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NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30, 31, 32, 35, 40, and 71
HUMAN USES OF BYPRODUCT MATERIAL

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to revise its regulations to modify the process for licensing medical users of radioactive byproduct material. The proposed revision would primarily affect future NRC licensing actions for hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the proposed regulation provides a single source of requirements for human use, thereby reducing the administrative burden on the licensee. The proposed regulation also provides the basis for allowing more flexibility in licensees' updating of their day-to-day procedures that would conserve licensee and NRC resources. The proposed revision to the regulations would provide a more efficient method for regulating the medical uses of byproduct material.

DATE: Comment period expires (insert 60 days after FRN). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date.

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

Copies of the preliminary regulatory analysis and the comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. Single copies of the preliminary regulatory analysis and environmental impact are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)427-4052.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)427-4052.

SUPPLEMENTARY INFORMATION:

Uses of Byproduct Material in Medicine

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 and blood clots, 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 15 to 20 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in the field of radiation therapy to treat cancer. A very highly radioactive source can be placed in a teletherapy unit that can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 2 million teletherapy treatments are performed annually by NRC licensees. 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 uniform beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or distribution of radiation that goes through the patient, which 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 procedures performed annually.

NRC's Role

Twenty-six states, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. They issue licenses for human use of byproduct material. In non-Agreement States, the NRC issues licenses to medical facilities and individual physicians. These licenses authorize certain uses of radioactive materials for diagnostic and therapeutic medical procedures in humans.

NRC's Current Licensing Practices

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for general and specific licenses for human use. The general license in § 35.31 authorizes physicians to use small quantities of prepackaged individual doses of radioactive materials. Physicians simply submit a registration form to NRC and a validated copy with an assigned registration number is returned to the applicant.

Most medical institutions and physicians who use byproduct material need more than can be safely permitted by a general license. A specific license, which authorizes a larger inventory of byproduct material and a wider variety of uses, may be issued for one or more of six types of human use, defined as 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 radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. All these license applications, which are much more detailed than a general license application and actually contain the applicant's step-by-step procedures, are reviewed individually by NRC.

NRC currently has about 2600 medical licensees. In 1981, the NRC received 73 new applications for specific licenses, 244 license renewal applications, and 1,303 license amendment requests for a total of about 1,600 licensing actions. The NRC has issued 650 general licenses, and in 1981 received five new applications.

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 human use of byproduct material generally poses no hazard to workers and the public.

Problems with Current Practice

The General License. This 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. Issuing a general license for all in-vivo use of radioisotopes to qualified applicants would be the simplest approach for the NRC and licensees. Unfortunately, it would not assure an acceptable level of safety in the regulated industry.

The NRC also believes it is no longer productive to issue human use general licenses. The tests authorized under § 35.31 have been superseded by new in-vitro procedures with more specificity and greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for the general license. As noted above, although NRC has on file 650 in-vivo general licenses under § 35.31, only five new applications were received by NRC in 1981.

To determine the status of general license use, the staff performed a telephone survey by attempting to contact 10 percent of the current registrants. The survey indicated that less than 9 percent of the current registrants still use material under a general license; many are using byproduct material under a specific NRC 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 human use of byproduct material.

The Specific License. Because of the increased potential radiation hazard to workers and the public, the specific license program 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 as 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," and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable," contain many recommendations that the NRC believes are critical 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 for NRC reviewers to conclude that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step 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 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 phone call for additional information because of the conservative licensing and review practices needed due to the incompleteness of the regulations. Deficiency letters are costly for the NRC and the applicant and greatly increase the time required to complete licensing actions.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for human use of byproduct material in accordance with the procedures submitted with 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 adding authorized users. 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 medical 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, and physician training curricula had not been established. Therefore, it was necessary to review each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment.

