Alabama 36104 (August 18, 1978)

COMMENT: The Board of Censors of the Medical Association of the State of Alabama, at its meeting on August 16, 1978, voted to oppose the proposed amendments to the Nuclear Regulatory Commission's Regulations.

It is the Board's opinion that the decision of reporting potentially dangerous misadministrations should be left up to the individual physican, and not made mandatory.

STAFF RESPONSE: The staff does not agree that misadministration reporting should be voluntary. The General Accounting Office, which originally proposed the misadministration reporting requirement, recommends that the Commission proceed with a final rule without the provision for mandatory reporting to patients (EMD-79-16, January 26, 1979.) GAO recommends that the Commission decide this controversial question at a later date. However, the trend in the Federal sector is that patients have a basic right to ensure that the information maintained as part of his medical relationship is accurate, timely, and relevant to that care. Also, Section 20.409 has a similar requirement for reporting occupational exposures to individuals.

39. J. H. Martens, M.D., Wausau Hospitals, Inc., Maple Hill, Wausau, Wisconsin 54401 (August 9, 1978)

COMMENT: I am against the proposed rule. I do feel the proposed rules are an infraction of a physician-patient relationship. I think they would cause severe additional distress to many patients who are already maximally stressed. Confidence in a physician is a crucial part of the treatment of cancer as it is seen with radiotherapy. In my own personal practice, strong relationships develop between the therapist and the patient. Referring physicians are frequently or usually not entirely knowledgeable on the action and significance of radiation. It is my own practice to send a completion letter to the referring physician, which outlines the disease parameters, treatment administration, treatment factors, comments on tolerance, etc. Most of the detailed information is for purposes of record should additional radiation be required elswhere. It has been my experience at times for physicians, in good faith, to represent the pains cancer patients experience as the result of reaction to radiation they may have received, when actually the cause is recurrent cancer. It may be difficult to objectively determine whether an effect is the result of radiation or the patient's own disease process.

STAFF RESPONSE: Under the rule, all therapy misadministrations, whether there is a clinically detectable adverse effect or not, must be reported to the patient by the licensee. This can easily be done through the therapist. Also, the referring physician can block the report to the patient or relative if he states that the information would harm one or the other, respectively.

COMMENT: It is my feeling that activating the proposed rule, would add a barely tolerable burden to the practice of radiotherapy and make it difficult to effectively treat many patients with cancer. I also believe the measure

would result in an increase in malpractice suits, again indirectly increasing medical costs and making practice much less pleasant.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

40. Milton A. Friedlander, M.D., Chief, Division of Nuclear Medicine, Polyclinic Hospital, Harrisburg, Pennsylvania 17105 (August 14, 1978)

COMMENT: It is my feeling that the proposed rules are totally unnecessary. I am a practicing nuclear medicine specialist and know from my own personal experience that if a diagnostic dose was prescribed and was twenty percent off in terms of its total dose, that this would have no effect upon a patient. Secondly, a ten percent mistake in the administration of a therapeutic dose, say of radioactive Iodine, would have no ill effects upon the patient as well and probably would do little in the way of over-treating or undertreating the patient's disease.

If a radiopharmaceutical is administered and is from a wrong source, that is unfortunate but this would be no worse than having to repeat a lumbar spine x-ray because the first x-ray was overexposed. Again, I doubt that this would have any effect upon the patient and there is no need to frighten the patient with this kind of report.

A radiopharmaceutical administered to the wrong patient happens rarely. If the dose given is a diagnostic dose, this would have no ill effect upon the patient who receives the dose of radioisotope.

In summary this ruling would build a huge bureaucracy serving no benefit to the general public and would end up frightening patients unnecessarily when no true harm has been done.

I can understand that when the output of a cobalt machine or linear accelerator is off by fifty percent that steps should be taken to correct this. However, I can see that the government has already taken steps to correct this situation by checking calibration of therapy apparatus. As far as nuclear medicine is concerned, this rule is totally unnecessary. If, by chance, a massive dose of radioactive Iodine was administered to a patient and ill effects took place, the possibility of a lawsuit for malpractice would correct whatever was going wrong in that laboratory.

STAFF RESPONSE: The Federal Register notice for the proposed rule states: "In this newly proposed rule, §35.33(a)(4) and (5) define misadministration in part as administrations differing from the total prescribed dose or exposure by more than 10% for therapeutic procedures or 20% for diagnostic procedures. These limits should not be viewed as the normal calibration limits for these procedures but rather the points where obviously an error has occurred. The narrower tolerance for the therapeutic procedures recognizes the greater risk to the patient from therapeutic misadministrations."

The rule requires recordkeeping for all misadministrations and requires reporting to NRC, the referring physician and the patient or a responsible

relative for all therapy misadministrations and only those diagnostic misadministrations causing a clinically detectable adverse effect. The purpose of the threshold for reporting diagnostic misadministrations is to pinpoint those serious diagnostic misadministrations that could have generic implications and will likely require some medical followup of the patient. There is no reporting threshold for reporting therapy misadministrations because, in general, the consequences of therapy misadministrations are serious. Notwithstanding the special cases where therapy misadministrations may not have serious consequences, such as certain I-131 therapies, the staff believes that all therapy misadministrations should be reported promptly.

The commenter's observation about cobalt machines or linear accelerators is at odds with statements such as "...deviations by as little as 5 to 10% may result in significant increases in probability of late complications" from G. W. Barendson in "Current Topics in Radiation Research," Quar. 9, p. 101, 1973, when referring to the total treatment dose for external beam therapy. The staff has 9 other literature references in the same vein.

41. G. Tom Surber, M.D., 1109 Norfolk Avenue, Norfolk, Nebraska 68701 (August 17, 1978)

COMMENT: I concur fully with the collecting of the data on misadministrations in errors and dosages for reasons of proper attempt at correction of the problem involved, and improvement of the regulations surrounding the use of nuclear materials medically. I think regulations of that type should have been enforced long ago. However, the notification of the patient or his representative in any and all cases seems to me an open invitation to increase the number of malpractice suits and increasing the dissatisfaction of the patient with the medical system. I would feel the regulation could be written to state that if the misadministration was such that it should cause definite harm then the patient should definitely be notified, however, in case of minor problem I think that the patient definitely does not need to have been told and the Regulations should reflect this.

STAFF RESPONSE: The regulation is written pretty much along these lines, although not because of malpractice suits.

42. Henry H. Kanemoto, M.D., Chief of Department of Radiology, Wausau Hospitals, Inc., Maple Hill, Wausau, Wisconsin 54401 (August 16, 1978)

COMMENT: I am opposed to the proposed amendment.

1. Our Nuclear Medicine Department as well as the Radiotherapy Branch routinely record all administrations of radioactive material.

2. Tracer studies using small microcurie or millicurie amounts of modern isotopes do not impose any significant somatic or genetic damage. As the result of the small amounts and their safety, there is routinely a wide variance as to the dosage which is administered at various institutions. The dosage may depend upon the disease process in the patient or may vary with the type of imaging apparatus or monitoring apparatus which is used.

868 058

If your proposed amendment were in effect, it could cause many institutions which are now using smaller dosages to increase their dosages and consequently cause a greater amount of radioactive tracers given to the population at whole. Since your definition of a misadministration would be a 20% difference, if one prescribed six millicuries of Technetium for a lung scan, one could administer [an additional] 1.2 millicuries and still stay within the guidelines. However, if, as in our institution, three millicuries is the dosage, we would only be able to administer an additional .6 millicuries before the reporting procedure would take effect. Consequently, I feel the proposed amendment would, indeed, increase "routine dosages" of radioactive isotopes. The intent of the amendment is to reduce dosages but its effect would be to increase prescribed dosages because of the 20% rule.

STAFF RESPONSE: This could be an unwanted side effect of the regulation. Errors in measurement would tend to be percentage errors and would not be affected by increasing the routine dosage, but errors of volume might be "reduced" by increasing the volume. The purpose of defining a diagnostic misadministration as a 20% difference between the intended and actual administration is to pick up errors.

COMMENT:

3. I am opposed to that section of the amendment which would report to the patient or the patient's responsible relative without consideration of the referring physician-patient relationship. I feel that the referring physician should be given the right to decide whether any "misadministration" is reported to the patient and the manner in which this report is performed.

STAFF RESPONSE: The staff agrees. The final rule will allow for the referring physician to inform the patient. The proposed rule already permitted the referring physician to block the report.

COMMENT:

4. I quote from the second column, third paragraph, of your proposed rules. "Licensees would also be required to report promptly all misadministrations that involve a therapy procedure and those diagnostic misadministrations that could cause a clinical detectable adverse effect on the patient." I feel the under-lined portions certainly in the therapeutic realm have no meaning, since all therapeutic doses of radiation potentially may cause an adverse effect. Similarly, diagnostic tracer amounts in theory cause an adverse detectable effect some time in the future and consequently, this sentence is meaningless.

STAFF RESPONSE: The underlined words do not apply to therapy misadministrations which would be reported in every case. The words "could cause" have been replaced by "causes" in the final rule in order to minimize ambiguity.

868 059

COMMENT:

5. I feel that your proposed regulation would, indeed, increase malpractice suits virtually through the power of suggestion. We would see a so called "reverse placebo effect," where normal patients when notified of a "misadministration" would develop potential symptoms.

STAFF RESPONSE: With the reporting threshold in place, if there is no harm, the licensee has the option of not reporting to the patient except for therapy misadministrations.

COMMENT:

6. I am not aware of any similar regulation applying to other diagnostic or therapeutic fields of medicine other than those employing radioactive materials. For example, is there such a regulation about misadministrations of intravenous solutions, oral or intramuscular medications, or chemicals used in diagnostic testings? The paperwork involved in such reporting procedure would serve only to hinder the practice of medicine without any significant beneficial impact.

STAFF RESPONSE: The staff is not aware of a similar requirement in other fields of medicine.

43. J. Howard Hannemann, M.D., Southern Maine Radiation Therapy Institute, 22 Bramhall Street, Portland, Maine 04102 (August 16, 1978)

COMMENT: The proposed regulation was discussed in detail at a recent departmental meeting here. Present were physicians, radiologic physicists, and technical personnel. The collective reaction of this group to proposed rule 35.33 was overwhelmingly negative.

1. The language of the proposal, at least as printed in the Federal Register, is imprecise. The intent of the proposed rule change is thus unclear in terms of its intent to delegate to the NRC authority over sources of ionizing radiation which heretofore did not fall under its aegis (i.e. radium and linear accelerators). If the intent of the proposed rule change is to interject the NRC into that sphere of activity, such should be plainly stated.

STAFF RESPONSE: The rule applies only to byproduct material, and the discussion of this comment in the Federal Register notice will make this clear.

COMMENT:

2. The stated purposes of the misadministration reporting requirements seem to us to be somewhat contrived. The first, to allow NRC investigation of specified incidents, presumes that current misadministrations of ionizing radiation are regularly uninvestigated by any responsible person or agency. We believe that presumption to be manifestly untrue. Even in the example of cobalt teletherapy overdose cited in the Federal Register a great deal of useful and responsible investigation preceded the entry of the NRC into the affair.

STAFF RESPONSE: NRC investigation of a misadministration would permit NRC to notify other licensees of potential problem areas, change our regulatory procedures if necessary, and assure that corrective action is taken to prevent recurrence.

COMMENT: The second stated purpose for the proposed rule change is to inform the patient or his relatives so that corrective action can be taken. This presumes of course, that substantive corrective action on behalf of the patient can be undertaken after the fact of such misadministration. This presumption is true only in some cases where the misadministration involves a lesser than prescribed dose of radiation or radiopharmaceutical. Fortunately, these misadministrations are of no danger to the patient and in most instances, when recognized, are easily correctable. The presumption is palpably false however, in misadministrations involving significant overdoses. It is these latter cases which place patients at considerable risk and to which the NRC, on behalf of patients, would presumably address its efforts. Thus the entire proposal seems to us to be purposeless.

STAFF RESPONSE: The staff wants patients to be informed of errors involving underdoses and overdoses so that the patients can make fully informed decisions concerning followup care.

COMMENT:

3. The proposed requirement stipulating that a copy of the NRC report be furnished to the patient or his responsible relative seems to us to be the worst kind of intrusion into the physician-patient relationship. If surety of doctor-patient communication is what this clause seeks, then the fact of the impossibility of concealing from a patient the consequences of a significant radiation overdose has been seriously overlooked. If the overdose has not been substantial (and it is not my intent to comment in detail upon the merits of the definition of ten and twenty percent as substantial, except to remark that we find them applicable and appropriate only at the upper limit of dose tolerance) an adverse reaction by the patient is unlikely and the rendering to him of a detailed report, bearing governmental sanction, will result only in a spate of spurious law suits and in the unnecessary destruction of a relationship with his physician(s) which a seriously ill patient desperately needs.

STAFF RESPONSE: The final rule will require the licensee to submit a written report of a diagnostic misadministration to the patient only if there is a clinically detectable adverse effect.

COMMENT: The Nuclear Regulatory Commission is to be commended for having achieved in large measure the admiration of both the public which it seeks to protect and serve and the professionals whom it seeks to regulate. We feel that these proposed misadministration reporting requirements represent a grave departure from established precedent which will prove to be counter-productive for both consumer and provider. The real question which we suspect this regulation attempts to address is how to facilitate the early detection of unrecognized misadministrations of ionizing irradiation of all types. We would suggest that more thought be given to an effective answer to that question, as we regard 35.33 as ill conceived, poorly structured, cumbersome, unenforceable, and if adopted, likely to be ignored.

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STAFF RESPONSE: The final rule will be enforced by NRC's Office of Inspection and Enforcement. It is not likely that licensees will be able to ignore it.

44. David S. Jacobs, M.D., Director of Laboratories, Providence-St. Margaret Health Center, 8929 Parallel Parkway, Kansas City, Kansas 66112 (August 21, 1978)

COMMENT: I would like to strongly recommend that, should such regulations be created, that they pertain only to doses of some clinical significance. That is, I think that a minimal level of activity should be considered, and levels of activity beneath that be excluded from the regulations. An example which comes to mind would be a problem with regard to determination of blood volume. Although such problems occasionally arise, the levels of radioactivity involved are so small that they probably are not meaningful either clinically or to the Nuclear Regulatory Commission.

STAFF RESPONSE: The final rule will have a threshold for reportable misadministrations which addresses the clinical significance.

45. Robert L. Meckelnburg, M.D., Delaware Medical Laboratories, Inc., 1 Pike Creek Center, Wilmington, Delaware 19808 (August 24, 1978)

COMMENT: With reference to radiopharmaceuticals, since distinct hazards of low-level radiation are not yet established, it would seem imprudent to needlessly worry a patient and/or his family with the suspicions of improbabilities. Any and all misadministrations, of course, should be recorded within the individual department records and steps taken within the department to assure that such misadministrations do not occur in the future. As in all other matters having to deal with the care of an individual patient, the patient's personal physician should be advised of the misadministration also, and he can then make the decision as to whether it is in the best interest of the patient to notify him or his family.

STAFF RESPONSE: The referring physician can block the report from going to the patient or patient's relative if the physician states that it will be harmful to the patient or the patient's relative to know of the misadministration.

COMMENT: The Nuclear Regulatory Commission may wish to ascertain that such records are kept by the individual department, but these should not be kept by the Commission since its records are all open to public purview. Needless to say, the unwarranted disclosure of a misadministration to a patient and/or his family could precipitate legal repercussions. This would then create an adversary position wherein the facts and known results are quite sketchy and incomplete, resulting in a legal panel or jury making decisions on emotional issues more than the facts at hand. Where direct harm can be demonstrated, then, the risk benefit ratio of the procedure has to be considered in light of the treated condition.

More data needs to be collected as to the possible harm of misadministration of radiopharmaceuticals than we now have, and the majority of effort should be directed toward programs aimed at obviating the miscalculations, inconsistencies or aberrations that result in misadministrations.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known. The investigations of incidents reported to NRC will provide the data to establish the harm from misadministrations of radiopharmaceuticals.

46. T. D. Moberg, M.D., Radiologists, Ltd., 727 Kenney Ave., Eau Claire, Wisconsin 57401 (August 23, 1978)

COMMENT: Our group feels that central to the question is the competence of the physician and ancillary personnel in the administration of these modalities. Demonstrated competence by virtue of training and experience and continued medical education we feel should be sufficient to prevent such misadministrations.

The method of determining what is the "bottom line" from which administered dose or exposure exceeding by 10 or 20% that bottom line is of course a major problem since different sections of the country do indeed use a different dosage schedule. Should a minor variation in that dosage be actually experienced even in spite of the closest forms of control in calculation and administration, the likelihood is that the administering physician would probably be inclined to watchfully observe for any adverse effect on the recipient, rather than purposely exposing himself and staff to possible medical legal charges.

While we do not propose to abdicate our responsibilities to the patient in any way shape or form, we do feel that, starting with demonstrated basic competence in any field, the current wave of attempts at protecting the rights of individuals has probably gone too far to the point of discouraging well trained and well meaning physicians from doing what they feel is right and proper for the referred patient.

STAFF RESPONSE: The staff does not believe that the rule will cause physicians to provide inferior care to their patients.

47. Kenneth N. Vanek, Ph.D., Medical Radiation Physicist, Department of the Air Force, USAF Medical Center, Keesler (ATC), Keesler Air Force Base, Mississippi 39534 (August 24, 1978)

COMMENT: The proposed referenced ruling is commendable in its intent; however, it is felt that this regulation would be virtually unenforceable. The intent is strongly supported and patient notification as well as preventive measures to preclude similar occurences is probably being practiced by most practitioners. It is likely that this group would voluntarily respond to this proposed regulation, but for those who would not, detection and enforcement is felt to be highly improbable. Because of this, its inclusion in 10 CFR 35 is questioned.

STAFF RESPONSE: The staff agrees that it will be difficult to enforce this regulation if a licensee tries to deliberately hide misadministrations. However, it will not be impossible to enforce under these circumstances and difficulty in enforcement does not warrant abandoning the rule.

48. Ferdinand A. Salzman, M.D., Lahey Clinic, Primary Care Clinic & Radiotherapy Center, 45 Burlington Mall Road, Burlington, Massachusetts 01803 (August 23, 1978)

COMMENT: I am responding to announced proposals of rule changes to Part 35, Section 3533 (f)(5) - defining "misadministration" as applied to " - exposure from a radiation source such that the total treatment dose or exposure differs from the prescribed dose or exposure by more than 10 percent."

I have serious qualms about this definition, particularly as it applies to external beam radiation therapy. It is misleading in possible misinterpretation of the words "prescribed dose"; it imputes a significance to a percentage value (i.e. 10%) which does not exist in the overwhelming majority of instances and does not give flexibility in those many situations where the initial prescribed dose is changed because of changing clinical conditions. If by prescribed dose is meant that a dose say of 150 rad is prescribed and a "misadministration" of 165 rad is made, then I cannot see the importance of initiating a series of reports, telephonic communications and letters to family physicians, patient and relatives! To what purpose? To alarm perhaps, to show that we are alert to minutiae albeit of no significance? Agreed that if this occurred in every treatment, say for a total of even 30 such treatments, a most rare and unlikely situation, the overdose would be insignificant in all except the most unusual case.

Suppose it is not reported? How will the agency monitor and pick this up? Why should I alarm my patient and raise the spectre of apprehension, doubt, and if subsequently an untoward or unpleasant result eventuates, completely unrelated to this single 10% overdose, leave me and my institution open to litigation based on unrelated but admitted single error? Who gains by all this? Certainly not the welfare and safety of the patient except for whatever monetary gain the litigation might give him!

In summary, this proposed rule change would simply be a redundancy (not in the meaning applied to information theory!) demeaning the other more pertinent regulations in Section 35.

STAFF RESPONSE: The definition of a therapy misadministration applies to the total treatment dose. NRC recognizes that therapists will vary the fractioned doses and the total treatment dose if clinical conditions indicate that a change is necessary.

49. F. Bing Johnson, M.D., Associate Professor of Radiology, Division of Therapeutic Radiology, University of Colorado Medical Center, 4200 East Ninth Avenue, Denver, Colorado 80262 (August 23, 1978)

COMMENT: A point could be made that the Nuclear Regulatory Commission could play a useful role in the prevention of misadministration of radiation by requiring notification of such an accident. This would be particularly true if a common pattern of a particular accident could be identified after having received notification of such accidents from the country at large. Measures then could be taken by the Commission to prevent further such accidents.

It is my very strong feeling that any requirement concerning the notification of referring physicians, patients and their relatives should not be a part of this proposed rule change, and, indeed, should not be a function of the regulatory commission. As you have pointed out in the Federal Register, this intrudes into the very important area of the physician-patient relationship. Also, the misadministration of irradiation is no different than the misadministration of any other substance or any other form of treatment. Adequate mechanisms for dealing with this type of problem already exist.

I, therefore, strongly believe that the Nuclear Regulatory Commission's role should be limited solely to the prevention of future misadministration of radiation and should not in any way deal with the physician-patient relationship.

STAFF RESPONSE: The staff believes that patients should be informed of serious misadministrations. The trend in legislation is that the patient has a basic right to ensure that the information maintained as part of his medical care relationship is accurate, timely, and relevant to that care.

50. Franklin D. Curl, M.D., Director of Nuclear Medicine, Providence Medical Center, 700 N.E. 47th Avenue, Portland, Oregon 97213 (August 15, 1978)

COMMENT: This proposal appears to represent a typical case of regulatory overkill which would not serve to protect the patient, public or physicians from any significant dangers as regards the misadministration of diagnostic radiopharmaceuticals. The quantities of radioactive materials used in routine radionuclide diagnostic procedures are not provably detrimental to the individual's health and should not occasion the type of excess paper work or general public alarm that would probably result from the extensive reporting procedures and requirements proposed in this regulation. If misadministration of diagnostic radiopharmaceuticals were to come under this regulation, it would be considerably more reasonable to require that the reportable dosage errors fall within a high therapeutic range rather than the 20% error level listed in the proposed regulation.

STAFF RESPONSE: Diagnostic misadministrations would not be required to be reported unless they caused a clinically detectable adverse effect.

COMMENT: Although a stronger case could be made for adoption of the regulation as regards the misadministration of therapeutic levels of ionizing radiation or radioactive materials, it is still likely that these reports will be used in support of a large number of unwarranted malpractice actions against physicians and health institutions where no significant injury has actually resulted and where any determination of damages would ultimately have to be made by a court of law. In any event it appears likely that the most serious radiation accidents involving significant risks of successful litigation would go unreported.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice inusrance. The amount of this increase is not known. The rule is enforceable. I&E has experience with similar reporting requirements for other NRC licensees.

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51. Jose' Oscar Morales, M.D., President, Pennsylvania College of Nuclear Medicine, A Chapter of the American College of Nuclear Medicine and the American College of Nuclear Physicians, 20 Erford Road, Lemoyne, Pa. 17043 (August 22, 1978)

COMMENT: As I see it, the concern of the NRC is to avoid exposure of patients to excessive or unnecessary radiation as a result of improper instrument calibration or malfunction and/or errors by personnel. There are already many existing regulations which address themselves to these problems, including unannounced on-site inspections. Further, I think it is very important to separate diagnostic studies and therapy with unsealed sources, from therapy with sealed sources and teletherapy. I will limit my comments to the first two.

Diagnostic nuclear medicine procedures pose little, if any, hazards to patients. Untoward effects have been for the major part limited to adverse reactions to the chemical constituents rather than to the radiation administered. The former is outside the concern of the NRC and is well covered by existing FDA regulations. The latter has been extremely rare.

Administration of a diagnostic dose where a) the wrong pharmaceutical is given to a patient, b) the radiopharmaceutical is given to a wrong patient, or c) the route of administration is incorrect (this is rare since most are given intravenously anyway) clearly poses no danger to the patient from the radiation aspect. Thus, the only possible real source of radiation harm to a patient, from a diagnostic procedure, could only come from administering the wrong dose. The 20% error limit you propose is much too low when you consider that:

a. The "proper" dose may vary by more than 200% between institutions.

b. Most studies are done with 99mTc and, therefore, the radiation exposure is minimal even after tripling a dose. A "clinical detectable effect," as pertains to radioactive exposure, would require even higher doses.

c. The amount of paper work generated with such a low limit would discourage reporting.

I suggest that if limits must be set, that the effective half lives be taken into consideration in arriving at the error limit.

STAFF RESPONSE: The threshold for reportable diagnostic misadministrations indirectly takes into account many factors. The threshold for reporting diagnostic misadministrations is when they cause a clinically detectable adverse effect. The definition of a diagnostic misadministration now takes into account the half-life. For half-lives less than 3 hours, a misadministration is defined as an error greater than 50% from the prescribed.

COMMENT: Therapeutic procedures with unsealed sources are basically limited to the use of 131-I, 32-P, and 198-Au with the former two predominating. In their case, your definitions of misadministrations would all apply, since the radiation given to the patient is not insignificant.

The limit, however, is too low. You should tailor the allowable error limit to each radiopharmaceutical, its use, and the original dose on which the percent error is based.

STAFF RESPONSE: The staff believes that this would be an unwieldy approach to the definition. The perturbations of radionuclides, sources, treatment geometries, etc., would unnecessarily complicate the definition of a therapy misadministration.

COMMENT: The Commission should also be very aware of the fact that these kinds of occurrences may be probable grounds for malpractice suits, and, therefore, malpractice insurance premiums will probably rise. This will undoubtedly deter reporting. Confidentiality must be assured by appropriate mechanisms. To do this we suggest:

a. That the report to the NRC does not include any information that could be used to identify the patient.

STAFF RESPONSE: The proposed rule and NRC procedures already provide for protecting the identity of the patient.

COMMENT:

b. That the decision to notify a patient be a matter of policy to be set within the institution that has the license.

c. That the proviso requiring notification of the referring physician be deleted as redundant, since this is a routine practice in the medical profession.

STAFF RESPONSE: The staff believes that the patient or responsible relative should be informed unless the referring physician states that it would be harmful to the patient or relative.

52. James G. Schroeder, M.D., Valley Radiology, L.T.D., P. O. Box 801, Devils Lake, North Dakota 58301 (September 1, 1978)

COMMENT: I wish to express my opposition to the proposal the NRC is considering. I am opposed to this proposed regulation for one reason, that is, it adds another layer to another needlessly loaded federal bureaucracy. Of course records are kept referable to the amount, type, time and form of administration of any radionuclide at this institution. Should a misadministration occur the patient's referring physician, and the patient or patient's responsible relative would be informed immediately. To require that this information also be relayed to a third party in some far off city is a ridiculous waste of money, an intrusion into the patient physician relationship and indeed just one further bureaucratic rat hole for money to be poured down without accomplishing any significant effect.

STAFF RESPONSE: With reports of misadministrations in hand, NRC can identify the causes of misadministrations and take steps to prevent their recurrence.

53. Neil D. Martin, M.D., Director Nuclear Medicine Department, Kettering Medical Center, 3535 Southern Boulevard, Kettering, Ohio 45429 (August 31, 1978)

COMMENT: In reference to the proposed rules concerning regulations to require licensees to keep records of all misadministrations of radioactive material, I feel that this is entirely unnecessary. The commission has expressed concern about the possible legal implications of such a proposal and considering the malpractice climate that exists today such reporting would be nothing short of a disaster.

Standard diagnostic doses vary from institution to institution and a 20% variation in one institution might be considered a normal dose in another. Should patients therefore be informed of a difference between the prescribed and the administered dose when in another institution this would be the standard administered dose? What is the radiobiological significance of a 10 mCi brain scan versus a 12 mCi brain scan?

My comments are directed toward diagnostic nuclear medicine procedures and this proposed rule would be unenforceable and I doubt it would have the support of any nuclear medicine physician in practice today. I would hope that this entire proposal would be withdrawn. There are enough rules and regulations at the present time and hopefully as a result of the Columbus, Ohio, incident, teletherapy calibration procedures are now satisfactory.

STAFF RESPONSE: The final rule has a threshold for reporting diagnostic misadministrations. Only those diagnostic misadministrations that cause a clinically detectable adverse effect on the patient would be reported to NRC, the referring physician, and the patient or a responsible relative.

54. Beverlee A. Myers, Director, State of California - Health and Welfare Agency, Department of Health Services, 4/744 P Street, Sacramento, California 95814 (August 30, 1978)

COMMENT: The Commission's objective of forestalling the recurrence of misadministrations is laudable and is purely consistent with the Department's own concerns for the quality of health care. However, it appears very doubtful to us that the proposed rule could fully achieve the objective for two reasons:

1. The voluntary reporting of misadministrations would probably be severely inhibited by fear of the possibility that such a report could be construed as an admission of malpractice.

