

§ 1425.22 OMB control number assigned pursuant to Paperwork Reduction Act.

The information collection requirements contained in these regulations (7 CFR 1425) have been approved by the Office of Management (OMB) under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0560-0040.

§ 1425.23 Appeals.

A cooperative may obtain reconsideration and review of determinations made under this part in accordance with the appeal regulations set forth at Part 780 of this title.

5. Part 1421 of Chapter XIV of Title 7 of the Code of Federal Regulations is amended as follows:

PART 1421—[AMENDED]

A. Part 1421 is amended by removing the following Subparts and sections:

Subpart—1978 and Subsequent Crops of Flaxseed Purchase Program Regulations (§§ 1421.150–1421.158);
Subpart—Regulations Governing the

Wheat Reserve Program for 1981 and Subsequent Crops and Alternative Program for 1981 and Prior Crops of Wheat (§§ 1421.700–1421.714); and Subpart—Regulations Governing the Feed Grain Reserve Program for 1981 and Subsequent Crops and Alternative Program for 1980 and Prior Crops (§§ 1421.720–1421.734).

§ 1421.3 [Amended]

B. The first sentence of § 1421.3(a) is amended by removing the word "and" in paragraph (1) and inserting a semicolon in its place; and by removing the period in paragraph (2) and inserting in its place the following: "; and (3) which meets the eligibility requirements prescribed in 7 CFR Parts 12, 713, 718, 770, and 791."

PART 1434—[AMENDED]

6. Part 1434 of Chapter XIV of Title 7 of the Code of Federal Regulations is amended by revising § 1434.3(a) to read as follows:

§ 1434.3 Eligible producers.

(a) *Producer.* An eligible producer shall be a person (i.e., an individual,

partnership, association, corporation, estate, trust, or other legal entity) who: (1) Extracts honey produced by bees owned by the producer; (2) meets the eligibility requirements prescribed in 7 CFR Part 12.

PART 1474—[AMENDED]

7. Part 1474 of Chapter XIV of Title 7 of the Code of Federal Regulations is amended by adding paragraph (c) to § 1474.4 to read as follows:

§ 1474.4 Eligible borrowers.

(c) The applicant meets the eligibility requirements prescribed in 7 CFR Part 12.

Signed at Washington, DC, on October 7, 1986.

Milton J. Hertz,

Acting Executive Vice President, Commodity Credit Corporation and Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc 86-23085 Filed 10-15-86; 8:45 am]

BILLING CODE 3410-05-M

FRIDAY

Thursday
October 16, 1986

Part III

Nuclear Regulatory Commission

10 CFR Parts 30, 31, 32, 35, and 40
Medical Use of Byproduct Material; Final
Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 35, and 40

Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its regulations to modify the process for licensing and regulating the medical use of radioactive byproduct material. The revision will primarily affect hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential radiation safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the regulation provides a single source of requirements related specifically to the medical use of byproduct materials. The regulation also provides flexibility for licensees by allowing them to update their day-to-day radiation safety procedures without applying for and receiving a license amendment. The revised regulations provide for a more efficient method of regulating the medical use of byproduct material.

EFFECTIVE DATE: April 1, 1987. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 1, 1987.

ADDRESSES: Copies of the regulatory analysis, analysis of major issues, environmental impact assessment, and the comments received on the proposed rule may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the regulatory analysis, analysis of major issues, and environmental impact assessment are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Byproducts Material in Medicine
 - Use for Patient Care
 - State and Federal Regulation
- II. NRC'S Regulatory Program
 - Policy Regarding the Medical Use of Byproduct Material

- Current Licensing Practice
- III. Revision of the Regulatory Program
 - Overview
 - Codification of Requirements in the Regulations
 - License Application, Issuance, and Authority and Responsibility
 - Training and Experience Criteria
 - Enforcement
 - Amendments
 - Renewals
 - Summary of Changes in the Regulatory Program
 - Transition Policy for General Licensees
 - Transition Policy for Specific Licensees
- IV. Analysis of Comments
 - Overview
 - General Comments
 - Comments on Specific Sections
- V. Derivation Table
- VI. Administrative Statements
 - Finding of No Significant Environmental Impact: Availability
 - Paperwork Reduction Act Statement
 - Regulatory Analysis
 - Regulatory Flexibility Certification
 - Resolution of Petition for Rulemaking PRM 35-2
- VII. List of Subjects in 10 CFR Parts 30, 31, 32, 35, and 40
- VIII. Text of Final Regulations

I. Byproduct Material in Medicine

Use for Patient Care

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. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 10 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy 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 to be treated. An estimated 100,000 patients receive cobalt-60 teletherapy treatments from NRC licensees each year. Smaller, less radioactive sealed sources 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. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

Sealed radioactive 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

Twenty-eight States, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized by the Atomic Energy Act.) They issue licenses for the medical use of byproduct material, and currently regulate about 5,000 licensees. In non-Agreement States, the NRC issues licenses to medical institutions (mostly hospitals and clinics) and to individual physicians. These licenses authorize certain diagnostic and therapeutic uses of radioactive materials.

II. NRC's Regulatory Program

Policy Regarding the Medical Use of Byproduct Material

In a policy statement published February 9, 1979 (44 FR 8242), the NRC noted that it regulates the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public, regulates the radiation safety of patients where justified by the risk to patients, and minimizes its intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC does have the authority to regulate the medical use of byproduct material 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.

This revision retains NRC's current balance between adequate controls and undue interference in medical judgments. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could

result in the unwarranted or unsafe use of radiation.

Current Licensing Practice

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for licensing medical institutions and physicians for medical use. A license may be issued for one or more of six types of medical use. The types of use are defined in Groups I-VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar physician training and radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. Applications for a specific license are very detailed and contain the applicant's step-by-step radiation safety procedures, which are reviewed and approved individually by NRC.

NRC currently has about 2500 specific medical licenses (2200 hospitals and 300 physicians in private practice). Each year the NRC receives about 100 new applications, 500 license renewal applications, and 2,000 license amendment requests.

To help licensees design their radiation safety programs, the NRC has published many NUREG reports and regulatory guides that contain radiation safety guidance. These publications address three general areas: radiological health and safety, personnel training and experience, and facilities and equipment. Experience has shown that if licensees follow the guidance in the publications, the medical use of byproduct material generally poses no hazard to workers and the public.

Because of the potential radiation hazard to workers and the public, the specific license program that NRC uses to regulate medical use incorporates three regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and in conditions attached to individual licenses. Suggestions for good practice are contained in NRC regulatory guides and technical reports (NUREG's). For example, Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs,"¹ and NUREG-0267,

"Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable,"² contain many recommendations that the NRC believes are important for the safe use of byproduct material. The revision of Part 35 incorporates those recommendations, and also corrects the piecemeal fashion in which the regulations have been amended over the years to address specific problems.

When preparing a specific license application for review under the current licensing program, the applicant must include sufficient information to assure NRC reviewers that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step radiation safety procedures. In many cases, the procedures are edited versions of procedures described in Regulatory Guide 10.8.

When NRC receives the application, a licensing reviewer evaluates the applicant's training and experience, facility, equipment, and radiation safety procedures in detail. If the application is found to be incomplete or inadequate, a "deficiency letter" is sent to the applicant explaining what additional information is needed. Review of the application is not resumed until a written response from the applicant has been received. Staff studies indicate that about 40 percent of all applicants receive either a deficiency letter or a phone call for additional information. The need for deficiency letters stems from two sources. Guidance on what submissions are required to get a license is unclear and scattered in various documents. Application review practice must be conservative because the application and license comprise the basis for regulatory control. Deficiency letters are costly for the NRC and the applicant and greatly increase the time needed to complete licensing actions.

Street NW., Washington DC. Copies of active guides may be purchased at the current Government Printing Office price. A subscription service for future guides in specific divisions is available through the Government Printing Office. Information on the subscription service and current prices may be obtained by writing to the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082.

² Copies of NUREG's may be purchased through the U.S. Government Printing Office by calling (202) 275-2060 or by writing to the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and copying for a fee in the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for medical use of byproduct material in accordance with the program described in the application. Requirements in addition to those contained in the regulations are frequently incorporated in the license as conditions of use. Since the licensee must comply with conditions specified in the license, the license, rather than the regulations, is frequently used to regulate radiation safety in the day-to-day use of byproduct material.

The specific license is valid for five years. The license must be amended before methods of use or procedures may be added or changed, or before permitting additional physicians to use materials. Amendments to a specific license involve an application, review, and approval process similar to that for new licenses. Renewals are treated in the same manner as new license applications.

This regulatory process was appropriate during the evolution of the use of byproduct material in medicine. Radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, physician training curricula had not been established, and there were no formal training programs for nuclear medicine technologists. Therefore, it was necessary to regulate by reviewing each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment.

III. Revision of the Regulatory Program

Overview

NRC is modifying its regulation of the medical use of byproduct material. The Commission has revised the regulations to provide a single source of requirements specifically related to medical use of byproduct materials. Within the boundaries set by the regulations, NRC will allow medical licensees to make minor changes in their radiation safety procedures that are not potentially important to safety. Such changes are sometimes needed so licensees can make prompt use of new safety methods and also meet new needs caused by changes in the demand for various patient care services or changes in the number of patients served by the licensee. The revision of 10 CFR Part 35 is consistent with the Commission's general policy on medical use of byproduct material issued February 9, 1979 (44 FR 8242). As stated

¹ Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H

in the policy statement, "NRC will continue to regulate the medical uses of radioisotopes, as necessary, to provide for the radiation safety of workers and the general public."

Codification of Requirements in the Regulations

The proposed revision was published for public comment on July 26, 1985 (50 FR 30616). In the proposal, the NRC said it would simplify regulation of medical licensees by incorporating all medical use requirements into 10 CFR Part 35. These regulations would become the primary means of regulating the medical use of byproduct material. General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also continue to apply to Part 35 licensees.

The current license application process will be unchanged. The applicant still will complete Form NRC-313, which asks for the following information: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; what materials are requested; the purpose (in this case, "medical use"); the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management.

Licensees will not face significant new regulatory burdens in their radiation safety programs because, in most cases, the information submitted on Form 313 is transformed into license conditions. Under the revised regulations the license authorizes medical use of byproduct materials for specified types of use. A licensee's use of byproduct material is controlled by the regulations and by license conditions for sitespecific circumstances that can not be generically covered by regulations. This simplifies inspections for NRC because inspectors need only be familiar with one set of regulations rather than a different set of license conditions and radiation safety procedures at each facility.

License Application, Issuance, and Authority and Responsibility Radiation Safety Programs

New revisions of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and Draft Regulatory Guide TM 608-4,³

"Guide for the Preparation of Licenses in Medical Teletherapy Programs," which were distributed to licensees for comment, contain instructions on the type and extent of information that must be submitted based on the byproduct materials for which the applicant has requested a license. The regulatory guides also contain model procedures that the applicant can use to develop site-specific procedures. (Consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow a model radiation safety procedure developed by NRC staff with public comment and published in a regulatory guide. This method significantly reduces the amount of time NRC must spend reviewing radiation safety procedures.) The applicant mails the completed license application, with application fee, to the NRC office identified on the form.

The NRC staff will continue to review the application to determine whether the applicant's radiation safety program is sufficient to comply with the regulations. After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter that describes the apparent shortcomings in the applicant's program and requests clarification or correction. If the applicant's response to the deficiency letter is satisfactory, or if no deficiency letter was needed, the license will be issued.

In most cases license conditions will only be used to identify authorized users for each type of use, the Radiation Safety Officer, a teletherapy physicist if required, types of material authorized, possession limits for teletherapy units and brachytherapy sources, and areas set aside for byproduct material use. This regulatory scheme will not incorporate the current license condition requirement that licensees use byproduct material in accordance with the statements made in the application.

Major radiation safety program changes that are clearly potentially important to safety are listed in §§ 35.13 and 35.605 of the final rule; they will require a license amendment. This is required because such changes could significantly affect the public health and safety. Licensees will be free to make minor changes in their radiation safety programs that are not potentially important to safety after conducting an

internal review and approval process. This will allow each licensee to make prompt use of new safety methods and to adjust radiation safety procedures to meet new needs caused by changes in demand for patient care services or patient load. A list of radiation safety topics that should be considered when reviewing proposed changes appears in the new revision of Regulatory Guide 10.8. The right to make minor changes does not relieve the licensee from the requirement to comply with the regulations. For example, requirements to have certain equipment on hand and to conduct certain surveys at a certain frequency are required by regulation and cannot be changed. See the analysis of comments on § 35.31 for further discussion of this matter.

The regulations require specific training and experience for each type of use. Proposed authorized user physicians, teletherapy physicists, and Radiation Safety Officers will have to submit summaries of their training and experience. The NRC will review those individuals' training and experience against the standards in the regulation before authorizing them to work under the license. Consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individual's training and experience with the assistance of its Advisory Committee on the Medical Uses of Isotopes, and may issue the exemption as a license condition.

Training and Experience Criteria

The NRC notes that, as a separate project, it is reviewing its physician training and experience criteria. If it decides that changes might be in order, the proposed changes will be published for public comment as a separate rulemaking action.

Enforcement

Licensees will be cited for failure to meet the requirements of the regulations or license conditions (which will list, for example, authorized users, address of use, types of use, byproduct material and inventory limits, and site-specific limitations), failure to have on hand the written procedures required by the regulations, failure to follow the procedures on hand, failure to have the records required by the regulations, or failure to follow technically valid radiation safety procedures (examples: using an instrument that doesn't work, not determining instrument detection efficiency, not allowing an instrument enough time to respond, or making

³ Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future

draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Technical Information and Document Control. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

unsubstantiated assumptions in calculations). Use of material can be authorized either by license or by virtue of working under the supervision of an authorized user. Use without authorization would be a violation of the regulations and the Act, which would subject the licensee and individual to enforcement action.

Amendments

Under current regulatory policy, the application coupled with the licensee condition requirement to use material in accordance with the statements made in the application usually provides the basis for inspection citations. Now the regulations will contain sufficient prescriptive and performance criteria on which to base enforcement actions. Therefore, the NRC will allow a licensee to make minor changes in its radiation safety procedures that are not potentially important to safety after making an internal review to assure that the change complies with the regulations in Part 35 and in other parts of 10 CFR Chapter I.

However, amendments still will be required for some changes. The NRC will review the training and experience of each proposed authorized user, Radiation Safety Officer, and teletherapy physicist before the individual is listed on a license. A licensee's request to add a type of use (for example, adding radiopharmaceutical therapy to a license that authorizes radiopharmaceuticals for imaging) to an existing license will be handled as a new application. The authorized user's training and experience and the procedures needed in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

A request to leave one location of use and begin working in a new location, for example when moving a private practice to a new office or when moving into a new hospital building, will have to be supported by a complete new license application package.

Licensees that are already allowed to receive packages, prepare radiopharmaceuticals, and package waste at a central facility, but use the byproduct material at satellite locations, will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC will generally not authorize licensees to perform therapies, except low-level iodine therapies, outside medical institutions. This type of request

will be handled on a case-by-case basis.)