Proposed Revision of the Regulatory Program

NRC intends to modify its regulation of the medical use of byproduct material. The Commission plans to revise the regulations to provide a single source of the requirements specifically related to human use of byproduct materials, and allow medical licensees to modify their procedures so they can make prompt use of new safety methods and also meet new needs caused by changes in need for various patient care services or patient load. The proposed revision of 10 CFR Part 35 is consistent with the Commission's general policy on human use of byproduct material issued February 9, 1979 (44 FR 8242), which states "NRC will continue to regulate the medical uses of radioisotopes, as necessary, to provide for the radiation safety of workers and the general public."

NRC proposes to simplify regulation of medical licensees by incorporating all human use requirements in 10 CFR Part 35. These regulations would become the primary source of requirements for the human use of byproduct material and would serve to regulate the day-to-day uses of radioisotopes for patient care. Licensees would not face new regulatory burdens because, in most cases, these requirements currently appear as license conditions which must be met. Under the proposed revision, the license would authorize medical use of byproduct materials. Licensees would be regulated by the requirements for use specified in the regulations. This would simplify inspections for NRC inspectors because they would only need to be familiar with one set of regulations rather than a different set of license conditions and procedures at each facility.

In conjuction with this effort the NRC will revise Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs." The revised guide will contain model procedures that the applicant can use to develop site-specific procedures to meet the requirements in the proposed regulations. Continuing with current practice, the NRC staff will review the procedures submitted by the applicant in order to determine whether they are sufficient to meet the requirements of the regulations. If they are incomplete or inadequate, NRC will stop processing the application and will issue a deficiency letter. Also consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow the model procedure developed by NRC staff and supplied in Regulatory Guide 10.8. However, to allow each licensee to make prompt use of new safety methods and to adjust procedures to meet new needs caused by changes in need for patient care services or patient load, licensees will be free to modify their procedures without NRC review or approval. At an institution, the Radiation Safety Committee must review and approve a modified procedure before it may be implemented. At non-institution facilities, the RSO and management must review and approve procedure modifications. Under this regulatory scheme, a licensee will be cited for 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, failure to follow technically valid procedures, or failure to meet the requirements of the regulations or license conditions (which would list, for example, authorized users, locations of use, authorized methods of use, authorized byproduct material and inventory limits, and other site-specific limitations).

The proposed regulations require specific training and experience for the use of material in each use group. Proposed authorized user (AU) physicians, and Radiation Safety Officers (RSO) and qualified teletherapy calibration experts (QTCE; identified in current Part 35 as the Qualified Expert) will have to submit summaries of their training and experience. This is currently required for AU's and RSO's, but would be a new requirement for QTCE's. The staff will review those individuals' training and experience against the standards in the regulation before authorizing them to work as an AU, RSO, or QTCE. (Also 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 individuals' training and experience with the assistance of its Advisory Committee on the Medical Use of Isotopes, and may issue the exemption as a license condition.) Use, or supervision of use, of material without authorization would be a violation of the regulations which would subject the user to an enforcement action.

Under the current regulatory scheme, the licensee is required to handle material exactly according to the procedures submitted with the application. The NRC frequently receives requests for permission to modify day-to-day operating procedures. Since the regulations will now contain sufficient prescriptive and performance criteria on which to base enforecment actions, the NRC will no longer require as a license condition that the applicant follow the procedures that were submitted for review if the licensee's Radiation Safety Committee, or outside an institution the RSO and licensee management, have reviewed and approved the modification. This will eliminate the licensee's need to prepare a formal amendment request for the NRC and pay an amendment fee in order to make modifications in procedures.

However, four types of amendments will still be required:

(1) New users. The NRC will review the training and experience of each proposed AU, RSO, and QTCE as described above.

(2) New type of use. Requests 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 AU's training and experience will be reviewed for adequacy with respect to the new type of use, and procedures which must be submitted 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.