2. While some instances of misadministration might be uncovered by inspectors examining laboratory and clinical records for that purpose, most instances are unlikely to be revealed through such a method; the increased inspection effort required would have quite limited effectiveness.

A different approach which we feel certain would be much more effective would be to require, in the case of therapy, that all dose calculations, measurements, and equipment settings be independently determined by two competent individuals, and that a signed record thereof be kept available

for inspection; in the case of diagnostic procedures, it could be required that the accuracy of all doses be verified immediately prior to administration, using an instrument accurately calibrated for each nuclide involved, and that a record of the instrument calibration be kept available for inspection. We believe such measures would prevent most errors, and that compliance would be more easily achieved and more readily verified at inspection.

STAFF RESPONSE: The second suggestion, that the accuracy of all doses be verified prior to administration, is actively under consideration by the staff at this time. All NRC licenses that authorize radionuclide generators currently require that doses be measured before administration. All new licenses and renewal licenses also include this as a condition. The staff is drafting a proposed rule that would require this for all medical licensees.

Regarding the first suggestion, that two persons be required to perform calculations and equipment settings, the staff considered and rejected a similar proposal for teletherapy calibrations. While independent checking is undoubtedly a good quality control procedure, there are not enough trained physicists or therapists to impose this as a requirement. This is particularly true in sparsely populated areas.

In the case of both suggestions, the staff does not believe they are adequate substitutes for a misadministration reporting requirement.

55. Alexander Ervanian, M.D., Director of Nuclear Medicine, Iowa Methodist Medical Center, 1200 Pleasant Street, Des Moines, Iowa 50308 (August 30, 1978)

COMMENT: I see no merit to the proposed regulations. We are already required to report misadministrations to the NRC and I see no point in frightening unknowledgeable physicians and patients regarding the small and harmless dosages of radiation that we use in diagnosis. Therapeutic doses are another matter entirely, but I believe that the existing regulations give adequate protection from that contingency.

STAFF RESPONSE: There is no NRC misadministration reporting requirement at present. Only those diagnostic misadministrations that cause a clinically detectable adverse effect in the patient need to be reported to NRC and the patient. All other diagnostic misadministrations are subject to the record-keeping requirement.

56. R. D. Berkebile, M.D., Elyria Memorial Hospital, 630 East River St., Elyria, Ohio 44035 (August 31, 1978)

COMMENT: To cite the tragic mistakes made at the Columbus Riverside Hospital makes the inference that all the rest of us who have been doing careful radiation therapy are just as stupid and that we need a big brother to watch over us with a large book of rules. Frankly, I am against such a proposed rule and the wordage that has been included in this proposal. I object to it on both professional and common sense grounds. I consider it insulting to any radiation therapist and to the medical profession as a whole.

STAFF RESPONSE: The rule is not intended as an insult to the medical profession. It is not uncommon for regulations to distress conscientious individuals.

57. George L. Jackson, M.D., Harrisburg Hospital, South Front Street, Harrisburg, Pa. 17101 (August 30, 1978)

COMMENT: Clarification should be made regarding whether extravasation of an intravenous dose constitutes a misadministration. Since no clinically detectable adverse effect would be anticipated even if a second dose were required, it would seem inappropriate to consider this as misadministration requiring reporting. We find the proposed rule ambiguous in this regard.

STAFF RESPONSE: The preamble to the final rule will state that extravasation is not a misadministration.

COMMENT: The stipulation that a therapeutic dose that differs by more than 10% constitutes misadministration shows considerable lack of understanding on the part of rulemakers. For example, we customarily order 150 mCi of radioactive iodine for a patient receiving treatment for thyroid cancer. The supplier can rarely provide that dosage exactly. If the dose is greater than 150 mCi, that is easily corrected by removing the excess. Not infrequently, however, we find it responsible and appropriate to give less than 90% of the prescribed 150 mCi, for to do otherwise would require ordering a substantial excess under circumstances which would not be cost effected. A therapeutic misadministration defined as 10% less than the prescribed dose, should be removed from the list of misadministrations

STAFF RESPONSE: The prescribed dose is the dose prescribed by the therapist/physician. The 10% difference is intended to indicate when an error has occurred, not the intentional delivery of a lower dosage—whatever the reasons.

COMMENT: The loss of confidentiality which is inherent, although possibly unlikely by virtue of this proposed rule, has the potential for considerable mischief.

Finally, testimony offered at a public hearing of the Nuclear Regulatory Commission in 1977 indicated that the involvement of another regulatory agency in the matter of assuring high quality patient care, is time consuming, costly and unnecessary. The benefits which the rule maker hopes to achieve by this recommendation is already accomplished in well run nuclear medicine departments. This is a responsibility of the hospital, its board of managers and its medical department structure.

STAFF RESPONSE: One purpose of the rule is to get the word out to other NRC licensees on potential generic problems. This cannot be accomplished unless misadministrations are reported to NRC.

58. James D. Van Antwerp, M.D., Nuclear Medicine/Ultrasound Department, St. Joseph's Hospital, 350 North Wilmot Road, P. O. Box 12069, Tucson, Arizona 85732 (September 1, 1978)

COMMENT: I am strongly opposed to the proposed amendment. In my opinion, this amendment is unwarranted, unnecessary, and quite possibly illegal and

unconstitutional. I feel that it is unnecessary as the handling of misadministration of radioactive material is quite adequately and responsibly handled at the local level, at least in our facility. It is unwarranted as the primary effectiveness of the NRC should be in the area of dealing with qualifications, licensure, distribution of radioactive materials, and assisting development and enforcement of hospital policies rather than dealing with the problems of day-to-day medical practice. Lastly, the question of legality and constitutionality of this amendment is raised. The amendment as written certainly represents what I consider undue and inappropriate involvement in the physician-patient relationship. It should be noted that this letter refers only to radioisotope administration as utilized in the practice of nuclear medicine and does not apply to other sources of radiation.

The following are more specific comments regarding the proposed amendments. These are not to be construed as implying that alteration of the amendment based on these comments would render it acceptable to the undersigned.

At St. Joseph's Hospital, Tucson, Arizona, misadministrations of radiopharmaceuticals are fortunately rare. When they do occur, the patient and referring physician are immediately notified and appropriate arrangements made to minimize inconvenience to the patient for completion of an adequate diagnostic study. To date, a situation has not arisen where a member of the medical "team" felt that informing the patient would be harmful. I feel that current departmental and hospital policies are fully adequate and the involvement of an additional agency would be burdensome and superfluous.

Reporting would be necessary when a misadministration would result in a "clinically detectable adverse effect." Adverse effect is not defined, and could be interpreted within a wide range varying from direct harm to the patient at one extreme to unsuitable diagnostic results at the other extreme. This renders totally invalid any realistic criteria for reporting.

STAFF RESPONSE: "Clinically detectable adverse effect" means harm to the patient. See also staff response to comment #21.

COMMENT: It is stated a diagnostic dose of a radiopharmaceutical differing from prescribed dose by more than 20% warrants being reported. It should be noted that some radiopharmaceuticals have a prescribed dose range that varies more than 20%, e.g., Xenon 133 Ventilation Studies. Also, if a patient appears in the department later than his appointment, a precalibrated dose may be more than 20% less than the actual prescribed dose. A radiation dose less than the prescribed dose certainly could in no way be harmful to the patient even though an adequate diagnostic study could probably be obtained.

STAFF RESPONSE: The final rule will have a clear threshold for reporting of diagnostic misadministrations, i.e., those having a clinically detectable adverse effect.

COMMENT: There is no statement in this regulation as to limitations on use of reports by the NRC. If this became public information, the potential for multiple nuisance malpractice suits is significantly increased.

STAFF RESPONSE: There are no limitations on the use of this information by NRC. It will be public information. The patient's identity will not be released in order to protect his privacy.

COMMENT: Suffice it to say, I feel that Amendment 35.33 to 10 CFR Part 35 is totally unnecessary and undesirable. This would be an addition to the already overwhelming number of federal mandates with which medical facilities have to handle by increased staff time and paperwork, which invariably increase the cost of medical care as well as expanding the associated bureaucracies and tax obligations necessary to support them. If the NRC is to be reasonably appropriate and effective in meeting the objectives implied by the amendment, attention should be focused on making certain that hospital, medical and administrative authorities appropriately deal with these problems at the local level.

STAFF RESPONSE: Without knowledge of the types or extent of misadministrations, NRC cannot make certain that these problems are handled at the local, State or Federal level.

59. Neal Neuberger, Health Planning Analyst, Quality Care Division, The State Medical Society of Wisconsin, 330 East Lakeside Street, P.O. Box 1109, Madison, Wisconsin 53701 (September 6, 1978)

COMMENT: I have been in contact with several physicians who are members of the Wisconsin Radiological Society and extremely knowledgeable in this area. It is their general consensus that the proposed regulations constitute an undue intrusion into the physician-patient relationship.

The physician's obligation to the patient, relatives, legal guardians, et al., is well defined under long-standing professional and legal medical malpractice standards on the state level. There appears to be little reason for further involvement from the federal level.

Perhaps there is some virtue in that portion of the regulation which would require an NRC licensee to notify the Commission of "misadministrations." This might include the Commission's desire to 1) send out educational materials to licensees, or 2) detect persistent patterns of "misadministration" for purposes of prescribing corrective procedures, methodologies of calibration, etc.

Therefore it is the suggestion of the State Medical Society that the proprosed rule be substantially modified to confine the reporting requirement by the licensee to the NRC only, and that any resulting action be limited to the NRC and the particular licensee in terms of the immediate situation.

STAFF RESPONSE: Although some individuals on the staff believe that the reporting requirement should be limited to reporting to the NRC and the referring physician, the consensus is that the requirement should extend to reporting to the patient or responsible relative.

60. John B. Dorian, M.D., President, Tennessee Medical Association, 112 Louise Avenue, Nashville, Tennessee 37203 (September 1, 1978)

COMMENT: The Executive Committee of Tennessee Medical Association's Board of Trustees has requested that I reply to your letter of July 26 regarding misadministration of radioactive material.

Consultation with the Tennessee Radiological Association reveals the opinion that the proposed regulations in misadministration are unnecessary, unwieldy, and expensive. Physicians in the specialty believe that reliance on physician's integrity has been an adequate safeguard in the past.

The Tennessee Medical Association concurs in this viewpoint, and therefore, opposes additional cumbersome administrative regulations of the specialty and of the profession.

STAFF RESPONSE: The staff believes that the benefits of misadministration reporting are worth the expense.

61. Theodore E. Keats, M.D., President, Virginia Chapter, The American College of Radiology, Department of Radiology, School of Medicine, University of Virginia, Charlottesville, Virginia 22901 (September 5, 1978)

COMMENT: When this was originally proposed, I believe that you received a number of comments regarding the implications of misadministration reporting to the NRC and to patients that might result in malpractice litigation suits and this problem should be considered before it is accepted. The stated reason for informing the patient of a misadministration is so that "corrective action can be taken." I am not sure what corrective action is anticipated. If in fact no corrective action would be envisioned (particularly for the diagnostic tests), what is the reason for inviting litigation by formal notification of patients of misadministration?

It is suggested that any misadministration that could lead to "clinically detectable adverse effect" be required to be reported immediately to the NRC. In the case of the diagnostic tests, it is difficult to envision a misadministration that would result in clinically detectable adverse effects, particularly with short half life nuclides.

I have no quarrel with the requirement that each facility maintain a record of misadministrations, even those with diagnostic tests. However, I think that the definition of misadministration needs clarification. In section 35.33 (F), misadministration is defined to include administration of a radiopharmaceutical by a route of administration other than that intended by the prescribing physician. Would this include the infiltration of a dose intended to be intravenous or intra-arterial? In our experience, some infiltration of the soft tissues occurs in as many as 1/3 of intravenous injections and I doubt that this is intended to be defined as a misadministration.

I hope that these potential problems are carefully weighed before any such regulations are adopted.

STAFF RESPONSE: The staff agrees that few diagnostic misadministrations are likely to cause a clinically detectable adverse effect. Extravasations are not misadministrations and the Federal Register notice of final rulemaking will so state.

62. Howard L. Smith, M.D., President, Chaves County Medical Society, Rio Pecos Ob-Gyn, P.A., North Office: 313 West Country Club Road, Roswell, N.M. 88201 (August 29, 1978)

COMMENT: I can only state I wish you people would cease citing some horrendous story of misadministration as the reason for further regulatory actions on your part. I am firmly convinced most regulatory actions only occur because somebody has to find a position and a form to prove to the world around them and, primarily to themselves, there is a reason and purpose for their miserable existence. I am absolutely sick, tired and fighting mad over you misguided altruists and the utilization of the Federal Register as your fighting ground.

If the government would get out of medicine I feel the judicial branch and the private practice of medicine would take care of it far better than what you are.....at much less expense.

STAFF RESPONSE: Comment noted.

63. John J. Fuery, M.D., Radiation Therapy and Oncology, Medical Group, Inc., Memorial Hospital, Modesto, 1700 Coffee Road, P. O. Box 942, Modesto, California 95353 (September 6, 1978)

COMMENT: We feel that the proposed changes in regulations are unnecessary and are potentially harmful. The Commission should understand that medical licensees are, in fact, licensees by virtue of their training and the fact that they are responsible people. Naturally, they are going to keep records of all misadministration of radioactive materials accordingly and report any potential dangers deriving therefrom to referring physicians and to handle the situation in a responsible manner.

Accordingly, we feel that the NRC demanding that these matters be reported personally to them is an unnecessary additional job to be performed and an additional expense both for the licensees and for the government.

In addition, in our present very difficult medicolegal climate, this type of information might be misunderstood and misused and result in serious intrusions and possible breaches of physician-patient relationship.

Our plea would be to remind the NRC that all licensees are well trained, responsible, morally sound people who can be expected to act in an intelligent, thoughtful and responsible manner and in the best interests of their patients at all times. Therefore, this proposed regulation would require unnecessary additional paperwork, in our opinion.

STAFF RESPONSE: A major purpose of the proposed rule is to notify other licensees when there are misadministrations that are generic in nature. The rule is not intended to insult or distress NRC licensees, although the staff recognizes that in fact the proposed rule has distressed many licensees.

868 074

64. Rene J. Smith, Ph.D., Medical Physicist, East Orange VAH; K. David Steidley, Ph.D., Chief Physicist, St. Barnabas Medical Center; Leo L. Meisberger, M.S., D.A.B.R., Radiation Physicist, St. Peter Med Center, New Brunswick, N.J. 08903; William R. Hollsinger, Radiation Physicist, United Hospitals Medical Center, Newark, New Jersey; John F. Lantz II, Physicist, New Jersey Medical School, CMDA, Newark, New Jersey; David Dabowitz, Physicist, Newark Med Center, Newark, New Jersey; Sharon M. Arbo, Dosimetrist, Clara Maass Mem. Hospital, Billartie, New Jersey; Marilyn Katz, RN, Radiation Oncology Coordinator, New Jersey Medical School, Martland Medical Center, Newark, New Jersey; and Henry A. Surtaj, Asst. Radiation Safety Officer, VA Hospital, East Orange, New Jersey (September 13, 1978)

COMMENT: We, the undersigned Medical Physicists, would like to make the following comments on the proposed rules concerning Misadministration Reporting.

The new proposed rules are an interference by the Nuclear Regulatory Commission into the affairs of a Nuclear Medicine Department, as well as a Radiation Therapy Department.

It is clear that in the case of most diagnostic procedures, even a 100 percent error in the dose is not going to produce a "clinically detectable adverse effect" because of the small doses involved.

As for reporting to a patient, "to the patient's referring physician...or the patient's responsible relative" a "therapeutic dose of a radiopharmaceutical or exposure from a radiation source ...which differs from the prescribed dose or exposure by more than 10 percent" is a decision that should be left entirely to the physician working in a Radiation Therapy Department. The NRC would be over-regulating if it were to command a physician what to tell and what not to tell a patient. It would also place the physician, medical physicist and any other allied personnel involved in a very handicapped position in case of a law suit. In court cases, the parties involved are assumed to be innocent, unless proven otherwise. If the new proposed rules are adopted, the NRC is effectively forcing the personnel involved into admitting their guilt beforehand.

There are, of course, many ways to circumvent these rules. The physician is not obliged to prescribe a dose at all, or he/she may prescribe a very large dose (not to be exceeded), state that the patient will be checked and evaluated at weekly or biweekly intervals and finish the treatment when he/she sees fit.

For the above reasons, we feel that the proposed rules on Misadministration Reporting Requirements should not be put into effect.

STAFF RESPONSE: The staff agrees that, with the possible exception of I-131, even a 100% error in a diagnostic dose will not usually result in a clinically detectable adverse effect. Also, there may well be ways to circumvent the rule, but loopholes can be closed through followup rulemaking.

65. George H. Foster, MAJ, MSC, Adjutant, Department of the Army, Head-quarters Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia 30905 (September 13, 1978)

COMMENT: It appears that only benefits would result in the reporting of misadventures of radioisotopes, and these proposals by Nuclear Regulatory Commission reflect the basis of good medical practice. However, it is felt that it is not appropriate to make these amendments into regulations requiring informing of the patient's physician and the patient or patient's relatives of misadventures. Such should remain the sole prerogative of the licensees and not be governed by regulation. The proposal should be in the form of recommendations only.

STAFF RESPONSE: The staff believes that a rule is necessary in the case of misadministration reporting. A recommendation in lieu of a rule would not be as effective.

66. Martin L. Pollock, 820 Chestnut Ave., Apt. 10, Los Angeles, Calif. 90042 (September 11, 1978)

COMMENT: I think that the NRC is going too far and stepping into the practice of medicine by mandating the reporting of misadministrations of radiation and radioactive material. Why is the NRC singling out radiological and nuclear medicine practitioners? If we are going to control those involved with radiation, then let's control the surgeons who are performing invasive procedures on the spinal cord, on the brain, on the heart, or on the circulatory system, all of which, if a mistake was made, could produce disastrous consequences. And what about drugs? What about the misadministration of chemotherapeutic agents in cancer cases. What about the administration of drugs and RADIATION to pregnant patients?

STAFF RESPONSE: The NRC only regulates physicians who use byproduct material. The staff is aware that the reporting of misadministrations will be unique in medicine.

COMMENT: Every practitioner has the right to the free practice of medicine, unless that practitioner does something to prove otherwise. Just because we happen to be involved with radiation doesn't mean that the government should be telling us what to do, because again, no one has the right to say that misadministration of radiation are any more dangerous and harmful than misadministrations of any other type of health care procedure.

Misadministrations of health care procedures are not discrete quantifiable events. Because one patient got a 40% overdose of Cobalt 60 and as a consequence developed a new malignancy or because one patient received 20% too much drug and developed such and such, or because a surgeon dug a half a millimeter too deep into someone's brain and that caused such and such...well, can you say OK let's regulate everyone? Of course not!

In the case of radiation use in hospitals, if the government wants to do something, let it see that each hospital has a radiation review (both therapeutic and diagnostic) committee that can oversee the functions of radiation therapy, radiology and nuclear medicine. If there is any problem with misadministration of radiation at all it is in the area of

straight diagnostic radiology. Many many many more patients are exposed to diagnostic x-rays in a given day than therapeutic radiation.

So the NRC should be seeing that each clinical facility in the country has a functioning RADIATION safety committee that can see to it that all machines are properly calibrated and that the personnel are familiar with proper use of the equipment. Any facility delivering therapeutic radiation should have at least a part time health physicist to insure that the machines are operating properly.

STAFF RESPONSE: There is a new rule requiring periodic teletherapy calibrations (44 FR 1722), and licensees are already required to have a person trained in radiation safety. This is not necessarily a health physicist.

COMMENT: If the NRC must regulate the practice of medicine, then let the Commission regulate those hospitals that fail to insure the proper medical use of radiation THEMSELVES.

A properly functioning radiation unit in a hospital should be able to monitor itself for mistakes, i.e., the mistake should be documented for the HOSPITAL'S internal records and the hospital radiation committee should insure that corrective action is taken to prevent a recurrence.

As far as reporting these misadministrations to the patient or representative thereof goes, again, no other practitioner is required to do this, why should we?

And economically, this is just what the malpractice lawyers want. Why they will have a field day! Radiation services of all categories will jump up in price, Blue Cross rates will go up faster than they are now. All this will mean just an escalation of the strangling of Middle Class America and it will be another earthquake for the already shaken up and distrusted health care delivery system which is hesitating RIGHT NOW to administer many radiation procedures for fear of impending law suits.

So please leave that practice of radiology, nuclear medicine and therapeutic radiation to be controlled by those who are best qualified, i.e., the PRACTITIONERS THEMSELVES. I would like you to be aware of two concepts as I close my comments:

> Using diagnostic nuclear medicine on a pregnant patient, is in my opinion, a misadministration, unless it has been thoroughly discussed by the patient and practitioner before the procedure. You do not mention this in your proposed rules.

STAFF RESPONSE: The FDA has done quite a lot of work in this area both for nuclear medicine procedures and x-rays. FDA is presently working on patient package-inserts for all drugs, including radiopharmaceuticals. This includes warnings to pregnant women.

COMMENT: Want to cut down on wrong drugs, wrong patients, and wrong quantities? (all this pertaining to diagnostic nuclear medicine) How about seeing that a nuclear medicine physician is always at the side of

the patient either administering or supervising the administration of that radiopharmaceutical? I'm sure you know that this rule is not always followed. If we are going to have regulations let's get to the problem BEFORE a mistake occurs. A technician or technologist administering radiopharmaceuticals without physician presence increases chances for mistakes.

STAFF RESPONSE: Where permitted by state law, NRC allows authorized physicians to delegate to technicians the administration of radiopharmaceuticals. The physician, however, is still responsible for this administration. The staff will consider the proposal suggested by this commenter at a later date and in the light of misadministration reports.

COMMENT: Also, I think it will be proper for the radiation committee to report mistakes and misadministrations to the attending physician, as this is something the attending MD has a right to know. But that's as far as it goes from the radiation practitioner to the attending physician. The radiation committee must deal with the problem and I cannot see at this time reporting to NRC or the patient, ESPECIALLY to the patient!--unless we see some drastic changes in the physician-malpractice-insurance firm-lawyer relationship.

STAFF RESPONSE: The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

67. Thomas P. Hayes, M.D., Radiation Therapist, Deaconess Hospital, 600 Mary Street, Evansville, Indiana 47747 (September 14, 1978)

COMMENT: Under the definitions of misadministration I would like to say that giving the wrong radiopharmaceutical other than the one intended, giving a radiopharmaceutical to the wrong patient, or administering a radiopharmaceutical by a route other than that intended are all situations which presently are documented and recorded in hospital records and of course are discussed with the patient and any other physicians involved.

With respect to a deviation in dose of 20% of the diagnostic radiopharmaceutical where the doses utilized are microcuries, I would question that such a relatively small deviation could be accurately determined or that it would have any impact whatsoever on the quality to study nor would it have any ill effect on the patient.

In the case of therapeutic implants, I would like to point out that it is rarely possible to determine in advance just exactly how much material can be implanted. We all observe adequate safeguards against excessive dosage and in the case that we are not able to apply as much as we would like the deficiency is invariably corrected by means of supplementary external irradiation. Radiotherapists cannot exactly determine in advance of an operative procedure just exactly what can be accomplished any more than a surgeon can prior to doing an exploratory operation. Radiotherapists frequently do not know how many radium or cesium capsules can be placed in the uterus before the actual procedure is carried out. Therefore, I think that the requirement of generating reports and documents for the NRC under those circumstances is superfluous and would serve no useful purpose to anyone.

STAFF RESPONSE: The staff recognizes that there are unique problems in administering a brachytherapy dose. The definition that is developed for the final rule will attempt to account for these uncertainties. The definition for a therapy misadministration is in terms of the prescribed (or intended) total treatment dose. In practice, this gives the therapist some leeway because his prescribed or intended dose may change during the course of therapy. When the final calculations are made and the therapist determines that there is a greater than 10% difference from the prescribed dose, then a misadministration has occurred.

COMMENT: The second category mentioned in Bernard Singer's letter is in reference to promptly reporting potentially dangerous misadministration to the NRC to the patient's referring physician and to the patient and the patient's responsible relative. I would like to point out that it has been a long established principle of medical practice to thoroughly discuss and explain any medical misadventure to the patient, their relatives and the referring physicians, and I feel that this suggestion on the part of the NRC is again superfluous and an unwarranted intrusion into the legitimate domain of the practice of medicine.

STAFF RESPONSE: It is not common practice to notify NRC of misadministrations. Without these reports NRC cannot help to prevent further misadministrations by, as a minimum, notifying other licensees of potential generic problems.

68. Juan V. Fayos, M.D., Professor of Radiology, University Hospital, The University of Michigan, Ann Arbor, Michigan 13109 (September 8, 1978)

COMMENT: My coments will be concerning therapeutic procedures. I consider that 10% deviation from the prescribed dose is a fair rule, particularly if one considers that every unit should be under continuous surveillance as is the case of the units in Radiation Therapy at University Hospital.

I consider that reporting promptly to NRC dangerous misadministrations should be done. However, I would take issue with having to report to the patient and/or responsible relatives in the event of an overdose slightly above the prescribed dose. If we were to consider an average dose of 6,000 rads given in six weeks period for the treatment of a tumor and if an overexposure of an 11% dosage were to be given, that is, 660 additional rads, over the same period of time, I do not think that biologically it would make a great deal of difference. If the initial prescribed dose would have been higher, then, obviously, one can get into the area where radiation damage could result.

I question what good would the patient receive from knowing that a reportable overexposure of minimal proportion had happened to him. Since it is not known generally what kind of difficulties he might encounter from this minimal overexposure, and no specific treatment exists, it would probably turn out to be more of an emotional or legal issue than of any benefit to the health of the patient.

In conclusion, it is my opinion that section 35.33a (3) and parts pertaining to patient's notification should be removed from the regulations.

STAFF RESPONSE: The staff believes that an error greater than 10% in therapy will most likely be harmful to the patient and the patient should be informed.

69. Natalie Davis Spingarn, Executive Director, National Commission on Confidentiality of Health Records, 1211 Connecticut Avenue, N.W., Suite 504, Washington, D.C. 20036 (September 7, 1978)

COMMENT: In general, this seems a reasonably balanced approach, but several items are omitted or unclear and should be more carefully defined:

1. The exposure reports should not be available to the NRC in personally identifiable form unless

   a. the patient consents; or

   b. the NRC determines that removal of identifiers and the obtaining of consent is impractical; and

   c. the NRC obtains the personally identifiable records pursuant to its written certification to the licensee and the subject that the information will not be available to any party outside the NRC and will not be used by the NRC to make a decision affecting the subject.

STAFF RESPONSE: The rule states that the misadministration report to NRC should not include the name of the patient. If the name of the patient does appear in the report, NRC will censor the name in any report released to the public or released under the Freedom of Information Act.

2. Licensees are required to inform subjects prior to commencement of treatment that in the event of a misadministration certain information about that misadministration may be made available to the NRC.

3. The misadministration information should always be disclosed to the subject or a subject's representative. (As currently drafted, the proposed rule permits licensees to dispense with any notice to the subject or the subject's responsible relative if the physician so advises. There is very little support for the argument that disclosure to the subject or some sort of subject representative can be altogether omitted on the say so of the physician.)

STAFF RESPONSE: (To be supplied by ELD.)

