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

CHAIRMAN

December 26, 1990

Dr. Bernard A. Fries
91 Acacia Drive
Orlinda, California 94563

Dear Dr. Fries:

Thank you for your letter of October 11, 1990, supporting the Nuclear Regulatory Commission's (NRC's) Below Regulatory Concern (BRC) policy statement. The Commission appreciates your thoughtful, candid, and informed comments on what we consider to be an important development in public policy on radiation safety and your willingness to express your views at the recent public meeting on the BRC policy in Oakland, California.

As you know, the purpose of the Oakland meeting and others held in various locations across the country was to explain the basis and need for the BRC policy and to answer questions about the policy. The views expressed by individuals and groups at these meetings will be considered by the NRC in implementing the policy. As you suggested in your letter, we are also examining the lessons learned from the series of public meetings that have been held to date to ensure that future NRC meetings on this and other topics are structured to provide a more productive forum for information exchange.

With regard to your comment on the potential health benefits that might be achieved by reducing radiation exposures in the practice of medicine, you refer primarily to potentially excessive use of X-rays. As you noted, the Atomic Energy Act does not give NRC the authority to regulate the use of X-rays. The authority for X-rays was given to the States. However, the NRC does have the authority to regulate the medical use of byproduct materials. In regulating the safe use of these materials, we expect that licensees will take steps to minimize any unnecessary doses resulting from treatment or diagnostic protocols. We also recognize that the exposure of individuals to byproduct materials that are beyond, or different from, those prescribed by a physician can be minimized through implementation of a comprehensive quality assurance program. The Commission issued a proposed rule on quality assurance and reporting requirements for medical use licensees (see enclosed Federal Register notice dated January 16, 1990) and will soon consider a final rule in this area.

Finally, the Commission believes that every citizen has a responsibility to understand and express his or her views and concerns through appropriate forums on complex issues such as the BRC policy. We value your contribution to the public debate on BRC and would welcome any additional comments you might care to offer on this and related issues.

Sincerely,

Kenneth C. Rogers

Kenneth C. Rogers
Acting Chairman

Enclosure: As stated

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Proposed Rules

Federal Register
Vol. 55, No. 10
Tuesday, January 16, 1990

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AC65

Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The NRC is proposing amendments to 10 CFR part 35 that would require medical use licensees to establish and implement a basic quality assurance (QA) program. The objective of the basic QA program is to provide high confidence that errors in the medical use of byproduct material will be prevented. The proposed amendments would enhance patient safety while allowing the flexibility necessary for proper medical care. The NRC is also proposing certain modifications to the definition of "misadministration" and to the related reporting and recordkeeping requirements.

DATE: Comments must be received by April 12, 1990. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except for the comments received by this date.

ADDRESSES: Submit written comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Copies of the draft regulatory analysis and the comments received on this proposed rule may be examined at the Commission's Public Document Room at 2120 L Street NW., Lower Level, Washington, DC. Single copies of the draft regulatory analysis are available from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Tse, see ADDRESSES heading, telephone: (301) 492-3797.

SUPPLEMENTARY INFORMATION:

I. Byproduct Material in Medicine

Medical Use[1]

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. An estimated 7 million diagnostic nuclear medicine procedures are performed in this country annually. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroids). An estimated 30,000 therapeutic procedures are performed each year.

Sealed sources that produce high radiation fields are used in radiation therapy primarily to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body in need of treatment. An estimated 100,000 patients receive cobalt-60 teletherapy treatments each year. Smaller sealed sources with less radioactivity are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. About 50,000 brachytherapy treatments are performed each year.

Sealed sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Medical use is regulated through State or Federal regulations. Twenty-nine States, known as Agreement States, have been delegated the authority by agreement with the NRC to regulate the use of byproduct material, including medical use (this type of agreement is authorized by Section 274 of the Atomic Energy Act). These States issue licenses for medical use and currently regulate about 5,000 licensees.

The NRC regulates medical use in twenty-one States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States and has licensed 2,200 medical institutions and 300 physicians in private practice.

II. NRC's Regulatory Program

NRC's Policy Regarding Medical Use

In a policy statement published February 9, 1979 (44 FR 8242), the NRC stated:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The NRC has the authority to regulate medical use to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

[1] "Medical use," as currently defined in 10 CFR 35.2, means "the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." Whenever this term is used in this rulemaking, this definition applies.

NRC's Responsibilities in Medical Use

The NRC draws a line between the unavoidable risks attendant to purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless medical use. The NRC is obliged, as part of its public health and safety charge, to establish and enforce regulations that protect the public from the latter.

Reports of Therapy Misadministrations and Diagnostic Misadministrations That Resulted in Doses in the Therapy Range

The NRC has reviewed 165 therapy misadministration reports over the period November 1980 through December 1988. The following analysis of these events provides the basis for determining that a potential benefit can result from this rulemaking. The specific causes of these therapy misadministrations, listed in Table 1, are related to the specific treatment modality. Nonetheless, there are three common problems related to all of these misadministrations: inadequate training, inattention to detail, and lack of redundancy.

Table 1—Therapy Misadministrations Reported to NRC from November 1980 Through December 1988

A. Teletherapy

Prescription

- Total daily dose was delivered from each port. (2 events)
- Oral and written prescriptions were different. (1 event)
- Boost dose of 500 rad/3 day was interpreted as 500 rad per day on each of 3 days, rather than 166 rad per day. (1 event)
- Proper body side was not clearly indicated. (1 event)

Treatment Planning

- Tumor depth was incorrectly measured. (1 event)
- Tumor depth was incorrectly recorded. (1 event)
- Dosimetrist used wrong computer program. (1 event)
- Dosimetry tables for wrong unit were used. (2 events)
- Error was made in dose calculations. (11 events)
- Incorrect formula used in computer program—21 patients affected. (1 event)

Records

- Arithmetic mistakes were made. (1 event)
- Poor handwriting of numerals caused misunderstanding. (1 event)
- Dose calculation result was transcribed incorrectly. (2 events)
- Error was made in a patient's chart and the chart was not checked. (1 event)

Physical measurements

- Wedge factors were measured incorrectly—53 patients affected. (1 event)

Application

- Field blocks were prescribed but not used. (1 event)
- Incorrect area was treated. (2 events)
- Patient was improperly identified. (1 event)
- Rotation switch on the machine was set incorrectly. (1 event)
- Co-60 machine was used instead of a linear accelerator. (1 event)
- Treatment time was misread. (1 event)
- Patient set up was not in accordance with the treatment plan. (1 event)

B. Brachytherapy

Treatment Planning

- Dose rate was much higher than first estimated. (1 event)
- Error was made in dose calculation. (3 events)