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material after the five-year license period the license must be renewed. The renewal application must completely describe the entire radiation safety program just as a new application does. If a radiation safety procedure, facility description, or equipment list that was submitted in the application or an approved amendment still accurately reflects that part of the licensee's program, the renewal applicant may simply make a clear reference to the previous submission. If the licensee has changed a procedure, or is using different equipment, a complete new description of the particular procedure or equipment must be submitted. The licensee may also take this opportunity to identify new authorized users or request wider authorization.

Summary of Changes in the Regulatory Program

In summary, the new regulation will require that licensees meet standards that are currently imposed by license conditions. The NRC will continue to review user training and experience. The NRC will review applicants' radiation safety programs, including the site-specific radiation safety procedures, for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to make minor changes in their radiation safety procedures that are not potentially important to safety after conducting an internal radiation safety review of each change. However, the right to change procedures does not relieve the licensee from the requirement to comply with the regulations. Amendment requests will generally be reviewed just as new applications are reviewed, but they may include by reference material contained in the original application and any previous amendments.

Transition Policy For General Licensees

The General License for Medical Use. The general license program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. The NRC believes it is no longer efficient to issue medical general licenses that allow the administration of byproduct material to humans. The tests authorized under § 35.31 have been superseded by newer procedures with greater diagnostic accuracy. These developments have been reflected by a

significant decrease in applications for general licenses.

To determine the status of general license use, the staff performed a telephone survey of 10 percent of the current registrants. The survey results indicated that less than 9 percent of all the current registrants still use material for medical use under a general license. Many general licensees are now using byproduct material under a specific license. Because of the low level of use of the general license, the NRC has concluded that it no longer serves a useful role in licensing the medical use of byproduct material.

The *in vivo* general license contained in current § 35.31 has been eliminated from the regulations. In the future, all medical use will be authorized by a specific license. Current general licensees, all of whom are physicians, will receive a specific license that will be incorporated into NRC's filing system for keeping track of specific licensees. However, these licensees will be limited to the clinical procedures described in the current § 35.31, and relieved, by license condition on a pre-printed license, from the requirements that are more burdensome than current requirements under the general licensee. The only action they will need to take is to respond affirmatively to an NRC notice that asks if they want to continue to have an NRC license that is limited to the clinical procedures authorized by the current general license.

The Commission will, under § 170.11(b), exempt these licensees from application and renewal fees as long as their programs are limited to the material uses described in current § 35.31. Under the new specific licensing system, former general licensees that want to make any changes in their programs, amend their licenses, or transfer them to other physicians, will have to apply for a specific license and will be subject to all the fees that apply to other specific licensees.

The Commission has decided to waive fees to former general licensees for the following reasons. General licensees do not now pay fees. About 90% of the 1,100 or so general licensees are inactive. Each year NRC receives only a very few requests for general licenses under § 35.31. There would be no NRC review time needed and only a minor NRC administrative cost to process these licenses. It would be unfair to charge these licensees the fees listed in 10 CFR Part 170, and it would be more costly for NRC to alter that fee structure than to grant the exemption.

The General License for in vitro use. The current Part 35 also grants a general

license for in vitro work described in § 31.11 to group licensees without requiring that they submit an in vitro registration form. The NRC will continue this program unchanged.

Transition Policy for Specific Licensees

Under the current regulatory program, the license document with the appended application is used to regulate each individual licensee. Because the requirements in the revision were taken from commonly used topical license conditions and from regulatory guidance that most licensees have incorporated into their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants that apply after the effective date of the regulations. Therefore, current licensees will normally be cited if they do not comply with the new regulations. However, because each current licensee's radiation safety program was reviewed individually and license conditions were tailored to meet the licensee's individual needs, there may be an occasional inconsistency between a license condition and the regulation (for example, a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually). There is no health and safety reason to undo these licenses to effect compliance with the regulation. To impose the regulation in addition to or in lieu of the license conditions would not provide for significant additional protection for the public health and safety. The Commission has decided to resolve possible temporary inconsistencies between license conditions and the regulation by providing in the regulation a transition period between the effective date of the rule and the expiration date of each license. During this transition period, if there is an inconsistency between a provision in a license (issued prior to the regulation) and the regulation, the license condition takes precedence over the regulation. Because the license conditions were reviewed from the perspective of overall safety and approved by the NRC, the inconsistency would not result in an increased risk to workers or the public.

In addition to the topical license conditions mentioned above (for example, sealed source leak test requirements, special bioassay requirements, radioactive patient surveys and release limits, or waste disposal restrictions), each specific license has an encompassing license condition that requires each licensee to possess and use licensed material in

accordance with the statements, representations, and procedures contained in the license application and in letters of clarification. Despite this encompassing condition, licensees would be allowed to make minor changes in their radiation safety procedures that are not potentially important to safety; permissible changes would be restricted to those identified in § 35.31, and the licensee would have to conduct the internal review required by that section.

In the case of record retention, the regulation will take precedence because, in the past, the Commission has not offered much guidance on this topic. If a record is substantively the same as a record described in the proposed regulation and the licensee has not stated a retention period for that specific record, licensees may adopt the retention period stated in the final rule. However, during the transition period, licensees still will have to comply with any record retention period required by a license condition that deals with a specific topic, or by another Part of 10 CFR Chapter I (for example Part 20). For example, surveys that provide the basis

for occupational dose records or measurements of effluent release are governed by Part 20. A license condition that requires retention of a particular record would only have been imposed for a specific public health and safety reason.

NRC does not currently review teletherapy physicist credentials, and does not identify the Radiation Safety Officer on the license. NRC will begin to review the credentials of the Radiation Safety Officer and Teletherapy Physicist and identify both of them just as it does now for authorized users. To add current licensees to this new scheme, licensees must submit the credentials for review and approval when the next amendment or renewal request is required. These individuals will be identified on the next license amendment.

IV. Analysis of Comments

Overview

The NRC analyzed all 113 comment letters that were received prior to drafting the final rule. Comments came from many different sources. A tally is provided in Table 1.

TABLE 1

Source ¹	PP	H	A	C	I	S	O	M
Comments submitted	18	42	8	10	6	22	2	5
ALARA	1	6	0	2	0	1	1	0
Minor changes	0	6	0	1	0	20	2	0
Misadministration reports	1	10	2	1	1	0	2	0
Technical comments	2	31	5	10	6	16	3	4

¹ PP-private practitioner; H-hospital; A-professional association; C-radiation safety consultant; I-individual; S-state regulatory program; O-Scientific organization; M-manufacturer.

Twenty-nine of the letters addressed training and experience criteria for diagnostic radiopharmaceuticals, an issue which the NRC stated in the Notice of Proposed Rulemaking was being handled as a separate project that will be published for public comment separately. Thirty-three complimented the agency on the completeness and clarity of the rule.

Many commenters addressed the three major issues raised by the proposed rule: the requirement to have an ALARA program, misadministration reporting requirements, and the provision that allows licensees to make minor changes in their radiation safety programs. Nine of the 11 comments received on the ALARA program requirement recommended that the requirement be placed on private practitioners as well as medical institutions. Two recommended either no change or lessening of the requirement. Of those that addressed the provision for minor changes in

licensees' radiation safety programs, individuals associated with state regulatory programs were unanimous in recommending that all program changes require license amendment. The other comments indicated satisfaction with the provision. Of the 17 letters that addressed the misadministration reporting requirement, 13 recommended deletion of the diagnostic misadministration reporting requirement, and 4 recommended no change.

The NRC mailed notices to all 1,100 general medical licensees that are licensed under the current § 35.31. Ten requested more information, and 5 indicated that they wanted a license that would allow them to continue their work. The Postal Service returned 141 of the notices as undeliverable.

General Comments

1. *Consolidation and clarification.* Commenters were almost unanimous in complimenting the agency for publishing

the proposed consolidation of requirements. Many endorsed the NRC's view that noncompliance is frequently born of ignorance rather than negligence, and that this problem is best dealt with by putting all requirements in one place. Furthermore, the timing of the revision is appropriate given the growth over the past two decades of the professional literature and various professional organizations.

2. *Word use.* In the notice of proposed rulemaking, the NRC clarified several terms of art that it proposed to use when dealing with medical licensees. Several comments were received.

Licensee. Several commenters noted that the regulations should be revised to allow contractors to do certain chores, noting that the regulation requires "the licensee" to perform certain tasks, while in practice licensees frequently hire outsiders to perform these tasks. The NRC stated in the Notice of Proposed Rulemaking, "The person (individual, partnership, corporation, or agency) listed on the license as the 'licensee' is responsible for compliance with regulations and license conditions. The licensee may effect compliance through full-time or part-time employees, contracts with consultants or service organizations, or other business arrangements. The word 'licensee' is used throughout the regulation to stress the fact that, no matter which method is used, the licensee is legally responsible in case of noncompliance." Therefore, there is no need to revise the regulations in this regard.

Operable. Some commenters suggested that the word "operable" should be inserted "where appropriate to obviate the need, in the future, to constantly explain to licensees that meters must, in fact, be operable." The NRC can only repeat what was stated in the notice of proposed rulemaking. "The word 'operable' is not used in the proposed regulation because every piece of equipment must be operable. If a piece of equipment is not operable or reliable, whether due to old or absent batteries, incomplete or improper maintenance, damage, inappropriate use, or improper use, it cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used." The NRC repeats: Every piece of equipment used to meet a regulatory requirement must be operable.

Teletherapy physicist. The current Part 35 uses the term "qualified expert," which is usually used to denote an individual with special training and experience in a field determined in context by the reader. The proposed Part 35 used the term of art "qualified

teletherapy calibration expert" to denote the field of special expertise. The final regulation uses the less unwieldy term of art "teletherapy physicist." Although the terminology was changed, the functions of the individual have not.

Roentgen, rad, and rem. These base units are used to measure three different quantities: exposure, dose, and dose equivalent respectively. The NRC notes in 10 CFR 20.4(c) that a dose of one rem is equal to an exposure of one roentgen of x or gamma radiation or a dose of one rad of x, gamma, or beta radiation. In this final rule the NRC has used the base unit rem throughout.

Dose and dosage. In pharmacy, the word "dose" is used to indicate the amount of chemical administered; in radiation biology it is used to indicate the amount of ionizing energy absorbed per unit mass; and in radiation safety it is used as a shorthand term to indicate a worker's exposure to radiation. In order to avoid confusion, the word "dosage" is used in the revised Part 35 to indicate quantities of radioactivity that are measured with the base unit Curie. The word dose is used to indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit rad or rem.

Record and report. A record is a user-retrievable notation or complete document. It may consist of something as small as a check-mark on a form or something as extensive as a survey of a newly installed teletherapy unit with appended calculations to demonstrate compliance with the limits on exposure in unrestricted areas. A report is a transfer of information which might be made face to face, by telephone, telegram, computer link, or hard copy transmittal.

Test and check. For many pieces of equipment, drafting committees comprised of industry experts have prepared standards of performance and complete calibration protocols. If a piece of equipment is subjected to the protocol in the calibration laboratory and meets all the standards, then the ability of the equipment to perform as expected in normal field use is assured. In the revised Part 35, this concept of complete examination is referred to as a "test." During field use it is common practice to subject a piece of equipment to a quick examination to determine whether it is working. This procedure does not examine all parameters of equipment performance. In the revised Part 35, this perfunctory examination is referred to as a "check."

Address of use, facility, and area of use. The phrase "address of use" is used to describe the building or buildings (typically identified by a single street

address) where byproduct material is used. The word "facility" connotes a room or contiguous rooms where byproduct material is used, such as a nuclear medicine clinic comprised of an office, an imaging room, and a dosage preparation and waste storage room. The phrase "area of use" connotes the space used by a worker when performing a specific task connected with receiving, handling, or storing byproduct material.

Dedicated check source. A long-lived radioactive source can be used to check the day-to-day constancy of an instrument. The same source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

3. *Instruction.* Several commenters asked if instruction for workers had to be in classroom lecture format. The NRC recognizes that instruction can be in the form of lectures, laboratory exercises, audiovisual packages, printed handouts, preceptorials, or apprenticeships. The important point here is not the format of the instruction, but rather that the instruction be retained and used by the worker. To help correct misunderstandings, an opportunity for questions and answers should be an integral portion of each instruction module.

The NRC did not address the frequency of review sessions because that judgment must be made on-site. If employees are performing all their assigned tasks correctly, there is no need to spend time reviewing procedures with the employees. If instruction has not been followed by regular use of the procedures taught, then review instruction is probably necessary. If an employee is unable to do things correctly, then review and continued close supervision, or re-assignment, is necessary.

4. *Signatures on records.* Several commenters stated that the requirement that a certain individual sign a record or report implicitly required that individual to perform the survey, check, or test that is documented by the record or report. No such implication was or is intended. The NRC realizes that technicians, students, and residents do many of the tasks required by the regulations. The purpose of having a particular individual sign a report is to assure that someone with special training or radiation safety program oversight responsibilities has reviewed the document for correctness, completeness, and need for follow-up action.

5. *Temporary absence.* Several commenters asked if a license amendment or notification was required if an authorized user, Radiation Safety Officer, or Teletherapy Physicist was absent for illness, vacation, sabbatical, or continuing education. Because the specific facts and circumstances would dictate the appropriate action by the licensee, it would be impossible for the NRC to make generic determinations in advance of the situation.

The point can not be reiterated sufficiently that the licensee, despite the absence of personnel, remains responsible for assuring continued compliance with NRC radiation safety requirements.

6. *Deletion of the general medical license in § 35.31.* As noted in the discussion of the transition policy for general licensees for medical use, the general medical license, which authorizes a few radiopharmaceuticals for a few listed clinical procedures, is not frequently used and therefore no longer an efficient way of regulating the medical use of byproduct material. Thus, it has been deleted. However, current general medical licensees will be allowed to continue using materials under specific licenses that the NRC will issue.

7. *Fees.* One licensee said NRC should reduce its medical license fees when applicants propose to use radiation safety procedures that are published in regulatory guides because that reduces the time NRC needs to review the application. The comment can not be addressed in this rulemaking because the proposed rulemaking did not propose any changes to the fee schedule in 10 CFR Part 170. A petition for rulemaking to change Part 170 may be submitted.

8. *Records.* A few commenters said the detailed nature of some recordkeeping requirements ran counter to the philosophy of flexibility on which the revision is based, and may require a change in other administrative procedures. The NRC has retained the detailed prescriptive requirements that describe the information that must be included in each record. The NRC has carefully reviewed each element of data required and believes each is an important part of the record or indicates completion of an important step in a procedure.

Some commenters said a certain record requirement duplicated other records kept elsewhere—for example, diagnostic radiopharmaceutical dosages may be listed in a clinical procedures manual. There is no need to duplicate that information unless the regulation

specifically requires that the information be posted or recorded in a certain place.

The NRC notes that, as a separate rulemaking, it is reviewing *all* of its record retention requirements. Some of the retention periods in this final rulemaking may be changed as a result of that project, which will be published for public comment.