70. R. Denny Wright, M.D., President, Medical Society of Mobile County, 248 Cox Street, P.O. Box 1782, Mobile, Alabama 36601 (September 18, 1978)

COMMENT: We have studied the proposed regulations and our Society is in agreement with the proposal except for (3) of 35.33. We recommend that the proposed (3) of 35.33 of 10 CFR Part 35 be rewritten to read as follows: "(3) The patient or the patient's responsible relative, unless the referring physician personally informs the licensee that in his medical judgment telling the patient or the patient's responsible relative would be harmful to one or the other, respectively, or, if in the

judgment of the licensee that no detrimental effect will accrue to the patient as a result of such administrations, with the concurrence of the referring physician, the patient or the patient's responsible relative need not be informed. This judgment, and the reasons therefore, will be made a part of the patient's record as well as the report to NRC. If in reviewing the incident, the NRC does not concur in the licensee's and referring physician's judgment, then the incident shall be reported to the patient, or the patient's responsible relative. Also, if the referring physicians does not concur in the licensee's judgment then the incident shall be reported to the patient, or the patient's responsible relative." The rationale behind this recommended rewrite is that "minor" misadministrations of radioactivity which in all likelihood will not affect the patient's welfare could cause undue alarm and apprehension that could lead to unnecessary and unwarranted litigation, or psychologically impair the patient, or the patient's family for an indeterminate length of time. In this day and age with the lay public exposed to a great deal of misinformation concerning radiation and radiation hazards, small incidents may be blown out of proportion to their actual potential detriment. In fact in the total spectrum of evaluation the use of radioactive materials has been around a very short time in terms of the generations exposed, and while we reap many benefits from such, the long term effects, in terms of succeeding generations are not fully understood.

STAFF RESPONSE: The final rule will have a threshold such that only serious diagnostic misadministrations will be required to be reported to the patient. All therapy misadministrations will be required to be reported to the patient. This should answer the commenter's concern that minor misadministrations would cause undue alarm to the patient.

71. Michael P. Murphy, M.D., Chairman, Radioisotope Committee, and Lincoln B. Hubbard, Ph.D., Consulting Physicist, Hinsdale Sanitarium and Hospital, 120 North Oak Street, Hinsdale, Ill. 60521 (September 14, 1978)

COMMENT: After reviewing this proposal, it was the feeling of the Radiation Safety Committee at Hinsdale Hospital that the proposal is unduly stringent in selecting the 10% figure for therapeutic procedures and 20% figure for diagnostic procedures. It is our feeling that a 10% variation in daily dose or total absorbed therapeutic dose is not always clinically significant. What then is the intent of the proposal? Should we report only clinically significant misadministrations which exceed 10%?

STAFF RESPONSE: The rule requires reporting of all therapy misadministrations. Therapy misadministrations are defined as errors in the total treatment dose that exceed 10% of what was prescribed.

COMMENT: Frankly, we would be reluctant to inform patients in writing about misadministrations unless we are describing a clinically significant mistake. To describe undesirable variations in administered dose as misadministrations seems excessive. The word misadministration is in our opinion an unfortunate choice of terms. Patients will not understand the distinction between misadministration and malpractice, inviting unwarranted litigation.

868 081

There are several ambiguities in the proposed rule as it relates to Nuclear Medicine and diagnostic procedures. For example, does a subcutaneous injection of a bone scanning agent constitute a misadministration? When a bone scan is done instead of the ordered brain scan, do you wish the patient informed in writing using the word misadministration to describe this event?

We agree with the intent of the proposed rule change, i.e., to prevent disasters such as occurred at Riverside Hospital in Columbus, Ohio. However, the proposed change in our opinion doesn't place enough emphasis on reporting only significant events. Further the requirement to notify patients in writing using the word misadministrations seems excessive.

STAFF RESPONSE: Accidental extravasation is not a misadministration. Subcutaneous injection when intravenous injection is indicated is a misadministration; when the wrong procedure is performed, that is a misadministration. The patient or a responsible relative must be informed only if a diagnostic misadministration causes a clinically detectable adverse effect.

72. Garry J. Brown, N 301 Palm Ave. #8, Alhambra, CA 91801 (received 9/25/78)

COMMENT: The potential benefit to the patient is obvious: The decreased incidence of misadministration of "radioactive material or radiation from radioactive material." I would be interested to know what kind of statistics are available concerning incidence of misadministrations of the types listed in the supplementary information of the Federal Register. It would be interesting to know the extent of damages resulting from such errors also.

STAFF RESPONSE: The Federal Register notice of final rulemaking will discuss some recent misadministrations that have come to NRC's attention.

COMMENT: I question the necessity of federal controls on reporting these incidents for two reasons:

1. expense of administration,
2. inability of the agency to enforce such a rule.

A thorough controlled study of the actual incidence of misadministration might prove valuable to demonstrate an actual need for enactment of this rule.

STAFF RESPONSE: Misadministration is a difficult area to study. Literature references are sparse. The reports and records generated by the rule will provide data to determine the actual incidence of misadministrations.

73. Thomas H. Kramer, Assistant Hospital Director, Deaconess Hospital, 600 Mary St., Evansville, Indiana 47747 (September 14, 1978)

COMMENT: I wish to go on record as stating, it is my opinion, that the retrospective recording process which you outline in your proposed rule 10 CFR 35.33, will do little to reduce the number of misadministrations of radioactive materials. Historically, retrospective reporting has done

little to minimize misadministration of any type of treatment or medication and, at best, will only reveal mistakes or errors that, once they have been made, are irreversible.

It seems that the most reliable method of reducing misadministration is not retrospective reporting but rather effective licensing procedures and certification procedures for personnel who give such treatments and also effective and timely requirements for proper calibration, use, and maintenance of equipment used in the administration of radioactive material.

STAFF RESPONSE: The staff believes, but cannot prove, that voluntary reports of misadministrations have resulted in regulations which have served to reduce the number of misadministrations. Examples are the Patient Radiation Survey Rule, the Molybdenum Breakthrough Testing Rule and the Teletherapy Calibration Rule.

COMMENT: Furthermore, I object to the proposed rule making from the standpoint that, without question, this is one more potential intrusion into the patient/physician relationship which, as we all know, is important in the ultimate outcome of most types of therapy. Your proposed requirement that a patient and/or relative be notified every time a misadministration occurs would result in undue alarm in most cases simply because most misadministrations that may occur would not have significant detrimental effects to the patient. Notifying such patients of a misadministration is going to cause them undue anxiety and worry which, at the least, is going to result in unnecessary, costly, and unwarranted litigation. In turn, this will raise the overall cost of health care due to the resulting increase in malpractice premiums and the cost of litigation.

Finally, I would like to point out that I oppose the proposed rule making on the basis that it would be very difficult in determining, in many cases, when, in fact, a misadministration has occurred based on your requirements of ten and twenty percent error rates. In many cases, as you well know, it is very difficult to determine the exact dosage given of certain types of irradiation. Therefore, it may be impossible to determine a ten or twenty percent variance.

STAFF RESPONSE: Measuring diagnostic dosages is straightforward, and the definition of 20% error for a diagnostic misadministration should not be a problem. In teletherapy and brachytherapy, the planned radiation dose is calculated and the exact dose to the tissue is not known. If there are errors in the calculation greater than 10% or there are errors in the way the radiation is applied to the patient such that the total, calculated, radiation dose is in error by greater than 10% from the total prescribed radiation dose; then there is a misadministration.

COMMENT: Although your proposed rules do not address this issue, another question which is raised in my mind has to do with reporting of underdosages of radioactive materials which may not be detrimental to the patient but according to your rules would be required to be reported as a misadministration. This seems like another paperwork process that will result in higher health care costs and additional work on the part of all parties with no benefit to anyone.

STAFF RESPONSE: A diagnostic misadministration of underdosage would be unlikely to cause a clinically detectable adverse effect and would therefore not be reportable. A therapeutic misadministration where the patient received less than the planned radiation dose would be reportable under the rule. In this case, the tumor may not be sterilized and followup actions may be necessary.

COMMENT: For the above reasons, I would strongly encourage the Nuclear Regulatory Commission to reconsider its proposed rule and rather than retrospectively addressing a potential problem, efforts be made to insure adequate licensure and certification of personnel administering radioactive materials and that effective measures are implemented to insure that equipment utilized in administering such materials are adequately maintained, properly calibrated, and properly utilized.

STAFF RESPONSE: Licensees are required to calibrate and use dose calibrators as a condition of their NRC licenses. The regulations in §35.21 require calibration of teletherapy units. Under NRC regulations, the physician may delegate certain tasks to paramedical personnel, including the administration of radioactive material (where State laws permit). NRC holds the physician responsible for those tasks which are delegated to paramedical personnel and NRC holds the physician responsible for evaluating the training and experience of those paramedical personnel.

74. B. T. Weyhing, M.D., Director of Nuclear Medicine, Grace Division of Harper-Grace Hospitals, Detroit, Michigan 48235 (September 15, 1978)

COMMENT: I am opposed to the proposed rules changes because I feel them to be unnecessary. Under present rules complete records of all radionuclides administered to patients are kept. The amount and nature of the administered material is part of the patient's permanent hospital and outpatient record. Any misadministration, therefore, is amply documented.

STAFF RESPONSE: NRC does not presently have requirements concerning records of misadministrations. An important feature of the rule is the requirement to notify NRC of serious misadministrations so that other licensees can be informed or new regulations issued to prevent recurrence. Another purpose is to have the records of misadministrations available for inspection.

COMMENT: In addition, at the present time it is virtually impossible for a patient to be given a dangerous dose of a diagnostic radionuclide. All adequately equipped departments have dose calibrators and the safety factor for most diagnostic isotopes is greater than 100 to 1.

STAFF RESPONSE: The rule will not require reporting to NRC or the patient for a diagnostic misadministration unless there is a clinically detectable adverse effect.

COMMENT: Finally, if a potentially dangerous misadministration should occur any ethical physician will immediately notify the patient and his physician in order that appropriate treatment can be immediately instituted. It is my opinion that the great majority of physicians practicing nuclear medicine are ethical and do not require a government watchdog to insure honesty when a patient's welfare is at stake.

In summary, I oppose the proposed rules changes because I feel them to be an unwarranted incursion into the physician-patient relationship which is of questionable necessity at best and would serve primarily to generate additional useless paperwork.

STAFF RESPONSE: The staff recognizes the intrusion into the physician-patient relationship and the expense of the rule. The staff believes that both are necessary to prevent future misadministrations.

75. Sam B. Baker, M.D., Evansville Medical Radiological Association, Inc., 611 Harriet Street, Evansville, Indiana 47710 (September 15, 1978)

COMMENT: I would like to go on record as opposing the proposed rules. It is my opinion that additional regulations such as proposed are unnecessary and arbitrary. Licensed physicians and health care providers have always and will continue to accept responsibility for prescribed medications and other treatments. Corrective actions are taken appropriately and discussed with attending physicians, pharmaceutical or byproduct suppliers and manufacturers as well as the patients and referring physician appropriately and immediately without need for prodding from third parties.

Significant misadministrations or misadventures of any kind whether or not related to radioactivity are already taken care of and when appropriate this information is conveyed through medical journals and through direct communication with appropriate individuals or other parties in order to insure corrective actions in the future if necessary. I feel that the new proposed rules and regulations would do nothing to improve health care but in fact might have the reverse effect because of its arbitrary limitations and inflexibilities.

I might suggest in place of the proposed rules, that the Nuclear Regulatory Commission might better serve its apparent intended purpose by recommending to licensed users that they merely consult or report to the Nuclear Regulatory Commission significant misadministrations which might be related to already existing rules and regulations.

STAFF RESPONSE: The final rule basically requires reporting of serious misadministrations and recordkeeping for all others.

76. D. Richard Jones, M.D., Lakeland General Hospital, Lakeland, Florida (September 11, 1978)

COMMENT: I suggest with respect to the rules, that records of misadministrations should be kept as part of the daily log of radioisotope administrations which already exists in every laboratory.

STAFF RESPONSE: A separate log or file of misadministrations is necessary for NRC review so that inspectors can get a profile of the activities of the department and determine if corrective actions are necessary to prevent further misadministrations.

COMMENT: I suggest, also, that reporting potentially dangerous misadministrations to the NRC would be unnecessarily cumbersome and of little use,

but that such incidents should be, of course, reported to the patient's physician and to the patient or a responsible relative.

Such misadministrations would be, as we all know, extremely rare, certainly with respect to diagnostic use of isotopes, however, it does seem to me as if every new regulation requiring reporting to some federal agency slowly adds to an already huge reporting burden.

STAFF RESPONSE: The staff recognizes the burden of the reporting requirements, but the staff believes that NRC can act to prevent future misadministrations if we can identify the causes.

77. Dennis D. Patton, M.D., Director, Division of Nuclear Medicine, The University of Arizona, Arizona Medical Center, Tucson, Arizona 85724 (September 13, 1978)

COMMENT: The proposed rule interferes to an unacceptable degree with the physician-patient relationship by imposing unrealistic constraints upon the physician in the practice of nuclear medicine. Proposed requirement 35.33(a) is without precedent in the practice of medicine and has no place in the proposed regulations. Specifically, the phrase "...a diagnostic procedure that could cause a clinically detectable adverse effect..." is left completely undefined. There is no diagnostic procedure in all of medicine that is incapable of causing a clinically detectable adverse effect. With regard to nuclear medicine procedures, surely we realize by now that they have an enviable safety record in comparison with other diagnostic procedures, against which they are often compared. A patient could incur a "clinically detectable adverse effect" by sitting next to a person who was smoking. Administration of a few millirads over the background dose could conceivably cause genetic damage in future generations which would be a clinically detectable adverse effect, but the chance that this would happen is infinitesimal, and yet the concept of low probability appears nowhere in the proposed rules.

STAFF RESPONSE: In the final rule, the word "could cause" has been replaced with the word "causes" in the criteria for reporting a diagnostic misadministration.

COMMENT: The objection to terminology could be resolved by rewording the requirement, if it were not for the other facet, namely the lack of precedent for requiring the reporting of potentially adverse diagnostic procedures. No such requirement exists for radiographic contrast agents, drugs given for diagnostic tests in other branches of medicine, or drugs given for therapeutic trials. Radioactive indicators used in standard nuclear medicine diagnostic procedures are extraordinarily safe by comparison and I see no reason why nuclear medicine should be singled out for reporting of hypothetically adverse effects, especially when the question of whether such effects actually exist is still unresolved. The medical literature would seem to document the safety of nuclear medicine diagnostic procedures, raising the question of whether further regulatory action is really in the best interest of the public.

The requirement for reporting "misadministrations" to the Nuclear Regulatory Commission, the referring physician, and the patient (or his responsible relative) interferes with the physician-patient relationship to an

unacceptable degree and will certainly do more harm than good. If there were some likely possibility that diagnostic studies done incorrectly would lead to patient harm, the reporting requirement would be reasonable, but under the circumstances, with the remarkable degree of safety that has been demonstrated with standard nuclear medicine procedures, the requirement is unrealistic and quite unmedical. It would be standard medical practice to inform the patient and referring physician of any occurrence or error that would affect the health, comfort, or well-being of the patient, and this would be true in any branch of medicine, certainly including nuclear medicine. But the definitions of "misadministration" that appear in the proposed rules impose such unrealistic constraints that patients and their physicians are likely to be inundated with reports of "misadministrations" that serve regulatory and bookkeeping purposes only and that do not relate to any measurable challenge to the patient's health, comfort, or well-being. We should be, and in fact we now are, obliged to report circumstances of potential harm, but most diagnostic nuclear medicine procedures do not fall within this category unless the "misadministration" greatly exceeds that outlined in the proposed regulations.

STAFF RESPONSE: Only those diagnostic misadministrations that cause a clinically detectable adverse effect would be reported to the NRC, the referring physician and the patient or a responsible relative under the final rule.

COMMENT: The discussion of "misadministration" in section (f) appears to have been written by someone not familiar with the practice of nuclear medicine. It is not clear whether the intent of the regulations was originally limited to teletheraphy sources, and was later extended to nuclear medicine, or what. For example, (f) (1), "...radiation from a source other than the one intended...", would require us to report a "misadministration" if two injected patients are sitting next to each other in the waiting room.

STAFF RESPONSE: This is not the case. However, patients should be separated sufficiently to avoid unnecessary exposure.

COMMENT: Section (f) (3) does not recognize the fact that any injection by the intravenous route involves extravasation of a certain amount of radioisotope.

STAFF RESPONSE: The statement of considerations for the final rule will clearly state that extravasation is not considered a misadministration.

COMMENT: Section (f) (4) is arbitrary and unrealistic. It defines a misadministration" as an administered amount of radioisotope that is not within 20% of the intended amount. The 20% figure is applied to all radioisotopes regardless of half life and type of emission. It imposes unrealistic restraints in the case of isotopes with short half lives.

For krypton-81m, a radioisotope that is used in studies of pulmonary function and myocardial blood flow, and which was introduced into nuclear medicine largely for the purpose of reducing radiation dose to patients, the half life is 13.3 seconds. The proposed rules would require that this radioisotope be administered to the patient within 3-1/2 seconds of the

intended time, otherwise the administration would be classified as a "misadministration" under the proposed rules. I fail to see what useful purpose is served by this requirement. Such a criterion would have the effect of discouraging the development of ultrashort-lived radioisotopes in medicine, a development that has seen a marked reduction in patient radiation dose, and a marked improvement in quantitative information available from diagnostic studies. The 20% criterion is arbitrary and does not take benefits versus risks into account.

STAFF RESPONSE: The staff agrees and the final rule will be modified to define diagnostic misadministrations for radionuclides with a half-life less than 3 hours as differences from the prescribed dose of greater than 50%.

COMMENT: This requirement inexplicably ignores the reduction in radiation dose that could be obtained by giving less than the prescribed dose. It is very difficult to imagine what harm could come to a patient from administering, say, half of the prescribed dose and imaging for twice the usual time. I see no reason why this should be called a "misadministration," nor why the government, the referring physician, and the patient should all be notified within twenty-four hours by telephone that I have given less than the prescribed dose.

STAFF RESPONSE: If there is an error of greater than 20% from the dosage prescribed by the physician, a mistake has occurred regardless of the direction of the error. However, an underdosage of a diagnostic procedure would not be reportable unless there was a clinically detectable adverse effect.

COMMENT: Section (f) (5) specifies that the total treatment dose must differ from the prescribed dose by no more than ten percent. This provision is utterly unrealistic and again suggests that the writer was not familiar with the practice of nuclear medicine, nor with basic principles of physiology of the human body. Most radioisotope treatments involve thyroid disease, and the dose of radioiodine that is to deliver a specified radiation dose to the thyroid is calculated on the basis of estimation of thyroid weight, measurement of thyroid uptake of I-131 using a tracer dose, and assumptions of uniform distribution within the thyroid and mono-exponential clearance from the thyroid. In the first place, even if the amount of I-131 that would deliver a specified radiation dose could be calculated exactly, the behavior of the thyroid during internal irradiation would not be the same as it was during the tracer diagnostic study. In other words, the basic physiology of the thyroid is altered by the treatment itself, and it is essentially impossible to predict what radiation dose will be delivered to the thyroid to within ten percent. In the second place, estimation of thyroid weight by palpation is subject to errors of from ten to thirty percent, and in the case of multinodular goiters, the error may be considerably higher. Assumptions concerning uniform distribution and mono-exponential clearance have been made to facilitate calculation of radiation dose and I-131 administration, but the assumptions are certainly not supported by our understanding of basic thyroid physiology. The distribution is at no time uniform, and the clearance is never mono-exponential. A great deal of research is currently underway to develop better models for thyroid physiology so that the radiation dosimetry can be better understood. To expect physicians at this point in time to be

able to actually deliver a treatment dose that is within ten percent of the calculated dose is incredibly naive and unrealistic. Did the writer have in mind that we should insert thermoluminescent dosimeters into the thyroid gland? I have been in the practice of nuclear medicine for fourteen years and I have never heard of a technique for measuring the actual delivered radiation dose to within ten percent.

STAFF RESPONSE: For therapy, the definition of a misadministration is an error in the administered radiation dose of greater than 10% of the prescribed radiation dose. In the case of radiopharmaceutical therapy, this is calculated in terms of a certain number of millicuries of the radiopharmaceutical. The prescribed number of millicuries should be measured before administration to the patient.

COMMENT: In summary, I would respectfully like to protest the proposed rules concerning misadministration. They interfere to an unacceptable degree with the physician-patient relationship, impose arbitrary and unrealistic (and probably unenforceable) constraints upon the physician in nuclear medicine, and do not reflect the remarkable safety record that the field of nuclear medicine has compiled.

STAFF RESPONSE: The Commission was aware of the intrusion into the physician-patient relationship at the proposed rule stage. The staff believes that the intrusion is necessary. The staff also believes that the rule is enforceable.

78. Anne Shane Bader, Executive Director, Medical Society of Delaware, 1925 Lovering Avenue, Wilmington, Delaware 19806 (September 18, 1978)

COMMENT: As you know in the field of diagnostic nuclear medicine there is no evidence that there are specific injurious results from any of the isotopes used today. I refer to both types and amounts of the material given. Large doses of radioactive material can hardly be misadministered since these have to be specially purchased and are obtained only one at a time for specific patients in the hospital.

STAFF RESPONSE: The final rule requires reporting to NRC and the patient or a responsible relative when there is a clinically detectable adverse effect from a diagnostic misadministration. Clinically detectable adverse effects are unlikely in diagnostic misadministrations unless an unusually large dosage is administered.

COMMENT: First and foremost of course, all government records are open to the public and any report that a physician makes to the government with regards to a patient immediately becomes public information. Another serious defect in this regulation proposed under Docket #7590-01 is that it imposes the NRC into the patient-physician relationship which is contrary to the purpose of the Nuclear Regulatory Commission. The regulation would tend to invite an increased number of medico-legal suits and costly, it won't accomplish the aim of the regulation which is really to determine why mistakes are made and how to prevent them in the future.

STAFF RESPONSE: The Commission was aware of the intrusion into the physician-patient relationship at the proposed rule stage. The staff

believes that the intrusion is necessary. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

79. David R. Brill, M.D., Chairman, Nuclear Radiology Committee, Pennsylvania Radiological Society, Geisinger Medical Center, Danville, Pa. 17821 (September 20, 1978)

COMMENT: Diagnostic nuclear medicine procedures are nearly always performed with either Technetium 99m which gives very minimal amounts of radiation to a patient or with small amounts of other radionuclides. With very few exceptions, the margin of safety is extremely wide and the administration of the wrong radiopharmaceutical or of a radiopharmaceutical to the wrong patient will in no way constitute a hazard to that patient.

The acceptable limits of error proposed for diagnostic radiopharmaceuticals are entirely too strict. A wide range of variability of dosage exists for many examinations between institutions so that a "misadministration" for the licensee may actually give less activity than the routine for another laboratory. Moreover, no attempt to separate diagnostic agents into those with short or long effective half lives has been made and no consideration of the spectrum of decay or the presence or absence of particulate radiation is given.

STAFF RESPONSE: The definition of a diagnostic misadministration is intended to uncover mistakes and is not based on the effect on patients. However, the licensee is not required to report a misadministration to NRC, the referring physician and the patient unless there is a clinically detectable adverse effect in the patient. The final rule will have a special provision for radionuclides with a half-life less than 3 hours. Misadministrations of these radiopharmaceuticals will be defined as errors greater than 50% from the prescribed dose.

COMMENT: The sanctions against licensee's proposed for "misadministrations" of radiopharmaceuticals are unique and are not applied to any other form of pharmaceutical. Inappropriate administration or dosage of cardiac glycosides, cytotoxic agents, or anticoagulants, for example, could have far more serious consequences than comparable errors in administration of most diagnostic radiopharmaceuticals.

STAFF RESPONSE: The staff recognizes that this misadministration regulation is unique to medicine. The staff believes that it is important that NRC be informed of misadministrations in order to regulate effectively.

COMMENT: With regard to therapy with unsealed radionuclide sources (i.e. Iodine 131, Phosphorus 32, and Gold 198), the problem of "misadministrations" is more understandable, but I must be critical of the fact that no distinction is made between higher and lower doses and longer and shorter effective half lives. The difference between 3.0 mCi and 3.5 mCi of Iodine 131 for Graves Disease and 150 mCi and 164 mCi of the same radionuclide for thyroid carcinoma are apparent, yet the former would be defined as a misadministration, and the latter would not.

STAFF RESPONSE: The staff considers all therapy misadministrations to be serious misadministrations even though the treatment of Graves' Disease involves one of the lowest dosages of a therapeutic radiopharmaceutical.

COMMENT: The strict requirement that patients and their families be notified of all "misadministrations" raises serious problems. The paper work generated could be a real burden to all concerned and the potential for misunderstanding of the seriousness of the error could result in unfortunate and often unnecessary breeches (sic) between doctor and patient and could produce a drastic upswing in litigation.

Since the scope of actions encompassed by the term "misadministration" is so wide, the extravasation of a single microcurie of technetium pertechnetate during an IV administration is the legal equivalent of a massive over-administration of a therapeutic radionuclide. The decision to inform the patient or his family of a significant error should rest with the licensee and the referrant and be based upon the seriousness of the error and the medical circumstances of the case.

STAFF RESPONSE: The statement of considerations in the final rule will clearly state that extravasation is not a misadministration. Only serious misadministrations will be required to be reported to NRC and the referring physician the patient or a responsible relative.

COMMENT: Finally, the requirement that the NRC be notified of all "misadministrations" is especially bothersome, since these reports become part of the public record and then available to anyone regardless of qualification or motivation. The potential for malicious mischief is serious. Safeguards to protect the identity of the licensee are imperative.

STAFF RESPONSE: The identity of the patients and individuals involved in the misadministrations will be safeguarded. The identity of the licensee will not be safeguarded and this includes individual physician licensees.

80. John R. Mohn, MAJ, MSC, Adjutant, Department of the Army, Headquarters, Tripler Army Medical Center, Tripler AMC, Hawaii 96859 (September 20, 1978)

COMMENT: Comments are a compilation of points discussed by members of the Tripler Radioisotopes/Radiation Control Committee after review of the proposed regulation.

The reporting requirements raised by the proposed regulation are acceptable, if the probability of adversely affecting the patient is reduced. However, several sections of the proposal require further clarification, and section 35.33 (f)(4) appears to be much too restrictive, in light of manufacturer's recommended dosage ranges.

STAFF RESPONSE: The definition of a diagnostic dose of a radiopharmaceutical as that differing from the prescribed dose by more than 20% is intended to indicate when a mistake has been made, regardless of the manufacturer's recommended dosage range.

COMMENT: 35.33(a), lines 1-4 as reads: "When a misadministration involves ... a diagnostic procedure that could cause a clinically detectable adverse effect ..."

a. "Clinically detectable adverse effect" is undefined.

STAFF RESPONSE: At the proposed rule stage, the staff recommended against trying to define a "clinically detectable adverse effect," leaving this judgement up to a physician on the scene. The diagnosis of an "adverse effect" may in one case be based or 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). The staff still believes that the final rule should refrain from attempting to define a "clinically detectable adverse effect."

COMMENT:

b. The responsibility for determining adverse effect (the referring physician or the licensed physician) and the procedures to follow when professional opinions vary are not stated

STAFF RESPONSE: The licensee, relying on the diagnosis of a physician, will determine if the diagnostic misadministration causes a clinically detectable adverse effect.

COMMENT:

c. Use of future tense requires prescience on the part of licensed physicians, or would require response in all cases, thus rendering modifying clause meaningless.

d. Use of "involves" leaves intent of proposed regulation unclear; it appears to require reporting of misadministrations associated with those procedures which could cause clinically detectable adverse effects, not misadministrations that themselves could cause clinically detectable adverse effects.

STAFF RESPONSE: The future tense has been removed from the final rule by changing "could cause" to "causes".

COMMENT: Having stated in section 35.33(a) that reports are required for those cases with clinically detectable adverse effects a numerical limit for diagnostic procedures is unnecessary and confusing. Does the NRC expect reports of those cases where greater than 20% excess material is administered without clinically detectable adverse effect?

STAFF RESPONSE: No. The final rule will be clear on this point.

COMMENT: An action level of 20% excess may not be a valid point in the case of diagnostic procedure radiopharmaceuticals. Product package inserts give suggested dosages of typically 5 to 15 millicuries, or 100 to 400 microcuries. When one could be as much as 200% off on the prescribed dose and still be within the manufacturer's recommended range, the need for elaborate notifications within 24 hours at an action level as low as 20% excess is questionable.

STAFF RESPONSE: Notifications will not be required for diagnostic administrations unless there is a clinically detectable adverse effect.

COMMENT: The status of repeated administrations is not addressed. If, as a result of equipment malfunction, patient non-cooperation or operator error, a diagnostic procedure must be repeated, it sometimes required the administration of a second dose to the patient. This 100% excess radioactivity to produce one usable study should not be considered a misadministration, since it is prescribed. and yet it is five times higher than the 20% excess action level requiring reporting within 24 hours.

STAFF RESPONSE: Repeated administrations, unless they are caused by misadministrations as defined in the rule, are not considered misadministrations.