Application

- Sources with wrong activities were loaded in applicator. (6 events)
- Source fell out of applicator. (2 events)
- Source was improperly seated in applicator. (2 events)
- Incorrect areas were treated. (1 event)
- Incorrect number of sources were loaded. (1 event)
- Leaking sources were discovered. (2 events)

C. Radiopharmaceutical Therapy

- Wrong radiopharmaceutical was administered. (3 events)
- Dosage was not assayed. (4 events)
- Patient was improperly identified. (1 event)
- Range switch for dose calibrator was set incorrectly. (1 event)
- The dosage of the radiopharmaceutical sent by the supplier was higher than the dosage ordered. (1 event)
- The dosage was improperly calculated. (1 event)

From November 1980 through December 1988, the NRC received 23 reports on diagnostic misadministrations involving I–131 that led to doses in the therapy range. In these misadministrations, patients were mistakenly administered 1 to 20 millicuries of iodine-131 with a resulting thyroid dose of about 1,000 to 20,000 rads. Many of the misadministrations demonstrated that the authorized user failed to review the medical history of the referred patient to determine the suitability of a particular clinical procedure. In many misadministrations, the referring physician, who is not a nuclear medicine expert, and the nuclear medicine technologist, who is not a medical expert, determine which radiopharmaceutical should be administered. Furthermore, in some misadministrations, technologists unfamiliar with the clinical procedure prescribed by the authorized user mistakenly administered a dosage that was not intended. It is apparent, therefore, that whenever radiopharmaceuticals capable of producing therapy doses are used, clear nomenclature, independent verification, and adequate training are essential.

Improved training of medical personnel who handle and administer byproduct material can reduce the potential for error. Training should clearly impress on each individual involved in medical use that clear communication of the prescribed medical use and the implementation of systematic checks to detect and prevent errors early in the process are essential for the delivery of quality care. All information integral to the diagnostic or therapeutic medical use, whether specific to the patient or to the clinic, should be carefully reviewed for clarity, applicability, and correctness. Each individual involved in the process should be instructed to ask for clarification if there are any unclear or nonroutine procedures or instructions.

Inattention to detail is often a significant factor in misadministrations. The NRC recognizes that this problem is not limited to medical use. Computerized radiation therapy treatment planning may reduce the number of mistakes in sealed source treatments, and "record and verify" systems that check teletherapy unit orientations and settings may reduce the number of mistakes in teletherapy administration. But even these systems must ultimately rely on quantities that are initially measured, recorded, and entered by workers.

Lack of redundancy means that there is no independent mechanism for detecting errors. Independent verification requires examination by a second individual of each datum entry, whether a physical measurement or a number copied from a table of values, as well as a check of arithmetic operations for correctness. Redundancy requires that two separate systems produce the same result. For purposes of planning radiation therapy, the best method for the early detection of mistakes may be a simple independent check. Independent verification may also need to be incorporated into procedures for measuring values of radiation parameters, treatment planning, and administering radiation to patients. In radiation therapy, for example, an independent auditor can detect mistakes in both process design and process application as well as recommend where a change in the process might reduce the chance of a future error.

These observations have led the NRC to some general conclusions regarding quality assurance. All medical use should be planned with the realization that individuals may make mistakes. Some simple aids may include using

tables and graphs that are clearly titled and easy to read, and using a written prescription. NRC inspections have revealed that about ten percent of teletherapy unit calibrations and periodic spot checks are incomplete. Checklists could be used to assure completeness.

Independent verification could be made an integral part of the design of the treatment process to detect errors. Some examples are: all entries and calculations in a treatment plan could be checked by an individual who did not develop the treatment plan; each patient's chart could be reviewed weekly to check for accumulated dose and implementation of prescription changes; and the teletherapy unit output could be checked periodically. Furthermore, the complete teletherapy process, including physical measurements, could be examined in detail occasionally by an expert in order to identify systematic mistakes and make system improvements.

A QA program that requires a physical measurement of the dose or amount of radioactivity actually administered to the individual patient would provide assurance that the administered dose is the same as the prescribed dose. Such measurements are currently required (10 CFR 35.53) for radiopharmaceutical therapy, using photon emitting radionuclides, and occasionally are done for some teletherapy cases, but because of expense or the unavailability of equipment, these measurements are not commonplace in sealed source therapy.

Voluntary Initiatives

The NRC is aware of voluntary initiatives to improve quality assurance. A notable example is the "Patterns of Care" study managed by the American College of Radiology. In addition to comparing prescriptions and survival rates for certain diseases at various therapy facilities across the nation, methods of calculating and measuring applied dose rates are examined for accuracy. Such an examination can detect whatever procedural flaws may be present as well as determine the precision and accuracy of day-to-day service. Furthermore, the American College of Radiology is currently developing a comprehensive Quality Assurance Program for volunatary use in radiation oncology.

The NRC encourages initiatives by the industry to develop consensus standards and will consider endorsement of them in its regulatory guidance at an appropriate time. However, because of the lack of enforceability, voluntary programs alone are not considered to be an adequate vehicle to ensure that the NRC objective of reducing unnecessary exposure from byproduct material will be met. Consequently, the NRC is considering this rulemaking.

Earlier NRC Efforts

This is not the first time the NRC has examined the matter of QA in medical use. In 1979 the NRC issued some QA requirements for teletherapy (see 44 FR 1722, published January 8, 1979). This rulemaking was precipitated by errors committed by a teletherapy licensee which ultimately affected a very large number of patients. The output of a teletherapy unit was incorrectly calculated and the licensee made no physical measurements to determine whether the calculation was correct. These errors resulted in cobalt-60 teletherapy being incorrectly administered to 400 patients. The 1979 rule addressed the circumstances surrounding that event but did not critically examine the entire radiation therapy process.

III. Proposed Rule on Basic QA Published in 1987

On October 2, 1987, the NRC published a proposed rule (52 FR 36942) that would require its medical use licensees to implement some specific basic QA practices to reduce the number of misadministrations involving the use of byproduct material in radiation therapy and the use of radioactive iodine in diagnostic procedures. This proposed rulemaking was based on an analysis of misadministrations reported to the NRC by its medical use licensees concerning errors in administering byproduct material. The result of the analysis indicated that most of the events originated in mistakes made by individuals. Public comments received on the proposed rule indicated that, although these proposed QA practices might reduce the number of such errors, the imposition of the prescriptive directions given in the 1987 proposed rule might interfere with the practice of medicine because the proposed rule did not afford sufficient flexibility for clinical practice.

In a public meeting held on January 26, 1988, members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an advisory body established for advising the NRC staff, also suggested that the 1987 proposed rule did not provide sufficient flexibility for clinical practice.