9. *SI Units.* A few commenters recommended that the newer International System of Units (SI), which has new units for amount of radioactivity, radiation exposure, radiation dose, and dose equivalent, be used in place of the special radiation units because the SI system is now being used more frequently. The NRC believes that, if indicated, such a change should be made through all NRC regulations at one time, not where it would affect only one group of licensees.

10. *Specialty certification.* Some commenters questioned whether certain physicians who have successfully completed an examination in a medical specialty (diplomates) should be authorized to serve as Radiation Safety Officer, and some recommended that other additional certifications be recognized. The NRC compared the examination criteria applied to diplomates to the responsibilities shouldered by certain individuals and made a judgment that the certifications identified for certain individuals provide an appropriate demonstration of adequate training and experience. Thus, some certifications have been added that were not listed in the proposed rule: American Board of Nuclear Medicine or Board of Pharmaceutical Specialties in Nuclear Medicine for Radiation Safety Officer; and American Board of Radiology for therapeutic use of radiopharmaceuticals.

11. *Training and experience criteria.* Several commenters recommended changes in the training and experience criteria the NRC applies to physicians who want to use radiopharmaceuticals for diagnostic clinical procedures. In the notice of proposed rulemaking the NRC noted that it had "received and is reviewing suggested alternative training standards for some methods of use. The review is being handled as a separate project. If any changes in training standards come out of that project, they will be published for public comment. . . ." The NRC is continuing to review recommendations for alternative training criteria; they will be published for public comment at a later date.

A few commenters said authorized users and Teletherapy Physicists should be at least "board eligible," meaning that they have training and experience sufficient to allow the individual to

apply for the certification examination. The NRC notes that most boards do not use this term (instead saying an individual is certified, not certified, or in the examination process), and believes the use of the term might create more confusion than it would resolve.

A few commenters said the required hour-by-hour distribution of content in the classroom and laboratory portions of the training and experience sections was overly restrictive, and would not recognize differences in students or programs. The NRC agrees, and has simply listed required topics, but has retained the *total time* requirements.

12. *Effect on medical broad licensees.* A few commenters said the NRC should indicate which sections apply to broad licensees authorized for medical use under Part 33; some are allowed to name authorized users and some are also allowed to develop new byproduct materials for medical use. The NRC has retained the solution to this question that was in the notice of proposed rulemaking, "These licensees would be required to comply with the proposed prescriptive and performance criteria of Part 35, but would be exempted from the training and experience requirements of Subpart J and the authorized materials and authorized use restrictions in proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500." These changes will not limit broad licensees' authority to conduct medical research and identify authorized users.

13. *Therapy patients.* One commenter suggested that requirements be drafted regarding the handling of deceased patients who had been administered therapeutic radiopharmaceuticals or implants. The NRC notes that § 35.404 requires that the licensee retrieve temporary implants. The regulations, in §§ 35.315 and 35.415, require prompt notification of the Radiation Safety Officer in case of the patient's death, who then is responsible for taking steps to ensure compliance with requirements in Part 20. In case of death after release from confinement for radiation safety purposes, the NRC expects licensees to take steps to reduce doses to pathologists, morticians, and other individuals, but also recognizes the licensee may no longer have control over the remains. Therefore, the NRC can not expect that the licensee is able to take appropriate action.

14. *Voluntary submission of economic data.* Several commenters noted that the application form asks applicants to indicate their annual receipts, number of employees, number of beds, and willingness to furnish additional cost information on the economic impact of

NRC regulations, and said this has nothing to do with NRC's responsibility to assure the public health and safety. The NRC notes that the Regulatory Flexibility Act of 1980 requires Federal agencies to fit requirements to the scale of the entity being regulated. That Act requires that each agency consider the economic effect of its regulations on small entities and that, if a proposed regulation will have a "significant economic impact on a substantial number of small entities," the agency prepare an analysis of the impact. Thus, the NRC requests voluntary submission of economic data to determine what portion of affected licensees are small entities, how they are affected, and whether the regulation could be changed to alleviate adverse effects.

Comments on Specific Sections

Section 35.14 Notification.

Comment: There is no need for a licensee with several authorized users to notify the NRC when one of them leaves. The collective expertise is still sufficient to assure the public health and safety.

Response: The NRC believes this notification is important because high turnover in professional staff may indicate inadequate management of the radiation safety program. The requirement has been retained.

Section 35.20 ALARA program.

Comment: All medical licensees should have such a program because the hazards are the same, whether in a hospital or a clinic. Although it may be burdensome, the private practitioners' programs should be reviewed by an outside consultant.

Comment: "It appears that the principle of ALARA is replacing maximum permissible dose as a standard in matters of radiation exposure. This means that an objective standard with a widely recognized and approved set of limits can no longer be relied upon in quality control and risk management. Instead, radiation exposure will be weighed, *post hoc*, by the 'reasonable man.'"

Response: The NRC agrees that individuals may have difficulty defining what is reasonable, although most can offer "reasonable" solutions to hypothetical problems. However, ALARA is an operating philosophy or principle on which safety programs should be based. It does not prescribe permissible exposure limits.

The NRC has broadened the requirement to apply to all medical licensees. Although on occasion this may result in a private practitioner

having a "one-participant conversation," the NRC believes that reviewing a radiation safety program from the perspective of worker protection rather than from clinical or business need may allow for insight or alternative methods that provide for increased safety. Moreover, the requirement for an ALARA program may help inculcate the philosophy of reducing unnecessary exposure in operating procedures.

The NRC agrees that an independent outside review may be helpful, but believes there is inadequate basis for imposing such a requirement. It is beyond the ken of a federal agency to know whether an outsider is needed to review the program managed by the Radiation Safety Officer.

Comment: There is no need for two trigger levels that initiate investigation of higher than usual worker doses; one is sufficient.

Response: The lower level initiates a timely investigation into the cause of a worker dose; the higher level initiates a prompt investigation and a review of viable mitigating actions because the investigation may indicate possibility of high worker dose or likelihood of unnecessary worker dose.

Section 35.21 Radiation Safety Officer.

Comment: It is unlikely that an authorized user/Radiation Safety Officer will have the time or inclination to do all the required tasks.

Response: The assigned responsibilities are essential elements of a radiation safety program. Because its inspection program has indicated a high degree of voluntary compliance, the NRC does not foresee adequate motivation as a problem. The NRC repeats that tasks, but not responsibility, can be delegated.

Section 35.22 Radiation Safety Committee.

Comment: The requirement that a licensee's Radiation Safety Committee approve each clinical procedure is unnecessarily burdensome. The NRC has acknowledged that physicians are motivated to act in the best interest of their patients, yet, because of the time needed to conduct the approval process, the physician may not be able to offer services needed by the patient. It is difficult to conceive of radiation safety issues that warrant this requirement.

Response: The NRC agrees that physicians need latitude to provide care for their patients. Once a physician has demonstrated training and experience adequate to safely use a group of materials with similar radiation hazards, an additional internal review is

unnecessarily burdensome. The requirement has been withdrawn.

However, to allow the Radiation Safety Committee to meet its oversight responsibilities, the authorized user should report these new diagnostic clinical procedures so they may be incorporated as part of the annual Radiation Safety Program review.

Comment: To avoid potential conflicts, the regulation should identify who should chair the Radiation Safety Committee.

Response: It is beyond the ken of a Federal agency to know which individual or officer in each of 2500 local organizations is best suited to chair a committee.

Comment: NRC should require that a radiopharmacist sit on each committee because medical use includes the use of new radiopharmaceuticals.

Response: FDA's review of new radiopharmaceuticals and package inserts provides adequate assurance that materials distributed for medical use can be used safely. Furthermore, diagnostic radiopharmaceuticals do not present a credible risk to the patient. Therapy radiopharmaceuticals are not compounded or reconstituted by medical licensees.

Comment: The proposed regulation would allow several committees to share the responsibilities of the Radiation Safety Committee. This may cause coordination problems.

Response: The NRC believes that allowing more than one committee to oversee the radiation safety program may lead to misunderstandings about jurisdiction and responsibility that result in incomplete oversight of the program. The section has been changed to call for a single committee. That committee may of course consult with other committees and individuals.

Comment: The Radiation Safety Committee should be allowed to name authorized users. Other committees in a hospital are allowed to confer certain medical privileges.

Response: The NRC considered this, but believes that an independent review of training and experience credentials is necessary to assure the public health and safety.

Section 35.23 Statements of authority and responsibilities.

Comment: The NRC should clarify the regulation to indicate that the Radiation Safety Committee and the Radiation Safety Officer should have not only technical responsibilities, but authority to assure that the policy is adhered to and that the radiation safety program is

managed in a businesslike and efficient way.

Response: The section has been modified to indicate that both must have the authority to manage the program so as to assure that materials are used in accordance with NRC regulations.

Section 35.25 Supervision.

Comment: There may be only one authorized user on a hospital's license. If the authorized user is absent, the hospital has to hire an authorized user from another area to care for the patients. There may be capable residents at a nearby medical college who cannot be hired only because they are not listed as authorized users on a license. Yet, they may have been supervised by the authorized user before and found capable of delivering proper care for patients.

Comment: The NRC should require that each physician authorized user and technologist be certified by the appropriate board. This would help assure that individuals have been trained.

Comment: Requiring the authorized user to be physically present on one hour's notice is arbitrarily stringent. Choose a more reasonable time.

Comment: There should be a time limit on use of the supervision clause with respect to a physician-in-training in order to avoid use of the supervision clause in lieu of licensure.

Response: The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety. The proposed requirement that the authorized user be immediately available by telephone and physically present on one hour's notice was an attempt at a prescriptive definition of supervision in the medical setting.

NRC recognizes that medical practice is regulated differently in each state, but that, in the end, the physician is responsible for providing quality medical care. A prescriptive definition that describes delegable tasks, timely response in case of untoward events, and training requirements that are suited for one setting may hinder the delivery of medical care in another setting. The authorized user physician identified on the license is responsible for delivering quality medical care, and is best situated to determine what tasks a certain physician or technologist is capable of performing and the amount of personal supervision that each needs.

Under the final regulation, a licensee may delegate to unnamed individuals

performance of any task associated with the medical use of byproduct material from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal. The delegations must be consistent with other institutional requirements and the state's regulation of medicine. The NRC did not retain the "immediately available by telephone and physically present on one hour's notice" clause.

The licensee can not delegate responsibility to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible.

The NRC believes this strikes the best balance between its responsibility to assure the public health and safety and a physician's responsibility to deliver quality medical care.

Section 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

Comment: The proposed requirement that mobile service not be provided to NRC-licensed hospitals because of clouded responsibilities eliminates an option a hospital needs for delivery of medical care in case of prolonged nuclear medicine department downtime. There could be significant delay in providing necessary clinical procedures and patients may have to be transported to another hospital. The regulation could result in inferior health care delivery to patients and could be counterproductive to health care cost containment.

Response: To respond to its charge to protect the public health and safety, it is appropriate for NRC to place restrictions on where and by whom byproduct material may be used. These restrictions make compliance more likely and corrective action simpler in case of hazards or noncompliance.

In this case, however, commenters properly pointed out that the regulation could have an adverse impact on the public health by making certain clinical procedures unavailable or inconvenient. The NRC's responsibility to assure public safety must be balanced with the responsibility of the NRC-licensed hospital-client of a mobile nuclear medicine service to provide care for its patients.

The regulation has been changed to allow mobile nuclear medicine services to provide service to NRC-licensed hospitals because they may need this option to provide timely medical care. However, when an NRC-licensed

hospital exercises its authority to invite a mobile nuclear medicine service to provide medical service, the NRC will deal with this as though the hospital has delegated tasks to another licensee. The NRC-licensed hospital, not the mobile nuclear medicine service, will normally be held responsible for items of noncompliance that occur at the hospital.

The same considerations and decision apply to NRC-licensed private practitioners who invite a mobile nuclear medicine service to provide service.

Comment: Can a mobile nuclear medicine service receive byproduct material at a client's address of use.

Response: This is not allowed because there is no assurance that the client knows what safety measures to initiate. The section has been clarified by adding a paragraph that clearly forbids such practice.

Section 35.31 Radiation Safety Program Changes.

Comment: Although the proposed section will relieve the licensing staff of some casework, the responsibility to assure that new radiation safety procedures are adequate will fall on the inspector's shoulders. An inspector does not have time to review procedures in the field, and will not have the opportunity to consult reference works or colleagues if necessary.

Comment: Many licensees do not have the expertise needed to properly review a proposed change. A licensee may unwittingly degrade a radiation safety procedure or the Radiation Safety Officer may be pressured into changing it; the degraded procedure could be in effect for years before an NRC inspection triggers its correction.

About 40 percent of amendment requests are deficient. This demonstrates that many licensees are not capable of making an adequate safety review of a proposed change. The NRC should reduce the scope of the term "minor change" or continue to review all changes.

Comment: The NRC is shirking its responsibility. Why is the NRC bothering to require applicants to submit radiation safety procedures if licensees won't be required to follow them?

Comment: A licensee should earn the authority to make minor changes. NRC should grant this authority case-by-case after examining a licensee's inspection history and radiation safety staff. Perhaps only those with certified physicists would be allowed to make changes.

Comment: Although the proposed policy will give management the opportunity to promptly implement new or better safety procedures, it may also allow for increased productivity at the expense of safety. Committee members might be removed without cause. This could be precluded by requiring licensees to notify the NRC of membership changes.

Comment: The Joint Commission on the Accreditation of Hospitals states that "The service of a health or radiation physicist should be available, at least on a consultant basis, for educational purposes and for safety evaluations of all equipment and storage and handling practices." This negates the argument made by some that inadequately trained hospital staff will make changes in radiation safety procedures without guidance.

While accreditation of hospitals is a voluntary system, it is important to note that if a hospital does not volunteer for accreditation, it cannot be reimbursed by Federal programs such as Medicare and Medicaid, and other insurance organizations will not reimburse that hospital either. Although this is a carrot and stick system, the stick is so large that very few hospitals are not accredited.

Therefore, national voluntary standards and business considerations provide alternative assurance that hospital licensees will not make untoward changes in their radiation safety programs.

Private practitioners and small medical institutions do not look for ways to change procedures so frequently because they are disinclined to change things if their most recent inspection was favorable and business is running smoothly.

Comment: NRC should clarify the distinction between major and minor changes. The examples given are extreme.

Response: Changes that require a license amendment are listed in §§ 35.13 and 35.606, License amendments. Before publishing the proposed rule, the NRC analyzed 5 percent of the requests for medical license amendments received in a one year period. A summary of the analysis appears in Table 1. The NRC believes the list of major changes that are potentially important to safety provides adequate guidance regarding those cases in which an amendment request must be submitted.

Table 1. Analysis of Medical License Amendment Requests

Number of completed actions that were analyzed.....	100
Number of requests that included a major change which would require an amendment under the proposed revision of 10 CFR Part 35.....	69
Users.....	51
Type of use.....	15
Address of use.....	5
Inventory.....	2
Number of requests for an administrative change, e.g., name change, change of address but not location, short-term extension, etc.....	6
Number of requests that included a minor change which would not require an amendment under the proposed revision of 10 CFR Part 35.....	37
Area of use.....	21
Replacement equipment.....	5
Equipment quality assurance procedures.....	11
Service contractor.....	8
Handling procedure.....	6

¹ Some requests contained both Major and Minor changes and therefore were tallied twice; thus the division by Major, Administrative and Minor does not add up to 100.