81. Melvin L. Hirsch, M.D., Diplomat, American Board of Nuclear Medicine, Member, American College of Nuclear Physicians, American College of Nuclear Medicine, Society of Nuclear Medicine, Our Lady of Mercy Hospital, Dyer, Indiana (September 21, 1978)

COMMENT: I am a licensed physician and have been practicing General Internal Medicine for 16 years and Nuclear Medicine for at least 12 years. I am definitely in favor of keeping records of all misadministration of radioactive material or radiation from radioactive material and promptly reporting potentially dangerous misadministrations to NRC.

However, I am strongly opposed to giving out such information to a patient unless there is definite evidence that there is potential harm to this patient. The patient's referring physician should be told but such information given to a patient can be extremely detrimental to the patient from a psychological point of view.

I work in a very busy general medical hospital. There are frequent times when patients are given the wrong drugs by nurses on the medical floors. The patients are not informed of this misadministration unless the patient's private physician feels it is to the welfare of the patient to be told this. However, when we are talking about radioactive drugs we are in a different ballgame. Can you imagine what a patient's response will be, "My God, I have been given a wrong radioactive material." We will be opening the doors to a flood of unnecessary malpractice suits. Our insurance premiums will soar. The cost of providing medical care will soar even higher than it is now.

Please, let's leave this up to the patient's referring physician to decide if a patient should be told of such an occurrence.

STAFF RESPONSE: Licensees will be required to report only serious diagnostic misadministrations to NRC, the referring physician and the patient. All therapy misadministrations will be required to be reported to NRC and the patient or a responsible relative.

82. J. B. Blood, Jr., M.D., Secretary, Bradford County Medical Society, Commonwealth of Pennsylvania, Bradford County, Pennsylvania (September 20, 1978)

COMMENT: We of the Bradford County Medical Society believe that this represents another unnecessary intrusion into the practice of medicine by government regulatory commissions. We further feel that this may encroach on the physician-patient relationship on one hand and on the other hand further increase the cost of medical care with establishment of additional regulation leading further government agencies and officials to oversee these regulations. It is the consensus of opinion of the County Medical Society that we would like to communicate our concern over the proposed regulations and state our opposition to them. Most of the Radiologists in our area are very careful about the administration of radioactive material and they would report any misadministration to the patient and the referring physician because of a moral obligation as well as an ethical obligation.

STAFF RESPONSE: The Commission was aware of the intrusion into the physician-patient relationship at the proposed rule stage. The staff believes that the intrusion is necessary and that the benefits of the rule outweigh the costs.

83. Edgar L. Surprenant, M.D., Chief, Division of Nuclear Medicine, Bauer Hospital, St. Mary Medical Center, 1050 Linden Avenue, P. O. Box 887, Long Beach, California 90801 (September 20, 1978)

COMMENT: This proposed regulation is totally inappropriate. Not only does it improperly interfere in the practice of medicine, substituting regulation for the medical judgment of physicians, it is totally impractical and serves no useful purpose. Its only effect will be to further increase the costs of providing nuclear medicine services to patients.

I am sure that the intention of the regulation is good, but I suspect those who have proposed this really do not understand the practice of nuclear medicine, the multiple precautions that we already take to protect our patients, and the damaging effect that such regulations have, further increasing the costs of delivering medical care.

STAFF RESPONSE: The staff believes that the increased costs of the regulation will be balanced by the benefits of preventing future misadministrations.

84. Peter Wootton, President, American Association of Physicists in Medicine, University of Washington, Seattle, Washington 98195 (September 8, 1978)

COMMENT: The American Association of Physicists in Medicine wishes to be recorded as being in opposition to the proposed, so-called "misadministration" rule, requiring prompt reporting to the Nuclear Regulatory Commission and the patients' relatives, of differences between prescribed and administered doses from radiopharmaceutical or isotopic therapy sources.

STAFF RESPONSE: Licensees will be required to report only serious diagnostic misadministrations to NRC, the referring physician and the patient. All therapy misadministrations will be required to be reported to NRC and the patient or a responsible relative.

COMMENT: The rule is self-defeating. Prompt reporting of differences between prescribed and administered doses will not generally help the patient, but may in fact, inflict psychological suffering and encourage malpractice suits, even when little harm has been done. Such suits will be potentially more punitive than any fines levied by NRC for non-reporting. Thus there will be little incentive to comply with the rule, particularly in any rare case where significant differences between planned and administered doses occurred.

Similar considerations apply to the reporting differences in the intended and actual administered quantities of diagnostic radiopharmaceuticals.

STAFF RESPONSE: The referring physician can block reports to his patient if he states that the report will harm the patient. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

COMMENT: The rule will encourage the development of methods of circumventing any clear statement of dosimetric intent - that is, the proposed rule will encourage counter-trends to that developed in modern therapy and set back the methodology of radiation therapy by several decades.

STAFF RESPONSE: The staff does not believe that the rule will encourage methods of circumventing clear statements of dosimetric intent.

COMMENT: The rule is selectively punitive. Other cancer treatment modalities, such as chemotherapy and surgery, are not subject to any such requirement. With something of the order of 100,000 patients per annum treated by isotopic sources, a very low percentage incidence of reports under the rule could be made to give a therapeutic modality that enters into some phase of the care and support of almost half of the cancer patients treated in the United States the appearance of being disproportionately hazardous. Patients who could benefit may then refuse treatment - thus the rule will be counterproductive in terms of patient welfare.

STAFF RESPONSE: The Commission was aware, at the proposed rule stage, that the reporting requirement is unique in medical practice. The rule should reduce misadministrations and make this mode of treatment safer.

COMMENT: Turning to the technical aspects of radiation therapy, it may occur, during the course of treatment that plans may change with a consequent change in the planned dose which will be different from the initially prescribed dose or exposure.

If this proposed rule is approved, then it would appear to be necessary to monitor the daily and/or total dose to effectively comply with the intent of the proposed rule. Technically this might create real problems.

If the dose delivered is lower than prescribed and this error is discovered promptly, then the physician may be able to correct the error by bringing the dose up to an equivalent prescribed level. If the dose is determined to be above the "prescribed level" then appropriate clinical measures will have to be carried out at the discretion of the physicans to minimize any

adverse effects. Informing the NRC and/or the patient will certainly interfere with the normal patient-physician relationship and would do nothing to improve treatment.

In the practice of tele-radiotherapy, dose variations greater than 10% are common within the treatment volume due to many factors. In brachytherapy, the dose variations may be great due to the distribution of the radiation sources within the treatment volume. A lawyer would have a field day in a malpractice suit if the 10% figure of "prescribed dose" were used and it could be shown that in fact the dose varied by an amount greater than that within the tumor volume. Radiotherapists may plan to deliver different doses within the tumor volume because of different tumor cell concentrations, better oxygenation of some portions of the tumor, radiation sensitivity of some structures, etc., (ref. Gilbert Fletcher, Radiology 127, 3-19, April 1978).

STAFF RESPONSE: The definition of a therapy misadministration specifies the total treatment dose. This accommodates changes in the fractioned dose.

COMMENT: In therapy, records applicable to the calibration of teletherapy and other radiation sources should be kept as well as complete patient treatment records, including applicable localization films of portals and brachytherapy sources. In addition, in brachytherapy a record should be kept of source counts and patient monitoring prior to discharge. Reporting of misadministrations, when discovered, would not benefit the patient. The judgment of the radiotherapist should be respected as to whether a report should be filed in order to minimize the chance of a similar occurrence.

If a misadministration were due to equipment malfunction, which might occur again on the same or other units, then a report to the equipment manufacturer, other users, and the NRC would be appropriate.

To minimize the chance of errors in dose administration, there is no good substitute for well-trained personnel who work accurately with attention not only to details but also to the complete picture.

As outlined in the proposed rule, the definitions of misadministration may easily lead to misinterpretations. The definition of prescribed dose or exposure does not take into account effects which may be important due to time-dose relationships, normal tissue sensitivity, relative biological effects.

The proposed rule relative to therapeutic doses does not appear to solve problems but may raise questions which will not be related to the successful treatment of tumor with teletherapy or brachytherapy sources.

The AAPM is supportive of the concept of accurate record-keeping, of avoidance of repetitions of the unfortunate, isolated incident recounted in the supplementary information, but submits that the proposed rule will not achieve the aims of the Nuclear Regulatory Commission.

STAFF RESPONSE: The staff believes that the patient has a right to know when there is a therapy misadministration. The definition of sealed source therapy, in the final rule, is in terms of dose-rate, time and geometry.

85. Stephen T. Slack, Ph.D., Radiation Safety Officer, West Virginia University, Medical Center, Morgantown, W. Va. 26506 (September 12, 1978)

COMMENT: The proposed addition of section 35.33 to 10 CFR Part 35, while superficially appealing, on closer examination seems inherently contra-productive. In any regulatory program,, the object should be to achieve a better or safer operation through following the regulations. The thrust of this section is disclosure and documentation, which, although it may lead to greater awareness, is just as likely to consume time and effort better spent in prevention. It will also have the insidious effect of penalizing those who comply faithfully and leaving unscathed those who do not; referring physicians are much less likely to refer patients to institutions reporting misadministrations.

STAFF RESPONSE: The purpose of the rule is to aid the prevention of misadministrations. Licensees who do not comply with the regulation will be subject to enforcement actions which could result in civil penalties or loss of license.

COMMENT: The actual wording of the proposed regulation combines specificity with obscurity in a way that would make it difficult to interpret and enforce in a real-world medical environment.

In a typical license the licensee is the institution and the radioactive material is used under the supervision of a physician or the radiation safety officer. While the licensee may be legally responsible, it seems clear that the physician in charge is the appropriate person to communicate with the patient or referring physician. Requiring the licensee to do so needlessly complicates the situation. Since the referring physician is generally less knowledgeable about radiation effects, he must rely on advice from radiation therapy or nuclear medicine specialists in any event.

STAFF RESPONSE: The licensee can inform the patient through an intermediary such as the physician in charge or the referring physician.

COMMENT: Misadministrations as defined, although they could cause a clinically detectable adverse effect, need not. When errors are discovered, compensatory actions are frequently possible. Changes can be made in radiation therapy prescriptions according to the NSD formalism or some similar methodolgoy. Blocking agents may be used for radiopharmaceuticals. For diagnostic radiopharmaceuticals, harmful effects are really difficult to envision, except as a statistical increase in the incidence of some neoplasms.

The concept of dose appears to be used equivocally, in sense of both amount prescribed and quantity of radiation. The prescription of a radiopharmaceutical is given in terms of an activity (units of Curies or Becquerels). The amount of radiation absorbed by the patient is generally called the dose (units of rad or grays). There is no simple relationship between the two. For I-131 treatments of the thyroid, physiological factors dominate; for interstitial or intercavitary implantation of sealed sources, the skill of the physician and the subsequent movement of tissues both contribute. In both cases, if a dose were prescribed as such, the actual dose would differ from it by more than 10% in a substantial portion of cases, assuming, that is, that everyone calculated it accurately.

It does not seem valid to make a general rule of calling treatment with the wrong source of radiation a reportable misadministration. Radium and cesium sealed sources are calibrated to be interchangeable. Cobalt-60 units and 4-MV linear accelerators are so similar that staff members inquire which is available and residents have to be reminded that both exist.

All errors are human errors, and are eliminated by constant vigilance, continually checking calculations and procedures. The proposed regulation, at least in its present form, will be a distraction rather than an aid in this process.

STAFF RESPONSE: In the final rule, the definition of a therapy misadministration distinguishes between radiopharmaceutical therapy and sealed source therapy. The definition of a sealed source misadministration refers to the total treatment dose and not the fractioned dose. If one type of sealed source is prescribed and another type is used, then that is a misadministration under the definition in the rule. This does not prevent a physician from changing the prescription to use whatever equipment is available.

86. Marvin N. Lougheed, M.D., F.R.C.P., Radiation Therapist, Roanoke Memorial Hospitals, Roanoke, Virginia 24014 (September 19, 1978)

COMMENT: On the subject of Misadministration Reporting Requirements. I am not addressing myself to diagnostic uses of nuclear material.

The whole substance of your requirement hinges upon the definition "administration - that could cause a clinically detectable adverse effect."

In Radiotherapy at a certain point in the Radiation Therapy an error of much greater than 10% would not cause a "clinically detectable adverse effect."

You will realize the amount of paperwork involved in an error unless the consequences of that error are deemed to be significant.

In such a case why not write a simpler regulation saying that when the physician (or Radiation Therapist) deems that a mistake has been made which is inimical to the patient's welfare that this and this shall apply. After all it is going to be a matter of judgment and all the paperwork in the world will then not accomplish otherwise. If I am doing a Cesium implant and we wish the needles to be parallel but one needle is 2 mm closer to another at one of its ends, the error is in the range of 10% and I am sure it affects the patient adversely but if I kept on trying to get the needle more parallel he would be even more adversely affected. As I say, good radiation therapy and safe radiation therapy is a matter of judgment and I would beg of you not to try to replace judgment with paperwork.

STAFF RESPONSE: Under the rule, all therapy misadministrations must be reported. The staff recognizes that the paperwork will be a burden.

87. Jerry Rothenberg, M.D., Director of Laboratory, Deaconess Hospital (September 18, 1978)

COMMENT: In my opinion, the proposed rules regarding records of misadministrations of radiopharmaceuticals or radiation from teletherapy and brachytherapy sources are impractical.

The Nuclear Regulatory Commission should, in my opinion, seek the consultative services of the American College of Radiology, The Joint Commission on Accreditation of Hospitals and the American Medical Association prior to instituting any additional regulations.

STAFF RESPONSE: The staff has solicited comments on this rule from the ACR, the JCAH and 2,000 State and county medical societies associated with the AMA. The ACR and many local medical societies responded with comments.

88. O. F. Gabriele, M.D., Professor and Chairman, Department of Radiology, Medical Center, School of Medicine, West Virginia University, Morgantown, West Virginia 26506 (September 12, 1978)

COMMENT: Although the proposed amendments are well intended I believe that the ultimate result may be less than optimal. As usual many rules and regulations are developed to prevent abuses and infractions. However, I believe that as is often the case the end result will produce a contrary effect. Institutions which rigidly report every minor misadministration of no clinical consequence will have numerous "incidents" which on the surface will appear very uncomplimentary. In fact, this may be manifestation of very rigid application of rules and compulsive reporting of extremely minor variations from intended procedures. On the other hand misadministrations of significant clinical consequence could easily be avoided by individuals or institutions who make a point to do so (sic). In view of the fact that the control of such a policy would be at the individual level I am not certain it would serve any useful purpose to have the proposed rules established as official policy.

There is such a variation in dosage that what would be considered a variation from intended dose in one institution may very well be within the usual prescription in other institutions.

In essence I believe that regulations which are essentially self inflicting would achieve no useful purpose. Ultimately we must rely on the exercise of good judgement by competent individuals.

STAFF RESPONSE: Minor misadministrations are not reportable under the rule. The rule will be evenly administered, and institutions that do not report serious misadministrations will be penalized.

89. J. F. Wunder, M.D., Radiologist, Mobridge Community Hospital, Mobridge, South Dakota 57601 (September 29, 1978)

COMMENT: This proposed rule is rather redundant in nature, since anyone with integrity and any honesty already records these misadministrations in the patient's chart and they are part of the record for any further reference or use. Progress notes as well as consultations to the referring physicians also identify any potential problems or misadministrations of contrast or radioisotopes.

Your proposed rule would do nothing to the person who is basically dishonest or wishes to hide the fact that a radioactive isotope was misadministered to a patient and that person did not want the referring physician or the patient to know about it. These items would simply not be written in any records at any place.

In my opinion, this proposed regulation would be setting up a highly potential malpractice situation which is open to public views since all of Federal Government documents and lists are freely available to anyone through the freedom of information act. I believe that you would have fewer physicians reporting problems or misadministrations in the future under the required rule, because of the threat of a potentially dangerous malpractice suit. I definitely see no benefit from this potentially liable listing of problems, particularly to a Federal Agency.

STAFF RESPONSE: At present, NRC receives very few reports of misadministrations. Persons who hide misadministrations will be penalized. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

90. Robert E. Hastings, Jr., M.D., President for the Board of Directors, Pima County Medical Society, 2555 E. Adams Street, Tucson, Arizona 85716 (September 28, 1978)

COMMENT: This amendment appears to be neither necessary nor desirable. Since there is no threshold value for radiation damage, and no probable (as opposed to the infinitely possible) likelihood of any "clinically detectable adverse effect" from misadministration of diagnostic dosages of radionuclides, there is no rational basis for a decision to report incidents involving diagnostic dosages.

The likelihood of any pattern of error other than carelessness and distraction being detected, and thereafter corrected by education, seems remote.

The existence of a file of medical errors will constitute an invitation to barratry by underemployed plaintiff's attorneys. The presence of lawyer's informants among hospital employees is well known, and permits easy identification of the patient, if the date of an incident is known.

It has been found sufficient by Federal, State and voluntary agencies to require hospitals and physicians to maintain their own procedures for handling misadministration of substances far more hazardous than diagnostic radionuclides, such as cardiotonic drugs, anesthetics and narcotics. To set up an additional bureaucracy to deal with a relatively innocuous group of agents can only intend to expand authority for its own sake.

By far the worst feature of this amendment, from the view of a County Medical Society, is the attempt to establish a precedent of direct interference in the practice of medicine, at the level of communication with the patient, by a federal agency. The practitioner operates under the burden of a large body of civil law in making his decisions. His determinations as to how much the patient's peace of mind should be disturbed with the knowledge of each error, harmless or otherwise, that is made in his care, must be made with the patient's optimal benefit in mind, not merely avoiding acts

which "would be harmful". Interference with this judgment by any outside source is mischievous. The laws of the States have wisely avoided interference with this judgment and it is totally improper for any agency to arrogate this authority by regulation.

By direction of the Board of Directors of the Pima County Medical Society, I strongly urge that the proposed amendment be dropped and that the Nuclear Regulatory Commission remain within its statutory limitations and remove itself from the practice of medicine.

STAFF RESPONSE: The Commission was aware, at the proposed rule stage, that the misadministration reporting requirement was unique and an interference in medical practice. The staff agrees that few diagnostic misadministrations will result in a clinically detectable adverse effect. The reporting requirement may well increase the cost of malpractice insurance. The amount of this increase is not known.

91. Anthony J. Piro, M.D., Professor and Chairman, Tufts-New England Medical Center, and Samuel Hellman, M.D., Director, Joint Center for Radiation Therapy, Professor of Radiation Therapy, Harvard Medical School, Tufts University School of Medicine, New England Medical Center Hospital, 171 Harrison Avenue, Boston, Mass. 02111 (September 28, 1978)

COMMENT: The reason for the new amendment No. 35.33 to the regulations is obvious, and the value of the preventive nature of the regulation has great merit. It is clear that knowledge of problems incurred by one licensee resulting in overdose to a patient should be disseminated to all other licensees as quickly as possible to help prevent similar errors. However, the sections concerning the mandatory notification of the referring physician and subsequent permission to inform the patient or the patient's relatives is, we believe, unprecedented in the patient/physician relationship. The concerns about intrusion into the patient/physician relationship in the regulation is appropriate and has serious consequences.

Somehow the nature of the referral process, the decision-making concerning treatment, and the ultimate responsibility for the actual treatment of the patient who is to receive a course of irradiation does not seem clearly understood in this proposed amendment. Possibly a brief review of the process is in order, at least as we understand it to be practiced in this country. The referring physician--either the primary care physician or an oncologic specialist--refers a patient (usually with neoplastic disease) to a Radiation Oncologist in consultation for an opinion as to the advisability of the Radiation Oncologist's therapeutic modality in the particular patient's situation, just as he would refer to a surgeon, dermatologist, cardiologist, etc., for that physician's opinion as to management of the patient considering his area of expertise. After speaking with the patient, examining the patient, reviewing all studies and biopsies and ordering additional appropriate studies, the Radiation Oncologist confers with the referring physician or usually with the other members of the oncology team (surgeon, medical oncologist) and arrives at a decision concerning radiation therapy. If the decision is to treat, the Radiation Oncologist discusses fully the benefits, side effects, and possible complications with the patient or the patient's relatives. Obtaining the patient's permission, a course of therapy is administered. This may involve combined modality approach with surgery or chemotherapy, immunotherapy, etc.

It is well understood by Radiobiologists and Radiation Oncologists that having given a course of irradiation, whether by external beam or by interstitial therapy, the dose given is irretrievable. There is very little that can be done to reverse possible long-term effects that can occur; these effects are the most important consequences of concern to the Radiation Oncologist in the benefit-risk consideration of treatment. The probability of these effects increases with increasing dose--a concept well understood by all Radiation Oncologists--a small probability risk must be taken very often to insure maximum cure and local control. Obviously, with the increasing total doses given by error greater than that prescribed, the probability of such normal tissue effects increases. These normal tissue effects can cause considerable morbidity and, rarely, mortality for the patient.

In many other subspecialties in medicine, inadvertent errors can occur with similar significant consequences. For example, a surgeon can inadvertently ligate the ureter or damage an artery during a procedure and be forced to remove an organ such as the spleen or kidney not intended to be removed, etc., all events that have serious consequences for the patient possibly, however not usually fatal and very often not remedial. Other examples could be given with regard to medications, procedures such as renal dialysis, cardiac catheterization, etc. In these instances, it is the surgeon's or physician's medical decision whether the patient should be informed, with the obvious given postulate that the patient should be informed whenever it is in their best interest to know about any such occurence, but it is not a legal mandate that it be so. It seems incredible that the following must be said, but it is the Radiation Oncologist's responsibility for the radiation treatment given, the dose and, of course, whether or not it is medically best for the patient to know about such occurrences. To write a regulation that infers that Radiation Oncologists are essentially the instrument of the referring physician and have the same responsibility for the treatment as a nurse or technician is not only legally incorrect but degrading and insulting.

In section (f)(5), "A therapeutic dose of a pharmaceutical or exposure from a radiation source such that the total treatment dose or exposure differs from the prescribed dose or exposure by more than 10 percent" is written. It is not clear that the regulation refers to a single daily tumor dose given by several fields which would then be the total dose to the prescribed area for that particular day (e.g., a minimum tumor dose prescribed to 200 rad by three fields, an error is made in one field and the patient receives 225 rad) or does this indicate the total prescribed (for example, 4000 rad prescribed over a four week period and the patient received 4500 rad). It is assumed that the latter is the intent of the regulation, but it is not clear. If the regulation indicates the former, this would entail enormous bureaucratic, irrelevant paperwork. The consequences of a single dose error of this magnitude, corrected within one or two doses, has no biologic significance. Whereas a greater than 10 percent difference in a total course of therapy may be quite biologically significant.

STAFF RESPONSE: The final rule will clearly state the "total treatment dose" in the definition of sealed source therapy misadministration.

92. Frederick G. Brown, M.D., Secretary-Treasurer, Montour County Medical Society, Danville, Pennsylvania 17821 (September 22, 1978)

COMMENT: Radiation doses from diagnostic nuclear medicine procedures are typically quite low, so that with very few exceptions, the margin of safety is extremely wide and the administration of the wrong radiopharmaceutical will in no way constitute a hazard to that patient.

The ± 20 percent acceptable limits of error proposed for diagnostic radiopharmaceuticals are entirely too strict. A wide range of variability of dosages exists for many examinations between institutions so that a "misadministration" for one licensee may actually give less activity than the routine dose for another laboratory. Also, no attempt to separate diagnostic agents into those with short or long effective half-lives has been made and no consideration of the presence or absence of particulate radiation is given.

The sanctions proposed against licensees for "misadministrations" are unique and are not applied to any other form of pharmaceutical. This raises the prospect of broadening the scope of such regulations to include other agents which constitute unacceptable interference with the practice of medicine on the part of the government.

With regard to therapy with unsealed radionuclide source (i.e. iodine 131, phosphorus 32, and gold 198) the problem of "misadministrations" is more understandable, but we must be critical of the fact that no distinction is made between high and low dosages and long and short effective half-lives.

A strict requirement that patients and their families be notified of all "misadministrations" raises serious problems. The paperwork generated could be a real burden to all concerned and the potential for misunderstanding of the seriousness of the error could result in unfortunate and often unnecessary breaches between doctor and patient and could produce a drastic upswing in litigation. The scope of actions encompassed by the term "misadministration" is very wide, so that errors of a very minor degree are the legal equivalent of much more serious mistakes. A decision to inform the patient or his family of the significant error should rest with the licensee and the referring physician and be based upon the seriousness of the error and the medical circumstances of the case.

Finally, the requirement that the NRC be notified of all "misadministrations" is especially bothersome, since these reports become part of the public record and are then available to anyone regardless of qualifications or motivation. The potential for malicious mischief is serious. Safeguards to protect the identity of the licensee and patients are imperative.

STAFF RESPONSE: See Staff Responses to comment #79.

93. John W. Vosskuhler, M.D., Flagstaff Radiology Associates, P.C., Main Office 1355 North Beaver Street, Flagstaff, Arizona 86001 (September 20, 1978)

COMMENT: I have read the Notice of Proposed Rule-Making. I am writing in Strong Protest. I request that the proposed change be WITHDRAWN.

I recognize that administration of medicine errors occur in hospitals. On occasion these can cause serious health problems for the patients involved.

In Nuclear Medicine, however, the greatest number of medications administered contain a minimal amount of radioactivity and are physiologically inert. These are true Tracer Doses and are chosen and adjusted so that the tests do NOT alter the systems being measured.

In our Department, the technician administering the dose is the same technician who will later do the test. All technicians in the department are cautioned about the importance of identifying the patient before doing examinations or administering medication for tests.

In our department, all therapeutic doses of radioactive medication are checked by the physician before ordering and are administered to the patient by the physician.

I strongly object to to the Mandate that reports of individual incidents have to be made to the government. This intrusion into the practice of medicine will not result in any improvement, but is another procedure that must be followed.

Also, I object to the requirement that the patient be notified in every instance of improper administration. As mentioned above, the greatest majority of the medications are physiologically inert. In this case the notice would greatly elevate the patient's concern about a matter which would involve no hazard to him.

In summary, I believe that the problem is a very important one in the Practice of Medicine. It is not as important relatively in Nuclear Medicine than in other areas. Getting the government into the problem will compound the Problem but do nothing for the solution.

STAFF RESPONSE: All therapy misadministrations will be reportable to the NRC, the referring physician and the patient or a responsible relative. Only those diagnostic misadministrations that cause a clinically detectable adverse effect will be reportable.

94. Gregory B. Vinardi, Administrator, St. Francis Hospital, 1802 South Main, Maryville, Mo. 64468 (September 28, 1978)

COMMENT: Respectfully request that the proposed amendment be disapproved.

Hospitals already have a procedure for instances of misadministration of any medication, and these procedures have generally proved satisfactory. We certainly support the idea that when harm can possibly result from a misadministration of a radiopharmaceutical, the patient should, in the overwhelming majority of cases, be informed. But we feel a government agency should not be involved in prescribing medical ethics.

STAFF RESPONSE: Without misadministration reports, NRC cannot act to help prevent future misadministrations.

95. David D. Snellings, Jr., Director, Division of Radiological Health, Bureau of Environmental Health Services, Arkansas Department of Health, 4815 West Markham Street, Little Rock, Ark. 72201 (September 26, 1978)

COMMENT: As noted in previous correspondence, dated November 17, 1977, the Committee "supports the concept of recording and reporting accidental misadministrations of therapeutic levels of radioactive material such that clinical damage could be produced." The Committee would also support the reporting of accidental delivery of a diagnostic radio-nuclide to the wrong patient to the extent that

a notification is made to the patient's record that an accidental administration of a diagnostic agent was given;

the patient's physician is notified;

the patient, or the patient's responsible relative, is notified at the time without a great deal of excessive importance being attached to the situation;

the study is interpreted; and

a thorough review of procedures by the licensee be conducted to prevent recurrence.

96. John J. Coupal, Ph.D., R. Ph., Nuclear Pharmacist, Nuclear Medicine Service, Veterans Administration Hospital, Lexington, Kentucky 40507 (September 29, 1978)

COMMENT: I am a nuclear pharmacist practicing in a clinical nuclear medicine department within a Federal hospital devoted to general medicine and surgery.