On April 7, 1988, members of the medical community, including several members of the ACMUI, briefed the Commission on their concerns regarding the 1987 proposed rule. They stated that a performance-based rule should be promulgated, rather than a prescriptive rule. They also suggested that a pilot program would be useful for determining whether the proposed QA steps would interfere with clinical practice. Furthermore, they stated that, under the existing NRC regulation, the definition of the term "misadministration" is unclear and that the related reporting requirements are confusing.

Subsequently, the NRC decided to develop a performance-based rule and a regulatory guide and, as a part of the same rulemaking, to review the term "misadministration" its scope and related reporting requirements. In addition, the NRC also decided to conduct a pilot program to determine the impact, and efficiency of the proposed basic QA program and procedures developed by licensees based on the draft regulatory guide.

On November 7, 1988, the NRC held a public meeting of the QA Subcommittee of the ACMUI to assist in the development of a proposed performance-based rule, regulatory guide, and pilot program. On January 30 and 31, 1989, the NRC staff held a public workshop to discuss drafts of a revised basic QA rule and a regulatory guide. Medical use licensees' personnel representing different disciplines (e.g., physicians, physicists, and technologists) were invited to participate in a round table discussion with the NRC staff. On March 3, 1989 the NRC staff also met with the American College of Radiology (ACR) to discuss the NRC's draft regulatory guide and the ACR's draft QA program. The ACR's draft QA program is a comprehensive model QA program that is designed to be readily adopted, in whole or in part, by ACR members.

The NRC staff has used the information provided in these meetings in developing the performance-based QA requirements and new reporting and recordkeeping requirements. These actions are combined in a single proposed rule that is being published for public comment. A draft regulatory guide containing general guidance for licensees to develop a QA program that would be acceptable to the NRC staff for meeting the performance-based QA rule is also being published for public comment.

The proposed amendment for a basic QA program is designed to complement other QA requirements contained throughout 10 CFR part 35. Examples of the existing QA requirements include: 10 CFR 35.50, "Possession, Use, Calibration, and Check of Dose

Calibrators"; 10 CFR 35.51, "Calibration and Check of Survey Instruments"; 10 CFR 35.632, "Full Calibration Measurements"; and 10 CFR 35.634, "Periodic Spot-Checks."

IV. Discussion of Proposed Regulatory Text

Section 35.2 Definitions

The NRC is proposing to clarify the term "misadministration" and to add the following terms: "basic quality assurance," "clinical procedures manual," "diagnostic event," "diagnostic referral," "prescribed dosage," "prescribed dose, "prescription," and "therapy event."

The NRC is proposing to modify the definition of "misadministration" in the regulations by defining "misadministration" as those occurrences specified in proposed §§ 35.33(b) or 35.34(b). The Commission believes that a misadministration is indicative of inadequate quality assurance on the part of the licensee, and as such, additional regulatory attention, including special inspections, additional analysis and evaluation, or other NRC action, may be appropriate. All of the diagnostic or therapy occurrences currently defined as misadministrations are retained in the proposed amendment except a separate reporting threshold has been established for brachytherapy. Misadministrations will be specified under separate sections relating to either diagnostic or therapy medical use. In addition, an error in teletherapy fractional dose and medical use involving the wrong target organ or site will specifically be listed as misadministrations.

The proposed amendment also adds the terms "diagnostic event" and "therapy event" to include the events specified in proposed §§ 35.33(a) or 35.34(a) for which a record or report is required. These events essentially involve, for example, deviations from the procedures in the licensee's basic QA program. The proposed amendment thus distinguishes between misadministrations, which involve certain errors in the administration of byproduct material (or the radiation therefrom), and other events that essentially involve deviations from procedures in the administration of the byproduct material.

The other six terms, "basic quality assurance," "clinical procedures manual," "diagnostic referral," "prescribed dosage," "prescribed dose," and "prescription," are proposed to clarify the regulatory requirements.

The Commission would especially appreciate public comment on the proper use of the term "misadministration." Should the term misadministration be reserved for the most serious events that would include overexposures resulting in death, serious injury, or occurrences resulting in receipt of substantially more than the prescribed dose (i.e., perhaps double the prescribed dose for a therapy procedure, or a dose in the therapy range for a diagnostic procedure)? How should "events" be distinguished from misadministrations"? Should the division of occurrences into "events" or "misadministrations" be done differently from those proposed in §§ 35.33 and 35.34?

Section 35.33 Records and Reports of Diagnostic Events or Misadministrations

The NRC is proposing to replace the existing 10 CFR 35.33, "Records and reports of misadministrations," with two sections: one for diagnostic events or misadministrations and the other for therapy events or misadministrations (§§ 35.33 and 35.34, respectively). Thus, depending on whether a diagnostic or therapy medical use is involved, licensees would be able to refer to one section of the regulations in order to determine whether an error in medical use constitutes a misadministration, a diagnostic event, or a therapy event, and to determine the related recordkeeping and reporting requirements. In the existing regulations, it is necessary to refer to one section (10 CFR 35.2) to determine what constitutes a misadministration and to another section (10 CFR 35.33) for the applicable recordkeeping and reporting requirements.

Paragraphs 35.33(a) and (b) set forth the types of diagnostic events or misadministrations, respectively, for which a record and, under certain circumstances, a report would be required, pursuant to §§ 35.33(c) and (d). The types of diagnostic misadministrations in proposed § 35.33(b) are essentially the same as the diagnostic misadministrations currently specified in the definition of "misadministration" in existing 10 CFR 35.2. In proposed § 35.33(a) three diagnostic events would be added. The first additional event, set forth in § 35.33(a)(1), is designed to identify any diagnostic medical use not authorized in the license. The other two additional events are designed to identify medical use without a prescription or a diagnostic referral [2] (in § 35.33(a)(2)) or without properly recording the radiation dose or radio-pharmaceutical dosage administered (in § 35.33(a)(3)). The NRC believes that prior to diagnostic administrations not involving I-125 or I-131, there must be a prescription or a diagnostic referral except under emergent situations; prior to diagnostic administration involving I-125 or I-131, there must always be a prescription. The prescription or the diagnostic referral is needed to communicate the instructions from the prescribing physicians to the individual administering the dose or dosage. Also, after the administration, a record must be made to indicate the administered dose or dosage. If these records are not properly completed, § 35.33(c) requires that the Radiation Safety Officer promptly investigate the cause so that actions can be taken to correct the deficiency in the QA program.

Paragraphs 35.33(c) through (e) specify the actions that a licensee would be required to take after the discovery of a diagnostic event or misadministration. Paragraph 35.33(c) requires an investigation by the Radiation Safety Officer. Paragraph 35.33(d) specifies the circumstances under which reporting of diagnostic events or misadministrations would be necessary. Paragraph 35.33(e) specifies the recordkeeping requirements. Although the requirements in these paragraphs are essentially the same as the requirements in the existing 10 CFR 35.33(c) and (d), there are certain changes, as discussed below. Paragraph 35.33(f) remains unchanged.