² The proposed rule would have allowed licensees to use byproduct material in areas of use that were not identified in the application. On further consideration the Commission believes that such changes are potentially important to safety and should be reviewed by the staff.

The NRC has clarified the concept of "minor change" by using a new word and providing a list of examples. Minor changes should be ministerial in nature. As used by NRC in this section, a ministerial change is one that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements are needed in the case at hand to assure the public health and safety. A licensee may not make discretionary judgments about things such as survey frequencies, minimum detectable amounts of radioactivity or dose rates, or what information constitutes a minimally adequate record of an action. The NRC has already made a discretionary judgment about such matters.

The examples provided in the regulatory text were taken from recently submitted amendment requests and staff suggestions. They are not the only kinds of minor changes that may be made. There will undoubtedly be unclear cases in which the licensee is not certain whether an amendment request should be submitted. In unclear cases, licensees may consult the licensing staff.

Before selecting a course, NRC reviewed its inspection and enforcement record for medical licensees. In 1985, the NRC took escalated enforcement action against 35 byproduct materials licensees. Only eight involved medical licensees, and none of those eight involved overexposures to workers or

the public. In 1982, NRC conducted 1,568 inspections of medical licensees. Almost all of the 1,240 line items that were cited were for minor safety infractions that did not represent a worker or public safety hazard. More recent data are similar. The NRC believes that its inspection findings demonstrate a high level of voluntary compliance with its requirements, whether they be couched in terms of regulations or site-specific license conditions.

The NRC believes the deficiency rate in the current application process is caused by having requirements scattered in several documents and not caused by ignorance of basic radiation safety practice. Thus, the deficiency rate is not a valid measure of a licensee's ability to design and operate a radiation safety program.

The NRC does not believe that administrators will pressure Radiation Safety Officers into compromising their programs. The impact of the adverse publicity that accompanies an escalated enforcement action far outweighs the potential short-term savings of a compromised program.

The NRC will provide, in Regulatory Guide 10.8, a list of questions that should be considered when a licensee makes an internal review of a proposed change. The NRC notes that many licensees use the services of radiation safety consultants to periodically review their programs now, and assumes that, in many cases, these consultants will also be asked to provide an independent review before a change is made. However, even absent an independent review, the NRC is convinced that safety will not be endangered by permitting licensees to make minor changes that are not potentially important to safety in their radiation safety programs.

The NRC notes that it currently receives about 800 requests for amendment each year from its 2,500 medical licensees for license amendments that are characterized as "minor changes" under this rule. This represents a minor radiation safety program change about once each three years for each licensee. The NRC does not believe it likely that licensees will make frequent changes in their radiation safety programs, even when spared the amendment fee.

The requirement to submit a detailed radiation safety program as part of the application process provides assurance that the licensee will have a program in place when byproduct materials are received. However, the NRC recognizes that a licensee's needs and resources change with time. At issue here is

whether a regulatory agency must approve minor changes in a licensee's day-to-day radiation safety program. Does a desk review of minor operational changes contribute significantly to public health and safety? The NRC is convinced that it does not.

The NRC believes the essential elements of a medical licensee's radiation safety program are well defined and have been consolidated in the regulation. The present review policy is resource intensive, causes backlogs due to the bulk of material submitted for review and the number of license amendments needed, and results in a different set of radiation safety requirements for each licensee. Inspectors may occasionally review changes to assure that the process required for making changes was followed. However, inspectors will examine the working day-to-day radiation safety program for compliance with the regulations.

The NRC believes this change in licensing policy provides both necessary flexibility by permitting licensees to make minor changes in their radiation safety programs and yet provides for NRC oversight of changes that might affect the public health and safety.

The NRC notes that the proposed rule would have allowed licensees to use byproduct material in areas of use that were not described in the application for license. The NRC now believes that such a change should require a license amendment because physical structures often provide features that are potentially important to safety. Such a change might also compromise NRC's ability to conduct an unannounced inspection.

Section 35.33 Records and reports of misadministrations.

Comment: The level of public emphasis that NRC has placed on misadministrations has proven to be an effective mechanism to limit their number. No change is needed.

Comment: At least to the extent that it deals with diagnostic clinical procedures, the misadministration rule should be deleted or substantially modified. The case for its deletion is made by the misadministration reports submitted to the NRC.

The misadministration rate for radiopharmaceuticals is much less than for non-radioactive drugs. The hazard to the patient is much less than that associated with the misadministration of physiologically active drugs or with other medical mistakes. In virtually all instances, the patient sustains neither actual nor theoretically significant

potential injury. The hazard to workers and the public is almost non-existent.

Misadministrations are precipitated by human error, such as momentary distraction or miscommunication, not radiation safety program deficiencies. Although a fail-safe system might be achieved through multiple levels of checking and cross-checking, the added costs would far outweigh the marginal benefit that would accrue to society.

Response: The NRC is well aware that the misadministration rate for radiopharmaceuticals is much lower than for other drugs, that there is no reporting requirement for misadministrations of cyclotron-produced radiopharmaceuticals, x-rays, and nonradioactive drugs, and that the risk to patients, workers, and the public is small. None of the assertions are at issue.

The fact that there are other greater potential hazards found in the medical arena does not relieve NRC of its responsibility to assure public health and safety as it may be affected by material under its jurisdiction. Rather, at issue is whether there is a safety problem, and, if so, can it be corrected at an expense that is reasonable compared to the hazard.

Therapy clinical procedures, in the view of the NRC, present a greater risk to the public and patients than diagnostic clinical procedures. Given the increased risk to the public health and safety, the reasoned judgment of the NRC requires the maintenance of the current misadministration rule for therapy uses of byproduct material. The NRC will continue to carefully review therapy misadministration reports. The NRC staff is also considering an advance notice of proposed rulemaking that would request public comment on regulations regarding quality assurance in radiation therapy as well as other NRC actions resulting from therapy misadministrations. This request for early public comment will be published at a later date.

The NRC believes that misadministrations that result in a dose to the patient greater than a dose to a member of the public permitted under § 20.105(a) should require a report to the NRC and the referring physician. Furthermore, licensees should keep records of all misadministrations. As a result, the diagnostic administration reporting requirement has been changed to require reports for misadministrations when such misadministrations result in a whole body dose greater than 500 millirem or an organ dose greater than 2 rem. (Licensees may use dosimetry tables in package inserts, corrected only

for administered millicuries, to determine whether a report is required.)

In order to assure that diagnostic misadministrations are not occurring in a particular licensee's program with excessive frequency, the NRC believes that there should be an internal investigation and report by the Radiation Safety Officer. The NRC will review these reports during its field inspections. In addition, the reports will assist the licensee in carrying out the ALARA principles of Parts 20 and 35.

Because of the public health and safety nature of the reporting requirement, the NRC will require Agreement States to implement compatible requirements.

Comment: While it should be retained, the therapy misadministration report trigger should be relaxed from 10 percent error to 20 percent error. That range better reflects the diversity of medical opinion on the optimum dose for a particular patient.

Response: The NRC has not changed its requirements that apply to therapy misadministrations because of their importance to public health and safety. The NRC reiterates that the 10 percent trigger level is *not* based on the diversity of medical opinion regarding the optimum radiation dose for a certain disease stage. Rather, the NRC recognizes there are uncertainties in the measurement and administration of radiation that make it impossible to demonstrate that the exact radiation dose that was prescribed was delivered. However, when the dose delivered is more than 10 percent different than the dose prescribed, it is clear that a mistake has been made. The mistake should be investigated and steps should be taken to prevent its recurrence.

Comment: NRC should take enforcement action against licensees who administer radioactive material when it might have serious consequences for the patient.

Comment: Enforcement actions may reduce compliance with the misadministration reporting requirement.

Response: The diagnostic misadministration reporting requirement will continue to require reports to the NRC for certain diagnostic misadministrations that are listed in the regulations. The reporting requirement for all therapy misadministrations has been retained.

The NRC deals with misadministrations case-by-case. Various levels of enforcement are available. It does not appear that NRC's enforcement program has caused

noncompliance in any area of its jurisdiction.

Section 35.50 Possession, use, calibration, and check of dose calibrators.

Comment: Does this possession and use requirement mean that even small licensees that use only precalibrated unit dosages of radiopharmaceuticals will have to buy a dose calibrator?

Response: The NRC believes that requiring licensees to ensure that the desired dosage has been prepared is essential to fulfilling its statutory responsibilities. The NRC recognizes that the overwhelming majority of its licensees use a dose calibrator to meet this requirement, and therefore, in the regulations, directly addresses their use. This does not prevent an applicant from proposing an alternative method for measuring dosages and requesting an exemption in the application. If the applicant is able to demonstrate that the alternative provides adequate accuracy and reliability, the licensee will be allowed, by license condition, to use the alternative method.

Comment: Is a volumetric determination of a dosage from a calibrated multi-dose vial an acceptable alternative method for measuring dosages?

Response: No. Any alternative must provide for the measurement of the amount of radioactivity in the individual dosage.

Comment: Sealed sources that are used for dose calibrator accuracy tests should be traceable to the National Bureau of Standards.

Response: The NRC reviews proposed label wording and traceability assertions before a manufacturer is authorized to distribute sealed sources. This provides adequate assurance of accuracy.

Comment: The regulation requires mathematical correction or repair if the dose calibrator shows inaccuracy greater than 10 percent; Regulatory Guide 10.8 has a 5 percent trigger level. Which is the requirement?

Response: The regulation imposes the requirement; the Regulatory Guide provides a method for meeting the requirement. The guide has a more stringent trigger level so the licensee can take action before the regulatory limit is passed instead of after. However, the licensee is not required to follow the Regulatory Guide. The licensee can specify an alternative method in the application. The NRC will review the alternative method to determine whether it provides adequate assurance of public health and safety.

Section 35.51 Calibration and check of survey instruments.

Comment: Not all survey instruments have a built-in check source. If an instrument is shipped to a calibration laboratory, the check source reading that is required at the time of calibration could be made instead when the instrument is returned.

Response: The NRC believes the check source reading made at the time of calibration is important to demonstrate that the instrument has not stopped operating properly since it was calibrated. Thus the source should accompany the instrument to the calibration laboratory. For instruments that do not have a built-in check source, the NRC notes that uncalibrated 10 microcurie Cs-137 sources are available for only \$25.

Comment: This requirement will increase personnel dose from handling the check source, and takes time. A daily or weekly check is sufficient.

Response: The NRC does not believe the check source presents a significant exposure source when compared to other sources in the laboratory, but agrees that a requirement to check instruments before and after each period of use may be unnecessarily burdensome. The section has been changed to require a daily check.

Comment: With all the errors inherent in measuring radiation, there is no need to calibrate a survey instrument within 20 percent; a factor of 2 would suffice.

Response: The NRC believes that a range of 20 percent provides adequate leeway in the calibration process. This is consistent with the recommendation in ANSI N323-1978, Radiation Protection Instrumentation Test and Calibration, section 4.2.2.1.⁴

Section 35.53 Measurement of radiopharmaceutical dosages.

Comment: Clarify when the measurement should be made.

Response: The NRC has purposefully not specified when the measurement must be made so as to allow for different licensees' procedural needs.

Comment: It is difficult to remove iodine-131 therapy dosage containers from their radiation shields and they should therefore be exempted from the measurement requirement.

Response: It is very important to assure that the manufacturer has supplied the prescribed therapy dosage so the patient will receive the prescribed radiation dose. The requirement to measure therapy dosages remains. The

majority of commenters did not mention difficulty making the measurement.

Comment: The NRC should allow the licensee to use the trade name or abbreviation in place of the generic name in the dosage measurement record. These alternative identifications are equally well-recognized.

Response: The alternative has been allowed.

Comment: The need for verifying the activity of manufacturer-supplied unit dosages is unclear.

Comment: Dose calibrators are too expensive to require their use for small programs.

Response: The NRC believes it is necessary to require an independent measurement, to the extent possible, to assure that the patient is receiving the prescribed dosage. Licensees that believe the expense of acquiring a dose calibrator is unwarranted may request permission to use an alternative method of assuring that the prescribed dosage is being administered.

Comment: The rule should not require the measurement of radiopharmaceuticals that emit only beta radiation. Such measurements are difficult when made in a calibration laboratory and tenuous when made in the clinical setting.

Response: The rule has been clarified only to require the measurement of photon-emitting radiopharmaceuticals.

Comment: It is not clear whether the proposed rule applies to brachytherapy sources.

Response: The proposed rule only applies to radiopharmaceuticals. The NRC recognizes that there are special problems associated with the measurement of brachytherapy source activity that must be worked out before a measurement requirement could be proposed.

Comment: It is not clear whether NRC expects licensees to suspend operations if the dose calibrator breaks.

Response: The NRC expects each licensee to measure dosages before administering them. Licensees may want to make arrangements that provide alternative measurement procedures in case of equipment breakdown.

Comment: The requirement to measure each dosage will increase technologist finger exposure.

Response: Any time radioactive material is handled there is the potential for exposure. The magnitude of the exposure must be balanced against the need to handle the material. NRC believes that the measurement is important because if the incorrect amount of radiopharmaceutical is administered to the patient, the

⁴ This report is available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

diagnosis or therapy may be compromised. The NRC believes its calculations and dose records of workers who measure dosages indicate that the amount of exposure is small compared to the benefit that comes with assurance that the correct amount of activity is being administered.

Section 35.57 Authorization for calibration and reference sources.

Comment: You should raise the sealed source design limit from 6 millicuries to 15 millicuries. These reference and calibration sources are needed by nuclear medicine clinics for quality assurance checks and do not pose a significant radiation hazard when used in that setting.

Response: The change has been made.

Section 35.60 Syringe shields and labels.

Comment: NRC should recommend, but not require, that licensees use syringe shields when drawing individual dosages. In some cases experience has revealed that only a leaded-glass syringe shield permits viewing the miniscus when drawing dosages—these syringe shields are expensive and fragile.

Response: No change has been made. However, the section has been reworded to clarify that syringe shields are only required when preparing radiopharmaceutical kits.

Comment: The open literature is ambiguous on the effectiveness of syringe shields.

Response: The NRC disagrees. Syringe shields may dramatically reduce finger dose ("Efficacy of various syringe shields for 99mTc," NL McElroy, *Health Physics*, v41 n3 pp 535-542, September 1981).

Comment: In some hospitals one individual draws a dosage and then immediately administers it. In this case a syringe label is not needed.

Response: The NRC does not believe this is an unreasonably burdensome requirement for the few licensees that fit that description. The NRC considered drafting criteria that addressed clinics with one technician but notes that, even in that case, some misadministrations have been caused by accidentally transposing syringes after drawing two dosages. Therefore, the benefits from avoiding misadministrations outweigh the costs to the licensee.

Comment: More information, such as amount of activity and time of syringe preparation, should be included on the label.