Section 35.33(F) (4) and (5) of the Proposed Rule define misadministration in part as administration of dose differing from the total prescribed dose or exposure by more than 10 percent for therapeutic procedures or 20 percent for diagnostic procedures. Those percentages are arbitrary, capricious, and imply that if exceeded will cause harm to the patient which is actually unsubstantiated by scientific fact. Moreover, because of variations in dosage for given diagnostic and therapeutic procedures, what would be "misadministration" in one clinical setting would be routine nonreportable administration in a neighboring institution. Use of such a percentage definition of misadministration is scientifically invalid and would make such a rule unenforceable.

STAFF RESPONSE: Only those diagnostic misadministrations causing a clinically detectable adverse effect would be reportable to NRC, the referring physician and the patient or a responsible relative. All therapy misadministrations would be reportable. The definitions of a misadministration are intended to reveal when a mistake has occurred.

COMMENT: If a "misadministration" of radiation or radiopharmaceutical occurs, this is actually the concern of the patient, his legal counsel, the responsible physician, supportive allied health personnel, and the

location of occurrence (e.g. hospital, clinic, etc.). This falls within the province of malpractice which our judicial system has proven very capable of handling. This is not the province of the Nuclear Regulatory Commission, and this rule would be an intrusion of the Commission into the practice of medicine.

In addition, the recordkeeping and reporting requirements of this Proposed Rule would increase paperwork and increase the number of Federal employees needed to handle the paperwork. It is the wish of the American people and President Carter to reduce Federal paperwork and the size of the Federal Government and not to increase it as this rule would do. In summary, this Proposed Rule is poorly written and would probably not be enforceable since it proclaims that harm to a patient has occurred under conditions where harm has not been shown invariably to occur by scientific evaluation. The "spirit of the law" in this case has some potential merit, but the "letter of the law" could be enforced by an overzealous commission employee to the detriment of everyone concerned. It would be a serious error to enact this Proposed Rule as drafted.

STAFF RESPONSE: The Commission was aware of the intrusion into medical practice at the proposed rule stage. The staff believes that the rule is enforceable and the benefit exceeds the burden on licensees.

97. Carl M. Mikail, Medical Center Director, Veterans Administration Hospital, Lyons, New Jersey 07939 (September 28, 1978).

COMMENT: In reference to your letter of July 3, 1978 concerning an amendment to the regulations governing temporary implants, our Chief of the Nuclear Medicine Section feels that this is an excellent idea and should be incorporated into the Nuclear Regulatory Commission regulations.

98. Robert T. Reinke, M.D., Radiologist, St. Mary Medical Center, 1050 Linden Avenue, Long Beach, California 90801 (September 22, 1978).

COMMENT: This proposed regulation is patently ridiculous. It is totally impractical and serves no useful purpose. A misadministration of a small amount of doage such as .2 millicuries would cause no harm to the patient anyway and the law would further increase the cost of medicine by providing unnecessary bureaucratic red tape. In short, I hope that this regulation will not be added to the other needless regulations of the Federal Government.

STAFF RESPONSE: Minor diagnostic misadministrations would not be reportable under the rule. The purpose of the rule is to identify the causes of misadministrations and prevent their recurrence.

99. Paul D. Bandt, M.D., Director, Division of Nuclear Medicine, Southern Nevada Memorial Hospital, 1800 W. Charleston Blvd., Las Vegas, Nevada 89102 (September 25, 1978)

COMMENT: Regarding your proposed regulation to require medical licensees to report administrations of radioactive material, this is clearly an undue intrusion of the federal government into the physician-patient relationship and is of great concern.

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It also has significant medical legal implications which are potentially disruptive to an already tenuous malpractice insurance crisis.

Over and above this, because of these very significant implications to this proposed regulation, I would like to register a strong objection to the proposal.

STAFF RESPONSE: The Commission was aware of the intrusion in the physician-patient relationship at the proposed rule stage. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

100. Howard Dworkin, M.D., President, American College of Nuclear Physicians, and Eugene L. Saenger, M.D., Chairman, Commission on Governmental Affairs, Suite 700, 1101 Connecticut Avenue, N.W., Washington, D.C. 20036 (September 21, 1978)

COMMENT: In Section 35.33A the ACNP would agree that the licensee should notify the patient's referring physician, the patient or responsible relative and should follow such other channels as are indicated within the hospital, institution or private office in which the physician practices for notification of misadministration.

The matter of notification of the NRC Regional Office or other agency of the NRC under current regulations is unacceptable since such notification becomes a matter of public record in the Public Document Room of the Nuclear Regulatory Commission and as such simply provides the physician and institution with identity for nuisance, unwarranted publicity and suits by parties who are not injured by the misadministration or would have any claims against the physicians or hospital except for the fact of the information provided through the Public Document Room. It should be emphasized in this regard that ACNP supports completely the proper notification of the patient, his family, the local institutional authorities and such other individuals as are party to a misadministration.

In regard to 35.33 item E, there is no objection to proper maintenance of records by a physician or an institution concerning misadministration.

Concerning item F, the definitions of misadministration are incorrect as applied to patient care. For a diagnostic dose there is no real relationship between a route of administration other than that intended by the prescribing physician and such circumstances as described in paragraph A resulting in a "clinically detectable adverse effect occurring within 24 hours or within a few days thereof." Also it is not possible to obtain a clinical effect with a 20% excessive dosage.

Under item F4, to propose a difference in amount more than 20% in a diagnostic dose is also unreasonable. Diagnostic doses of greater orders of magnitude vary in different institutions depending on the nature of the patient's clinical problem, the experience of the physician, the nature of the detecting apparatus and the information sought in the proper management of a particular case.

STAFF RESPONSE: The 20% difference in a diagnostic dose is intended to reveal when a mistake has been made. Diagnostic misadministrations would not be reportable to NRC, the referring physician and the patient or a responsible relative unless there were a clinically detectable adverse effect from the misadministration.

COMMENT: Similarly item F5 requiring reporting of a difference of more than 10% in a therapeutic administration is also incorrect since doses of greater than 10% have been given to patients under many circumstances without untoward results. It may be possible to generate proper criteria for definitions of misadministration but such criteria should be arrived at by appropriate review of medical experience and not by arbitrary definition.

STAFF RESPONSE: The staff has 10 literature references that indicate that deviations by as little as 5-10% in the therapy dose may result in significant increases in late complications.

COMMENT: Administration of a radiopharmaceutical to the wrong patient might occur from time to time with the frequency of 1 in 5,000 or 1 in 10,000. No data are offered comparing misadministration of these drugs or other laboratory tests to patients.

In regard to therapy there has been only one incident of a serious nature regarding misadministration, that occurring at the Riverside Methodist Hospital in Columbus, Ohio. There were certainly two clearly demonstrable deaths resulting from this circumstance. There have been about 4 or 5 deaths from errors in dosage or chemical form between 1950 and 1978. The impact of such a rule for misadministration will result in the termination of the use of cobalt-60 teletherapy units and substitution of linear accelerators and similar radiation-producing sources not under the control of the Nuclear Regulatory Commission. Similarly this 10% limit is an excellent way to encourage the replacement of the more suitable cesium-137 brachytherapy sources with radium sources, again not a change in the best interests of patients or the public.

One of the major objections to this entire document is the fact that nothing is stated concerning the disposition of records to be required by the Nuclear Regulatory Commission in relation to the Freedom of Information Act. If, as noted above, such documents are placed in the Public Document Room identifying clearly the licensee, this practice will simply expose the institution to unnecessary deleterious publicity, suits for malpractice, nuisance suits and will not serve either the interest of the patient or the institution. If there is evidence of malpractice the patient is appropriately notified and protected by institutional requirements through the notification of himself or his family, the referring physician and the institution.

If the NRC persists in this course of public recordkeeping it is doubtful that many physicians will comply, preferring to take their chances with the situation of "misadministration" as defined under this rule rather than exposing themselves in a unilateral fashion. It is also difficult to know just exactly what the NRC would propose to do after this public notification and the degree of penalty that the NRC might assess could not be in the best service of the patient to whom the misadministration

occurred. It is also possible that this activity could create various conflicts with state licensure.

STAFF RESPONSE: All reports of misadministrations, less the names of those involved, would be placed in the Public Document Room. It is also likely that many of the reports of misadministrations would be classed as abnormal occurrences and reported to Congress with an additional notice in the Federal Register. This is likely because serious misadministrations would be required to be reported to NRC, and this threshold tends to place the reports in the category of abnormal occurrences for reporting to Congress.

COMMENT: Therefore the present proposed rule seems entirely inadequate and should be withdrawn and reevaluated so that patients can be properly protected without subjecting the institution and physicians to unnecessary abuse. The ACNP would be pleased to cooperate with the NRC to develop suitable recommendations for untoward events affecting patients being diagnosed or treated by byproduct materials or other radioactive substances for which the NRC has jurisdiction.

101. Frederick B. Fitts, M.D., Head, Department of Nuclear Medicine, Lahey Clinic, 605 Commonwealth Avenue, Boston, Mass. 02215 (September 28, 1978)

COMMENT: I perceive the intent of the regulation is to ensure a high level of quality assurance with respect to the administration of ionizing radiation. The intent is commendable. The proposed regulation is, however, ridiculous. The government is merely being officious in proposing a regulation which does not take into consideration the exigencies of the real world.

The diagnostic doses of radionuclides are low enough that 20% increase in dose is insignificant with respect to somatic effects upon the patient. It is, of course, desirable to keep radiation doses to the general population as low as achievable to prevent the statistical problem of increase in genetic mutation rate. It would be detrimental, however, to try to explain that the patient has been given an "over-dose" which in effect is not an over-dose. Because of the possibility of inducing hysteria in a population already becoming chary of radiation and its effects, to contribute to this problem by a regulation which can have no beneficial effect correlates with irresponsible government.

STAFF RESPONSE: Only those diagnostic misadministrations that cause a clinically detectable adverse effect need be reported under the rule.

102. Durward Lang, M.D., Pathologist and Director of Nuclear Medicine, Laboratory of Clinical Medicine; John O. Judge, M.D., Radiologist, Radiation Safety Officer; David Rykhus, Executive Director; and John K. Willis, B.A., Chief Technologist, St. Joseph Hospital, The Presentation Sisters, Fifth and Foster, Mitchell, S. Dakota 57301 (September 20, 1978)

COMMENT: The Nuclear Medical Committee of Saint Joseph Hospital has reviewed these proposed rules changes and felt that these changes added a great deal of additional paper work and expense. (The added expense would be difficult to assign). The changes would not improve the control of errors. This could create more misunderstanding by the general public of nuclear materials.

Each nuclear license is issued only to qualified medical personnel and responsible institutions.

Saint Joseph Hospital uses only diagnostic nuclear material with a very short half life, and wave length, with a very minimal hazard to all concerned. These proposed rules may be more applicable to users of therapy doses, as the hazard would be much greater.

STAFF RESPONSE: The staff believes that the misadministration recordkeeping and reporting requirements can be applied with benefit to diagnostic nuclear medicine by reducing unnecessary radiation exposures.

103. C. Douglas Maynard, M.D., President, The Society of Nuclear Medicine (October 4, 1978)

COMMENT: The Society's position of unequivocal opposition to mandatory misadministration reporting to the Nuclear Regulatory Commission, or any other regulatory agency, remains unchanged.

It should be noted at the outset that the 1972 GAO Report to the Congress (from which the present Proposed Rule under 10 CFR 35.33 presumably stems) cited some 20 misadministrations which had been brought to the (then) Atomic Energy Commission's attention over an 11 year period, 1961 to 1972. AEC's own estimate of 8 million administrations of byproduct material per year at that time would indicate an incidence of misadministrations of less than 1 in 4,000,000 doses administered. Or, in terms of "worst case" - had all 20 of the reported misadministrations occurred in a single year, the incidence would have been less than 1 in 400,000 dose administrations. In either case, the incidence is far less than that believed to be the case with non-radioactive drugs, some of which are at least as toxic as radiopharmaceuticals in wide use today. Thus, it would appear that the Proposed Rule unfairly singles out radioactive drugs, in that a much higher incidence of misadministration occurs with non-radioactive pharmaceuticals, a much larger group drugs, in wider use, without any similar mandatory misadministration reporting requirements.

STAFF RESPONSE: The staff does not know the incidence of misadministrations from those activities that are regulated by NRC. The staff agrees that the misadministration reporting requirement is a unique Federal requirement in medicine.

COMMENT: However, more fundamental to our opposition to mandatory misadministration reporting to the Nuclear Regulatory Commission as it is specified under the proposed new amendments to 10 CFR Part 35 is the fact that the safety of a patient is, and always should be, the responsibility of the physician who provides medical care for that patient. That responsibility cannot be delegated - to either another individual, or to a regulatory agency. Thus, we can only view the Proposed Rule as an unwarranted (and, indeed, unnecessary) intrusion into the practice of medicine. Furthermore, the Proposed Rule will not prevent misadministrations, nor is it likely to further reduce the number of misadministrations which occur.

The Society subscribes fully and completely to existing medical ethics, which support the right of a patient to be informed when he has suffered

harm during his medical care, so long as the information he receives is not likely to result in additional harm. The overwhelming majority of physicians in practice today also subscribe and adhere to this exceedingly important ethical concept. If there are those who do not, it is doubtful that compliance with any regulation requiring verbal and written reports to the NRC would be any more likely to occur.

The Proposed Rule would unquestionably increase the cost of medical care in this country, in that it would tend to generate additional numbers of malpractice litigations against NRC licensees. Although most licensees currently are hospitals or similar institutions, there remain a number of physician-licensees who maintain private practices. The fact that the Proposed Rule under Part 35.33(d) which states, "... However, the report should not include the names of others involved in the misadministration, such as the patient, physicians, and allied health personnel" would be of no protection to these physician-licensees, in that the report is required to contain the licensee's name. In either case, however, the fact that these reports become public information under the Freedom of Information Act can only increase the malpractice and liability insurance costs of hospitals and physicians alike. These costs will have to passed along to patients, whose actual benefit from the Proposed Rule has already been questioned.

What is the NRC's definition of a "a clinically detectable adverse effect?" If the usual definition applies, it is highly unlikely that a clinically detectable adverse effect will occur because of the misadministration of a radiopharmaceutical in a diagnostic procedure. To produce such an effect would require of the order of 25 Rads whole body and 100 Rads to other than hematopoietic organs.

STAFF RESPONSE: The determination of a "clinically detectable adverse effect" is the responsibility of the licensee and will ultimately rest on a physician's judgement.

COMMENT: "A telephone report to the patient or the patient's responsible relative is required within 24 hours of the discovery that a misadministration is likely to have occured [Part 35.33(a)(3)]. Yet, in Part 35.33(c), a written report to the NRC is required within 15 days of the licensee's discovery of the possible occurrence of a misadministration; part of this written report is a "copy of the report to the patient ... under (a)(3) of this section."

Question: How does one "copy" a telephone report?

STAFF RESPONSE: The licensee is required to furnish the patient or relative with a copy of the written report to NRC. The language of the final rule will be clear.

COMMENT: The definition of a misadministration to include "the administration of a radiopharmaceutical by a route of administration other than that intended by the prescribing physician" is clearly too broad. There are occasions when the oral administration of a radiopharmaceutical will provide the same information as that provided by an administration by an injectable route, without harming the patient. Accidental extravasation which can

easily occur during a venipuncture; although this causes no harm to the patient, it would be classified as a misadministration under this definition.

STAFF RESPONSE: If the physician prescribes intravenous injection then an oral administration would be a misadministration under the rule. Extravasation is not a misadministration and the statement of considerations to the final rule will clearly state this.

COMMENT: The limit on 20% difference from the prescribed dose in a diagnostic dose and 10% in a treatment dose is unrealistic.

Current assay standards in monographs for radiopharmaceuticals (both diagnostic and therapeutic) in the United States Pharmacopeia (USP XIX) permit at least a 20% variance. For example, in the description section of the USP XIX monograph for Sodium Phosphate P 32 Solution, the following is found: "Sodium Phosphate P 32 Solution contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of ^{32}P as phosphate expressed in microcuries or millicuries per ml at the time indicated in the labeling.

STAFF RESPONSE: The example cited from USPXIX is a 10% difference from the labeled amount. With one exception USPXIX allows a 10% difference from the labeled amount. The staff believes the limits in the rule are realistic.

COMMENT: In conclusion, The Society of Nuclear Medicine opposes the Proposed Rule as published and suggests that it be withdrawn. We would suggest also that an additional study be made by the Commission to determine other ways of minimizing the number of misadministrations (if a more current study indicates this to be possible in a practical sense). These may include a requirement that patient doses be identified and calibrated prior to administration and a submission by the licensee to the NRC of his procedures which are meant to avoid the misadministration of radiopharmaceuticals. Another public hearing on the overall concept would certainly be indicated prior to the reintroduction of another Proposed Rule on this subject in the future.

STAFF RESPONSE: Most medical licenses require that patient doses are measured prior to administration. The staff is preparing a proposed rule to place this requirement in the regulations.

104. Robert T. Anger, Jr., M.S., Medical Nuclear Physicist; Eugene D. Van Hove, M.D., Director, Nuclear Radiology; Larry Heck, M.D., Radiologist; Jerry Kight, M.D., Radiologist, Methodist Hospital of Indiana, Inc. (October 3, 1978)

COMMENT: The proposed 35.33(a) requires clarification. We assume that the intent is to report diagnostic misadministrations that could cause a clinically detectable adverse effect. 35.33(a) currently reads that the diagnostic procedure itself must be able to cause a clinically detectable adverse effect.

The statement "When a misadministration ... could cause a clinically detectable adverse effect" is far too nebulous to be practical or enforceable. The interpretation of "Could cause," "adverse" and even "clinically

detectable" requires a judgement decision for which no clear guidelines are provided.

STAFF RESPONSE: The word "could" has been removed and the term "clinically detectable adverse effect" is intended to be a judgement.

COMMENT: A reportable therapy misadministration should also be based on an expected or actual adverse effect rather than merely a 10 percent difference between the actual total treatment dose or exposure and the prescribed dose or exposure.

STAFF RESPONSE: The staff considers all therapy misadministrations to be serious.

COMMENT: The definition of a misadministration as "a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 20%" is unreasonable. For one thing, the accepted dosage ranges in many radiopharmaceutical package inserts cover considerably more than a 20% variation. A "misadministration" at one hospital may involve a quantity of radioactive material administered routinely at another hospital. Also, the phrase "differing ... by more than 20%" implies that an administered activity 20% less than the prescribed dose constitutes a misadministration. In order to guarantee compliance with this definition it will be necessary to assay each syringe (and perhaps tubing, stopcocks, etc) after injection. In the event that the syringe originally contained 10% less than the "prescribed" dose, another 10% left in the syringe after injection would constitute a misadministration.

STAFF RESPONSE: To comply with the regulation, it will not be necessary to assay the syringe after the administration. It will be necessary to assay the syrirge before administration.

COMMENT: The use of the word "prescribed" implies the presence of a written prescription for each patient. Since such a prescription is currently not required, it would appear that the term "prescribed dose" is open to liberal interpretation.

STAFF RESPONSE: The staff has advised licensees not to rely on verbal orders for radiopharmaceutical dosages. However, NRC regulations do not require written prescriptions.

COMMENT: Items (1) through (3) of proposed section 35.33(f) are clearly errors in administration. However, to refer to these errors as misadministrations in the Code of Federal Regulations and require the extensive documentation specified in the proposed 35.33(e), may lead to unwarranted conclusions about the hazards of diagnostic nuclear medicine procedures.

It appears that the Riverside Hospital incident is being used to resurrect the misadministration requirements proposed in 1973. While there is no question that errors involving the use of radiation or radioactive materials that "could cause a clinically adverse effect" should be reported to the NRC, referring physician and the patient, the determination that a particular error presents a potential hazard to the patient is a judgment decision

by the physician that is difficult to regulate. The recordkeeping requirement in the proposed 35.33 is unacceptable due to the definitions of a misadministration (see earlier comments) and the fact that a misadministration record available for Commission inspection implies that the Commission may judge, after the fact, the judgment decisions made by the physician.

STAFF RESPONSE: The staff does not believe that the definitions of misadministrations in the final rule will cause unwarranted conclusions about the hazards of diagnostic nuclear medicine procedures.

105. Donald Marger, M.D., Therapeutic Radiologist, Hospital and Health Center, 2222 Philadelphia Drive, Dayton, Ohio 45406 (September 29, 1978)

COMMENT: I do not think this is an appropriate regulation. First, if radiation is used as a therapeutic modality, why should the physicians administering it be singled out in terms of having a federal regulation requiring disclosure. Many medical accidents occur every day throughout this country not requiring reporting and with what I think are potentially more disastrous side effects. Secondly, records are kept of radiation so that a misadministration would be recorded. It need not be separately isolated as such but of course would be noted in the physician's record on the patient. Thirdly most misadministrations will not result in any harm as is true of many medication errors and to make a special point of notifying referring physicians and patients would significantly increase the radiation physicians liability as well as the anxiety of the patient. In short, I am absolutely opposed to the suggested amendments.

STAFF RESPONSE: The purpose of the misadministration recordkeeping requirement is to permit inspections by NRC inspectors. In this way, inspectors can detect patterns of minor misadministration which may indicate lax controls by the licensees. It would be virtually impossible for inspectors to call all of the patients' records for misadministrations.

106. J. C. Spencer, M.D., Radiologist, Edward W. Sparrow Hospital Association, 1215 East Michigan Ave., Lansing, Mich. 48902 (October 3, 1978)

COMMENT: If these proposals are put into effect, they will make it almost impossible for most of us to practice nuclear medicine or nuclear radiology.

Regarding the requirement to report misadministrations to third parties, such as the patient's referring physician, or responsible relative, will create staggering increases in medical legal problems besides intruding on ethical physician-patient confidential relationships.

Equally important is the requirement that administrations not exceed 20 percent of intended dose for diagnostic or 10 percent of intended dose for therapeutic purposes. I am including the nuclear regulatory alert sent me by the Nuclear Medicine Associates which speaks to the problem very well. Diagnostic quantities of radioisotopes are by no means standard from institution to institution and very often from patient to patient. Therefore, this requirement would be essentially meaningless from the standpoint of reporting a 20 percent error. Furthermore, with respect to therapeutic administrations, again there is no set standard dose, particularly as applies to radioiodine and it would be impossible to establish

what is a reportable figure. The figures are much too restrictive. I do not believe the intent of these regulations is to make radioactive materials less available to patients where are needed, but I believe that that will be the ultimate effect and strongly recommend not adopting these proposals.

STAFF RESPONSE: The definition of a diagnostic misadministration as a 20% error from the prescribed dose is intended to reveal when a mistake has occurred. Diagnostic misadministrations would be reported to NRC, the referring physician and the patient or a responsible relative only when the misadministration causes a clinically detectable adverse effect in the patient. The definition of a therapeutic misadministration as a 10% error from the total prescribed dose or exposure is also intended to reveal when a mistake has been made. However, all therapy misadministrations would be reportable because the staff believes that all therapy misadministrations are clinically significant.

107. Theodore R. Purcell, M.D., Alta Bates Hospital, 1 Colby Plaza at Ashby, Berkeley, Calif. 94705 (September 29, 1978)

COMMENT: Philosophically, we are most concerned about the intrusion into the physician-patient relationship and how this would be altered should this law be passed. I think we speak for the majority of our colleagues in stating that where there has been an error of significance in the therapeutic administration of radiation that would have some therapeutic consequence, it has always been our policy to inform a patient or do whatever is necessary to indicate the potential risks involved. I think this same relationship would occur in any area of medicine and not just where nuclear medical materials are used.

I would further state a major inconsistency in dealing with this problem only where radioactive materials are involved since certainly in this department we have equally lethal machines in a Linear Accelerator and lower voltage therapeutic x-ray machines.

As for record keeping, as with any medical record, these records are kept and are available where appropriate and under proper circumstances.

STAFF RESPONSE: The rule would have the reports of misadministrations held separately from regular patient medical records. This would enable NRC inspection of records of misadministrations.

COMMENT: I would further state that in therapeutic radiology, alterations of 10% in dose are, for all intents, undetectable. I think it is totally arbitrary to use that point for departure since, as in most of medicine, the biologic differences in patients are such that a 10% alteration in dose simply isn't detectable in almost any therapeutic endeavor, whether it be radiation or administration of drugs, etc.. This is not to suggest that errors of this nature are in any way to be condoned, hidden or supported, it is to suggest that legislation does not correct biologic variability. The machines themselves undergo constant attention which is already under strict legislation and, in general, I think there are an excellent series of checks and balances to maintain the accuracy of equipment in any competent department.

STAFF RESPONSE: The staff has 10 literature references which indicate that deviations by as little as 5-10% in the therapy dose may result in significant increases in late complications.

108. Ken J. McDonald, Acting Executive Director, North Kansas City Memorial Hospital, 2800 Hospital Drive, North Kansas City, Mo. 64116 (October 2, 1978)

COMMENT: As a health care institution utilizing the services of trained physicians in administration of radioactive materials, we are greatly concerned over the impact of this proposed rule.

The approval of this regulation would seriously interfere with the physician/patient relationship which is essential to the delivery of high quality patient care. In addition, we feel the dangers inherent in the Federal government interference with this relationship far outweigh any advantage. The reporting requirements provide to parties not directly involved and can seriously interfere in the cost effective administration of health care.

We feel that the needs to which this rule are directed can be best left to the role of the attending physician and should not be superseded by governmental requirement.

STAFF RESPONSE: The Commission was aware of the intrusion into the physician-patient relationship at the proposed rule stage. The staff believes that the benefits in preventing future misadministrations are worth the detriment caused by the intrusion.

109. Kenneth A. Wright, Massachusetts Institute of Technology, Cambridge, Massachusetts 02139 (October 3, 1978)

COMMENT: I would like to register my opposition particularly to the radiotherapy aspects of the proposed "misadministration" rule. Although the aims may be well directed, the methods proposed do not appear to result in any direct or long-term benefit to the patient other than to provide a basis for a malpractice suit. Such reporting might well result in a negative psychological reaction and in a lack of confidence in the physicians whether justified or not. If real harm is done, which cannot be corrected by proper medical care, then the malpractice approach is available to the patient.

From the technical aspects of radiation therapy, there are a number of problems which would have to be considered if this rule is adopted. During a course of radiation therapy treatment plans may change, for example tumor response, patient reaction, side effects or a revaluation might result in a change in the planned dose or exposure. If an error were discovered that a lower dose was delivered than prescribed, then suitable corrective action probably would be feasible. If a higher than prescribed dose were delivered then appropriate clinical action would be required to minimize adverse effects. Informing the patient, the referring physician, and the NRC would interfere with the normal patient-physician relationships and would not improve the treatment.

In the preparation of teletherapy treatment plans, dosage variations greater than 10% are common within the treatment volume. Some radiotherapists plan different doses within the tumor both for reasons of tumor response and protection of radiosensitive structures within the treatment volume. In treatment planning time-dose relationships, normal tissue sensitivity, and relative biological effects must be considered. A different total dose number for the same effective biological dose may result with any change in the treatment plan. Radiological inhomogeneties are included in dosage calculations by some centers but not by others. The numerical values obtained for a given treatment plan may vary markedly dependent on the inclusion or not of these inhomogeneity corrections. In brachytherapy, due to the geometrical positioning of finite sources, large dosage variations within the tumor volume are normal. A lawyer in a malpractice suit probably would have no difficulty in showing that a dose within the treatment volume differed by more than 10% from the prescribed dose.

In therapy it is reasonable that records should be kept of radiation source calibrations as well as complete treatment records including films related to the treatment. In addition, in brachytherapy a record of source counts and patient monitoring before discharge is reasonable.

To prevent recurrence of a misadministration caused by equipment malfunction, which might occur again or with other units, then a report to the NRC, BRH, equipment manufacturer and users would be appropriate. Operational and calculational errors may be minimized by employment of well trained personnel who work accurately with attention to details and the complete picture. Establishment of careful procedural methods within a therapy center which include provision for checks of patient set-up, treatment planning and calculations would also help minimize misadministration of dose.

To comply effectively with the intent of the proposed rule, it would be necessary to monitor the daily and/or total dose delivered to the patient. This would entail in vivo dosimetric techniques and would not be feasible in many cases.

STAFF RESPONSE: The definition of a therapy misadministration refers to the total treatment dose and not the fractioned dose or any changes in the course of treatment. The final rule will state clearly that errors in source calibrations, the time of exposure or source positioning that result in a calculated total treatment dose differing from the prescribed total treatment dose by more than 10 percent, are considered misadministrations.