In proposed § 35.33(d), a requirement is added for the licensee to notify the patient if the diagnostic event or misadministration has the potential to cause serious harm to the patient. This change is being made to make proposed § 35.33(d) consistent with the patient notification provisions in the current regulations in 10 CFR 35.33(a) and proposed § 35.34(d). The NRC believes that if a diagnostic event or misadministration is serious enough to lead to a dose in the therapy range, then notice to the patient is also warranted, unless circumstances make notifying the patient inappropriate. Another change in § 35.33(d) is that provisions have been added describing the information that should be set forth in the written report, comparable to existing 10 CFR 35.33(b) and proposed § 35.34(d). A minor change is that the reference to NRC-Form 473 in existing 10 CFR 35.33(c) has been deleted from proposed § 35.33(d) since that form will probably be either superseded or updated to be consistent with the other modifications in the rule.

[2] The terms "prescription" and "diagnostic referral" are defined in the proposed § 35.2.

In proposed § 35.33(e), provisions have been added requiring that the licensee retain, in an auditable form, records of prescriptions, diagnostic referrals, and diagnostic clinical procedures for three years. These records may be part of medical records currently kept by the medical use licensees. These records are necessary to facilitate the inspection process.

Section 35.34 Records, Reports, and Notifications of Therapy Events or Misadministrations

The NRC is proposing to add § 35.34 that specifies reporting and recordkeeping requirements for therapy events or misadministration. Paragraph 35.34(a) lists five proposed therapy events for which records and a report to the licensee management would be required, and under certain circumstances, a telephone notification and a written report to the NRC would also be required. Paragraph 35.34(b) lists therapy misadministrations for which notification of licensee management and a telephone notification and written report to the NRC would always be required. The therapy misadministrations listed in § 35.34(b) include the types of therapy misadministrations currently specified under the definition of "misadministration" in existing 10 CFR 35.2, as well as misadministrations related to teletherapy fractional doses and to brachytherapy.

Three therapy events (§§ 35.34(a)(1), (a)(2), and (a)(4)) are similar to those previously discussed under proposed § 35.33 but apply to therapeutic, rather than diagnostic, medical use. Paragraph 35.34(a)(1) provides that a therapy event includes a therapeutic medical use in which there was not both a prescription and a prior review of the patient's case by an authorized user or a physician under the supervision of an authorized user. Because a large radiation dose is involved in therapy cases, the NRC believes that both a prescription and a prior review of each patient's case are necessary before the byproduct material is administered.

An additional therapy event (§§ 35.34(a)(3)) is related to teletherapy fractional doses and is intended to alert the Radiation Safety Officer and the licensee management of minor deviations from procedures in the basic QA program so that actions can be taken to correct deficiencies in the QA program.

The first two therapy misadministrations (§§ 35.34(b)(1) and (b)(2)) are the same types of misadministrations specified in existing 10 CFR 35.2. The following therapy misadministrations (§§ 35.34(b)(3) and (b)(5)) are intended to clarify existing 10 CFR 35.2, Paragraph (6), which states that the definition of a "misadministration" includes "a therapy 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." This definition implies that the total treatment dose applies to a combined dose for teletherapy treatment and brachytherapy treatment if both modalities were administered to the same patient. In the proposed amendment, teletherapy events and brachytherapy events are specified separately, and criteria for fractional doses for teletherapy treatment fractions are provided.

Furthermore, on its face, the language in the existing definition addresses only errors in total treatment dose and does not explicitly address errors in fractional doses that may have occurred during any one of many teletherapy treatment fractions. This definition causes confusion about whether certain events should be reported (e.g., if there is a significant error in a fractional dose but the administered total dose is still within 10 percent of the prescribed total dose).

The proposed modifications relating to a teletherapy event (§ 35.34(a)(3)) and a teletherapy misadministration (§ 35.34(b)(3)) are designed to identify any one of the following types of overdose or underdose therapy events: for any treatment fraction, the administered fractional dose differs from the prescribed franctional dose by more than 20 percent of the prescribed fractional doze (§ 35.34(a)(3)) but less than the percentage of fractional dose set forth in § 35.34(b)(3)(ii); the total administered dose differs from the total prescribed dose by more than 10 percent of the prescribed total dose (§ 35.34(b)(i)); for any treatment fraction, the administered fractional dose is greater than twice or less than one-half the prescribed fractional dose (§ 35.34(b)(3)(ii)); or for the fractions administered to date, the sum of the administered fractional doses differs from the sum of the prescribed fractional doses by more than 10 percent of the prescribed total dose, i.e., the prescribed dose for all fractions, not just for the franctions administered to date (§ 35.34(b)(3)(iii)).

It must be emphasized here that the purpose of §§ 35.34(a)(3) and (b)(3) is to identify therapy events in which the administered dose is significantly different from the prescribed dose as a result of errors made in the source calibration, the time of exposure, treatment geometry, or other errors. Neither the current requirement nor the proposed requirement are intended to preclude a prescribing physician from properly changing the prescription if, based on medical judgment, such changes would benefit the patient. For the purpose of the reporting requirement, such a change will make the most recent prescription the prescription of record that supersedes the original prescription. For example, a prescribing physician might prescribe a certain fractional dose for the first few treatment fractions and later, depending on the reaction of the patient, might make a new prescription for a different dose for the remaining fractions. However, assume that a physician prescribes a fractional dose of 200 rads, and the licensee discovers after the fifth fractional dose is given that, due to an error, the administered fractional dose was 250 rads for each of the five fractions. Because the error in dose exceeded 20 percent of the prescribed fractional dose, regardless of whether a new prescription is written by the authorized user for subsequent fractions, the Radiation Safety Officer would be required to investigate the cause of the error, make a record for NRC review, retain the record as directed in § 35.34(f), and notify licensee management to take corrective action.

The following examples illustrate the kind of therapy events that fall within the scope of §§ 35.34(a)(3), (b)(3)(ii), and (b)(3)(iii). The prescribed total dose for a patient is 5,000 rads to be given in 25 daily fractions of 200 rads per fraction. If, as a result of an error, the patient is given less than 160 rads or more than 240 rads (but less than the percentage of fractional dose set forth in § 35.34(b)(3)(ii)) for any one fraction, such an event would constitute a therapy event under proposed § 35.34(a)(3). Under proposed § 35.34(c), the Radiation Safety Officer would be required to investigate the event and to report such an event to licensee management, but not to the NRC, the referring physician, or the patient because subsequent fractional doses could be adjusted to compensate for the error.