Response: The NRC believes the required information supplies sufficient

information to those handling the syringes.

Comment: The NRC should allow color coding of syringes with different radiopharmaceuticals rather than requiring the name or abbreviation.

Response: Different manufacturers use different color schemes for the same radiopharmaceutical. Allowing the use of color coding in place of labeling may lead to misadministrations. Therefore labeling is required.

Section 35.61 Vial shields and labels.

Comment: This label should also include the lot number, activity, and expiration time.

Response: This information may be included in the dosage measurement records, but is not required by NRC because these are matters of pharmacy.

Section 35.70 Surveys for contamination and ambient radiation exposure rate.

Comment: A licensee may occasionally administer a dosage in the patient's room. Is a survey necessary there?

Response: No. However, employees should be reminded to take care to collect all potentially contaminated material.

Comment: The regulation allows a licensee flexibility in setting removable contamination levels, then removes that flexibility by arbitrarily setting a sensitivity limit of 200 disintegrations per minute. Can't wipe samples be evaluated by holding them next to the GM tube of a survey instrument?

Response: The purpose of setting a sensitivity limit is to ensure that samples are not simply compared to the background counting rate of the measurement system; that comparison does not provide a measure of the amount of radioactivity on the sample. Action levels indicate when mitigating action should be taken. The regulation allows the Radiation Safety Officer to set different trigger levels for different areas of use because different levels of contamination are to be expected in different areas of use.

Comment: The sensitivity limit of 200 disintegrations per minute is unnecessarily restrictive.

Response: The NRC agrees. For most of the radionuclides used in medical use, a sensitivity limit of 2000 disintegrations per minute provides adequate assurance of public health and safety. (The NRC has retained the 200 disintegrations per minute limit for radiopharmaceutical therapy rooms. See § 35.315 Safety Precautions.)

Section 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

Comment: The NRC should require that patients released with residual radiopharmaceutical or permanent implants be provided information regarding the activity of the byproduct material so that special precautions can be taken if the patient is re-hospitalized elsewhere.

Response: The NRC believes the release criteria, which are similar to criteria recommended by NCRP (NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Chapter 4⁵) provide adequate assurance of safety. Although the suggestion is well taken, it seems most likely that the patient would visit a physician familiar with the patient's medical history. In case of emergency treatment there is no assurance the patient would be capable of reporting the information to the attending physician.

Comment: The proposed rule stated that the 30-millicurie release limit is based on NCRP guidance. In fact, NCRP provides a range of limits.

Response: The NRC meant to imply that the limit was based on considerations addressed in the subject chapter, not that it was adopting an NCRP recommendation.

Release limits are based on approximate dose rates emanating from the source-patient and time-at-a-distance assumptions for household members. Although the calculations are straightforward, the validity of the assumptions (biological half-life of the radioactive material in the patient for the radiopharmaceutical used, physical size of the patient, duration of proximity and exact distance of household members) for a specific case is tenuous. The NRC believes that a 30-millicurie release limit provides an adequate measure of public health and safety.

The alternative 6 millirem per hour criterion has been reduced to 5 millirem per hour to provide a more conservative and more easily remembered criterion. It is the approximate dose rate that would be expected from a patient with a 30-millicurie burden of I-131, the most radiotoxic byproduct material used for medical use.

⁵ This report is available from NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

Section 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

Comment: A ban on the mobile use of generators seems unnecessary.

Response: The NRC considered this when drafting the proposed regulation, but believed the greater public benefit accrued from the present system under which generators are received, stored, and eluted only at a base station. There were no commenters who demonstrated that this system deprives some members of the public of the benefits of diagnostic nuclear medicine, or that the requirement to use generators only in a base station is unduly burdensome.

Comment: Mobile service licensees should be allowed to reconstitute radiopharmaceuticals at a client's facility.

Response: The NRC recognizes that many radiopharmaceuticals should be used within six hours after reconstitution, and in some cases within one hour. Thus, it is possible that the proposed requirement for mobile diagnostic nuclear medicine services to transport only prepared radiopharmaceuticals may adversely impact the delivery of services because the licensee may not be able to reach all the day's patients within a few hours after reconstituting the radiopharmaceuticals at the base station. Therefore, the section has been reworded to allow licensees to transport radiopharmaceutical kits in addition to prepared radiopharmaceuticals.

Comment: You should not require quality assurance programs for imaging equipment. Quality assurance is the responsibility of the user.

Response: Nuclear medicine equipment is generally not designed for daily highway transportation (some nuclear medicine imaging equipment is designed to be transported within a hospital). The possibility of damage to the equipment during transportation might lead to useless administration of byproduct material. Thus, the NRC believes an equipment performance check prior to the administration of radiopharmaceuticals is indicated and is not unduly burdensome. No change has been made.

Section 35.90 Storage of volatiles and gases.

Comment: There is no apparent need for additional containment systems when storing xenon. The manufacturer's original packaging is sufficient. The ventilation posting requirement should take care of any problems.

Comment: Clarify what is meant by storing these materials "in a container with two barriers against release."

Response: The NRC has re-examined this proposed requirement and agrees with the comments. The NRC has determined that storage in the original shipping container will provide adequate control. This does not require retention of the entire package, but rather just the radiation shields and containers.

Section 35.92 Decay-in-storage.

Comment: The requirement to store waste for ten half-lives is unduly burdensome. The requirement that the container surface dose rate be at background is sufficient.

Response: This section allows for uncontrolled release of material that was contaminated with large amounts of radioactivity. Given that, the NRC believes that the storage requirement, which reduces the amount of radioactivity in the container by radioactive decay, coupled with a confirmatory survey is not unduly burdensome.

Sections 35.100 Use of radiopharmaceuticals for uptake, dilution, and excretion studies, and 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

Comment: The requirements to use diagnostic radiopharmaceuticals in accordance with the FDA-approved package insert should be removed. The risk associated with the administration of diagnostic radiopharmaceuticals is too small to justify a regulation that denies nuclear medicine practitioners the latitude needed to provide up-to-date medical care for their patients.

The package insert represents a summary of available scientific evidence indicating that a drug is safe and effective for a particular indication when used in accordance with the directions in the package insert. The FDA does not intend for the package insert to be a restrictive document; a physician may use any drug in any fashion deemed to be in the best interest of the patient. This is predicated on the assumption that physicians are motivated to act in the best interest of their patients.

New uses of approved radiopharmaceuticals are developed at medical research institutions and reported, along with safety and effectiveness information, in the scientific literature. However, the package insert is usually not updated because the process for revising a package insert is expensive and slow.

Manufacturers are not inclined to shoulder this burden because the additional sales that would result would not justify the expense of the revision.

Response: NRC's concern for worker and public health and safety must be balanced by the physician's need to provide proper medical services to the patient. The NRC believes that diagnostic radiopharmaceuticals have proven to be safe when handled by individuals with appropriate training. For diagnostic radiopharmaceuticals, the requirement to follow the package insert may have an adverse impact on the public health and safety because it prevents physicians from performing diagnostic clinical procedures needed by their patients, and is therefore withdrawn.

Comment: The NRC should not allow licensees to change the chemical form of a radiopharmaceutical.

Response: If a licensee altered the chemical form of a radiopharmaceutical, the modified radiopharmaceutical would be a new radiopharmaceutical that would not be the subject of an FDA acceptance or approval. Therefore it would not be authorized for use.

Comment: Why does NRC list approved radiopharmaceuticals in the regulations? It is only necessary to have a list available.

Response: The list has been deleted from the regulation; it will be available from NRC's regional offices.

Sections 35.120, 35.220, 35.320, 35.520, 35.620 Possession of survey instruments, and 35.420 Availability of survey instrument.

Comment: A low level survey meter cannot be used to survey around a stuck teletherapy source.

Comment: The NRC should require a low level meter for brachytherapy programs.

Response: Quoting at length from NCRP Report No. 57, Instrumentation and Monitoring Methods for Radiation Protection, Chapter 5, Instrumentation:

"If the dose equivalents are small compared to the maximum permissible value, then measurement errors by a factor of 2 are acceptable . . . For dose equivalents close to the maximum permissible value, an accuracy of about 30 percent is desirable . . . Most of the x-ray and gamma-ray exposure rate measurements . . . are made with small, portable ionization chambers . . . G-M counters are used in surveys for the detection of x- and gamma-ray fields. This generally limits their use to exposure rates in the range from background up to a few mR/h. . . The counters respond to the number of

ionizing events within them and give no information about the energy associated with the events. Therefore, they do not respond with equal count rates to equal exposure rates from photons of different energies. . . . They are generally used only for detection rather than measurement . . . G-M counters are sometimes used to estimate exposure rates where the rate is low enough for the resulting inaccuracy of its measurement to be unimportant. . . ."

The NRC has reviewed its rationale as stated in the notice of proposed rulemaking for requiring certain licensees to have certain survey instruments on hand or available. The only change that has been made is to require that brachytherapy licensees have a detection instrument on hand because it might be needed to find a lost brachytherapy source. The wording of each section has been revised to better indicate the range of dose rates the instrument must be capable of detecting or measuring.

Section 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

Comment: The NRC should not list xenon-133 in a group with radiopharmaceuticals that are administered by injection. The regulations should require agency approval of areas of use because there are special ventilation needs for its safe use.

Response: The training and experience needed for safe use and the radiological hazard of all the materials permitted under each subpart are similar. The NRC realizes that special ventilation is necessary for the safe use of gases and aerosols, and therefore placed additional requirements in § 35.205 Control of aerosols and gases.

Section 35.204 Permissible molybdenum-99 concentration.

Comment: The NRC notes that dose calibrators cannot measure accurately below 10 microcuries, yet proposes that radiopharmaceuticals not have more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m. How is this to be measured?

Response: The amount of Mo-99 in an elution of Tc-99m is usually measured, and recorded as a concentration of microcuries of Mo-99 per millicurie of Tc-99m, before using the elution. If the fresh elution has as little as 200 millicuries of Tc-99m, then the licensee need only demonstrate that there is less than 15 microcurie of Mo-99 in the elution. Note that this is one-half the allowed concentration; for sake of this

explanation the NRC assumes that the freshly eluted Tc-99m is administered over the next six hours, at which time, due to the radioactive decay of the Tc-99m, the Mo-99 concentration would be about doubled.

Comment: The NRC should require licensees to notify the NRC in case of excessive Mo-99 concentration. This could indicate a widespread manufacturing defect.

Response: Notification is required under 10 CFR 21.21(b).

Section 35.205 Control of aerosols and gases.

Comment: The need for negative pressure in a room where aerosols and gases are used is not apparent given the other safety measures that are required.

Response: The NRC disagrees. A patient who is having trouble breathing, is under mental stress, or is disoriented may remove the breathing mask that is used to administer the xenon gas and spill the dosage. Dispersion of a spill throughout the workplace, which would result if the room were at positive pressure, is not an acceptable cleanup method. The requirement has been retained.

Comment: Trapping units should be checked more frequently.

Response: The NRC notes that there has not been much study of breakthrough rates of collection systems that are used in the clinical setting. Given the simplicity of the procedure used to check for breakthrough. The NRC believes that a more frequent check may be beneficial and is not unduly burdensome.

Section 35.315 Safety precautions, and § 35.415 Safety precautions.

Comment: It is not necessary for the Radiation Safety Officer and authorized user to authorize each visit by an individual under age 18 on a case-by-case basis.

Comment: Visits by individuals under age 18 should only be allowed in special cases.

Response: The NRC did not mean to imply that each individual visit need be approved. Rather, the NRC recognizes that the benefits that might be derived by the patient must be balanced against the radiation dose incurred by the visitor. If the physician determines that the greater benefit derives from allowing visits, then a notation on the patient's chart or door that visits are allowed is all that is needed. No changes have been made.

Comment: The patient release criteria in § 35.75 may cause unnecessary radiation dose to members of the

patient's household and the public from patients who still have radioactivity.

Response: The sections have been modified to require the licensee to provide radiation safety guidance to the patient prior to release. "Guidelines for Patients Receiving Radioiodine Treatment," published by the Society of Nuclear Medicine, and NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,"⁷ provide appropriate guidance.

Section 35.315 Safety precautions.

Comments: The proposed rule appears to require that extensive safety precautions be taken when caring for any patient receiving radiopharmaceutical therapy while hospitalized. This does not differentiate between patients who receive low dosages and patients who receive high dosages.

Response: The wording has been revised to clarify that the safety precautions are only required when patients must be hospitalized until the amount of radioactivity in them is low enough to allow their release.

Comment: It is not necessary to measure the thyroid burden of personnel who administer encapsulated iodine-131.

Response: The NRC disagrees. It has been observed ("Contamination from Therapeutic I-131 Capsules," by D. R. Shearer, et al., *Health Physics* v49 p81, July 1985) that individuals who handle encapsulated iodine-131 may be exposed to levels of surface contamination for which thyroid monitoring is indicated. No change has been made.

Comment: Does the 2000 dpm/100cm² removable contamination requirement apply to patient rooms that are released for unrestricted patient use?

Response: No. Because of its greater radiotoxicity, the removable contamination limit for iodine-131 in patient rooms following completion of high level radiopharmaceutical therapy is 200 dpm/100cm².

Comment: This section should require a survey of the ambient dose rate in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20.

Response: The requirement has been added.

⁶ This publication is available through the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

⁷ This publication is available through NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

Comment: We administer several dosages of I-131 each week. A weekly measurement of the technician's thyroid burden would be sufficient.

Response: The regulation assumes administration of a therapeutic dosage is an occasional event. Those licensees who frequently administer I-131 may propose an alternative monitoring program that would be approved by license condition.

Comment: There is no need to quarter a radiopharmaceutical therapy patient in a private room. These patients can be quartered safely with teletherapy patients.

Response: The NRC disagrees. This would unnecessarily expose patient care staff and visitors for the teletherapy patient to removable contamination from the radiopharmaceutical therapy patient.

Section 35.400 Use of sources for brachytherapy.

Comment: The NRC should require source intensity checks for brachytherapy sources.

Response: The NRC considered this but is not convinced that the requisite equipment and procedures are readily available. The NRC may address this matter at a later date in a separate rulemaking proceeding.

Section 35.406 Brachytherapy sources inventory.

Comment: The requirement to count all the sources after returning to storage the few that were used will increase personnel dose.

Response: The licensee need only count the number of sources returned to storage, and add that to the number on hand to determine the total number in storage. There is no need to count each source that remained in storage.

Section 35.415 Safety precautions.

Comment: A hospital may have a radiation-shielded room designed for two brachytherapy patients. The proposed requirement to provide a private room for each patient would not allow it to efficiently use this resource.

Comment: Because the dose rate around an I-125 implant patient is only about 0.2 millirem per hour at one meter, there is no need for a private room.

Response: In the past, most licensees ensured low dose rates in uncontrolled areas by providing brachytherapy patients with private rooms. The NRC notes that some licensees have gone to the expense of shielding a room for these patients. Portable radiation shields specifically designed for brachytherapy use are now commercially available. Therefore,

shielding is available and provides an acceptable method of keeping doses in uncontrolled areas within limits. The section has been changed to allow quartering more than one radiation therapy patient in a room. Licensees are reminded that, for patient care staff and visitors, dose limits in Part 20 for workers and the public apply.