(3) New method of use. Two types of amendment will be needed:

(a) If a new radioactive material (RAM) becomes available, and the procedures needed for its safe use are identical to the procedures already established for an already established and authorized use (for example, a new imaging agent administered by intravenous injection), the new RAM will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail to licensees who are authorized to use material in that use group a notice that says they may begin using the new RAM on the effective date of the final rule that adds the new RAM to the regulations. No individual licensing action will be taken.

(b) If a new RAM becomes available but its safe use depends on following a new procedure that current licensees have not submitted and NRC has not reviewed, two actions will be taken.

(i) The new RAM will be added by rulemaking to the appropriate use group in the regulations but authorization to use it will be limited to persons licensed after it was added to the use group. These persons would have submitted the new RAM procedure for review in their application packages.

(ii) NRC will mail to current licensees a notice that says they may apply for authorization to use the new RAM. With that notice, NRC will also supply a model procedure, which would become a new appendix in Regulatory Guide 10.8, for the new RAM. Those licensees who want to use the new RAM will have to submit a request for amendment which includes a proposed procedure that will be reviewed by NRC for completeness and adequacy.

(4) New location of use. A request to leave one location of use and begin working in a new location will have to be supported by a

complete new application package. A request to add a satellite location for diagnostic studies will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC does generally not authorize licensees to perform therapies at satellite locations. Such requests will be handled on a case-by-case basis.)

In summary, the regulation will be amended to require that licensees meet standards that are currently imposed by license condition. The NRC will continue to review user training and experience. The NRC will review site-specific procedures for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to modify procedures that were submitted in support of the application if the Radiation Safety Committee, or management and RSO outside an institution, approves the modification. Amendments will generally be handled just as new applications are handled.

Discussion of Proposed Regulations

The primary purpose in initiating this revision to the regulations is to simplify the regulatory process by providing licensees with a single source of requirements for the human use of byproduct material. Radiation protection standards now contained in several existing regulations, Inspection and Enforcement orders that modify a single license or group of licenses, technical reports (NUREGs), standard conditions of licenses, and regulatory guides would be consolidated into a concise set of regulations. The requirements that apply to all licensees appear first, followed by the specific requirements for each of the six basic types of use. (The phrase "type of use" in this Part indicates a collection of similar methods of using byproduct material for patient care. There are six types of use: uptake, dilution, and excretion; imaging and localization; radiopharmaceutical therapy; brachytherapy; diagnostic sealed sources; and teletherapy. Each type of use is comprised of many methods of use. For example, the use of technetium-99m as pertechnetate for brain imaging is a method of use).

The general license in current §35.31 has been eliminated from the proposed regulations, and all human use will be specifically licensed. Current general licensees will be incorporated in the specific license system. They will be limited to the methods of use described in the

current § 35.31, and relieved, by license condition, from those provisions of the proposed Part 35 that are more burdensome than current requirements for general licensees. All this will be done by notice to general licensees. The only action they would need take is to respond affirmatively to a notice that asks if they want to continue to have an NRC license. They will not be assessed application, amendment, or renewal fees as long as their material use is limited to that described in current §35.31. 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. Under the proposed regulation, applicants would have to specifically request this authorization. Current licensees would receive a letter authorizing them to continue their in vitro work without filing a registration form.

In the proposed regulation, items of general information, general administrative requirements, and general technical requirements are addressed first in Subparts A through C, respectively. Subparts D through I contain the additional technical requirements that apply to licensees for each of the six types of human use. Subpart J lists the training and experience requirements, and Subpart K lists the penalties for violations of the regulations.

In order to maintain consistency among the various parts of NRC's regulations, conforming amendments have been made to the affected sections of Parts 30, 31, 32, 40, and 71. These conforming amendments can be found immediately after the revised Part 35. A section-by-section discussion of the proposed revision of Part 35 follows.

Authority

This listing provides notice that the NRC may initiate criminal prosecution of persons who do not comply with the prescriptive requirements issued under sec. 161b or the recordkeeping and reporting requirements issued under sec. 161o.