Under § 35.34(b)(3)(ii), using the same example given above, if the administered dose for any fraction is more than 400 rads (greater than twice the prescribed fractional dose) or less than 100 rads (less than one half of the prescribed fractional dose), the licensee would be required to report to NRC and

others as required under proposed § 35.34(d).

Paragraph 35.34(b)(3)(iii) addresses a therapy misadministration involving cumulative errors in fractional doses for several treatment fractions. Using the same example given above, if 16 fractions have already been administered, and the administered dose for each fraction is found upon recheck to have been 240 rads instead of the prescribed fractional dose of 200 rads, the sum of the prescribed fractional doses is 3,200 rads and the sum of the administered fractional doses is 3,840 rads. The difference is 640 rads, which exceeds 500 rads (10 percent of the total prescribed dose). The event would constitute a therapy misadministration under § 35.34(b)(3)(iii) and would be reported to NRC, the referring physician, and the patient (after conferring with the referring physician). Continuing the same example, if for 6 fractions the individual administered doses varied about 200 rads, i.e., 210, 190, 205, 195, 215, and 185, the sum of the administered fractional doses would be 1,200 rads, which would equal the sum of the prescribed fractional doses. This would not be a therapy misadministration under § 35.34(b)(3)(iii). In fact, any combination of such small variations is not reportable if the criteria of §§ 35.34(a)(3) and (b)(3) are not exceeded.

With respect to brachytherapy, if a sealed source is leaking or lost during the patient's treatment, questions have arisen whether this constitutes a "misadministration" under existing 10 CFR 35.2. To clarify the reporting requirement, § 35.34(b)(4) is being proposed to make it explicit that the definition of a therapy administration includes all cases in which a source is leaking during treatment, regardless of the cause, or in which a source is lost during treatment, or mistakenly is not removed from the patient upon completion of the treatment. Of course, for purposes of this regulation, sealed sources that are permanently implanted are not considered to be "lost."

Also regarding brachytherapy, the intent of § 35.34(b)(5) is to identify significant mistakes that are made during treatment planning or execution so that these mistakes may be prevented in the future. The sealed sources for brachytherapy are implanted inside the tissue or placed in close contact with the tumor. The dose distribution changes significantly with even a few millimeters change in distance from the source. In many instances, the physician may not be able to determine the exact size and shape of the tumor until the patient is in the operating room. During the implant operation, the physician may not be able to implant the sealed sources at the precise location planned. Therefore, the NRC believes that a criterion of a 20 percent difference between the prescribed treatment parameters and the administered treatment parameters (rather than 10 pecent) is appropriate for brachytherapy. This proposed requirement is not intended to preclude a physician from properly updating the prescription after the implant to reflect the actual loading of the sealed sources or from properly changing the prescription if, based on the medical judgment of the physician, such changes would benefit the patient.

Paragraphs 35.34(c) through (e) specify the actions that a licensee would be required to take after the occurrence of a therapy event or misadministration. These paragraphs are comparable to proposed §§ 35.33(c) through (e) for diagnostic events or misadministrations. The requirements in these paragraphs are substantially the same as the requirements currently specified in existing 10 CFR 35.33(a), (b), and (d). In § 35.34(f), provisions have been added requiring that the licensee retain, in an auditable form, records of prescriptions for three years. These records may be part of medical records currently kept by the medical use licensees. Paragraph 35.34(g) is the same as the existing 10 CFR 35.33(e).

Proposed § 35.34(h) retains the requirement to notify the patient or the patient's responsible relative (or guardian) when a misadministration involving a therapy procedure occurs. The Commission continues to believe that patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them. See "Misadministration Reporting Requirements," 45 FR 31701, 31702 (May 14, 1980). This is an important requirement which is parallel to other NRC requirements that licensees report to an individual certain radiation exposure data pertaining to that individual. Furthermore, Federal legislation, such as the Privacy Act of 1974, recognizes the right of individuals to learn information about themselves which is contained in the records of institutions both inside and outside of the Federal sector. The NRC encourages the authorized user or a physician under the supervision of the authorized user, upon obtaining the patient's consent or before administering the radiopharmaceutical or radiation, to advise the patient or the patient's responsible relative (or guardian) that a record of the treatment will be available if requested.

During the QA Subcommittee meeting held on November 7, 1988, an attendee from the medical community questioned the appropriateness of the dose criterion, which is based on a percentage of the prescribed total dose, for determining whether a therapy event must be reported to the NRC. As an alternative, the attendee suggested the use of a radiation tolerance dose for each specific organ as a criterion for determining whether an event must be reported. The attendee stated that since the tolerance dose is selected as the dose that might cause damage to an organ not in the treatment volume, any dose in excess of the tolerance dose should be reported.

The NRC staff has considered this comment. However, a criterion based on a percentage of the prescribed total dose has been retained for the following reasons:

(1) The NRC's purpose in requiring reporting errors in medical use is to identify their causes in order to correct them and prevent their recurrence. The NRC can expedite this by notifying other licensees if there is a possibility that they could make the same errors. Reporting is designed to identify events that could have generic significance for medical use licensees and to indicate whether a licensee has QA problems. The types of events that must be reported may indicate a breakdown in the licensee's QA program. Although a difference of 10 percent or more between the administered total dose and the prescribed total dose for teletherapy may not necessarily indicate harm to the patient, it exceeds the normal uncertainties of the treatment planning and delivery system. If the cause of the event is not determined and corrected, similar errors may occur in the future that could harm patients. Because the uncertainties in most teletherapy administrations are 2 to 3 percent, the staff believes the criterion of a 10 percent difference would avoid identifying events that are part of the normal uncertainties of the treatment planning and delivery system.

(2) The tolerance dose system may be unwieldy. If this approach were adopted, a table of the ranges of acceptable doses for each organ would need to be published. However, there would be many exceptions to the published dose ranges for a variety of reasons. The amount of tolerance to radiation depends on the specific organ, the dose rate, fractionation schedule, the volume exposed, oxygen supply within

the organ, heterogeneity of dose, the patient's age, adjuvant therapy, genetic makeup, and other medical conditions. When all these factors are taken into account, there is still a large uncertainty in what is currently known about individual organ tolerances. In some cases, based on a physician's medical judgment, exceeding the accepted tolerance dose to normal tissues or organs not in the treatment volume may be appropriate if the need exists to provide definitive treatment to a cancer that threatens the patient's life, that causes unendurable pain, or that causes unacceptable loss of normal life capacities.

In summary, the NRC believes that the proposed modifications in reporting and recordkeeping requirements would continue to address the purpose of the current regulations and to provide the NRC with information that may be used to assess the effectiveness of the licensee's basic QA program.