Because the dose rate around these I-125 implant patients is very low, the section has been revised to allow a licensee to quarter an implant patient with a patient who is not receiving radiation therapy if the licensee can show compliance with criteria for dose rates in unrestricted areas.

Comment: This section should require a survey of the ambient dose rate in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20.

Response: The requirement has been added.

Comment: The NRC should also prescribe radiation safety procedure requirements for cases in which the sources are loaded in other than the patient's room.

Response: The dose rate limits in Part 20 apply. In this case, the NRC cannot prescribe safety measures specifically suited to each licensee's needs.

Section 35.500 Use of sealed sources for diagnosis.

Comment: This subpart should also allow the use of bone mineral analyzers that use gadolinium-153.

Response: When the proposed regulation was drafted the NRC did not foresee the extent of medical interest that would develop regarding the gadolinium-153 scanner. However, several commenters recommended it be included here. The NRC has determined that the training and experience and radiation safety procedures needed for use of gadolinium-153 in a bone mineral analyzer are similar to those for other devices in this subpart. The NRC has added this device to this subpart.

Section 35.632 Full calibration measurements, and § 35.633 Periodic spot-checks.

Comment: Timer accuracy is not important because the same timer that is used in source calibration is used in patient treatments. Timer constancy is important and is indirectly checked each month by measuring the output. However, timer linearity need not be checked under the proposed regulation but is important because many dosimetry systems can only measure about 70 rads, while a single treatment dose may be much higher than this.

Response: The requirement to measure timer accuracy has been changed to timer constancy and linearity. The NRC agrees that constancy is indirectly checked by measuring the output, but believes that the additional assurance of accuracy that is provided by an independent check far outweighs the minimal cost.

Section 35.900 Radiation Safety Officer.

Comment: Authorized users have sufficient training and experience to oversee the management of a radiation safety program. To require an authorized user to be authorized for all of the types of use authorized by the license before being designated as the Radiation Safety Officer is unduly burdensome.

Response: The requirement has been modified to allow any authorized user listed on the license to serve as Radiation Safety Officer.

Comment: Revise the wording regarding the one year of full time experience you require so that a consultant who gets experience by working at several institutions over a year can be listed as Radiation Safety Officer.

Response: The NRC believes that the experience should be gained working full time at one institution because an individual serving as a consultant is not likely to be exposed to the day-to-day business management problems that must be effectively dealt with in a radiation safety program.

Comment: The grandfather clause in § 35.901 would require a Radiation Safety Officer to get additional training and experience if only one new material is added to a license.

Response: The NRC recognizes that new developments in medical care require changes in radiation safety procedures for which formal training of experienced individuals is unnecessary. Similarly, Radiation Safety Officers are capable of determining what requirements apply to the receipt, use, storage, and disposal of new byproduct material that comes under their jurisdiction. The requirement has been relaxed.

Section 35.930 Training for therapeutic use of radiopharmaceuticals.

Comment: The proposed rule requires that authorized users who are not certified have experience using soluble phosphorus-32 and colloidal intracavitary radiopharmaceuticals. These clinical procedures are not frequently performed, so it may not be possible for physicians to get the

required clinical experience.

Furthermore, physicians who only want to treat hyperthyroidism do not need experience treating thyroid carcinoma.

Response: The infrequently performed clinical procedures have been removed from the clinical experience requirement because experience with them would be difficult to obtain and they no longer reflect the current state of medical practice. New sections have been added delineating training and experience criteria for physicians who only want to treat either hyperthyroidism or thyroid carcinoma.

Section 35.961 Training for Teletherapy Physicist.

Comment: One cannot become expert in teletherapy physics after doing just one full calibration and working for just one year. The criteria should be more stringent.

Response: The NRC notes that the proposed regulation required one year of full time training and also one year of supervised full time experience. The NRC's training criteria are not designed to provide assurance of clinical expertise, but rather adequate assurance of public health and safety. The NRC believes this assurance can be gained with two years of full-time training and experience.

Section 31.11 General license for use

of byproduct material for certain in vitro clinical or laboratory testing.

Comment: The requirement to list in vitro use on the medical application will cause more confusion than letting the current system stand. It has proven adequate to assure protection of public health and safety.

Response: The NRC agrees that the current method is adequate. The section has been revised to reflect current drafting conventions but is, for practical purposes, unchanged.

Sections 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under group licenses, 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material, and 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

Comment: The NRC should not require manufacturers to pay an amendment fee to request approval of word changes on package inserts that are necessitated solely because of NRC's change in nomenclature. The NRC should also provide a transition period during which manufacturers may continue to use package inserts that are in stock.

Response: The NRC agrees. The final regulation simply prescribes the necessary wording. NRC expects manufacturers to incorporate this ministerial change in their programs, and will check for compliance during its inspections. A transition period has been added.

Comment: Because some of the old Part 35 groups were divided and some were amalgamated, you should provide a table that clarifies what a manufacturer can deliver to a medical licensee whose license is drafted in terms of the old Groups I-VI.

Response: A manufacturer may only deliver to a licensee the byproduct material authorized by the license. If a license only lists some of the materials in a subpart, the licensee is not authorized to receive the other materials in the subpart.

V. Derivation Table

The following derivation table identifies the origin of each section of the regulation. Origins of sections include current 10 CFR Parts 19, 20, 30, and 35, Federal Register Notices (FR), frequently used license conditions, licensing staff policy, current regulatory guides (RG), Office of Inspection and Enforcement bulletins, the United States Pharmacopeia, and new text prepared by staff.

Final section No.	Proposed section No.	Topic	Origin
Subpart A—General Information			
35.1	35.1	Purpose and scope	35.1 revised.
35.11	35.2	License required	35.2 revised.
35.8	35.8	Reporting, recordkeeping, and application requirements: OMB Approval	New text.
35.2	35.15	Definitions	
		Address of use	New term.
		Agreement State	20.3.
		ALARA	Acronym.
		Area of use	New term.
		Authorized users	Term used on licenses.
		Brachytherapy source	New term.
		Dedicated check source	New term.
		Dental use	New term.
		Dentist	New term.
		Management	New term.
		Medical institution	New term.
		Medical use	35.3(a) revised.
		Misadministration	35.41.
		Mobile nuclear medicine service	New term.
		Output	New term.
		Physician	35.3(b) revised.
		Podiatric use	New term.
		Podiatrist	New term.
		Teletherapy physicist	New term.
		Radiation Safety Officer	Term used on licenses.
		Sealed source	30.4(r) verbatim.
		Visiting authorized user	New term; similar to "visiting authorized user" license condition.
35.12	35.16	Application for license, amendment, or renewal	35.4 revised.
35.13	35.17	License amendments	New text; compare 30.38
35.14	35.18	Notifications	New text.
35.18	35.28	License issuance	New text; compare 30.36
35.19	35.29	Specific exemptions	New text; compare 30.11.

Final section No.	Proposed section No.	Topic	Origin
Subpart B—General Administrative Requirements			
35.20	35.30	ALARA Program.....	New text; see RG 10.8 Appendix O revised.
35.21	35.31	Radiation Safety Officer.....	RG 10.8.
35.22	35.32	Radiation Safety Committee.....	35.11(b) revised.
35.23	35.33	Statements of authority and responsibilities.....	New text.
35.27	35.34	Visiting authorized user.....	License condition.
35.29	35.35	Mobile nuclear medicine service administrative requirements.....	Licensing policy.
35.31	35.36	Radiation safety program changes.....	New text.
35.33	35.37	Records and reports of misadministrations.....	35.42.
35.25	35.38	Supervision.....	Expanded from RG 10.8 p. 3.
35.49	35.49	Suppliers.....	35.14 revised.
Subpart C—General Technical Requirements			
35.50	35.50	Possession, use, calibration, and check of dose calibrators.....	RG 10.8 Appendix D2 revised, and new text.
35.51	35.51	Calibration and check of survey instruments.....	RG 10.8 Appendix D1 revised and new text.
35.53	35.53	Measurement of radiopharmaceutical dosages.....	Proposed rulemaking 35.15 (46 FR 43840; Sept. 1, 1981).
35.58	35.58	Authorization for calibration and reference sources.....	35.14(d) revised.
35.59	35.59	Requirements for possession of sealed sources.....	35.14(e)(1)(i), 35.14(f) revised.
35.60	35.60	Syringe shields.....	Inspection and Enforcement letter Apr. 16, 1979.
35.61	35.61	Vial shields.....	Inspection and Enforcement letter Apr. 16, 1979.
35.60	35.62	Syringe labels.....	New text.
35.61	35.63	Vial shield labels.....	New text.
35.70	35.70	Surveys for contamination and ambient radiation exposure rate.....	RG 10.8 Appendix I revised.
35.75	35.75	Release of patients containing radiopharmaceuticals or permanent implants.....	New text.
35.80	35.80	Mobile nuclear medicine service technical requirements.....	Licensing policy.
35.90	35.90	Storage of volatiles and gases.....	RG 10.8 Appendix M revised.
35.92	35.92	Decay-in-storage.....	License condition.
Subpart D—Uptake, Dilution, and Excretion			
35.100	35.100	Use of radiopharmaceuticals, for uptake, dilution, and excretion studies.....	35.31 and 35.100(a) (Group I) revised.
35.120	35.120	Possession of survey instrument.....	RG 10.8 page 5.
Subpart E—Imaging and Localization			
35.200	35.200	Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.....	35.100 (b) and (c) (Groups II and III) revised.
35.204	35.204	Permissible molybdenum-99 concentration.....	US Pharmacopeia.
35.205	35.205	Control of aerosols and gases.....	RG 10.8 Appendix M revised.
35.220	35.220	Possession of survey instruments.....	RG 10.8 page 5.
Subpart F—Radiopharmaceuticals for Therapy			
35.300	35.300	Use of radiopharmaceuticals for therapy.....	35.100 (d) and (e) (Groups IV and V) revised.
35.310	35.310	Safety instruction.....	19.12 revised.
35.315	35.315	Safety precautions.....	RG 10.8 Appendix K.
35.320	35.320	Possession of survey instruments.....	RG 10.8 page 5.
Subpart G—Sources for Brachytherapy			
35.400	35.400	Use of sources for brachytherapy.....	35.100(f) (Group VI) revised.
35.404	35.404	Release of patients treated with temporary implants.....	35.14(b)(5)(vii) revised.
35.406	35.406	Brachytherapy sources inventory.....	RG 8.18 page 8.
35.410	35.410	Safety instruction.....	19.12 revised.
35.415	35.415	Safety precautions.....	RG 10.8 Appendix L.
35.420	35.420	Possession of survey instruments.....	New text.
Subpart H—Sealed Sources for Diagnosis			
35.500	35.500	Use of sealed sources for diagnosis.....	New text.
35.520	35.520	Availability of survey instrument.....	New text.
Subpart I—Teletherapy			
35.600	35.600	Use of a sealed source in a teletherapy unit.....	New text.
35.605	35.605	Maintenance and repair restrictions.....	License condition.
35.606	35.606	Amendments.....	New text.
35.610	35.610	Safety instruction.....	License condition and new text.
35.615	35.615	Safety precautions.....	License condition.
35.620	35.620	Possession of survey instrument.....	New text.
35.615	35.621	Radiation monitoring device.....	35.25 (48 FR 2115; January 18, 1983).
35.615	35.622	Viewing system.....	License condition.
35.630	35.630	Dosimetry equipment.....	35.22, 35.23 revised.
35.632	35.632	Full calibration measurements.....	35.21 revised.
35.634	35.633	Periodic spot-checks.....	35.22 revised and license condition.
35.641	35.641	Radiation surveys for teletherapy facilities.....	License condition.
35.636	35.642	Safety checks for teletherapy facilities.....	License condition.
35.643	35.643	Modification of teletherapy unit or room before beginning a treatment program.....	New text.
35.645	35.644	Reports of teletherapy surveys, checks, tests and measurements.....	License condition.
35.647	35.645	Five-year inspection.....	License condition.

Final section No.	Proposed section No.	Topic	Origin
Subpart J—Training and Experience Requirements			
35.900	35.900	Radiation Safety Officer.....	New text.
35.901	35.901	Training for experienced Radiation Safety Officer.....	New text.
35.910	35.910	Training for uptake, dilution, and excretion studies.....	New text.
35.920	35.920	Training for imaging and localization studies.....	Revision of Federal Register Notice (47 FR 53476; December 2, 1982).
35.930	35.930	Training for therapeutic use of radiopharmaceuticals.....	Revision of Federal Register Notice (47 FR 53476; December 2, 1982).
35.932	(New)	Training for treatment of hyperthyroidism.....	Recommended by commenters.
35.934	(New)	Training for treatment of thyroid carcinoma.....	Recommended by commenters.
35.940	35.940	Training for use of brachytherapy sources.....	Revision of Federal Register Notice (47 FR 53476; December 2, 1982).
35.941	35.941	Training for ophthalmic use of strontium-90.....	Revision of Federal Register Notice (47 FR 53476; December 2, 1982).
35.950	35.950	Training for use of sealed sources for diagnosis.....	New text.
35.960	35.960	Training for teletherapy.....	Revision of Federal Register Notice (47 FR 53476 December 2, 1982).
35.961	35.961	Training for teletherapy physicist.....	35.24 revised.
35.970	35.970	Training for experienced authorized users.....	New text.
35.971	35.971	Physician training in a three month program.....	New text.
35.972	35.972	Recentness of training.....	Revision of Federal Register Notice (47 FR 53476 December 2, 1982).
Subpart K—Enforcement			
35.990	35.990	Violations.....	New text.
35.999	35.999	Resolution of conflicting requirements during transition period.....	New text.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission is revising the regulations governing the medical use of byproduct material. 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 promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The radiation levels and release of byproduct material authorized by this regulation are consistent with the Commission's other regulations and internationally accepted standards. Most radiation experts agree that levels and releases that are within these regulations and standards will not have a significant effect on the quality of the human environment. The assessment analyzes the possible impact of release of radioactive patients, the transportation of byproduct material for medical use, storage and control of aerosols and gases, waste disposal by decay-in-storage, and dose rates outside teletherapy rooms. The environmental assessment and finding of no significant impact on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the environmental assessment and finding of no significant impact are

available from Mr. McElroy (see "**FOR FURTHER INFORMATION CONTACT:**" heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under OMB Number 3150-0010.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from Mr. McElroy (see "**FOR FURTHER INFORMATION CONTACT:**" heading).

Regulatory Flexibility Certification

In accordance with section 605(b) of the Regulatory Flexibility Act of 1980, the Commission certifies that this rule, will not have a significant economic impact on a substantial number of small entities. The NRC has issued approximately 2500 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 300 by individual physicians. Most of the institutional licensees are community

hospitals. The NRC has adopted size standards that classify a hospital as a small entity if its average gross annual receipts do not exceed \$3.5 million, and a private practice physician as a small entity if the physician's annual gross receipts are \$1 million or less. Under these size standards, some NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

The number of medical licensees that would fall into the small entity category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The primary objective of the rule is to simplify the medical licensing process by consolidating requirements without lessening the protection necessary for public health and safety. This has been accomplished by incorporating frequently used license conditions into the regulations and eliminating or modifying requirements that are not essential to the protection of public health and safety. These steps will make it easier for persons to determine what is required to obtain a license and what is required of licensees. Therefore, there should not be a significant economic impact on these small entities.