110. V. P. Collins, M.D., Member, NRC Medical Advisory Committee.

COMMENT: "Misadministration," as indicated below, is too vague to allow compliance or enforcement. Records should be, or must be, kept on all administrations of radioactive material or radiation. This would be inclusive of any misadministration. The record of administration should be authenticated by the licensee acknowledging his responsibility for correctness or error.

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The aspect of this proposal that seems to be a chief concern is the reporting of misadministration of and the effect on physician-patient relationship. This subject was discussed in the hearing of 5/16/78 and the objections raised were:

1. self-incrimination,

2. unwarranted malpractice suits,

3. the government as a third party,

4. a matter of medical ethics, and

5. no comparable requirements for any other drug or other field of medicine.

These objections are still valid. An additional aspect concerns the policy of insurance companies providing medical liability insurance. They commonly require that they be notified promptly of any possible basis for claim or action against a physician policy holder, as a condition of the protection offered. Notification of the NRC, the referring physician and patient of a misadministration or "overdose" would clearly call for notification of the insurance company. Even if no action ensued it is very likely that this would have an effect on premiums and continuance of insurance. It is also possible or likely that the insurance company and its attorneys would take a dim view of gratuitous notification of the patient of a "misadministration" that, at the levels prescribed, might be quite innocuous.

In that proposal, the criterion for reporting to NRC, the referring physician and the patient, was "a demonstrably adverse effect on the patient." This criterion for a misadministration would be a proper basis for justified concern. In the present proposal the criteria for reporting are: (1) Misadministration of diagnostic (tracer) dose by radionuclide by more than 20% of the prescribed dose; and (2) Misadministration of a therapeutic dose from a teletherapy or brachytherapy source, by more than 10% of prescribed dose. These criteria for misadministration do not provide a sound basis for the action proposed. The term "dose" is used in totally different contexts for diagnostic and therapeutic uses. The "dose" of a radionuclide for diagnostic purposes is stated in terms of the radioactivity of the radioactive material as measured before being given to the patient. The "dose" of radiation from a teletherapy source or brachytherapy source is stated in terms of "rads" or absorbed energy at an indicated site within the patient and is a very incomplete description of the total energy and distribution of energy delivered to that patient. To suggest that "10 percent for therapeutic procedures" and "20 percent for diagnostic procedures" represent comparable statements as to tolerance or risk involved in misadministration indicates the need for a crash course in dosimetry within some branch of NRC. An increase of 20% in a tracer dose would be totally insignificant, as would an increase of 100%. An increase of 1000% could probably not be detected and would be far below producing any "demonstrably adverse effect on the patient." Yet for an insignificant increase of 10% a patient would be told that he had had a misadministration of a greater than intended dose, which would be an "overdose" in the

patient's understanding. This would be a grossly erroneous and unjustified impression but still a basis for panic on the part of the patient. This proposal cries "Fire" in a crowded theater, if a patron lights a cigarette.

STAFF RESPONSE: In the proposed rule the term dose is always modified by the adjective diagnostic or therapeutic to distinguish the two traditional usages for diagnosis and therapy. Greater than 20% error for diagnostic administrations is considered a misadministration because a mistake has occurred and not because of clinical significance. Only those diagnostic misadministrations causing a clinically detectable adverse effect would be reportable to NRC, the referring physician and the patient or a responsible relative. All therapy misadministrations, which are defined as errors greater than 10%, are reportable because the staff believes that all therapy misadministrations are potentially serious.

COMMENT: An increase of 10% in a therapeutic dose from a teletherapy or brachytherapy dose is meaningless. The numerical dose in a treated volume may vary by 20% or more with teletherapy and by 100% or more with brachytherapy. The dose distribution in the irradiated volume can never be uniform under clinical conditions and variation of this order is customary within the tumor volume. One must be prepared to adjust the amount of radiation delivered during the course of treatment. To blindly adhere to a first estimate would risk avoidable overdose or underdose in many patients. A proposal to subject this discretion to the remoteness of a regulation of NRC merits some thoughtful contemplation as to how such a suggestion could arise. Such a proposal can only indicate a gross misapprehension of the nature of dose as a clinical tool. Dose is not a number. The greatest hazard in radiotherapy is to rely on a prescription of a number as a determination of adequate or tolerance dose. Without providing a dissertation on dose, suffice to say that the concept of dose includes the description of a physical agent and the prediction of a response in a complex biologic system. Clinical judgment and experience are necessary to deal with the paradox that in the matter of dose, different numbers may produce the same effect or the same numbers may produce different effects.

STAFF RESPONSE: The definition of a therapy misadministration refers to the total treatment dose or exposure and would accommodate changes during treatment.

COMMENT: The practice of medicine is the balancing of competing risks, the risk of the progressive disease versus the risk of the effect of treatment. The balance to be achieved is subject to manipulation based on judgment as to whether one should, (a) risk complication to achieve cure, (b) risk failure to assure safety. If the consequence of reporting as here proposed represent an additional risk factor, the balance will be altered and not necessarily for the better. Objections to proposed regulations must be balanced with the reasons requiring such regulation. It may be that there is evidence of a hazard that must be contained and this would overrule objections. If there is not, then an objection may be valid. If suggestions as to appropriate safeguards are to be developed, a presentation of the hazard would be pr er basis for discussions.

STAFF RESPONSE: The staff believes that the benefits of the rule outweigh the risk referred to in this comment.

111. James F. Vandergrift, M.S., Assistant Professor of Radiology (Health Physics), University of Arkansas for Medical Sciences, 4301 W. Markham, Little Rock, Arkansas 72201 (September 29, 1978)

COMMENT: In order to preserve some respect for the NRC's integrity and ethics, I must assume that the intent of this rule is to 1) safeguard the public (us) as consumers from irresponsible health care practices, and 2) identify the causes for misadministrations for the purpose of correcting them and preventing their reoccurrence in the future or at other sites. Both of these objectives are appropriate, needed, and worthy, in my opinion.

The manner in which the rule is stated and in light of the realities involved, I do not feel that this rule will accomplish either goal.

The reasons it will not prevent misadministrations are: (1) It is after-the-fact and there is no provision for what the NRC will do with the information compiled to correct the production, packaging, shipping, handling, administration, detection, or any number of potential causes for the error. (2) There is such variation across the country in the prescribed "dose" that a misadministration in one facility would not be so in another. Therefore, the 20% or 10% stated is effectively arbitrary and meaningless. These variations are not necessarily due to arbitrary choices in a given facility, however, The "correct" dose depends upon the patient, their condition, the instrumentation to be used, and other factors which can only be stated on a case by case basis. (3) The definition of misadministration (" ... other than the one intended") constitutes no definition at all.

STAFF RESPONSE: NRC will use the misadministration reports to identify the causes of misadministrations in order to prevent their recurrence. The staff recognizes the wide variations in prescribed doses, but the definitions of misadministrations are intended to uncover mistakes. The quote "...other than the one intended" is meaningful in context.

COMMENT: Until or unless standardization of protocol, equipment, quality control, and training of personnel can be achieved, the efforts of the NRC in this area are futile. Far more would be accomplished by establishing equipment performance standards (realistic ones) and stipulating more concisely the competence of all personnel involved in nuclear medicine studies than will ever be accomplished by this rule. The emphasis should be on prevention not "finger pointing."

STAFF RESPONSE: The misadministration data will be used for the prevention of future misadministrations.

COMMENT: The second objective is also not met by the proposed rule. The self-incriminating nature of this rule will in no way affect the truly unscrupulous, irresponsible, or ignorant person. Only those of high moral character, with true dedication, and a sense of professional responsibility will comply with this rule. These individuals need only to become aware of a misadministration to take the proper action. This will inevitably

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result in smothering the flowers with (expletive deleted) and promoting the growth of weeds.

In a much broader sense, I question the wisdom of this rule because: (1) To my knowledge the NRC has not been given authority over accelerator produced or naturally occurring radionuclides. Both of these constitute a major source of diagnostic and therapeutic nuclides. (2) The Society of Nuclear Medicine has for sometime been compiling a registry of adverse reactions and other administration problems. These are made available to the FDA and the manufacturer.

I hope that I have conveyed a concern for and an interest in the same problems as the NRC because I am. I also hope I have conveyed my concern for regulations for the sake of regulations and not for the sake of correcting or preventing injury to the public.

STAFF RESPONSE: The commenter is correct; NRC has not been given authority over x-rays or accelerator-produced radionuclides. The SNM adverse reaction registry does not usually uncover misadministrations and is voluntary.

112. Steven J. Figiel, M.D., Director of Nuclear Medicine, Harper Hospital, 3990 John R. St., Detroit, Michigan 48201 (September 26, 1978)

COMMENT: I believe it is important not to create any undue anxiety in the patient. Misadministrations are normally reported to the referring physician and he should determine what action should be taken, if any at all. The great majority of mistakes result in absolutely no harm whatsoever to the patient and the proposal submitted by the Nuclear Regulatory Commission would in many instances create great anxiety in the patient. Besides the proposal would result in an undue amount of paperwork and record keeping.

Currently if a diagnostic study is performed on the wrong patient, the referring physician is informed so that he can discuss the issue with the patient. No charge is made to the patient for the examination and the results of the exam are included in the patient's medical record.

If a diagnostic or therapeutic study was performed wherein harm could come to the patient then by all means this should be reported to the patient both by the refering physician and the physician responsible for the misadministration. This will be duly recorded in the medical record of the patient and I see no need to report the incident to the Nuclear Regulatory Commission.

STAFF RESPONSE: Only those diagnostic misadministrations that cause a clinically detectable adverse effect would be reported to NRC, the referring physician and the patient or a responsible relative. All therapy misadministrations would be reportable. The vast majority of misadministrations that do no harm would not be reportable but would be subject to the record-keeping requirement.

113. Stanley W. Kimball, D.O., Chairman, Department of Nuclear Medicine, Richmond Heights General Hospital, Richmond Heights, Ohio 44143 (October 3, 1978)

COMMENT: Basically, I have no objection to a workable regulation. However, I'm concerned about the percentage of error proposed on a diagnostic dose.

As I understand, dose calibrators are allowed a 10% error. In addition, there is no standard dose for certain examinations. In my experience, the dose for a particular study may vary by over 20% among laboratories.

Though I do not do therapy, I presume the above argument would apply, also.

STAFF RESPONSE: The American National Standard for "Calibration and Usage of 'Dose Calibrator' Ionization Chambers for the Assay of Radionuclides" (ANSI N42.13-1978) provides a method for obtaining measurements that are accurate to within ±10 percent and reproducible to within ±5 percent. Thus, the greater than 20% error for diagnostic administrations is a point where an error has occurred and not a performance requirement. The greater than 10% error for therapy administrations (some measurements use a dose calibrator) recognizes the greater hazard from therapy.

114. Alan H. Robbins, M.D., Secretary, Massachusetts Radiological Society, Inc., Chapter of the American College of Radiology, 150 South Huntington Avenue, Boston, MA 02130 (October 5, 1978)

COMMENT: The Massachusetts Radiological Society agrees that in the event of misadministration, a licensee should notify the patient's referring physician, and the patient or responsible relative. Notification should also be extended through other channels within the hospital, institution or private office in which the physician practices. It is not reasonable to the Massachusetts Radiological Society that the NRC Regional Office or any other agency of the NRC be notified, because such notification becomes a matter of public record and provides an opportunity for unwarranted publicity and suit by parties who are not injured by the administration.

The maintenance of records by the licensee concerning this administration are reasonable and warranted.

The Massachusetts Radiological Society welcomes the opportunity to respond to this proposed rule. Because of the Freedom of Information Act, the Society feels that the proposed rule would not be in the best interest to the practice of medicine because the possible unnecessary negative publicity and harm to a licensee could far outweigh any clinical side effects from misadministration as defined within the rules (Section F).

Further, defining a misadministration by 10 to 20% variation from the prescribed dose is both arbitrary and not necessarily of known adverse effect upon patients.

STAFF RESPONSE: The definition of 10% error in therapy as a misadministration is based on the effect in patients. The definition of 20% error in diagnostic use as a misadministration is not based on the effect in patients; but, rather, is the point where a mistake has been made. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

115. Richard E. Myers, M.D., St. Vincent Hospital and Medical Center, Toledo, Ohio 43608 (October 4, 1978)

COMMENT: This letter is to indicate my strenuous objection to the proposed rule to 10 CFR Part 35, for the following reasons:

The total prescribed dose, a percent of which is taken as a misadministered dose, is often not directly prescribed by the Nuclear Medicine physician; rather, the dose recommended by the manufacturer is used.

The total prescribed dose for a teletherapy patient is often changed as the patient's clinical progress is followed. In addition, because of the nature of administration of the teletherapy doses, the total prescribed dose often varies by more than ±10% throughout the tumor itself. In short, a single prescribed dose value does not adequately reflect the realistic management of the teletherapy patient.

There is often significant lack of evidence of altered biological effect due to misadministrations in this ±10% teletherapy dose in ±20% Nuclear Medicine dose range. It is felt that this arbitrary range does not accurately reflect clinical evidence of a misadministration.

It is felt to be unwise to needlessly alarm either a patient or a referring physician who may have little or no knowledge of radiation dose values and their concomitant biological effects.

The increased incidence of malpractice suits arising from such documented "evidence" of misadministration, will conceivably lead to less or certainly less precise dose prescription documentation. Such resulting dose "range" prescriptions would lead to poor patient management.

In summation, it is felt that the criteria for misadministration as defined by this proposed rule, are not only nebulous, but also do not accurately reflect the clinical situation. Such simple criteria should not be employed to regulate the complex patient care commonly present in the Nuclear Medicine and Radiation Therapy clinics.

STAFF RESPONSE: The definition of a therapy misadministration is in terms of the total treatment dose. The definition of a 10% error as a therapy misadministration is based on the effect in the patient. The definition of 20% error as a diagnostic misadministration is not based on the effect in the patient, but rather on the point where a mistake has been made. All therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect need be reported under the rule.

116. George A. Collodi, M.D., Director of Radiology and Nuclear Medicine Departments, St. Vincent Memorial Hospital, 201 East Pleasant Street, Taylorville, Illinois 62568 (October 4, 1978)

COMMENT: In regards to the proposed misadministration rule FR Document No. 78-18735 it is my feeling that the proposal is undesirable for the following reasons: (1) There are no hard and fast rules regarding dosage of diagnostic or therapeutic radioactive material. (2) The 20% error is

too limiting in view of the fact that the dose calibrators are required to operate only within plus or minus 10% error, and (3) The routine reporting of the misadminstration to the patients referring physician and relative may act to create an undesirable apprehension and misunderstanding on the part of the parties notified. Thank you very much for your attention.

STAFF RESPONSE: The greater than 20% error for a therapy administration is intended to reveal when a mistake has occurred. All misadministrations are subject to a recordkeeping requirement, those diagnostic misadministrations that cause a clinically detectable adverse effect on the patient and all therapy misadministrations would be reportable NRC, the referring physician and the patient or a responsible relative.

117. Ronald I. Veatch, M.D., Nuclear Medicine Department, Winona Memorial Hospital, 3232 N. Meridian St., Indianapolis, Indiana 46208 (October 5, 1978)

COMMENT: Serious interference in medical practice and patient management may be the result of the proposed rules for the administration reporting requirements. Grave concern has been expressed to me by primary care physicians that reporting inconsequential "misadministration" for diagnostic doses in which no risk to the patient is involved, to the patient and or his family as stated in the proposed rules would have a very definite adverse effect in a majority of instances of patient management. This would also apparently apply if, in routine usage, extravasation would occur at the time of intravenous administration, and also prevent readministration for the study that was being attempted. As Medical Director of the Nuclear Medicine Department, in conjunction with the medical isotope committee of Winona Memorial Hospital, and the referring primary care physicians, we are definitely opposed to the proposed rules as they relate to diagnostic uses of isotopes.

On 5 October 1978 a motion was made to the medical isotope committee by a primary care physician, a cardiologist, that this committee recommend reporting to the referring physician any possible "misadministration" and if either the referring physician or the nuclear physician felt that any risk to the patient was involved, a record should be made at that time about the misadministration and proper reporting to the NRC and to the patient or his family be made. In the event of a low risk or inconsequential administration error, reporting to anyone other than the primary care physician responsible for the patient's care would be definitely inappropriate. This motion was seconded and unanimously passed.

I certainly hope the proposed rules relating to diagnostic usages are reassessed with more careful attention to the true medical implication and consequences of such regulations. As currently stated, these regulations definitely interfere with patient management and good patient care.

STAFF RESPONSE: The statement of considerations to the final rule will clearly state that extravasation is not considered a misadministration. Only those diagnostic misadministrations that cause a clinically detectable adverse effect and all therapy misadministrations are reportable to NRC, the referring physician and the patient or a responsible relative.

118. Bengt E. Bjarngard, Ph.D., Associate Professor of Radiation Therapy, Director of Physics and Engineering; and Kenneth R. Kase, Ph.D., Assistant Professor of Radiation Therapy, Chief, Dosimetry Laboratory and Radiation Safety, Harvard Medical School, 44 Binney Street, Boston, Massachusetts 02115 (October 5, 1978)

COMMENT: Radiotherapy departments should keep adequate records of dose prescriptions and treatment given for all patients including any incidents of misadministration of dose. These records should be available to appropriate review and control agencies for periodic inspection. However, the NRC is not the appropriate agency for this review and control for two reasons: 1) It is not an agency staffed for the review of medical practice. 2) It does not have jurisdiction over all radiotherapy delivery units, namely x-ray machines, accelerators and radium.

STAFF RESPONSE: The investigations of incidents of misadministrations does not require a review of medical practice. I&E staff have successfully investigated several incidents of misadministrations. Also, it is not necessary to have jurisdiction over all forms of radiotherapy to investigate misadministrations of byproduct material.

COMMENT: From the technical standpoint the definition of misadministration is too general, ambiguous and totally inappropriate. Prescribed dose is usually either a minimum dose, or the dose to a specified point, within the defined treatment volume. However, there are several difficulties with the terminology "prescribed dose":

1. Prescribed dose is the product of a tradeoff between dose to the tumor and dose to normal tissues. As such it does not provide sufficient information to allow evaluation of the therapy given. Knowledge of the dose distribution is essential. Application of the dose distribution to patient treatment is very much clinical practice and must remain the responsibility of the physician.

2. Treatment geometry quite often results in dose distributions within the treatment volume which vary from the "prescribed dose" by more than 10%. These variations are generally quite unavoidable and should not be considered a misadministration of dose.

Variations in biological response among individuals may necessitate different treatment strategies. This may result in changes in the treatment plan & the patient's response is evaluated. Thus the final dose delivered may, by design, be different from the original "prescribed dose." In fact, a serious misadministration would occur if individual response is ignored and an original, somewhat arbitrary, "prescribed dose" is insisted upon.

The deleterious effects of error in dose delivery are more likely to occur because some normal structure outside the treatment volume received an excessive dose. This can occur even when the prescribed dose is delivered within ±10%.

STAFF RESPONSE: The definition of a therapy misadministration in the final rule has been changed to answer these comments. The definition is in terms of the "total treatment dose" and the "source calibration," "time of exposure" and "treatment geometry."

COMMENT: Unquestionably, certain people should be informed in the event of a true misadministration of dose, but who those people are may change with circumstances and should not be specified in an NRC regulation. It is obvious that to inform the patient indiscriminately, in many cases will unnecessarily increase the suffering and psychological distress of the patient, and open the door to unjustified and unreasonable law suits. The question of errors in treatment and requirements for reporting those errors is a serious problem for all medical practice and a solution should be worked out. However, the mechanism proposed (i.e. NRC regulation of a small segment of medical practice) is, in our opinion, not the way to proceed.

STAFF RESPONSE: The referring physician will be able to block reports to the patient if he states that the information will harm the patient. The reporting requirement in this rule may well increase the cost of malpractice insurance. The amount of this increase is not known.

COMMENT: As the licensing agency the NRC has the authority to ensure proper calibration of teletherapy and brachytherapy sources and the institution of proper controls to protect patients, workers and the public from unnecessary radiation exposure from these sources. Enforcement of regulations specifying source calibrations and requiring reporting to the NRC errors in such calibrations will accomplish the purpose stated in the proposed rule 35.33 without generating the problems we have discussed. For these reasons we most emphatically urge that the proposed rule not be adopted.

STAFF RESPONSE: There are NRC regulations requiring periodic calibration and checking of teletherapy units. A similar regulation is planned for brachytherapy.

119. Frank R. Hendrickson, M.D., Chairman, American Society of Therapeutic Radiologists, 20 North Wacker Drive, Room 2920, Chicago, Illinois 60606 (October 6, 1978)

COMMENT: We have had an opportunity to have read to us the response made to you by the American College of Radiology which takes significant exception to the proposal as written. We wish to concur with and to support the points made by the ACR and to associate our membership with them. We think this could do quite a lot of mischief and provide very little beyond the current practice of good medicine. May we also urge that these not be adopted or at the very least, modified significantly to meet the problems we have outlined.

STAFF RESPONSE: See responde to comment # 134.

120. Robert N. Class, M.D., Chief, Nuclear Medicine Service, Veterans Administration Hospital, 10701 East Boulevard, Cleveland, Ohio 44106 (October 5, 1978)

COMMENT: The new paragraph to be added to 10 CFR, Part 35, "Records and Reports of Misadministrations," is confusing and ambiguous in certain aspects.

For example, the wording of paragraph (a) could be interpreted to mean that unless the Nuclear Medicine physician believes the misadministration

would cause a clinically detectable adverse effect that there would be no need to notify the listed authorities. This would be true whenever a normal prescribed dose happens to be administered to the wrong patient. For this reason, paragraph (a) is ambiguous when compared to the definitions listed in paragraph (f).

For example, if the proper dose of a diagnostic radionuclide is administered to a patient because of error by a ward clerk in stamping the name on the Nuclear Medicine request form - there would be no need to believe that the procedure could cause any clinically detectable adverse effect from this individual. From the present wording of this paragraph, I would not know whether or whether not to consider this a misadministration; in particular, since no error on the part of the Nuclear Medicine Service was involved. Instead, such a situation would appear to be reportable as a nursing error or error on the part of the referring physician. I suggest that paragraph (a) be reworded to avoid such statements as "could cause a clinically detectable adverse effect" and substitute "has a high probability of producing a clinically detectable adverse effect." Furthermore, where misadministrations are not definitely proven to have occurred, and where no clinically detectable adverse effect could ensue - I strongly recommend that no report be made in such circumstances. This is important to avoid a deterioration of patient-doctor relations and the ensuing possible litigation.

STAFF RESPONSE: The original proposed rule was intended to have a threshold for reporting diagnostic misadministrations. The final rule will have a clear threshold for reporting diagnostic misadministrations, such that only those diagnostic misadministrations causing a clinically detectable adverse effect will be reportable to NRC, the referring physician and the patient or a responsible relative. The ambiguity introduced by the phrase "could cause" has been removed by deleting the word "could."

121. Mario Nunez, M.D., Medical Director, Nuclear Medicine Department, Alexian Brothers Medical Center, 800 West Biesterfield Road, Elk Grove Village, Illinois 60007 (October 5, 1978)

COMMENT: As proposed, the regulation on misadministration of radioactive material will create havoc in the practice of Nuclear Medicine for several reasons. (a) There are no specific standards on dosage for many procedures in Nuclear Medicine. (b) There are no specific standards on dosage according to age, etc. The proposed 20% error would be meaningless because of the above. What is the value of reporting a misadministration with an error of - let's say - 30% if there is no clinically detectable adverse effect. The medical legal aspects could also be very difficult particularly since radiation effects by Nuclear Medicine procedures are not usually well understood by the public. There would be if accepted, double standards in the same hospital. Ex. misadministration of radioactive materials have to be reported to an outside agency. Repeat diagnostic X-ray procedures are not, although the radiation dosages can be comparable or superior.

STAFF RESPONSE: Only those diagnostic misadministrations causing a clinically detectable adverse effect are reportable to NRC, the referring physician and the patient or a responsible relative. The staff recognizes that the regulation will introduce a double standard versus other radiological procedures, but the staff does not feel that this is a good reason to abandon the rule.

122. George C. Hoebing, B.S., R.T., Chief Technologist, Oklahoma Children's Memorial Hospital, P. O. Box 26307, Oklahoma City, Oklahoma 73126 (October 3, 1978)

COMMENT: We support the concept of each individual facility keeping a record of all misadministrations. However, we oppose the proposed rule as presented in its current form. Particularly, we are opposed to that portion of the proposal requiring the reporting to the Commission of all misadministrations. Our opposition is based on the following specific comments.

Most responsible Nuclear Medicine facilities are, for legal and professional reasons, keeping records of all administrations as well as misadministrations. For this hospital and I am sure for many others, this includes a report to the Radiation Safety Committee. It would be redundant to require a second set of records to be kept by the Commission.

STAFF RESPONSE: All misadministrations would be subject to the record-keeping requirement. All therapy misadministrations and only those those diagnostic misadministrations causing a clinically detectable adverse effect would be reported to NRC, the referring physician and the patient or a responsible relative.

COMMENT: Difficulty of Monitoring Non-Compliance. If a hospital chose to "overlook" reporting a misadministration, there would be no way for the Commission to learn that it had happened. Consequently you would only create additional workload for responsible facilities who comply, and there would be no way for you to know if you are receiving an accurate report of either the frequency or the type of misadministration.

Unclear Definition of What Constitutes a Misadministration. There is a very large difference in the level of radiation received from a diagnostic study as compared to a therapeutic procedure. In a diagnostic procedure, an overdose of 20% would not appreciably increase the radiation dose to the body. However, in therapy, a 10% overdose would certainly be significant. Also, in Part F of Section 3 of the proposed amendment, your definition of misadministration is unclear. Number 4 under that section says " ... a diagnostic dose of radiopharmaceutical differing from the prescribed dose by more than 20% ..." Is this 20% above or 20% below the prescribed dose? Section 5 for therapeutic procedures is the same way. Is this 10% above or 10% below the prescribed dose or exposure? I realize this is understood to be overdoses, but this could be interpreted by many persons to include any doses that were less than that prescribed would also have to be reported in the same manner. Certainly this would serve no useful purpose.

STAFF RESPONSE: The rule is enforceable. I&E has experience with similar reporting requirements for other licensees. The term "differing" means both "above" and "below". This is intended to pick up mistakes in the case of diagnostic administrations and pick up both mistakes and clinical significance in the case of therapy administrations.

COMMENT: Unclear Definition of Potentially Dangerous Misadministration. The amendment would require the reporting of all misadministrations that

could cause a clinically detectable adverse effect. There are a number of unknown aspects of this statement: a) At what level of radiation does and adverse effect become clinically detectable? b) Who will decide this? Technologist? Physician? Radiation Safety Officer? c) There are clinically detectable adverse effects in almost all radiation therapy (nausea, depressed bone marrow, etc), how do we decide what is an adverse effect and what is a normal body reaction?

STAFF RESPONSE: All therapy misadministrations would be reportable. The licensee would be responsible for determining which diagnostic misadministrations cause a clinically detectable adverse effect. This will ultimately require a physician's judgement.

COMMENT: The telephone reporting of potentially hazardous misadministrations within 24 hours is impractical. It also requires a value judgment by the administering physician that is unrealistic. A potential hazard will not be the same for two physicians. Therefore reports on dangerous misadministrations would be sketchy at best.

STAFF RESPONSE: The future tense had been removed and only diagnostic misadministrations that cause a clinically detectable adverse effect will be reportable.

COMMENT: It is our combined opinion that the monitoring efforts of the Nuclear Regulatory Commission should be directed to certain specific areas regarding the medical use of radioactive materials rather than keeping tallies of misadministrations.

There are areas where Nuclear Regulatory Commission inspections are already in progress but because of heavy workload they are inadequately enforced. We believe your continued efforts to correct these deficiencies would serve all of us better.

STAFF RESPONSE: Comment noted.

123. C. Fillmore Humphreys, M.D., Secretary, Medical Advisory Board, Alameda-Contra Costa Medical Association, 1 Colby Plaza at Ashby, Berkeley, California 94705 (September 29, 1978)

COMMENT: While on the surface this would appear to be a correct and justifiable procedure specifically in nuclear medicine, some deviations of administration of radioactive materials which would have to be classified as misadministered would too often occur in our opinion. Therefore, with all due respect, we strongly disapprove of these proposals.

STAFF RESPONSE: The benefit of the rule is proportional to the number of reports of misadministrations.