Section 35.35 Basic Quality Assurance Program

In 1987, the NRC published for public comment a proposed amendment to 10 CFR part 35 (52 FR 36942, October 2, 1987). The proposed amendment prescribed certain QA procedures that the NRC believed should be incorporated into each licensee's medical program to prevent the most common errors in medical use involving therapy and iodine. These QA procedures were based on a review of QA publications and case reports of the incidents. Many commenters stated that certain requirements in the 1987 proposed amendment might be disruptive, uneconomical, or difficult to comply with because of factors such as patient compliance, available staff, or medical care considerations. They recommended that, instead of prescriptive requirements, a performance-based amendment should be promulgated and that the details of the basic QA procedures should be left to the licensees.

The NRC has adopted this recommendation in this proposed amendment. The NRC would require that a medical use licensee establish a written basic QA program to prevent, detect, and correct the cause of errors in medical use.

A draft regulatory guide has also been prepared by the NRC staff. The regulatory guide provides guidance for licensees to develop a basic QA program that would be acceptable to the NRC staff for meeting the performance-based amendment (the proposed § 35.35). Many licensees may also have implemented a basic QA program that would substantially meet the requirements of proposed § 35.35. Medical use licensees will be expected to use the guidance in the regulatory guide as they develop a program specific for their clinical situation. However, a licensee may propose a basic QA program based on other source of guidance; the NRC staff would review these proposed QA programs on a case-by-case basis.

Under the 1987 proposed rulemaking, specific QA procedures would have been applied only to radiation therapy and to diagnostic procedures involving radioactive iodine. However, under this broad performance-based amendment, the QA program will cover all diagnostic and therapeutic procedures because a licensee has the responsibility to administer the prescribed dose or dosage to the correct patient in the manner prescribed. The NRC recognizes that implementation of a basic QA program is more likely to have the desired effect if it establishes a consistent performance requirement for the organization and all personnel involved in the medical use. NRC would appreciate comment on whether exemptions to the proposed QA requirements should be granted to medical use licensees who only perform diagnostic procedures and do not possess I-125 or I-131.

V. Enforcement

In addition to amending the regulations to require medical use licensees to establish a written basic QA program covering both diagnostic and therapeutic procedures and clarifying, modifying, and strengthening the misadministration reporting requirements, the Commission intends to modify the NRC Enforcement Policy in 10 CFR part 2 in conjunction with the final rulemaking. The Commission views the occurrence of misadministrations and other reportable events as evidence of inadequate quality assurance in the medical use of byproduct material and may subject the licensee to enforcement action. The enforcement policy will be modified by amending current examples dealing with misadministrations and adding specific examples of violations of the Commission's QA requirements to Supplement VI of Appendix C to 10 CFR part 2.

Such examples would include: At Severity Level I, failure to follow procedures in a QA program that results in a death or serious injury to a patient; at Severity Level II, failure to follow procedures in a QA program that results in substantial overexposure to the patient; at Severity Level III, failure to establish a written QA program, failure to conduct adequate audits of a QA program or take prompt corrective actions for deficiencies identified through such audits, failure to follow procedures of a QA program that results in therapy misadministrations, failure to follow QA program procedures that results in a number of diagnostic misadministrations over the inspection period, or a recurrent violation from the previous inspection period that results in a diagnostic misadministration, and failure to make a report as required by proposed § 35.34(d) or (e); at Severity Level IV, failure to follow procedures of a QA program not amounting to Severity Level I, II, or III, or other violation resulting in a diagnostic misadministration, and failure to make a report as required by proposed § 35.33(d).

VI. Implementation Plan and Agreement State Compatibility

The NRC is proposing the effective date of the amendment to be six months after the publication date of the final amendment in the Federal Register. On or before the effective date, all medical use licensees must have their basic QA programs developed and implemented, and submit to the NRC a written certification that the QA program has been implemented. As part of NRC's inspection program, NRC contract inspectors will determine whether the QA program has been fully implemented. An application for a new medical use license or renewal submitted to the NRC will have to include a written basic QA program as part of the license application. Medical use licensees will be subject to the revised reporting and recordkeeping sections of the amendment on the effective date.

Because the proposed amendment has safety significance for the Agreement State licensees as well as the NRC licensees, it will be a matter of compatability for the Agreement States.

VII. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this amendment, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendment would require NRC medical use licensees to establish a written

basic QA program to prevent, detect, and correct the cause of errors in medical use. The proposed QA requirements and a regulatory guide have been developed to include generally accepted good practices in basic medical quality assurance and include specific measures intended to prevent many of the kinds of human error observed and reported to the NRC over a number of years. Based on analysis of reported therapy misadministrations the Commission expects that the proposed requirements will provide assurance that the safety of patients involved in medical use will be enhanced by reducing the frequency of certain types of misadministrations. The NRC is also proposing to modify the reporting and recordkeeping requirements for medical use.

The proposed amendments, if adopted by the NRC and implemented by licensees, would likely result in fewer errors in medical use and, thus, would likely reduce unnecessary radiation exposures. It is expected that there would be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the dose to the patient. The draft environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC. Single copies of the draft environmental assessment and the finding of no significant impact are available from Dr. Tse (see **ADDRESSES** heading).

Paperwork Reduction Act Statement

This proposed amendment modifies information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This rulemaking has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Public reporting burden for this collection of information is estimated to be about 64,650 hours per year (for 2,500 NRC licensees and 5,000 Agreement State licensees) or an average of about 9 hours per licensee, including the time for reviewing instructions, searching existing data sources, collecting and maintaining the data needed, and reviewing the collection for completeness. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch, Division of Information Support Services, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Paperwork Reduction Project (3150-0010), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis for the proposed amendment. The analysis examines the benefits and impacts considered by the NRC. The draft regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW., Lower Level, Washington, DC. Single copies are available from Dr. Tse (see **ADDRESSES** heading).

The Commission requests public comments on the draft regulatory analysis. Comments are specifically requested on (a) factors affecting the balance between benefits to patients from lower rates of human errors and the values of resources that would be needed to produce these lower rates and (b) whether these resources could be used in other ways to better optimize patient safety and treatment than could be accomplished through development and implementation of QA programs for medical use. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this amendment, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed amendment affects about 2,500 NRC medical use licensees under 10 CFR part 35. Of these, about 2,200 licenses are issued to institutions and 300 are issued to physicians in private practice. Under the size standards adopted by the NRC (50 FR 50241, December 9, 1985), some medical use licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act (average gross annual receipts do not exceed $3.5 million for an institution and do not exceed $1 million for a private practice physician). The number of medical use licensees that would fall into the small entity category is estimated to be a very small percentage of the total number of licensees and does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The proposed amendment would require NRC medical use licensees to establish a written basic QA program to prevent, detect, and correct the cause of errors in medical use. The NRC is also proposing to modify the reporting and recordkeeping requirements relating to such medical use. The Commission believes that most licensees currently have a quality assurance program that is designed to prevent errors in medical use. Furthermore, all medical use licensees are currently subject to the existing reporting and recordkeeping requirements which, except for certain clarifications, are not significantly different from the proposed reporting and recordkeeping requirements. Therefore, there should not be a significant economic impact on these small entities. (See the Regulatory Analysis for the anticipated economic impact of this regulation on licensees.)