The Commission has prepared a regulatory analysis for this regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the regulation will not result in

significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from Mr. McElroy (see "FOR FURTHER INFORMATION CONTACT:" heading).

Resolution of Petition for Rulemaking PRM 35-2

The American Association of Physicists in Medicine filed a petition regarding dosimetry equipment calibration frequency (Petition Docket No. PRM 35-2; see 47 FR 4311, January 29, 1982). This rulemaking resolves that petition in § 35.630 Dosimetry equipment. The petition is granted essentially as recommended by the petitioner.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

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.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

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. 553 the NRC is adopting the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

VII. Text of Final Regulations

1. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A—General Information

Sec.

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.8 Information collection requirements: OMB approval.
- 35.11 License required.
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.18 License issuance.
- 35.19 Specific exemptions.

Subpart B—General Administrative Requirements

- 35.20 ALARA program.
- 35.21 Radiation Safety Officer.
- 35.22 Radiation Safety Committee.
- 35.23 Statements of authority and responsibilities.
- 35.25 Supervision.
- 35.27 Visiting authorized user.
- 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.
- 35.31 Radiation safety program changes.
- 35.33 Records and reports of misadministrations.
- 35.49 Suppliers.

Subpart C—General Technical Requirements

- 35.50 Possession, use, calibration, and check of dose calibrators.
- 35.51 Calibration and check of survey instruments.
- 35.53 Measurement of radiopharmaceutical dosages.
- 35.57 Authorization for calibration and reference sources.
- 35.59 Requirements for possession of sealed sources and brachytherapy sources.
- 35.60 Syringe shields and labels.
- 35.61 Vial shields and labels.
- 35.70 Surveys for contamination and ambient radiation exposure rate.
- 35.75 Release of patients containing radiopharmaceuticals or permanent implants.
- 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.
- 35.90 Storage of volatiles and gases.
- 35.92 Decay-in-storage.

Subpart D—Uptake, Dilution, and Excretion

- 35.100 Use of radiopharmaceuticals for uptake, dilution, and excretion studies.
- 35.120 Possession of survey instrument.

Subpart E—Imaging and Localization

- 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.
- 35.204 Permissible molybdenum-99 concentration.
- 35.205 Control of aerosols and gases.

- 35.220 Possession of survey instruments.

Subpart F—Radiopharmaceuticals for Therapy

- 35.300 Use of radiopharmaceuticals for therapy.
- 35.310 Safety instruction.
- 35.315 Safety precautions.
- 35.320 Possession of survey instruments.

Subpart G—Sources for Brachytherapy

- 35.400 Use of sources for brachytherapy.
- 35.404 Release of patients treated with temporary implants.
- 35.406 Brachytherapy sources inventory.
- 35.410 Safety instruction.
- 35.415 Safety precautions.
- 35.420 Possession of survey instrument.

Subpart H—Sealed Sources for Diagnosis

- 35.500 Use of sealed sources for diagnosis.
- 35.520 Availability of survey instrument.

Subpart I—Teletherapy

- 35.600 Use of a sealed source in a teletherapy unit.
- 35.605 Maintenance and repair restrictions.
- 35.606 License amendments.
- 35.610 Safety instruction.
- 35.615 Safety precautions.
- 35.620 Possession of survey instrument.
- 35.630 Dosimetry equipment.
- 35.632 Full calibration measurements.
- 35.634 Periodic spot-checks.
- 35.636 Safety checks for teletherapy facilities.
- 35.641 Radiation surveys for teletherapy facilities.
- 35.643 Modification of teletherapy unit or room before beginning a treatment program.
- 35.645 Reports of teletherapy surveys, checks, tests, and measurements.
- 35.647 Five-year inspection.

Subpart J—Training and Experience Requirements

- 35.900 Radiation Safety Officer.
- 35.901 Training for experienced Radiation Safety Officer.
- 35.910 Training for uptake, dilution, and excretion studies.
- 35.920 Training for imaging and localization studies.
- 35.930 Training for therapeutic use of radiopharmaceuticals.
- 35.932 Training for treatment of hyperthyroidism.
- 35.934 Training for treatment of thyroid carcinoma.
- 35.940 Training for use of brachytherapy sources.
- 35.941 Training for ophthalmic use of strontium-90.
- 35.950 Training for use of sealed sources for diagnosis.
- 35.960 Training for teletherapy.
- 35.961 Training for teletherapy physicist.
- 35.970 Training for experienced authorized users.
- 35.971 Physician training in a three month program.
- 35.972 Recentness of training.

Subpart K—Enforcement

- 35.990 Violations.

35.999 Resolution of conflicting requirements during transition period.

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

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), 35.49, 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), 35.120, 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), 35.633(a)-(i), 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)-(d), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(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(j), 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)).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

"Address of use" means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

"Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

"Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry 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.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

"Management" means the chief executive officer or that person's delegate or delegates.

"Medical Institution" means an organization in which several medical disciplines are practiced.

"Medical use" 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.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

"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 dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;

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

(6) 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.

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry 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.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Commission license.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a Commission license.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, Form NRC-313 is approved under control number 3150-0120.

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A

request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this Part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.27, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 30.6 of this chapter.

§ 35.18 License issuance.

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards

established by the Commission in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of Part 30 of this chapter.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements**§ 35.20 ALARA program.**

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

§ 35.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

- (i) Authorizing the purchase of byproduct material;
- (ii) Receiving and opening packages of byproduct material;
- (iii) Storing byproduct material;
- (iv) Keeping an inventory record of byproduct material;
- (v) Using byproduct material safely;
- (vi) Taking emergency action if control of byproduct material is lost;
- (vii) Performing periodic radiation surveys;
- (viii) Performing checks of survey instruments and other safety equipment;
- (ix) Disposing of byproduct material;
- (x) Training personnel who work in or frequent areas where byproduct material is used or stored;
- (xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

- (i) The date of the meeting;
- (ii) Members present;
- (iii) Members absent;
- (iv) Summary of deliberations and discussions;
- (v) Recommended actions and the numerical results of all ballots; and
- (vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this Part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective actions; and
- (3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for two years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with Subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for two years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal,

and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone 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 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, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible

relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed in § 35.33(d). The licensee shall also notify the referring physician and the appropriate NRC Office specified in § 30.6 of this part in writing on Form NRC—¹ within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended 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 500 millirem. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

(e) 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).

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the

¹ The staff is developing this form and will make it available before the effective date of this regulation. A notice of its availability will be published in the Federal Register.

preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this

section for two years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for two years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for two years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this Part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for five years. The records must contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment

involved, the test results, and the action taken.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 100 microcuries or less of beta or gamma-emitting material or 10 microcuries or less of alpha-emitting material;

(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit

and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for two years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the

detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

- (1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or
- (2) The activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter.

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for two years. The record must include the date of the survey, a plan of each

area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

§ 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.301 of this chapter if it:

- (1) Holds byproduct material for decay a minimum of ten half-lives;
- (2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- (3) Removes or obliterates all radiation labels; and
- (4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Subpart D—Uptake, Dilution, and Excretion

§ 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

A licensee may use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

§ 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee shall administer radioactive aerosols and gases in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in Appendix B to Part 20 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the operation of collection systems each month, and measure the ventilation rates available in areas of use each six months.

§ 35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

A licensee may use any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this

requirement, the instruction must describe the licensee's procedures for:

- (1) Patient control;
- (2) Visitor control;
- (3) Contamination control;
- (4) Waste control; and
- (5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for two years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

- (1) Provide a private room with a private sanitary facility;
- (2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;
- (3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
- (4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for two years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until

removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by § 20.401(c)(1) a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- (d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- (e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
- (f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to

confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for two years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

- (1) The names of the individuals permitted to handle the sources;
- (2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;
- (3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for two years.

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient control;
- (4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.415 Safety precautions.

(a) For each patient receiving implant therapy, a licensee shall:

(1) Not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.105(b) of this chapter at a distance of one meter from the implant;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for two years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose

rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and
- (b) Iodine-125 as a sealed source in a portable imaging device.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with § 35.51 of this part.

Subpart I—Teletherapy

§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:

(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§ 35.606 License amendments.

In addition to the changes specified in § 35.13 of this part, a licensee shall apply for and must receive a license amendment before:

- (a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

§ 35.610 Safety instruction.

(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if:

(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(b) A licensee shall provide instruction in the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.

(c) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.615 Safety precautions.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(1) A radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.

(2) A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(4) A licensee shall maintain a record of the check required by paragraph (d)(3) of this section for two years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d)(4) of this section.

(6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

§ 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section.

the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in

accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in *Physics in Medicine and Biology* Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics* Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213. (Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW., Washington, DC 20555. Copies of the documents are also on file at the Office of the Federal Register, 1100 L Street NW., Room 8301, Washington, DC 20408. A notice of any change in the material will be published in the **Federal Register**.)

(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the licensee's teletherapy physicist.

(g) A licensee shall retain a record of each calibration for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

§ 35.634 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) of this part; and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for two years.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for two years.

The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606 (a)-(d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for two years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a)-(d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10

millirem per hour and 2 millirem per hour, respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 20.101 of this chapter; and

(ii) Radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in § 20.105(b) of this chapter.

(b) If the results of the surveys required in paragraph (a) of this section indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(2) Until the licensee has received a specific exemption pursuant to § 20.501 of this chapter.

(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 20.105(b) of this chapter, before beginning the treatment program the licensee shall:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.105(b);

(2) Perform the survey required by § 35.641 again; and

(3) Include in the report required by § 35.645 the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of this section, and the results of the second survey.

(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under § 20.105(a) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.105(b). A licensee may not begin the treatment program until the license amendment has been issued.

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:

(a) Is certified by:
(1) American Board of Health Physics in Comprehensive Health Physics;

- (2) American Board of Radiology;
- (3) American Board of Nuclear Medicine;
- (4) American Board of Science in Nuclear Medicine; or
- (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or
- (b) Has had classroom and laboratory training and experience as follows:
 - (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Be an authorized user identified on the licensee's license.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:

- (a) Is certified in:
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology; or
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:
 - (1) 40 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

- (i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- (iii) Administering dosages to patients and using syringe radiation shields;
- (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
- (v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

- (a) Is certified in:
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology; or
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:
 - (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiopharmaceutical chemistry; and
 - (v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating dose calibrators and diagnostic instruments and performing

checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

Except as provided in § 35.970, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who:

(a) Is certified by:

- (1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology or therapeutic radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized

user of a brachytherapy source listed in § 35.400 for therapy to be a physician who:

- (a) Is certified in:
 - (1) Radiology or therapeutic radiology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent the misadministration of byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(a) 24 hours of classroom and laboratory training that includes:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

- (1) Examination of each individual to be treated;
- (2) Calculation of the dose to be administered;
- (3) Administration of the dose; and
- (4) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in:

(1) Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

- (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
- (2) Radiation biology;
- (3) Radiation protection; and
- (4) Training in the use of the device for the uses requested.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

- (a) Is certified in:
 - (1) Radiology or therapeutic radiology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

- (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;
- (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) Review of the full calibration measurements and periodic spot checks;
 - (ii) Preparing treatment plans and calculating treatment times;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology

under the supervision of an authorized user at a medical institution that includes:

- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
- (ii) Selecting the proper dose and how it is to be administered;
- (iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
- (iv) Post-administration followup and review of case histories.

§ 35.961 Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who:

- (a) Is certified by the American Board of Radiology in:
 - (1) Therapeutic radiological physics;
 - (2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or
 (4) Radiological physics; or
 (b) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in §§ 35.59, 35.632, 35.634, and 35.641 of this part.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained

within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart K—Enforcement

§ 35.990 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of:

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) Any rule, regulation, or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed for violation of:

(1) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 under section 234 of the Atomic Energy Act of 1954, as amended;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these Acts;

(4) Any term, condition, or limitation of any license issued under these Acts; or

(5) Any requirement for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any rule, regulation, or order issued under the Act may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both as provided by law. Regulations issued under the Act include regulations issued under sec. 161, and cited in the authority citation at the beginning of this part for the purposes of sec. 223.

§ 35.999 Resolution of conflicting requirements during transition period.

If the rules in this part conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Commission before April 1, 1987 and has not been renewed since April 1, 1987, then the requirements in the license will apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under § 35.31 of this chapter, the portion changed must comply with the requirements of this Part. At the time of license renewal and

thereafter, these amendments to this Part shall apply.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

2. The authority citation for Part 30 continues to read as follows:

Authority: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

3. Section 30.4 is amended by revising paragraphs (h) and (i) to read as follows and by adding new paragraphs (y) and (z) as follows:

§ 30.4 Definitions.

(h) "Medical use" 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.

(i) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

(y) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(z) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4. Section 30.34 is amended by revising paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

(g) A licensee may prepare technetium-99m radiopharmaceuticals only with technetium-99m that contains less than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m. The licensee shall perform tests and retain the records required by § 35.204.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

5. The authority citation for Part 31 is revised to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 68 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842). Section 31.6 is also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273): §§ 31.5(c)(1)-(3) and (5)-(9), 31.8(c), 31.10(b), and 31.11(b), (c), and (d) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 31.5(c)(4), (5), and (8), and 31.11(b) and (e) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

6. The authority citations following §§ 31.2, 31.5, 31.6, 31.7, 31.8, 31.10 and 31.11 are removed.

7. Section 31.11 is amended by revising paragraph (b) to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

- (1) Has filed Form NRC-483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and received from the Commission a validated copy of Form NRC-483 with a registration number assigned; or
- (2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

8. The authority citation for Part 32 continues to read as follows:

Authority: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.70 [Removed]

9. Section 32.70 is removed.

10. In § 32.72 the section heading, the introductory text of paragraph (a), and paragraph (a)(4)(i) are revised to read as follows:

§ 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under Part 35.

(a) An application for a specific license to manufacture and distribute

radiopharmaceuticals containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

(4) * * *

(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label, or the leaflet or brochure that accompanies each package, contains a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the radiopharmaceutical to persons licensed to use byproduct material listed in §§ 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

11. In § 32.73 paragraph (a)(5)(ii) is revised to read as follows:

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

(a) * * *

(5) * * *

(ii) A statement that this generator or reagent kit (as appropriate) is approved for distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in § 35.200 or under an equivalent license of an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

12. In § 32.74 the introductory text of paragraph (a) and paragraph (a)(3) are revised to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500 of this chapter will be approved if:

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of

assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.58, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

13. The authority citation for Part 40 continues to read as follows:

Authority: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

14. Section 40.4 is amended by revising paragraph (g) to read as follows:

§ 40.4 Definitions.