Subpart A--General Information

§ 35.1 Purpose and scope.

The regulations in this part apply to all persons licensed by the Commission to intentionally administer byproduct material or the radiation

from byproduct material to humans, and to individuals working under their supervision.

§ 35.2 License required.

This section requires that persons have a license issued by the Commission or an Agreement State before they handle byproduct material for human use. The Commission uses the specific licensing process to limit the use of byproduct material to persons who have the equipment, facilities, training, and experience needed to ensure its safe use. Individuals who are working under the supervision of an authorized user do not need a license, but this does not relieve them of the requirement to conduct their work in accordance with requirements of the license and the regulations of this chapter. The licensee remains responsible for the noncompliance of such agents or employees, and may be subject to sanctions for their failure to comply.

§ 35.8 Reporting, recordkeeping, and application requirements: OMB Approval.

This section certifies that the Office of Management and Budget has reviewed and approved the information collection requirements contained in this part.

§ 35.15 Definitions.

The term "Agreement State" was included to identify those states that have agreed with NRC to assure the safe use of byproduct material within their borders.

The word "ALARA" was added to identify the acronym for the phrase "as low as reasonably achievable."

The term "authorized user" was added to identify individuals who are identified by name on a license and who are authorized by the Commission or an Agreement State to administer byproduct material, or the radiation therefrom, to humans for medical care, and supervise its use by others.

The term "dentist" was added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "human use" was included to help identify the scope of this part. The word "intentional" was added to the current definition

of the term human use to make it clear that occupational and non-occupational exposures under the regulations of Part 20, accidental exposures, and unwanted exposures from other sources of radiation (e.g., nuclear powered cardiac pacemakers, smoke detectors, and radioactive waste) are not considered human use.

The word "institution" was added to identify organizations with medical byproduct material programs in which the safe use of byproduct material depends on the cooperation of individuals from several different departments.

The word "management" was added to identify the individual responsible for defining the licensee's policies and allocating personnel, budget, and space resources.

The word "misadministration" was included to define those instances in which a mistake has been made in the human use of byproduct material. The definitions are consistent with the current § 35.41.

The term "mobile service" was added to describe the transport of byproduct material for the purpose of offering diagnostic nuclear medicine services at addresses other than the principal business address of the licensee.

The word "output" was added to describe the amount of radiation in a teletherapy beam.

The word "physician" was included to identify individuals licensed by the States to practice medicine and therefore eligible to apply for a license to use byproduct material in the practice of medicine.

The word "podiatrist" was added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "qualified teletherapy calibration expert" was included to replace the term "qualified expert" which is used in the current § 35.24. The new term better reflects the training, experience, and responsibilities of the individual who is responsible for calibrating a licensee's teletherapy unit.

The term "Radiation Safety Officer" was added to identify the individual named on a license and who is responsible for managing the licensee's radiation safety program.

The term "sealed source" was included to identify byproduct material that is specially encapsulated to prevent leakage or escape during use and storage. It is the same definition as used in § 30.4.

The term "visiting authorized user" was added to identify authorized users who, while working for a licensee on a temporary or occasional basis, use byproduct material under the restrictions of the temporary employer's license, which does not identify the visitor as an authorized user. This term was taken from a frequently used license condition.

§ 35.16 Application for license.

A physician, dentist or podiatrist in private practice may apply for a license. An individual physician may not apply for a license if his use of material is at an institution, (an organization that provides various medical services). At an institution, only management may apply for a license, and the individual physicians would be listed as authorized users. This requirement reflects the need for coordination with other employees who may not be under the administrative control of the authorized user. An application must be filed on Form NRC-313 because it elicits information in an orderly manner that will allow for uniformity in application review procedures.

Teletherapy applications must be submitted separately because the scope and nature of information needed is much different than that needed for the other types of human use. This requirement does not imply that the applicant should have two separate safety programs.