There is a potential that the gains in patient protection will outweigh the economic impact for medical use licensees, including the small entity licensees. However, because there are uncertainties in the analysis of these benefits and impacts, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which medical use licensees operate.

Any small entity subject to this regulation who determines that, because of its size, it is likely to bear a disproportionately adverse economic impact should notify the Commission in a letter that indicates the following:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to establish a QA program could be more effectively used in other ways to optimize patient safety, as compared to the economic burden on a larger licensee.

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee.

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of federal programs as opposed to providing special advantages to any individual or group.

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed amendment, and thus, a backfit analysis is not required for this proposed amendment, because it

does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

VIII. List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

IX. Text of Proposed Regulation

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 533, the NRC is proposing to adopt the following amendments to 10 CFR part 35.

PART 35—MEDICAL USES OF BYPRODUCT MATERIAL

1. The authority citation for part 35 is revised to read as follows:

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

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273): §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31(a), 35.35, 35.49, 35.50(a)–(d), 35.51(a)–(c), 35.53 (a) and (b), 35.59(a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)–(f), 35.75, 35.80(a)–(e), 35.90, 35.92(a), 35.100, 35.200(b), 35.204 (a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.630 (a) and (b), 35.632(a)–(f), 35.634(a)–(e), 35.636 (a) and (b), 35.641 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b., 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27 (a) and (c), 35.29(b), 35.33(a)–(f), 35.34(a)–(g), 35.36(b), 35.50(e) 35.51(d), 35.53(c), 35.59 (d) and (f)(2), 35.59 (g) and (i), 35.70(g), 35.90(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o., 68 Stat. 950, as amended (42 U.S.C. 2201 (o)).

2. In § 35.2, the term "misadministration" is revised and the terms "basic quality assurance," "clinical procedures manual," "diagnostic event," "diagnostic referral," "prescribed dosage," "prescribed dose," "prescription," and "therapy event" are added to read as follows:

§ 35.2 Definitions.

* * * * *

Basic quality assurance means, for the purposes of this part, the aggregate of those planned and systematic actions designed to prevent the occurrence of any error in medical use produced by, made by, caused by, or attributable to any individual acting on behalf of the licensee (including omissions or commissions).

* * * * *

Clinical procedures manual means a collection of written procedures in a single binder that describes each method (and other instructions and precautions) by which the licensee performs clinical procedures; each diagnostic clinical procedure approved by the authorized user for medical use includes the radiopharmaceutical, dosage, and route of administration.

* * * * *

Diagnostic event means any medical use for which a record, and under certain circumstances a report, are required pursuant to § 35.33(a).

* * * * *

Diagnostic referral means a written request dated and signed by a physician before a diagnostic medical use that includes the patient's name, diagnostic clinical procedure, and clinical indication.

* * * * *

Misadministration means any error in medical use as described in §§ 35.33(b) or 35.34(b) for which a record, and under certain circumstances a report, are required pursuant to §§ 35.33 (c) and (d) or 35.34 (c), (d), and (e).

* * * * *

Prescribed dosage means the quantity of radiopharmaceutical activity as documented before administration of the radiopharmaceutical, either (a) on the prescription or (b) in the clinical procedures manual if the procedure is performed pursuant to a diagnostic referral.

* * * * *

Prescribed dose (a) In teletherapy, means the quantity of the radiation absorbed dose stated on the prescription, as documented before administration, or (b) In brachytherapy, means the quantity of the radiation absorbed dose or equivalent stated on the prescription, as documented before administration and as revised to reflect actual loading of the source or sources immediately after implantation.

* * * * *

Prescription means a written direction or order for medical use for a specific patient, dated and signed by an authorized user or a physician under the supervision of an authorized user, containing the following information:

(a) For diagnostic use of radiopharmaceuticals: the radioisotope, dosage, chemical form, and route of administration;

(b) For radiopharmaceutical therapy: the radioisotope, dosage, physical form, chemical form, and route of administration;

(c) For teletherapy: the total dose, number of fractions, and treatment site; or

(d) For brachytherapy: the total dose (or treatment time, number of sources, and combined activity), radioisotope, and treatment site.

* * * * *

Therapy event means any medical use for which a record and a report are required pursuant to § 35.34(a).

* * * * *

3. § 35.33 is revised to read as follows:

§ 35.33 Records and reports of diagnostic events or misadministrations.

(a) A diagnostic event for which a record, and under certain circumstances a report, is required (as set forth in paragraph (d) of this section) consists of the following:

(1) Any diagnostic medical use not authorized in the license;

(2) Any diagnostic medical use without a prescription or a diagnostic referral; or

(3) Any diagnostic medical use without daily recording the administered radiation dose or radiopharmaceutical dosage in the appropriate record.

(b) A diagnostic misadministration for which a record, and under certain circumstances a report, is required (as set forth in paragraphs (c) and (d) of this section) consists of the following:

(1) Any diagnostic medical use other than the one stated in the prescription or in the diagnostic referral [1] and clinical procedures manual. Incorrect medical use would include treatment of the wrong patient, administration of the wrong radiopharmaceutical or radiation from the wrong sealed source, administration of a radiopharmaceutical or radiation to the wrong organ or site, or via the wrong or unintended route of administration; or

(2) Any diagnostic medical use such that errors result in an administered dosage differing from the prescribed

[1] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription or diagnostic referral would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.2 for a prescription or diagnostic referral) shall be made in the patient's record within 24 hours.

dosage by more than 50 percent of the prescribed dosage.

(c) For any diagnostic medical use that results in a diagnostic event or misadministration as described in paragraphs (a) and (b) of this section, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, retain the record as directed in paragraph (e) of this section, and notify the licensee management to take appropriate corrective action.