124. John A. Ash, M.D., Secretary, Arizona Medical Association, Inc., 810 West Bethany Home Road, Phoenix, Arizona 85013 (October 4, 1978)

COMMENT: The Arizona Medical Association strongly recommends that regulation of the practice of medicine be left with the licensing agencies in individual states and not tampered with by the Federal Government.

STAFF RESPONSE: Comment noted.

125. Joseph M. McDade, M.C., Congress of the United States, House of Representatives, Washington, D.C. 20515 (October 5, 1978)

COMMENT: I thank you for any consideration given the enclosed comments. (J. B. Blood, Jr., M.D.)

125. J. B. Blood, Jr., M.D., Secretary, Bradford County Medical Society, Sayre, PA (September 20, 1978)

COMMENT: We feel that this is an intrusion in the physician-patient relationship and also would further the increase of cost of medical care within an inevitable establishment of additional regulations and people to administer these regulations. We feel that the physician who administers the material is a licensed M.D. and has a moral and ethical responsibility of reporting misadministrations to the patient and the patient's relatives. We do not feel that records of this should be kept specifically for a perusal by outside people. Therefore, we are greatly opposed to these new rules and would like to express our opposition to them hoping that you will be able to use some influence in this regard.

STAFF RESPONSE: Without reports of misadministrations, NRC cannot act to prevent their recurrence.

126. Steven Pinsky, M.D., President, Nuclear Physicians of Illinois, Michael Reese Hospital and Medical Center, 29th Street and Ellis Avenue, Chicago, Illinois 60616 (October 3, 1978)

COMMENT: I have reviewed the proposed rule changes and I am concerned with some of the proposed changes. I am in agreement that licensees should report all misadministrations that involve therapeutic procedures. However, those diagnostic administrations that cause a clinically detectable adverse effect on the patient should be excluded. There are to my knowledge no routine approved diagnostic radioisotope procedures that would cause a clinically detectable adverse effect on the patient. Radiation exposure from doses administered for diagnostic purposes is so low that even a ten-fold increase would not cause clinically detectable adverse effects. Therefore, I would suggest that the requirement be limited to therapeutic procedures.

The other area I wish to comment on relates to notification of the patient. As the physician in charge of the Nuclear Medicine Department does not usually develop a close patient-physician relationship with the patient undergoing the procedure, I feel great difficulty would be created in his having to inform the patient of any misadministration. The nuclear physician may not be able to assess the psychiatric status of the patient and by informing the patient could create more harm than benefit. I feel it is appropriate that the Commission be informed as well as the patient's referring physician. The referring physician with the information supplied by the nuclear medicine physician can make the decision whether or not to inform the patient. Just as the nuclear physician does not under ordinary circumstances notify the patient of the results of this study, likewise, he should not notify the patient if there is a misadministration. This

remains the responsibility of the referring physician who best knows the patient.

STAFF RESPONSE: The proposed rule allowed the referring physician to veto the report to the patient if the referring physician personally informs the licensee that in his medical judgement telling the patient or the patient's responsible relative would be harmful to one or the other, respectively. The final rule will also permit the referring physician to veto the licensee's report to the patient if the referring physician personally informs the licensee that he will report the misadministration to the patient or a responsible relative.

127. David Y. Lai, M.D., Diplomate of the American Board of Nuclear Medicine, Blanchard Valley Hospital, Findlay, Ohio 45840 (October 2, 1978)

COMMENT: I do not think a government agency should be involved in the prescribing of medical ethics. As you know, most of the nuclear medicine procedures (excluding therapeutic doses) are safer than many of the other drug prescriptions such as digoxin, cancer chemotherapeutic agents, anti-coagulants, etc.

I do agree that we should keep good and true records and notify the patient's referring physician which I believe every nuclear physician is doing at the present time. If the government is interested in knowing the statistics of misadministration, the government should contact us every year to obtain the information.

Your proposed amendment only produces more red tape and reports which is one of the reasons of high medical cost. I would like you to modify the amendment so that it only involves therapy procedure or a few diagnostic procedures which involve a large radiation dose to the patient.

STAFF RESPONSE: Essentially, this is what the final rule accomplishes (and what the proposed rule was intended to accomplish). All therapy misadministrations would be reportable and only those diagnostic misadministrations that cause a clinically detectable adverse effect would be reportable.

128. John Chen, M.D., Chairman, Radiation Safety Committee, Mid-Maine Medical Center, Waterville, Maine 04901 (October 4, 1978)

COMMENT: It is the opinion of members of the Radiation Safety Committee at the Mid-Maine Medical Center that these amendments are inappropriate as presented.

If enacted as published, these would substitute arbitrary, inflexible guidelines and regulations for the individual clinical judgment of the physician, would infringe inappropriately upon the physician/patient relationship, and would be generally disregarded because of the unrealistic definition of the term "misadministration." It is our opinion that, at present, in the event of any significant misadministration of radioactive material, appropriate notification is promptly made to the referring physician and/or patient. Consequently, arbitrary guidelines seem superfluous considering current practice.

STAFF RESPONSE: The Commission was aware of the intrusion into the physician-patient relationship at the proposed rule stage. Without reports of misadministrations, NRC cannot act to prevent their recurrence.

129. Joseph P. Kriss, M.D., Chairman, Radioisotope Safety Committee, Stanford University School of Medicine, Stanford, California 94305 (October 3, 1978)

COMMENT: The proposed rule deals with record keeping and reporting of "potentially dangerous misadministrations" of radionuclides to patients. The Committee members unanimously agree that the proposed rule is unnecessary and administratively cumbersome. More importantly, we believe the adoption of the proposed rule would not eliminate the type of error which generated the proposed regulation.

Accordingly, we strongly urge the Nuclear Regulatory Commission to abandon the proposal.

STAFF RESPONSE: The staff believes that, with the rule, NRC can help prevent future misadministrations.

130. M. B. Logie, M.D., Lutheran Medical Center, 2639 Miami Street, St. Louis, Missouri 63118 (October 3, 1978)

COMMENT: I feel that the "potentially dangerous" level defined as plus or minus 20% of the intentional administered dose is too small an error to warrant all of the paper work. I do feel that in house records of all misadministrations would be worthwhile and that perhaps these should be reviewed in conjunction with license renewal. The same data could be accumulated for study and potential corrective action as would be available from reporting separately each misadministration.

STAFF RESPONSE: Records of all misadministrations would be required. Reporting of all therapy misadministrations, and only those diagnostic misadministrations causing a clinically detectable adverse effect, would also be required.

131. Sister Sheila Lyne, R.S.M., President, and Irvin H. Strub, M.D., President, Medical & Scientific Staff-Faculty, Mercy Hospital and Medical Center, Stevenson Expressway at King Drive, Chicago, Ill. 60616 (October 3, 1978)

COMMENT: On behalf of nuclear medicine management and the medical staff at Mercy Hospital and Medical Center, we are unequivocally opposed to the proposed NRC rule to require all medical licensees to report radioactive material or radiation from radioactive material misadministrations to the NRC, to the patient, and to the patient's referring physician. The primary reason for this opposition is that this is not required for other types of pharmaceuticals whether routine, investigative, or research.

We have not experienced any misadministrations of radioactive materials or radiation from radioactive materials. In the event that we should have one, it shall be reported to the patient's referring physician and indicated in the patient's chart.

STAFF RESPONSE: The staff recognizes that the misadministration rule is unique, however, the staff does not believe that this is reason to abandon the requirement.

132. David A. Pistenma, M.D., Ph.D., Acting Director, Division of Radiation Therapy, Stanford University Medical Center, Stanford, California 94305 (October 2, 1978)

COMMENT: I am submitting comments pertaining to the proposed rule as it might apply to the administration of radiopharmaceuticals or radiation from teletherapy and brachytherapy sources as might be used in radiation therapy. Comments pertaining to the proposed rule as it might affect the use of radiopharmaceuticals for diagnostic purposes have or will be submitted by others in our department.

My colleagues and I in the Division of Radiation Therapy recommend that the proposed rule be dropped. We recognize the importance of minimizing the radiation dose in all patients, even when they might receive thousands of rads to large regions of the body, such as with total lymphoid irradiation. Although the proposed rule is well intended, and we agree that the technical delivery of radiation should not vary from the total prescribed dose by more than 10%, we believe that the selection of the total radiation dose and the irradiation volume by the radiation therapist, and the time-dose and fractionation factors employed in delivering the radiation are far more critical than a 10% variance from the total prescribed dose. We do not believe it is possible, at this time at least, to develop rules that would ensure that good judgment is used in the treatment of an individual patient, especially in an era where improved results are being obtained with time-dose and fractionation schemes different from those considered conventional even as recent as several years ago and with renewed emphasis on combined modality treatment (combinations of radiation therapy, chemotherapy and surgery). In addition, we are just witnessing the beginning of combined treatment with radiation therapy and hyperthermia, and radiation therapy and radiosensitizers, both of which may require modification of what has been considered a safe and adequate radiation dose.

It is our opinion that your Commission should work through the appropriate medical societies to achieve your objectives.

STAFF RESPONSE: The definition of a therapy misadministration in the final rule has been changed to accommodate these comments. "Total treatment dose" allows for changes in the fractioned dose.

133. Anna E. Wasserbach, Chmn., N.Y. Federation for Safe Energy, Box 2303 W. Saucerties Rd., Saucerties, N.Y. 12477 (October 2, 1978)

COMMENT: From personal experience, I can assure you that requirement to inform NRC of misadministration of byproduct material is necessary. I know of two people, just this year, who had a GI series at the same local hospital, and were required to go through the same routine over again, because it was not done right the first time. This is actually torture for people who are taking the test because they are sick in the first place. To add insult to injury, they were required to pay for both tests.

If it happened once, you could say it was a mistake, but if it happens repeatedly, it would indicate lack of training on the part of hospital personnel giving the tests. There is no way of knowing, on the patient's part, if the personnel are properly trained and supervised, but if a reporting system existed, and is enforced, inept personnel could be re-trained or fired. As it is now, the patient is completely at the mercy of the health care providers.

The patient, or the patient's responsible relative must be informed. To leave the physician the option of only telling the licensee of misadministration, because "in his medical judgment telling the patient or the patient's responsible relative" would be harmful leaves entirely too much discretion to the physician. Doctors, fearing a lawsuit, or with financial interests in a hospital or other health care facility, would be reluctant to divulge either an honest mistake, or just plain negligence, as a reflection on themselves, and you will find very little reporting of misadministration to the patient or relative. And the patient has a right to know, and change hospitals or doctors, if so inclined.

STAFF RESPONSE: The staff believes that the referring physician's veto is necessary in spite of the chance for abuse. The referring physician is usually insulated from the pressures mentioned in this comment. Also, to exercise the veto, the referring physician will have to personally inform the licensee that in his medical judgement telling the patient or the patient's relative about the misadministration would be harmful to one or the other, respectively.

COMMENT: If there is no "responsible" relative, as in the case of a nursing home patient or a child who is ward of the State, the responsible social service agency should be notified. If not, these wards of the State would be prime targets for human experimentation with new byproduct material, or subjected to careless administration.

STAFF RESPONSE: The words "(or guardian)" will be appended to the phrase "responsible relative". The term guardian includes social service agencies.

COMMENT: The licensee should maintain for a 30 year period inspection records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. This should be required for two reasons. (1) If the licensee feels that the record will be wiped clean after 5 years, there is no incentive to keep it so. While reports of misadministration may prompt an NRC inspection, the licensee may see that stringent measures against repetition are enforced for a while, and then, with records destroyed, can fall back into same habits. (2) More important, the patient should have a source to go to get information on misadministration if health problems occur at a date later than the 5 year period. Since radiation-induced cancer takes from 15 to 30 years to develop, records should, in the interest of public health, be maintained for that 30 year period. An example of the need of long-term record retention is the X-ray therapy routinely used by physicians for scalp disease, thyroid problems, etc., 20 years ago, that is now manifesting itself in above normal cases of thyroid cancers in persons so treated. Hospitals are having great problems notifying patients of this treatment as records were lost or destroyed in many cases. And this was not a misadministration of X-rays,

but was considered, at that time, perfectly safe. And doctors are still making mistakes.

STAFF RESPONSE: As explained in the staff response to comment #1, the licensee will be required to keep records for 50 years.

COMMENT: I feel very strongly that patients have the right to know of misadministrations of byproduct treatment. This is all the more important since even the administration in the first place is a judgment by the physician based on radiopharmaceutical information provided by a drug manufacturer, or equipment manufacturer in the case of an X-ray machine.

STAFF RESPONSE: The rule provides for patients to be informed of all therapy misadministrations and those diagnostic misadministrations that cause a clinically detectable adverse effect.

134. Otha W. Linton, Director of Governmental Relations, American College of Radiology, 20 North Wacker Drive, Chicago, Illinois 60606 (October 5, 1978)

COMMENT: The following comments are offered on behalf of the members of the American College of Radiology regarding your proposed misadministration reporting requirements, as published in the July 7 Federal Register. The members of the ACR include the largest group of physicians and physicists who use ionizing radiation for diagnostic or therapeutic purposes and who are numbered among NRC and state licensees for that purpose.

The proposal will add a new section 35.33 to 10 CFR part 35 which would place several requirements upon physicians to report "misadministrations" of radioactive materials to the NRC, to the patient's referring physician and to the patient or to a responsible relative.

It appears to us that this requirement is essentially unnecessary and would be productive only of an increased amount of record-keeping and probably litigation. Thus, we would urge that it not be adopted as proposed.

The members of the College recognize their obligation as physicians to be responsible for the proper care of patients placed in their charge. When this involves exposures to ionizing radiation for diagnostic or therapeutic purposes, they accept this responsibility. They also accept responsibility for maintaining accurate records of the kinds and amounts of radionuclides administered to patients for any purpose.

However, the proposed language contains some problems which need correction, if the proposal is not dropped as we recommended above.

In the draft language of 35.33 (a) is found the phrase "...misadministration involves either a diagnostic procedure that could cause a clinically detectable adverse effect or therapy procedure,... " This phrase is perhaps the most valid expression of any basis for reporting such an event. However, in 35.33 (f) we have further definitions of a misadministration as being in (4) a variation of 20 percent from a diagnostic dose or 10 percent from a therapeutic dose. These may not produce a "clinically detectable adverse effect." However, their reporting to an unsophisticated patient might well produce such an effect.

In the instance of the diagnostic doses currently employed, our committees tell us that a variation of 20 percent is most unlikely to produce a "clinically detectable adverse effect." Thus, expressing the problem as a fraction of a dose which might vary in in the first instance according to the manufacturer's instruction, the physician's preference and the accuracy of administration poses the greatest dilemma in those facilities where accuracy is most prized and best achieved.

STAFF RESPONSE: The staff's intention at the proposed rule stage was to have a threshold for reporting diagnostic misadministrations. This will be clear in the final rule which will require reporting to NRC, the referring physician and the patient or a responsible relative only those misadministrations that cause a clinically detectable adverse effect.

COMMENT: In the instance of nuclides used in therapy, a dose variation of 10 percent in a much greater magnitude is likely to be significant and observable. However, we are uncertain from our reading of 35.33 (f) (5) whether the regulation embraces the entire radiation treatment, perhaps involving 30 to 40 sessions for teletherapy, or whether it refers to the total dose per session. Obviously, an over or under exposure detected during a course of treatment can be corrected. An under exposure detected at the conclusion of a planned treatment can be corrected. An over exposure could not be corrected. However, the range of expert opinion among radiation therapists could mean in a given instance that a 10 percent variation from the intent of the involved therapist is still below the level of doses employed by other equally qualified radiotherapists. Even here, the "clinically detectable adverse effect" would be more cogent than the fraction of the dose.

We appreciate that a requirement to report a "clinically detectable effect" is less precise than a requirement expressed in numbers. However, it would be more valid in meeting the objective of your proposal without imposing undue burdens upon radiologists.

STAFF RESPONSE: The greater than 10% error in therapy refers to the total treatment dose and not the fractioned dose. All therapy misadministrations would be reportable. The staff believes that reporting all therapy misadministrations is valid because all errors of greater than 10% in the total treatment dose could be expected to have an adverse effect.

COMMENT: With regard to the reporting requirements to the parties named in 35.33 (a), we make the following observations. Historically, radiologists have been prompt in advising the NRC or the states or manufacturers and suppliers of any untoward radiation incident. We strongly support the need to solve the immediate problem and to learn from it how others may avoid similar difficulties.

However, with the advent of the Freedom of Information Act, reports to the NRC for scientific purposes could expose the reporter to harassment of a kind not intended but not avoided by the commission. The willingness of various people to interpret a 10 or 20 percent variation in dose as a demonstration of certain harm to a patient is unjustified in medicine but not always in law.

STAFF RESPONSE: The reports of misadministrations, less the identity of the patient, would be public information. The comment is noted.

COMMENT: Reporting a "clinically detectable adverse effect" to a referring physician is routine good medical practice. In the instance of a diagnostic procedure, the radiologist may not be in a position to observe the patient sufficiently long to detect such a reaction, if it should occur. Thus, detection and verification depends currently upon proper relations between responsible physicians. The proposed regulations would formalize such relations. But in equating a 20 percent variation to a "clinically detectable adverse effect" the requirement strains the concept and imposes a technically unproductive burden upon both physicians.

STAFF RESPONSE: The rule does not equate a 20% variation with a "clinically" detectable adverse effect. A 20% error is the point where a mistake has been made.

COMMENT: The requirement of reporting to another physician in the instance of a therapeutic variation may be unproductive where the patient is directly under the care of the radiotherapist. He might tell the physician who has relinquished the patient to him. But he would be in the best position to assess any needed corrective action and also in the best position to determine the value or hazard of informing the patient or the patient's representative.

Reporting to the patient or his representative on all medical treatment or mistreatment is a basic premise of good practice. However, reporting on the variations in dose covered by your specifics which are not "clinically detectable adverse effects" is an invitation for patient distress. Placing the burden of determining the advisability of such information upon a referring physician is at best an unhappy compromise which could be avoided by dropping the requirement.

STAFF RESPONSE: All therapy misadministrations must be reported under the rule because they are assumed to have an adverse effect on the patient. Only those diagnostic misadministrations that cause a clinically detectable adverse effect in the patient are required to be reported under the rule.

COMMENT: Looking at (f) (3), we find a problem with the stipulation of reporting a maladministration by "...a route of administration other than that intended by the prescribing physician..." In the first instance, it should be noted that the routes of administration are relatively standard and variations from them are rare. Even so, such would not necessarily result in a "clinically detectable adverse effect" and thus a reporting requirement is unproductive. Further, since most isotopes are injected intravenously or subcutaneously, it is always possible to monitor a hotspot at the site of the injection because of the impossibility of avoiding residual radioactivity from the needle tip. We doubt that this is the commission's intent. However, a literal interpretation of this requirement, measured against the allowable 20 percent variation, could produce sufficient correspondence to eliminate the postal deficit.

STAFF RESPONSE: The statement of considerations to the final rule will clearly state that extravasation is not considered a misadministration

and that the licensee will not be expected to account for material remaining in the syringe when determining if a misadministration has occurred.

COMMENT: To summarize, we fully believe and concur that misadministration of radioactive materials which result in "clinically detectable adverse effects," should be noted, investigated, recorded and corrected. We think the NRC has a proper concern for these and is entitled to know about them. The reason for that knowledge is to correct the circumstance which caused the abberation.

However, for the reasons stated above, we object to the promulgation of the proposed regulations as written and strongly urge that they be disapproved.

STAFF RESPONSE: This is basically how the final rule is written.

135. Luther E. Preuss, Secretary, Medical Isotope & Radiation Safety Committee, Edsel B. Ford Institute for Medical Research, Henry Ford Hospital, 2799 West Grand Boulevard, Detroit, Michigan 48202 (October 2, 1978)

COMMENT: As secretary of the Medical Isotope and Radiation Safety Committee administering NRC Broad License #21-04109-16 at this institute, I have been asked to relay a committee question to your offices, relative to misadministration of radioactive materials.

The question is: 'must all misadministrations of diagnostic dosages be reported to the NRC?' (misadministrations are defined in your release dated July 7, 1978, as differing by 20% of the prescribed dose). Clarification of this point would be appreciated by this committee.

STAFF RESPONSE: The final rule will clearly show that only those diagnostic misadministrations that cause a clinically detectable adverse effect and all therapy misadministrations are required to be reported.

136. Joseph P. Hile, Associate Commissioner for Regulatory Affairs, HEW, Public Health Service, FDA, Rockville, Md. 20857 (October 13, 1978)

COMMENT: The Food and Drug Administration's authority under the Federal Food, Drug, and Cosmetic (FD&C) Act and reporting requirements for new drugs, require holders of approved new drug applications to report adverse experiences. A physician of nuclear medicine, however, is not required by the FD&C Act to notify the manufacturer of a new drug or this agency of any misadministration of an approved new drug. Therefore, we have concluded this proposal, if finalized, will not impose dual reporting requirements on any persons and, in that respect, conforms with our joint memorandum of understanding currently in preparation.

Based on a review of the document, staff of our Bureau of Radiological Health have offered the following comments on specific sections of the July 7, 1978 proposal:

1. Proposed § 35.33 requires the licensee to notify various parties of misadministration involving diagnostic procedures only if that procedure could cause a clinically detectable adverse effect. It is not

clear from the context what kind of effects the NRC has in mind. Are they acute effects such as erythema, chronic effects such as cancer, or either acute or chronic?

While the discussion of type of effects is important, it is secondary to an even more important deficiency embodied in this statement. The phraseology using "could cause" is ambiguous. In radiological health, one of the basic principles of protection is to avoid all unnecessary radiation exposure because it is prudent public health policy to assume that any amount of radiation, no matter how small, represents some risk of harmful biological damage. However, if this rule is to be practical, the adverse effects must be those that are expected to be clinically detectable as a direct result of the misadministration. Thus, the rule must clarify that the "adverse effects" of concern are those of an acute nature and that would be expected, because adoption of the radiation protection philosophy would require every misadministration to be reported.

STAFF RESPONSE: The final rule will delete the word "could" and will read "...a diagnostic procedure that causes a clinically detectable adverse effect...".

COMMENT: Further, there is a significant dichotomy between the requirement for diagnostic and therapy misadministration reporting because it has not been shown that a therapy misadministration causes an adverse effect. The concern on misadministration reporting is apparently to assure the safety and effectiveness of the procedure; therefore, the "adverse effects" provision must apply to both the diagnostic and therapeutic procedures.

STAFF RESPONSE: The staff believes that it is reasonable to assume an adverse effect has occurred from any therapy misadministration and therefore the staff is recommending that all therapy misadministrations be reported to NRC, the referring physician and the patient or a responsible relative.

COMMENT:

2. Proposed § 35.33(e) should be revised to require records only of misadministrations that are reportable under § 35.33(a) in the absence of a documented need for records of the insignificant misadministrations that are included in § 35.33(f).

STAFF RESPONSE: Records of all misadministrations, including those that are clinically insignificant, are necessary in order for NRC inspectors to determine if there are trends of misadministrations at a particular medical institution.

COMMENT:

3. Delete the phrase "from a source" from proposed § 35.33(f)(1) as this only confuses the meaning of the provision. The word "source" as used in the construct of this sentence is subject to dual meanings. It should be considered a misadministration if the wrong radiopharmaceutical is administered, not if the "source" or manufacturer is different than intended.

STAFF RESPONSE: The term "radioactive source" will be used in the final rule.

COMMENT:

4. It is common practice that the administered dose of a radiopharmaceutical will vary as much as 100 percent between institutions (hospital A may use a 15 mCi brain scan dose while hospital B will use a 30 mCi dose for the same procedure). Such variation is within normal range specifications or the labeling approved by the Food and Drug Administration and is a matter of professional medical judgment. Variations in the calculated and administered dose may occur between initial generator eluate assay and single dose prepared from subsequent reagent kit manufacture. Therefore, in proposed § 35.33(f)(4), a given dose should be considered a diagnostic misadministration only if the administered dose exceeds the prescribed dose by a factor greater than 100 percent. The problem of underdosing is different because it is not likely to be related to a clinically detectable adverse effect but to be an inadequate dose for the procedure, thus requiring a second administration. Accordingly, underdosing should be deleted from § 35.33(f)(4) and the reporting of repeat administrations treated separately if the need can be justified.

STAFF RESPONSE: The staff believes that underdosing or overdosing by more than 20% represents a mistake and should be recorded as a misadministration.

5. For purposes of clarity, it may be important to specify whether "dose" as used in this proposal refers to pharmaceutical dose or radiation dose. Apparently, in proposed § 35.33(f)(5), "dose" means radiation dose or absorbed dose.

STAFF RESPONSE: This language is clear in the final rule which identifies both the radiation dose and radiopharmaceutical dose as the subjects of the definition.

137. Roland Cull, M.D., Department Head, Nuclear Medicine, Memorial Medical Center, Southern Illinois University, School of Medicine, P. O. Box 3926, Springfield, Illinois 62708 (October 11, 1978)

COMMENT: The suggested guidelines of 20% error from the intended dose for diagnostic purposes, and of 10% error from the intended dose for therapeutic purposes is too limiting. There are no definitive rules regarding dose administered and, hence, there are certainly larger variations than those suggested from facility to facility. Thus a 20% error or misadministration at one facility may be considered acceptable or even a low dose at another's. Yet the implication of misadministration would certainly carry the connotation of "injury" to the patient.

Furthermore, I think that the legal ramifications may be more complicated than the situation warrants because there seems to be no absolute standards as a basis for judgment. I suggest that this proposal not become a regulation.

868 140

STAFF RESPONSE: The limit of greater than 20% error in the diagnostic administration is intended to reveal mistakes and not clinical significance. The limit of greater than 10% error in the therapeutic administration is intended to reveal mistakes and also is considered by the staff to be clinically significant.

138. Nicholas A. Detorie, Ph.D., Director of Physics, Department of Radiology, Memorial Medical Center, Southern Illinois University, School of Medicine, P. O. Box 3926, Springfield, Illinois 62708 (October 11, 1978)

COMMENT: I would like to comment on the subject of notification of the NRC for any misadministration of radioactive materials.

The suggested guidelines of 20% error from the intended dose for diagnostic purposes, and of 10% error from the intended dose for therapeutic purposes is too limiting. There are no definitive rules regarding dose administered and, hence, there are certainly larger variations than those suggested from facility to facility. Thus, a 20% error or misadministration at one facility may be considered acceptable or even a low dose at another! Yet, the implication of misadministration would certainly carry the connotation of "injury" to the patient.

Furthermore, I think that the legal ramifications may be more complicated than the situation warrants because there seems to be no absolute standards as a basis for judgment. I suggest that this proposal not become a regulation.

STAFF RESPONSE: See staff response to comment #137.

139. John W. Travis, M.D., F.A.C.R., F.A.C.P., Clinical Director, St. Francis Hospital and Medical Center, St. Francis Capital Region Radiotherapy Center, 1700 W. 7th St., Topeka, Kans. 66606 (October 9, 1978)

COMMENT: Though I am strongly in favor of safety-conscious care and precision in the medical use of radioactive isotopes, I object to the imposition of an incubus on the physician which presumes frequent malperformance, invites flagrant abuse by an already overeager plaintiff's bar, substitutes impersonal regulatory sanctions for my judgment as a physician in dealing with individual patients, ignores my prerogatives as a direct-care physician, brushes aside patients' feelings and concerns, and establishes the base for a fundamentally punitive bureaucratic incursion into my practice by yet another layer of self-perpetuating, paper-generating, practically inexperienced busybodies at public expense. You are hitting a fly with a baseball bat!

I am especially offended by the mandated substitution through an arbitrary regulation of the quick response of some "primary" physician who may know the patient and his clinical problem far less well than I do for my judgment as a direct-care physician in dealing with my cancer patients. There is an obvious complete lack of insight and understanding of the role of the therapeutic radiologist in patient management at the heart of some of these rules which are just plain dumb. They reflect an almost willful intent to avoid meaningful discourse with the professionals most concerned. The individuals who drafted these regulations should be cornobbled!

Since the proposed regulations do not spell out how it is to be determined that a daily dose is outside the 10% variation from "prescribed" dose on a daily basis, we can only presume that this silliness will be magnified in an additional set of clarifying regulations to specify and proscribe our behavior on a daily basis. How is such activity to be "policed"? The record-keeping and reporting requirements are absurd. Wait'll malpractice insurance carriers learn of this one! Up go the rates again!