This section also reflects the Commission's decision to delegate to Regional Administrators some licensing functions which, until recently, were conducted in the headquarters. This program was described in a Federal Register notice published April 14, 1983 (48 FR 16030).

§ 35.17 License amendments.

The Commission requires that the licensee obtain an amendment for any changes in the byproduct material program that might increase the potential for radiation exposure to workers and the general public, or make it difficult for the Commission to determine whether a licensee is in compliance with its regulations. The Commission has determined that certain changes are potentially significant for the following reasons and thus will require an amendment:

(1) The NRC must be assured that the licensee has adequate training and experience and facilities before authorizing a change in the type or method of human use or amount of byproduct material used. Such a change might also indicate a need for increased inspection frequency.

(2) The use of byproduct material at an address not identified on the license would make it impossible for the Commission to make unannounced inspections. For the purpose of this part, the phrase "location of use" refers to a building. Except for teletherapy, moving from one room to another would not constitute a change in location of use.

(3) The Commission must be assured that the training and experience of Radiation Safety Officers, authorized users, and qualified teletherapy calibration experts is sufficient to ensure safe use of byproduct material.

(4) Any other program changes that might result in an increase of radiation exposure or risk to workers or the public requires an amendment.

§ 35.18 Notifications.

A notification requirement was added to require the licensee to notify the Commission if an authorized user, Radiation Safety Officer (RSO), or qualified teletherapy calibration expert is no longer affiliated with the licensee's byproduct material program, because the NRC would no longer be assured that the collective training and experience of the licensee's remaining personnel is adequate to assure the safe use of byproduct material for all the types of use authorized by the license. The Commission has made a judgment that notification within 30 days is sufficient, because technicians who have worked under the supervision of the authorized user can adequately assure the safe receipt and proper storage of byproduct material for a few weeks. (This parallels the Commission's judgment that common carriers who handle byproduct material packages need not be licensed). However, over a longer period of time, absence of an individual to oversee a byproduct material program may increase the probability of an accumulation of unused byproduct material or unauthorized use of material. This presents an unacceptable potential hazard.

§ 35.28 License issuance.

The Commission has selected a license term of five years. A shorter term would not benefit the public health and safety because past experience indicates that medical programs do not generally change significantly over that period of time. A shorter term may unduly interfere in patient care because the licensee would spend an inordinate amount of time requesting renewals. A longer term may lead to unintentional abandonment of the license.

The applicant must use Form NRC-313 to provide for an orderly safety review of the applicant's program. The Commission will apply certain standards when reviewing an application so as to ensure that the safety of workers and the public will not be compromised if the license is granted. The staff must be assured that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property (§ 30.33(a)(2)), and that the authorized users are qualified by training and experience to use the material for the purposes listed in the application in such a manner as to protect health and minimize danger to life or property (§ 30.33(a)(3)), and that the applicant has established procedures adequate to assure the safe use of byproduct material. It is the sense of Congress that fees may be necessary to recover operating costs. The Commission's discussion of this topic is in 36 FR 145, published January 6, 1971.

§ 35.29 Specific exemptions.

A person may request an exemption from any requirement of this part. The Commission may allow the exemption if the applicant can show that it will not compromise the health and safety of workers and the public.

Subpart B--General Administrative Requirements

§35.30 ALARA program.

An ALARA program is a management tool needed to assure that all reasonable efforts are made to assure the safe use of byproduct material in institutions. (See 'Management Organization and Administration for

ALARA' by Kathren, Health Physics, Vol. 42, No. 2, February 1982, p. 119-131, and 'Radiation Safety in a Nuclear Medicine Department,' by Gandsman et al., Health Physics, Vol. 38, No. 3, March 1980, p. 399-408.) Many workers from different departments within an institution might be occasionally exposed to byproduct material. The Commission has made a judgment that a formal ALARA program is the only management tool that can provide assurance that sources of radiation and work procedures in a large facility are regularly reviewed for safety. Specific requirements usually considered part of an ALARA program are required by §§ 35.31 and 35.32. Since outside of an institution the safe use of byproduct material does not usually depend on the cooperation of individuals from several different departments, and in most cases the authorized users are also the management, non-institutional licensees need not have a formal written ALARA program.