* * * * *

(g) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

* * * * *

Dated at Washington, DC, this 7th day of October 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 86-23168 Filed 10-15-86; 8:45 am]

BILLING CODE 7590-01-M

Federal Register

Thursday
October 16, 1986

Part IV

Department of Defense General Services Administration

National Aeronautics and Space Administration

48 CFR Parts 1, 6, 8, 13, 15, 31, 33, 36, 44,
52, and 53

Federal Acquisition Regulations; Final
Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES
ADMINISTRATIONNATIONAL AERONAUTICS AND
SPACE ADMINISTRATION48 CFR Parts 1, 6, 8, 13, 15, 31, 33, 36,
44, 52, and 53

[Federal Acquisition Circular 84-23]

Federal Acquisition Regulation

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: Federal Acquisition Circular (FAC) 84-23 amends the Federal Acquisition Regulation (FAR) with respect to the following: Changes to FAR 6.302-5(c)(2) to clarify procedures for certain noncompetitive purchases; Extension of Agency Policies and Procedures concerning Acquisition of Utility Services; OFPP Policy Letter 80-6 concerning appeal rights; Should-Cost Analysis to clarify its definition; Revision to FAR 33.210, Contracting Officer's Authority, to emphasize limitations in settlement of claims involving fraud; Definition of Architect-Engineer Services; Subcontracts—Clause Preface and Title (FAR 44.201, 52.244-1, and 52.222-28); and Editorial Corrections.

EFFECTIVE DATE: September 30, 1986.

FOR FURTHER INFORMATION CONTACT: Margaret A. Willis, FAR Secretariat, Room 4041, GS Building, Washington, DC 20405, Telephone (202) 523-4755.

SUPPLEMENTARY INFORMATION:**A. Public Comments**

Public comments have not been solicited with respect to these revisions since such revisions either (a) do not alter the substantive meaning of any coverage in the FAR having a significant impact on contractors or offerors, or (b) do not have a significant effect beyond agency internal operating procedures.

B. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because these final rules do not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501, et seq.

C. Regulatory Flexibility Act

Analyses of these revisions indicate that they are not "significant revisions" as defined in FAR 1.501-1; i.e., they do not alter the substantive meaning of any coverage in the FAR having a significant

cost or administrative impact on contractors or offerors, or a significant effect beyond the internal operating procedures of the issuing agencies. Accordingly, and consistent with section 1212 of Pub. L. 98-525 and section 302 of Pub. L. 98-577 pertaining to publication of proposed regulations (as implemented in FAR Subpart 1.5, Agency and Public Participation), solicitation of agency and public views on these revisions is not required. Since such solicitation is not required, the Regulatory Flexibility Act (Pub. L. 96-354) does not apply.

List of Subjects in 48 CFR Parts 1, 6, 8, 13, 15, 31, 33, 36, 44, 52, and 53

Government procurement.

Dated: October 9, 1986.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

Federal Acquisition Circular

[Number 84-23]

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 84-23 is effective September 30, 1986.

Eleanor R. Spector,

Deputy Assistant Secretary of Defense for Procurement.

Terence C. Golden,

Administrator.

S.J. Evans,

Assistant Administrator for Procurement.

Federal Acquisition Circular (FAC) 84-23 amends the Federal Acquisition Regulation (FAR) as specified below.

Item I—Changes to FAR 6.302-5(c)(2)

FAR 6.302-5(c) is revised to clarify that written justifications and approvals described in FAR 6.303 and 6.304 are not required when a statute expressly requires that a procurement be made from a specified source.

Item II—Extension of Agency Policies and Procedures Concerning Acquisition of Utility Services

The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering a revision of FAR Subpart 8.3, Acquisition of Utility Services. A proposed rule was published in the *Federal Register* on May 7, 1986 (51 FR 16988), with comments due July 7, 1986. The public comment period was extended on June 26, 1986 (51 FR 23248) to September 7, 1986, to ensure the adequacy of the time made available for public consideration of the proposed rule. Comments received to date raise a number of significant policy issues. Until these issues are resolved, a final rule will not

be promulgated and FAR 8.300 is amended to extend the period in which agency policies and procedures predating the effective date of the FAR may continue to be used for the acquisition of utility services. If, after the policy issues are resolved, a revision to the FAR is necessary, a proposed rule again will be issued for full public comment.

Item III—OFPP Policy Letter 80-6

FAR 13.105 is revised to clarify that existing appeal rights of small business specialists and SBA representatives with respect to set-asides apply to small business-small purchase set-asides.

Item IV—Should-Cost Analysis

FAR 15.801 is revised to clarify the definition of cost analysis as it relates to should-cost analysis. FAR 15.810 is revised to (1) provide a definition of should-cost analysis, which distinguishes it from cost analysis; (2) clarify the objective of a should-cost analysis; (3) provide guidance in determining the scope and size of the should-cost analysis team; and (4) require the submission of a separate audit report, if a report is appropriate.

Item V—Revision to FAR 33.210, Contracting Officer's Authority

The current instructions in FAR 33.210 are revised to emphasize the limitations on the contracting officer's authority in the settlement of claims involving fraud.

Item VI—Definition of Architect-Engineer Services

The revision to FAR 36.102, Definitions, corresponding revisions to FAR 53.236-2 of the definition on Standard Form (SF) 254, Architect-Engineer and Related Services Questionnaire, and SF 255, Architect-Engineer and Related Services Questionnaire for Specific Projects, and FAR 36.601, Policy, implement the Office of Federal Procurement Policy Letter 83-3, June 8, 1983. The revisions add a definition and guidance regarding the acquisition of architect-engineer services.

Item VII—Subcontracts—Clause Preface and Title (FAR 44.201-1, 52.244-1, and 52.222-28)

In the April 1984 edition of the FAR the clause preface at 52.244-1 included an instruction to the contracting officer which authorized lowering the subcontract dollar threshold for contracting officer consent under certain circumstances. This authority was deleted when the preface was revised by FAC 84-7, thereby creating an

ambiguity as to whether lowering the threshold is still permissible. There has been no change in policy, and the present revision simply reinstates the instruction in the clause preface.

Item VIII—Editorial Corrections

FAR 15.805-5(h) and 52.233-1(c) are revised to make corrections to FAC 84-18 published in the Federal Register on July 29, 1986 (51 FR 27114). FAR 1.105 and 31.205-46(a)(2)(ii) are revised to make corrections to FAC 84-19 published in the Federal Register on July 31, 1986 (51 FR 27488).

Therefore, 48 CFR Parts 1, 6, 8, 13, 15, 31, 33, 36, 44, 52, and 53 are amended as set forth below.

1. The authority citation for 48 CFR Parts 1, 6, 8, 13, 15, 31, 33, 36, 44, 52, and 53 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

2. Section 1.105 is amended by adding, in numerical order, a FAR segment and a corresponding OMB Control Number to read as follows:

1.105 [Amended]

FAR segment	OMB control No.
31.205-46(a)(3).....	9000-0088

PART 6—COMPETITION REQUIREMENTS

3. Section 6.302-5 is amended in paragraph (c)(2) by inserting a dash following the word "for" and removing the remainder of the sentence and by adding paragraphs (c)(2)(i) and (c)(2)(ii) to read as follows:

6.302-5 [Amended]

(c) ***

(2) ***

(i) Contracts awarded under (a)(2)(ii), (b)(2), or (b)(4) of this subsection; or

(ii) Contracts awarded under (a)(2)(i) of this subsection when the statute expressly requires that the procurement be made from a specified source.

(Justification and approval requirements apply when the statute authorizes, but does not require, that the procurement be made from a specified source.)

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

8.300 [Amended]

4. Section 8.300 is amended by inserting in the second sentence a period following the word "used" and removing the remainder of the sentence and by removing in the third sentence the words "or any policies or procedures to be used after September 30, 1986,".

PART 13—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

5. Section 13.105 is amended by adding in paragraph (d)(2) a second sentence to read as follows:

13.105 Small business-small purchase set-asides.

* * * * *

(d) ***

(2) *** If the SBA procurement center representative disagrees with a contracting officer's decision not to proceed with a small business-small purchase set-aside, the SBA procurement center representative may appeal the decision in accordance with the procedures set forth in 19.505.

PART 15—CONTRACTING BY NEGOTIATION

6. Section 15.801 is amended by revising the definition of "Cost Analysis" to read as follows:

15.801 Definitions.

"Cost analysis" means the review and evaluation of the separate cost elements and proposed profit of (a) an offeror's or contractor's cost or pricing data and (b) the judgmental factors applied in projecting from the data to the estimated costs in order to form an opinion on the degree to which the proposed costs represent what the cost of the contract should be, assuming reasonable economy and efficiency.

* * * * *

15.805-5 [Amended]

7. Section 15.805-5 is amended in paragraph (h) by removing in the first sentence the words "the contracting officer believes" and by inserting in the second sentence a period following the word "necessary" and removing the remainder of the sentence.

8. Section 15.810 is amended by revising paragraphs (a) and (e), by redesignating the existing paragraph (c) as (f), and by adding a new paragraph (c) to read as follows:

15.810 Should-cost analysis.

(a) Should-cost analysis is a specialized form of cost analysis which is used to evaluate the cost of production programs by evaluating and challenging a contractor's management and operating systems or portions thereof. It does not assume the use of the contractor's existing workforce, methods, materials, facilities, or management and operating systems. It addresses significant cost drivers and may be tailored to a specific part of the contractor's operations, for example, indirect expense activities, factory layout, etc. This analysis is accomplished by an integrated team of Government contracting, contract administration, pricing, audit, and engineering representatives. The objective of should-cost analysis is to promote both short- and long-range improvements in the contractor's economy and efficiency by evaluating and challenging the contractor's existing workforce, methods, materials, facilities, or management and operating systems to identify uneconomical or inefficient practices. In addition, by providing rationale for any recommendations and quantifying their impact on cost, the Government will be better able to develop realistic price objectives for negotiation.

* * * * *

(c) The scope of a should-cost analysis can range from a large-scale review examining the contractor's entire operation (including plant-wide overhead and selected major subcontractors) to a small-scale review examining specific portions of a contractor's operation. When a should-cost analysis is conducted relative to a contractor proposal, a separate audit report on the proposal is required. In determining the team size for the review, the various factors outlined in this paragraph (c) should be considered.

* * * * *

(e) In acquisitions for which a should-cost analysis is conducted, a separate should-cost analysis team report, prepared in accordance with agency procedures, is required. Field pricing reports are required only to the extent that they contribute to the combined team position. The contracting officer shall consider the findings and recommendations contained in the should-cost analysis team report when negotiating the contract price. After completing the negotiation, the contracting officer shall provide the administrative contracting officer a report of any identified uneconomical or inefficient practices, together with a

report of correction or disposition agreements reached with the contractor. The contracting officer shall establish a follow-up plan to monitor the correction of the uneconomical or inefficient practices.

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

31.205-46 [Amended]

9. Section 31.205-46 is amended in paragraph (a)(2)(ii) by removing "Stock No. 906-010-00000-1" and inserting in its place "Stock No. 908-010-00000-1".

PART 33—PROTESTS, DISPUTES, AND APPEALS

10. Section 33.210 is amended by revising paragraph (b) to read as follows:

33.210 Contracting officer's authority.

(b) The settlement, compromise, payment or adjustment of any claim involving fraud.

PART 36—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

11. Section 36.102 is amended by adding in alphabetical order the definition "Architect-Engineer Services" to read as follows:

36.102 Definitions.

"Architect-Engineer Services" means—

(a) Professional services of an architectural or engineering nature associated with research, development, design, construction, alteration, or repair of real property that are required by virtue of law to be performed by a registered or licensed architect or engineer; or

(b) Such other professional services, as determined by the contracting officer, which uniquely or to a substantial or dominant extent logically require performance by a registered or licensed architect or engineer; and

(c) Incidental services that members of the architect or engineering professions or those in their employ may logically or justifiably perform in conjunction with professional architect-engineer services acquired by Pub. L. 92-582 procedures.

12. Section 36.601 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

36.601 [Amended]

(a) * * *

(b) Other than "incidental services" as specified in the definition of architect-engineer services in 36.102, services that do not require performance by a registered or licensed architect or engineer, notwithstanding the fact that architect-engineers also may perform those services, should be acquired pursuant to Parts 13, 14, and 15.

PART 44—SUBCONTRACTING POLICIES AND PROCEDURES

44.201-1 [Amended]

13. Section 44.201-1 is amended by removing in paragraph (d) the words "Under Fixed Price Contracts" and inserting in their place the words "(Fixed-Price Contracts)".

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

52.222-28 [Amended]

14. Section 52.222-28 is amended by inserting a colon in the introductory text following the word "clause" and removing the remainder of the sentence.

52.233-1 [Amended]

15. Section 52.233-1 is amended by removing in the first sentence of paragraph (c) of the clause the words "certain sum" and inserting in their place the words "sum certain".

16. Section 52.244-1 is amended by removing the colon in the introductory text following the word "clause" and inserting a period in its place and by adding a second sentence to read as follows:

52.244-1 Subcontracts (Fixed-Price Contracts).

* * * The threshold in subparagraphs (b)(2) and (b)(3) of the clause may be lowered when closer surveillance of subcontracting is necessary because of the nature of the industry involved, criticality of the work expected to be subcontracted, absence of competition in placing the prime contract, uncertainties as to the adequacy of the contractor's purchasing system, or novelty of the supplies or services being purchased.

PART 53—FORMS

17. Section 53.236-2 is amended by adding at the end of paragraph (b) a second sentence and the definition "Architect-engineer services"; and by adding at the end of paragraph (c) a

second sentence and the definition "Architect-engineer services" to read as follows:

53.236-2 Architect-engineer services (SF's 252, 254, 255, 1421).

(b) * * * Pending issuance of a new edition of the form, the definition "Architect-engineer and related services" is replaced by the following: "Architect-Engineer Services" means—

(1) Professional services of an architectural or engineering nature associated with research, development, design, construction, alteration, or repair of real property that are required by virtue of law to be performed by a registered or licensed architect or engineer; or

(2) Such other professional services, as determined by the contracting officer, which uniquely or to a substantial or dominant extent logically require performance by a registered or licensed architect or engineer; and

(3) Incidental services that members of the architect-engineer professions or those in their employ may logically or justifiably perform in conjunction with professional architect-engineer services acquired by Pub. L. 92-582 procedures.

(c) * * * Pending issuance of a new edition of the form, the definition "Architect-engineer and related services" is replaced by the following: "Architect-Engineer Services" means—

(1) Professional services of an architectural or engineering nature associated with research, development, design, construction, alteration, or repair of real property that are required by virtue of law to be performed by a registered or licensed architect or engineer; or

(2) Such other professional services, as determined by the contracting officer, which uniquely or to a substantial or dominant extent logically require performance by a registered or licensed architect or engineer; and

(3) Incidental services that members of the architect-engineer professions or those in their employ may logically or justifiably perform in conjunction with professional architect-engineer services acquired by Pub. L. 92-582 procedures.

[FR Doc 86-23299 Filed 10-15-86; 8:45 am]

BILLING CODE 6820-61-M