(d) The licensee shall notify the referring physician and the appropriate NRC Regional Office in accordance with 10 CFR 30.6 in writing within 15 days of the discovery of the diagnostic event or misadministration if it involved the use of byproduct material not authorized for medical use in the license, administration of a dosage differing by at least five-fold from the prescribed dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 0.5 rem. Licensees may use dosimetry tables in package inserts, corrected only for the amount of radioactivity administered, to determine whether a report is required. The written report must include the licensee's name; the prescribing physician's name, a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence, and for a diagnostic event or misadministration for which notification to the patient is required (as set forth below), whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report to the NRC must not include the patient's name or other information that could lead to identification of the patient. If the diagnostic event or misadministration involved the administration of iodine and has the potential to cause serious harm to the patient (e.g., a microcurie amount was prescribed but more than 1 millicurie was administered), the licensee shall also notify the patient or a responsible relative (or guardian) within 24 hours after the licensee discovers such a diagnostic event or misadministration, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. If the referring physician, patient, or the patient's responsible relative (or guardian) cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative (or guardian) without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of any delay in notification.

(e) Each licensee shall retain the following records:

(1) Each prescription, diagnostic referral, and record of administered radiation dose or radiopharmaceutical dosage, in an auditable form, for three years after the date of administration;

(2) Each written diagnostic clinical procedure, in an auditable form, for three years after its last use; and

(3) The report of each diagnostic event or misadministration for ten years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

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

4. § 35.34 is added to read as follows:

§ 35.34 Records, reports, and notification of therapy events or misadministrations.

(a) A therapy event for which a record and report to licensee management are required consists of the following:

(1) Any therapeutic medical use without both a prescription [1] and a prior review of the patient's case by an authorized user or a physician under the supervision of an authorized user;

(2) Any therapeutic medical use without daily recording in the appropriate record the administered radiation dose or radiopharmaceutical dosage;

(3) A teletherapy administration from a sealed source such that errors in the source calibration, the time of exposure, treatment geometry, or other errors result in an administered fractional dose differing from the prescribed fractional dose by more than 20 percent of the prescribed fractional dose, but less than the percentage of fractional dose set forth below in paragraph (b)(3)(ii) of this section; or

(4) Any therapeutic medical use not authorized by the license.

(b) A therapy misadministration for which records and reports to the NRC and licensee management are required consists of the following:

(1) Any therapeutic medical use other than the one stated in the prescription, including treatment of the wrong patient, administration of the wrong radiopharmaceutical or radiation from the wrong sealed source, administration of a radiopharmaceutical or radiation to the wrong target organ or treatment site, or via the wrong or unintended route of administration;

(2) Any therapeutic medical use of a radiopharmaceutical such that errors result in an administered dosage differing from the prescribed dosage by more than 10 percent of the prescribed dosage;

(3) A teletherapy administration from a sealed source such that errors in the source calibration, the time of exposure, treatment geometry, or other errors result in any of the following:

(i) The administered total dose differing from the prescribed total dose by more than 10 percent of the prescribed total dose;

(ii) For any treatment fraction, the administered fractional dose being greater than twice or less than one-half of the prescribed fractional dose, or

(iii) For the fractions administered to date, the sum of the administered fractional doses differing from the sum of the prescribed fractional doses by more than 10 percent of the prescribed total dose;

(4) A brachytherapy administration with a sealed source that is leaking, is lost, or is unrecoverable during the brachytherapy treatment; or

(5) A brachytherapy administration such that errors in brachytherapy treatment planning or execution result in the prescribed dose differing from the administered dose by more than 20 percent of the prescribed dose.

(c) For any medical use that results in a therapy event or misadministration as described in paragraphs (a) and (b) of this section, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, retain the record as directed in paragraph (f) of this section, and notify the licensee management to take appropriate corrective action.

(d) For any medical use that results in a therapy event as described in

[1] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.2 for a prescription) shall be made in the patient's record within 24 hours.

paragraph (a)(4) or a misadministration as described in paragraph (b) of this section, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of 10 CFR part 20 no later than the next Federal Government working day after discovery of the therapy event or misadministration. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian) within 24 hours after the licensee discovers the therapy misadministration, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. If the referring physician, patient, or the patient's responsible relative (or guardian) cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative (or guardian) without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of any delay in notification.

(e) Within 15 days after an initial telephone report to NRC of a therapy event or misadministration, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician and shall furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (d) of this section. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, the actions taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative (or guardian) and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(f) Each licensee shall retain the following records:

(1) Each prescription and record of administered radiation dose or radiopharmaceutical dosage, in an auditable form, for three years after the date of administration; and

(2) The report of each therapy event or misadministration for ten years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence.

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

5. § 35.35 is added to read as follows:

§ 35.35 Basic quality assurance program.

(a) Each applicant or licensee under this part shall establish a written basic quality assurance program to prevent, detect, and correct the cause of errors in medical use. The objective of the basic quality assurance program is to provide high confidence that errors in medical use will be prevented. This basic quality assurance program must include written policies and procedures to meet the following specific objectives:

(1) Ensure that any medical use is indicated for the patient's medical condition;

(2) Ensure, prior to any medical use, that a prescription [8] is made for any therapy procedure and any diagnostic radiopharmaceutical procedure involving more than 30 microcuries of I-125 or I-131;

(3) Ensure, prior to any medical use, that a prescription or a diagnostic referral [8] is made for any diagnostic procedure not involving more than 30 microcuries of I-125 or I-131;

(4) Ensure, prior to any medical use, that the prescription or the diagnostic referral and clinical procedures manual is understood by the responsible individuals;

(5) Ensure that any medical use is in accordance with a prescription or a diagnostic referral and clinical procedures manual;

(6) Ensure, prior to any medical use, that the patient's identity is verified as the individual named on the prescription or the diagnostic referral;

(7) Ensure that any unintended deviation from a prescription or a diagnostic referral and clinical procedures manual is identified and evaluated, and

(8) Ensure that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

(b)(1) The licensee shall develop procedures for and conduct a comprehensive audit at intervals no greater than 12 months to verify compliance with all aspects of the basic quality assurance program. The licensee's management shall evaluate each of these audits to determine the effectiveness of the basic quality assurance program and promptly implement modifications within 30 days that will prevent the recurrence of errors in medical use. The licensee shall maintain records of each audit and management evaluation, in an auditable form, for three years.

(2) The licensee may make modifications to the approved basic quality assurance program without NRC approval only if the modifications do not decrease or potentially decrease the effectiveness of the basic quality assurance program. The licensee shall furnish the modification to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 within 15 days after the modification is made. Modifications that decrease, or potentially decrease, the effectiveness of the approved basic quality assurance program may not be implemented without prior application to and approval by the NRC.

(c)(1) Each applicant for a new license shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a basic quality assurance program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by (insert effective date) a written certification that a basic quality assurance program designed in accordance with this section has been implemented.

(3) Each license shall maintain the written basic quality assurance program, in an auditable form, for the duration of the license.

Dated at Rockville, Maryland, this 8th day of January, 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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[8] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription or diagnostic referral would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.2 for a prescription or diagnostic referral) shall be made in the patient's record within 24 hours.