How much better it would be if the NRC would spend the public's time and money assisting the profession in the development of simple, reliable, inexpensive equipment and techniques for regular, reliable determination of operational integrity and dose output from isotope teletharapy sources! Such an effort would cost only a fraction of the endless, self-exanding waste of taxpayers' money which is going to result from the proposed new regulations.

As you know well, BRH-FDA conducted a survey of dose integrity from cobalt teletherapy units a number of months ago which was then hastily--and perhaps with considerably less precision--duplicated by NRC. The results of both surveys indicate that my suggestion is the area in which work needs to be done by NRC itself before imposing strictures on our practices. Neither survey supports the need for the nitpicking and costly approach the proposed regulations take toward external radioisotope teletherapy (i.e., cobalt treatment), Riverside Hospital notwithstanding.

One other practical matter is worth mentioning. Even with the best of computer-based dosimetry, the specification and delivery of dose from the ever-widening use of temporary and permanent interstitial radioisotope source implantation is subject to at least ± 10% variation. How in the devil you people are going to impose a standard which exceeds the most sophisticated technology is beyond me. You can't meet it yourselves!

Portions of the proposed regulations reflect an inspired ignorance of reality on the part of the framers which is nothing short of terrifying! What's next, folks?

Why don't you try something that seems to be working with fair success in the area of advancing medical technology, i.e., the "consensus" conference of recognized working medical leaders--including a significant number of physicians practicing at the community level--and state radiation safety officials who are accustomed to dealing with local problems?

I think it is fatuous for you on the NRC to assume a priori that your generic concerns for public safety are somehow deeper than the concern I have for my individual patients. You might really be amazed at how much time and effort we devote in a community-based practice to quality control, avoidance of unnecessary exposure and to the appropriate administration of the high energy radiation we use and for which we have the greatest respect. Come and find out!

STAFF RESPONSE: Comments noted.

868 142

140. C. Fillmore Humphreys, M.D., Secretary, Medical Advisory Board, Alta Bates Hospital, 1 Colby Plaza at Ashby, Berkeley, CA 94705 (September 29, 1978)

COMMENT: The Medical Advisory Board of Alta Bates Hospital reviewed the proposed role of the Nuclear Regulatory Commission requiring that misadministrations of radioactive material be reported to the patient or the patient's responsible relative.

While on the surface this would appear to be a correct and justifiable procedure specifically in nuclear medicine, some deviations of administration of radioactive materials which would have to be classified as misadministered would too often occur in our opinion. Therefore, with all due respect, we strongly disapprove of these proposals.

May we take this opportunity, however, to thank you and the other members of the Commission for their diligence in protecting all of us.

STAFF RESPONSE: The benefits of misadministration reporting is proportional to the number of misadministrations. The more that occur the greater the benefit.

141. Robert E. Henkin, M.D., Director, Nuclear Medicine, Foster G. McGaw Hospital, Loyola University Medical Center, 2160 South First Avenue, Maywood, Illinois 60153 (September 29, 1978)

COMMENT: The concept of record keeping and reporting of misadministrations of therapeutic materials is an excellent one. It is a practice consistent with good medical care and is currently employed in many medical centers. The wording of the rule suggests that misadministrations that may cause "a clinically detectable adverse effect on the patient" be reported. The administration of diagnostic radiopharmaceuticals, even misadministrations, cannot to the best of anyone's knowledge cause such an effect. If therefore, it is the Commission's intent to require only the reporting of misadministrations that can cause clinical effects, I would suggest that the wording be changed to reflect that we are discussing therapeutic administrations. I believe there would be considerable confusion in the medical community as well as possibly undue concern upon the part of patients who might undergo misadministration of diagnostic materials from which there would be no anticipated clinical effects.

Secondly, the requirement placed on the Nuclear Medicine physician to report directly to the patient or his representative, the misadministration, is poor medical practice.

Since in general, physicians in Nuclear Medicine do not report favorable findings to patients, why should the restriction that they must report unfavorable results to the patient be imposed on them. It is our obligation to report our findings and actions to the referring physician who is in charge of that patient's management. Direct reporting to the patient's family or the patient himself interposes the Nuclear Medicine physician between the referring physician and the patient. There may be legitimate circumstances under which the reporting of such information to the patient would be detrimental to the patient's medical condition. The only individual who would be aware of this possible effect would be the physician in charge of the case. Therefore, I would propose that the requirements

of reporting to NRC and to the referring physician be maintained. However, the direct reporting by the Nuclear Medicine physician to the patient or his representative, should be deleted from the proposed rule.

I have taken the opportunity to discuss my comments with a number of my colleagues in Nuclear Physicians of Illinois, the State organization for Nuclear Medicine physicians. I am responding as chairman for legislative affairs of Nuclear Physicians of Illinois.

STAFF RESPONSE: The final rule will clearly state that for diagnostic misadministrations only those that cause a clinically detectable adverse affect will be reportable. The final rule will also permit the referring physician to inform the patient instead of the licensee.

142. Harlan R. Knudson, CAE, Executive Director, Washington State Medical Association, United Airlines Building, 2033 Sixth Avenue, Seattle, Washington 98121 (October 3, 1978)

COMMENT: Thank you for the opportunity to comment on proposed amendments to regulations which would require medical doctors to keep records of all misadministrations of radioactive material and to report potentially dangerous misadministrations. From the nature of your letter, you have some concern regarding the confidentiality of patient records and this is our concern as well.

As you know, there exists by statute in most states including Washington a privilege against legal compulsion of disclosure of matters related to a physician by a patient in the course of his treatment. The privilege is for the benefit of the patient to the end that he will be encouraged to disclose his ailments to a physician so that they may be properly treated. While the proposed regulations apparently do not require disclosure of a patient's name initially, the report which the licensee must hold "for Commission inspection" might create a confidence disclosure problem at a later date.

STAFF RESPONSE: (To be supplied by ELD.)

COMMENT: The proposed rule also provides for direct contact of the patient by the licensee within 24 hours after discovery that a misadministration has likely occurred. A licensee often may not be the regular treating physician of a patient, and a notice of misadministration coming from someone only collaterally involved in the patient's treatment may produce a high level of anxiety in the patient. Furthermore, there is nothing in the proposed rules which insures that in the 24 hour period in which notice must be provided to the patient, that the patient's regular attending physician will receive notice with enough time so he/she may respond if notification of the patient would be detrimental.

Perhaps a better approach would be to remove the requirement of direct notification of the patient by the licensee. Rather, the licensee should have the responsibility to notify the referring physician, who would then have the responsibility of informing the patient unless the physician believes in his medical judgment that telling the patient would be harmful.

To summarize, it is our opinion that NRC should not have direct and immediate access to the names of patients and their referring physicians in a licensee's records. A patient's informed consent should be obtained before information is made available to the Commission. A licensee should not directly contact a patient, but his duty should be to inform the patient's regular physician of the misadministration, except in the instance of a medical emergency. At a minimum, the rule should expressly provide that a patient's regular physician should be given an opportunity to exercise his medical judgment relative to disclosure before the patient or a responsible relative are informed.

STAFF RESPONSE: The final rule will allow the referring physician to veto the licensee's report to the patient if the referring physician personally informs the licensee either that he will inform the patient or responsible relative or that the information will be harmful to the patient or relative.

143. Jonathan N. Law, C.R.P., Atlantic City Medical Center, Division of Radiology, Nuclear Medicine, and Ultrasound, 1925 Pacific Avenue, Atlantic City, N.J. 08401 (October 4, 1978)

COMMENT: In response to the proposed rule 35.33, I would like to make the following comments on behalf of the Medical Isotopes Committee of the Atlantic City Medical Center.

The concept of the proposed rule is good, however, one must be very careful in determining conditions warranting patient or responsible relative notification. Of course, when clinically adverse effects are expected, the patient and/or responsible relative have the right to be informed. However, some of the misadministrations set forth by the Commission do not suggest the eventuation of clinically adverse effects, in particular, the 20% error in a diagnostic administration. We agree that with the state of the art instrumentation and technic 20% errors should not be made, but if they are the probability of ensuing clinically detectable adverse effects are exceedingly small. It seems inconsistent to require reporting a 10% error in therapy resulting in a typical dose discrepancy of several hundred rads and a 20% error in diagnosis which results typically in a dose discrepancy of less than one rad. If the Commission considers dose discrepancies of less than one rad to be clinically significant, then errors of the order of hundredths of a percent should be reported for therapy. Obviously, accuracy to better than 3% is very difficult to achieve in radiotherapy and to insist upon hundredths of a percent is ridiculous. The point is that alerting a patient to a diagnostic misadministration of 20% serves no benefit to anyone and should not be required by the NRC. Recording an incident of misadministration and reporting it to the Medical Isotopes Committee, who would in turn decide as to whether the patient's referring physician and/or the patient or responsible relative should be notified, would be a more reasonable solution. Naturally, such misadministration and subsequent decisions would be recorded in the minutes of the Medical Isotopes Committee for review by the NRC.

In conclusion, we agree that misadministrations as outlined in proposed rule 35.33 should be recorded and that, within a reasonable time dependent upon the magnitude of the misadministration, the NRC should be notified.

However, we disagree that all misadministrations warrant referring physicians, patient or responsible relative notification as directed by 35.33. Instead, we recommend that the Medical Isotope Committee be charged with reviewing the extent of the misadministration and other pertinent patient parameters, and the decision of notifying the referring physician and/or patient or responsible relative.

STAFF RESPONSE: All therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect are subject to the reporting requirement.

143. Henry N. Wellman, M.D., Chairman, Radionuclide Radiation Safety Committee, Indiana University Medical Center, 1100 West Michigan Street, Indianapolis, Indiana 46202 (October 19, 1978)

COMMENT: I am responding to the above proposed rules change in the name of the Radiation Safety Committee of the Indiana University Medical Center and the professionals utilizing byproduct materials at its associated institutions. Basically, as per the attached comments of my associates, there is sympahty with the concept that misuse of byproduct materials in their use with human beings should be documented and brought to the attention of the NRC. We have felt that this was an implicit requirement of licensees, however, all along. Obviously, the intended rulemaking would primarly affect the field of radiation therapy or radiation oncology, which is involved int eh therapeutic use of byproduct materials. As noted in the proposed rulemaking, it was misuse of byproduct material in radiation therapy that probably brought this problem into focus. It would thus seem reasonable that the rulemaking only be proposed for therapeutic uses. Such a rule would also affect the field of nuclear medicine insofar as internally administered radioactive byproduct materials are given for a therapeutic response. That is to say, primarily the treatment of thyroid diseases. By and large in the diagnostic uses of nuclear medicine, the quantities of administered radioactivity are so little as to be well within the proposed guidelines, causing no effect.

The proposed rulemaking text is not totally clear that the only reporting necessary would be events that could cause a significant clinical radiation effect. For example, in section 35.33-3F, it is not made clear that misadministrations would only refer to those of a therapeutic nature, or that could cause a clinically detectable adverse effect. Thus I believe the overall document would be clarified if discussion of diagnostic doses were deleted and rulemaking only apply to therapeutic administrations or administrations simulating therapeutic effects. The latter, of course, could result from the use of Iodine-131 for diagnostic purposes with the patient being given a larger dose of Iodine-131, which might cause anticipated clinical response. Thus I believe it is the consensus of my colleagues that the inclusion of reporting of usual diagnostic doses would not be efficacious and would serve no purpose.

The criteria for calibration of therapeutic radiation doses over which there is more control, seems reasonable at a 10% tolerance level. However, in many cases diagnostic doses are approximated from commercial package calibration values and achieved on a dilutional basis. Furthermore, the logistics of operation of a diagnostic nuclear medicine facility are such

that significant delay can result from the time of drawing up a dose and its anticipated administration time. Such inherent errors could easily result in frequent variances of the dose, not intended, greater than 20%. Furthermore, it is likely that a dose intended to be in a diagnostic range but having a possible observable clinical effect, would be considerably above a 20% error. For example, with Iodine-131 if one were to assume that a frequently used diagnostic dose of 100 mCi were inadvertently measured out to be an actual dose of 3 mCi, that is, a borderline amount, causing a significant clinical effect, this would be an error of roughly 3000%. Thus, an error on diagnostic doses of 50-100% might even be reasonably tolerable in everyday practice.

The proposed rulemaking probably does not address itself to the prime problem regarding diagnostic administration of radiopharmaceuticals. As a constructive suggestion, it might be well for the NRC to include in the rulemaking rather than the reporting of diagnostic administrations that are less than one would anticipate causing a significant clinical effect, rather than licensees who utilize diagnostic amounts of byproduct materials be required to record a written prescription for the administration of these radioactive drug products prior to their administration to patients. A prescribing practice at least adhering to the minimum rules for all other drugs would be much more effective in monitoring and encouraging their proper use in diagnosis.

STAFF RESPONSE: The final rule will require reporting of all therapeutic misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect. NRC recently notified all licensees not to rely on verbal orders for nuclear medicine procedures. The notification refers to a recent misadministration and recommends that licensees use written orders for radiopharmaceutical dosages.

COMMENT: Much of the requirements, I believe, treads on matters which are already within the realm of good practice of medicine. Other than reporting of a therapeutic or potentially therapeutic simulating dose inadvertently to a patient, the requirements in the proposed rulemaking of reporting to the patient's physician, the patient or his representative, etc., are already provided for within the practice of medicine and are totally unnecessary. In the middle of the fourth paragraph under item, supplementary information, the statement, "and other purposes and to inform the patient or the patient's responsible relative so that corrective action can be taken," is made. The sense of this statement totally escapes the readers. What is meant by corrective action and indeed, how will informing the patient, anyway, help the NRC take corrective action.

STAFF RESPONSE: The staff believes that the patient has a basic right to be informed of his condition, particularly when something has gone wrong. The patient should be able to understand what is being done to mitigate the misadministrations and seek followup care as he sees fit.

COMMENT: Likewise, most of the items under Section 35.33 3F also have to do with the good practice of medicine. Thirty-five point thirty-three F-4 furthermore points out inconsistencies in the rulemaking in that it would almost nearly be impossible to have a simulated therapeutic effect from a diagnostic dose differing by 20% from that intended. As noted above,

it would take an error of usually many hundred percent to "cause a clinically detectable adverse effect on the patient."

In summary, alteration of the proposed rulemaking to require that therapeutic or therapeutic-simulating misadministrations of radiation dose from byproduct material be reported to the NRC is reasonable. A 10% limit on these therapeutic doses is also probably within reason. However, because of the wide variability and the wide range of tolerances possible with diagnostic doses, the rulemaking should not be confused with such requirements. Rather, separate rulemaking requiring that the practice of a for each administration of a byproduct material, whether of a therapeutic or diagnostic nature, be a requirement. Other than requiring that misadministrations be reported to the NRC, the rest of the reporting requirements suggested in the rulemaking infringe on the provisions of present good medical practice and are unnecessary.

STAFF RESPONSE: Comment noted.

145. Nicholas P. Krikes, M.D., President, California Medical Association, 731 Market Street, San Francisco, California 94103 (October 27, 1978)

COMMENT: We have carefully reviewed the regulations and commend the Commission's interest in quality health care. But it is doubtful the proposed regulations will achieve this objective. These regulations will not prevent "misadministraitons" nor are they likely to reduce the already low incidence of "misadministrations" as reported in the 1972 GAO Report to the Congress.

We feel a primary responsibility of the physician who provides medical care is patient safety. It is not necessary to share this responsibility with the NRC, or any other regulatory agency or individual.

In reference to the limits established as a misadministration, i.e., a difference from the prescribed dose by 20% in diagnostic procedures and a difference from the prescribed doses by 10% in therapeutic procedures, the United States Pharmacopeia (USP XIX) permits at least a 20% variance for both therapeutic and diagnostic procedures. We feel that these standards are adequate and present no real problem to the patient.

The above reflects the position of many physicians who believe the present laws and regulations controlling the practice of medicine already protect the patient in regard to medications, whether radioactive or not and that additional unneeded regulations tend to diffuse responsibility which is now accepted by physicians.

STAFF RESPONSE: With a single exception, USPXIX specifies that radiopharmaceuticals assay within 90.0 to 110.0 percent of the labeled amount which is equivalent to ±10% error in the prescribed dosage. USPXIX is binding on radiopharmaceutical manufacturers and not on the users. USPXIX specifications apply to the labeling on the vial and the dose should be assayed in the syringe prior to administration.

146. Eugene A. Cornelius, M.D., Ph.D., Chairman, Hospital Radioisotope Committee, Yale-New Haven Hospital, 789 Howard Avenue, New Haven, Connecticut 06504 (November 7, 1978)

COMMENT: The above proposed rule was discussed at the last meeting of the Radioisotope Committee of Yale-New Haven Hospital.

The consensus of opinion of the members of this committee was as follows:

1. The proposed rule is an intrusion into the physician-patient relationship.

2. After the fact reporting is of no value; furthermore, the proposed rule will not prevent future misadministrations, which are already at an exceedingly low incidence rate.

3. Practicing physicians are fully aware of the ethics of medical practice - that a patient must be fully informed of all aspects of his care, particularly if possible harm is involved.

4. This proposed rule would increase the cost, because of the time spent on administrative chores, without improving the level of medical care.

5. Records of all administrations are already maintained, including misadministrations. The proposed regulation is redundant.

STAFF RESPONSE: The staff recognizes the intrusion. The staff does not know that the incidence of misadministrations is low although it may well be when compared to other drugs because of the stricter control of radiopharmaceuticals which includes measuring the dosage before administration to patients.

147. Eugene L. Saenger, M.D., Medical Consultant, University of Cincinnati, College of Medicine, Radioisotope Laboratory, Cincinnat General Hospital, Cincinnati, Ohio 45267 (November 24, 1978)

COMMENT: This letter is being written in my capacity as consultant to the Nuclear Regulatory Commission as a result of a recent case in which a misadministration of a radiopharmaceutical occurred.

For a number of reasons I was not called in my consultant capacity for a period of about two weeks following this incident. The particular circumstances which are dealt with in the official reports rendered to the NRC concerned the fact that the wrong radioactive material was administered to a patient.

In spite of not being called during this interval the physicians involved, the hospital at which this incident occurred immediately notified the family, the various attending physicians and the administration of the hospital were immediately notified. The Regional Office of the NRC was notified by phone.

My only point in bringing all of this to the attention of the Commission is to urge re-thinking of the statements on misadministration. Had this incident been reported promptly to a medical consultant it is probable that the bulk of the offending inappropriate radioactive material could have been eliminated from the patient rather promptly. By the same token, the hospital fulfilled its responsibilities in notification of the patient, his family and other appropriate indiduals within the region.

It still seems to me to be a severe penalty to publicize such incidents in the public document room. Insofar as the care of an injured patient is concerned what is needed is expert medical attention rendered promptly. To this degree I would urge that the proposed regulation be reconsidered in some detail perhaps by the panel of medical consultants. The course of action which would seem to me to be most practical would be to publicize widely the availability of medical consultation through the NRC and such other consultants as the NRC consultants themselves would recommend and that the matter be handled with complete anonymity in regard to notification in the public document room.

If the purpose of supervision by the NRC and the use of medical consultation is to be directed to the best possible medical care of the patient rather than administrative and/or punitive actions by the NRC such a course would seem to be most logical.

I would be pleased to discuss this matter in greater detail if requested.

STAFF RESPONSE: One purpose of the rule is to determine the causes of misadministrations to prevent their recurrence. When it appears that the licensee can use assistance, NRC consultants will be available. Even though the misadministration reports will not be "publicized" in NRC's Public Document Room, they will be available for public scrutiny.

148. Fred M. Palace, M.D., Morristown Memorial Hospital, Department of Radiology, 100 Madison Avenue, Morristown, N.J. 07960 (August 10, 1978)

COMMENT: There is no doubt in my mind that it is appropriate for the Nuclear Regulatory Commission to attempt to reduce radiation exposure to the population as a whole, nor would I deny that there has been less activity toward this end on the part of the old Atomic Energy Commission than might have been considered most beneficial to the people of the United States. BUT, I am afraid that this proposal will not achieve this end and will rebound to the detriment of the people and represents an unnecessary and unwelcome intrusion by the Nuclear Regulatory Commission upon the practice of medicine.

It would not be inappropriate for the Nuclear Regulatory Commission to prescribe a specific dose of radioactive material for each examination.

The requiring that the patient be notified of an overdosage which may have been entirely accidental which will certainly in terms of millicurie dosages of Technetium 99m or micricurie amounts of I-131 is ridiculous. It will A) unnecessarily produce anxiety on the part of the patient as to the effects of the overdosage, on the patient with all the adverse effects that anxiety can lead to, B) it will increase the malpractice risk because notification does not prevent such legal action and the physician can be sued for the anxiety produced by the notification even though there was no adverse effect of the radioactive overdosage itself, and C) if the attending physician advises that the patient not be notified, then (he/she) will share in the negligence liability which is caused entirely by the actions of the NRC. This regulation will not prevent overdosage since they are accidental in any event, and will not reduce the possible side effects of such overdosage. The NRC assumes that increased apprehension on the part of the physician will prevent accidents. This is an unproved assumption and a

dangerous one to boot. Nuclear Technologists and Nuclear Physicians, as all physicians, use their best efforts at all times. Mistakes and accidents of the nature that will require notification are not preventable as such and patient notification is not an answer to the problem of overradiation.

The problem of notifying a patient if a radium source is left in the vagina for several weeks after the bulk of the applicator has been removed is a far different matter than the accidental injection of 1.5MC of Technetium 99m rather than 1.0MC. If your regulations are intended to cause immediate malpractice suits on the part of the patient who has had 10mg of radium left within a body cavity through gross negligence by the physician, then you might be successful. The incompetence of a physician that would allow this to happen will not be assuaged by the fact that he must report it to the patient.

The whole regulation - applied to therapeutic and diagnostic doses alike - represents an unnnecessary, unwelcome, incompetent, and ridiculous intrusion in an area where the Nuclear Regulatory Commission has no reason to be; it will not fulfull your expectations of reduction of unnecessary radiation exposure to the population. I would hope that you would continue your efforts to this end, but with a different, hopefully more effective approach.

STAFF RESPONSE: The final rule will require notification of NRC, the referring physician and the patient or responsible relative of all therapy misadministrations and only those diagnostic misadministrations that cause a clinically detectable adverse effect.

149. Charles P. D'Assaro, Administrator, Ormond Beach Hospital, 264 South Atlantic Avenue, Ormond Beach, Florida 32074 (February 15, 1979)

COMMENT: We would like to be on record as being opposed to the proposed rule change requiring notification of misadministration of radiopharmaceuticals. We feel that we have this situation under control and any further action is unnecessary.

STAFF RESPONSE: Comment noted.

150. T. K. DeBoer, Director of Nuclear Operations, State of New York, Energy Office, Agency Building 2, Empire State Plaza, Albany, New York 12223 (February 16, 1979)

COMMENT: The proposal has been reviewed by the New York State and New York City Departments of Health which, as you know, are responsible for regulating medical users of radioactive material. Based on their respective considerations of the proposal, they have expressed somewhat opposing views on the merits of such a reporting requirement. Although the formal comment period has expired, I nevertheless feel that their comments would be of interest to the Commission in its deliberations on the proposed amendment.

The New York State Department of Health is opposed to the proposed requirement concerning the recording and reporting of misadministrations of radioactive materials for the following reasons:

1. Hospitals already keep records of misadministrations of all drugs through an incident reporting system. These reports are not a part of the patient's records, but are kept on file.

STAFF RESPONSE: This practice is not universal and not necessarily available for NRC inspection.

COMMENT:

2. By requiring the reporting to the patient of misadministrations that "could" cause a clinically detectable adverse effect, the hospital and/or physician would quite likely be placed in a liability situation. This could result in expensive litigations that would lead to increased patient care costs through increased insurance premiums. On a risk vs cost basis, this proposed rule does not seem justified.

STAFF RESPONSE: The word "could" has been removed from the final rule.

COMMENT: An informal survey of hospitals has indicated that an extremely small percent (less than 1%) of misadministrations occur from radioactive drugs or radiation therapy due to the tight control of these operations by NRC/State agencies. It appears that gross misadministration, such as the teletherapy incident, get reported with existing rules. This proposed rule certainly will not prevent misadministrations and might even deter their reporting because of the liability involved. If NRC/State inspectors wish to see records of misadministrations they could request to see the incident reports on file.

STAFF RESPONSE: Misadministration records are not usually seggregated from patient records and thus are not easily reviewed. The Riverside Teletherapy Incident was not reported to NRC by the licensee. The actual incidence of misadministrations is not known. Even 1% of the estimated 15 million administrations per year is not a small number.

150. Dr. Leonard R. Solon, Bureau for Radiation Control, Department of Health, New York, New York (December 4, 1978)

COMMENT: We cannot agree with the position expressed by the New York State Department of Health in their memorandum to you of November 10, 1978. We also have considered the possible consequences of reporting the misadministration to patients and the possibility of malpractice suits against the institutions involved. We believe that the rights of patients take precedence over the vulnerability of institutions to malpractice suits and support adoption of the Code of Federal Regulations as recommended by the U.S. Nuclear Regulatory Commission.

REPORT JUSTIFICATION ANALYSIS FOR GAO

AND

VALUE-IMPACT ANALYSIS

I. Type of Recordkeeping and Report

Under the misadministration rule, licensees will be required to keep records of all misadministrations and report to NRC, the referring physician, and the patient or responsible relative (or guardian) all therapy misadministrations and those diagnostic misadministrations that cause a clinically detectable adverse effect. The initial 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 written report will contain the same information with the exception that the names of individuals will not be reported.

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 rec irement 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 one misadministration (as defined in the proposed rule) per year and 4 percent of these are reportable, there will be 2,500 records and approximately 100 reportable incidents (requiring reports to NRC the referring physician, and the patient).

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.*

*Because the names of individuals will not be reported, the reporting requirement need not infringe on physician-patient privileges.

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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 requirement is therefore 4 man-hours per reportable 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 is estimated to require one man-hour to receive and write up. Each written report is estimated to require one man-hour to review. The total cost to the NRC is estimated to be one man-hour per recordable incident and 2 man-hours per reportable incident. With these assumptions the following calculations apply:

(1) 1 man-hour per record x 2,500 records = 2,500 man-hours annually for licensee recordkeeping; and 2,500 man-hours annually for NRC review.

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

(3) (2,500 + 400) man-hours = 2,900 man-hours annually to licensees for recordkeeping and reporting.

(4) (2,500 + 200) man-hours = 2,700 man-hours annually to NRC for reviewing records and receiving and reviewing reports.

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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.

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 50 years) records of all misadministrations and reports of serious misadministrations is estimated to $50 for each of the 2,500 misadministrations or $125,000. The actual cost in dollars to licensees for reporting misadministrations is estimated to be $750 for each of 100 reportable misadministrations or $75,000. This $200,000 total annual cost to licensees does not include the cost of investigating the incidents, followup medical care, or malpractice - costs.

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 serious 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 2,500 licensee records of misadministrations, preparing preliminary notifications, preparing Abnormal Occurrence reports, etc. The Office of Standards Development estimates that 2 additional persons will be needed to prepare regulations and standards to prevent future misadministrations. The Office of Nuclear Materials Safety and Safeguards estimates that one additional person will be needed to plan corrective actions, prepare orders to licensees and review new regulations. 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 15 persons at $30,000 per person or $450,000.

The estimated, total annual cost of the misadministration rule is $650,000 ($450,000 + $200,000). 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.

DRAFT CONGRESSIONAL LETTER

Dear Mr. Chairman:

Enclosed for the information of the subcommittee are copies of Nuclear Regulatory Commission amendments to its regulations in 10 CFR Part 35 regarding medical misadministration of radioactive material. Under the proposal, NRC medical licensees would be required to keep records of all misadministrations to the NRC, the patient's referring physician and the patient or the patient's responsible relative. The licensee would not be required to report to the patient or the responsible relative if the referring physician personally informs the licensee that in his medical judgement such a report would be harmful to that patient or relative.

The purpose of the misadministration reporting requirement is to identify the causes for misadministration's in order to correct them and prevent this recurrence.

The rule will be published in the Federal Register to be effective in 75 days. Enclosed also are copies of a public announcement to be released by the Commission in this matter in the next few days.

Sincerely,

Robert B. Minogue, Director
Office of Standards Development

Enclosures:
1. Proposed Rule
2. Public Announcement