§ 35.31 Radiation Safety Officer.

The Radiation Safety Officer (RSO) is an individual with special expertise who is needed to coordinate the safe use of byproduct material in accordance with the license and regulations.

§ 35.32 Radiation Safety Committee.

The proposed Part 35 requires institutional licensees to establish a Radiation Safety Committee to oversee the use of byproduct material. Under this proposal, committee membership must include a physician identified on the institution's license as an authorized user of byproduct material for each type of use permitted by the license, the institution's Radiation Safety Officer, a representative of the institution's management and a representative of the nursing service. A similar requirement was published as a proposed rule on April 9, 1979 (44 FR 21023). (Institutions that only request a license for diagnostic sealed sources will be exempted from this requirement by license condition because the radiation safety program, due to the nature of the source and its method of use, would not depend on the cooperation of individuals from several different departments.) The NRC is not soliciting comments on the Radiation Safety Committee rule of Part 35 because an opportunity to comment on the rule has already been provided

in the recently completed rulemaking on the Radiation Safety Committee. That rulemaking, published as a final rule on September 13, 1982 (47 FR 40149), has been incorporated in the proposed wording of Part 35.

To assure the safety of workers and the public in light of site-specific exigencies, the Committee must review on the basis of safety (1) the qualifications of each individual to be listed as an authorized user, and (2) each proposed method of use. In its reviews, the committee should consider compliance with NRC regulations, special physical or chemical containment problems, the amount of byproduct material that will be used, and the relative hazard of the material.

The committee must review occupational exposures. A review more frequent than quarterly would inappropriately emphasize normal and expected statistical variations in exposure data. A less frequent review would allow an unnecessary or unnecessarily high exposure to continue uncorrected for an unacceptably long period. The quarterly review should be guided by two trigger levels for individual exposures. The lower level would be a minimum level below which no action need be taken. Above the minimum level, the source of exposure should be determined and consideration given to methods of reducing the exposure rate. The higher level should trigger immediate intervention by the Radiation Safety Officer to reduce the exposure. The committee should review the appropriateness and completeness of the intervention, and should develop a permanent solution to maintain exposures at a lower level.

The annual review of the safety program is needed to determine its adequacy in light of the current and projected use of all byproduct material. In the Commission's judgment, a review at least once each year is adequate to assure that exposures remain ALARA considering the few program adjustments typically made during any single year. More time between reviews might not permit the committee to make timely recommendations for avoiding unnecessary worker or patient exposures.

§ 35.33 Requirement for Authority and Statement of Responsibilities.

To ensure that material is used safely, the RSO and Committee need a clear statement of their duties from management so that questions about authority, responsibility, and jurisdiction do not keep these individuals from acting.

§ 35.34 Visiting authorized user.

In the Commission's judgment, the uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a licensee for a limited period. The sixty-day limit of § 35.34 will allow licensees to provide uninterrupted service at times when its permanent staff may be unable to do so. Since the visiting authorized user has the required training and experience, public health and safety will not be adversely affected. Visits of more than 60 days in one year suggest that the visiting authorized user is an integral part of the host licensee's health care delivery system, and should be identified as an authorized user on the license.

§ 35.35 Mobile service administrative requirements.

Mobile service has been limited to diagnostic human use because the inherent hazard of therapeutic amounts of byproduct material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or equipment. Mobile service licensees are required to have a letter of permission from the management of each client facility to assure that the client management is aware of and in agreement with the human use of byproduct material within the facility.

§ 35.37 Records and reports of misadministrations.

The proposed Part 35 retains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. A discussion of these requirements is in 45FR 31701, published May 14, 1980. NRC is not soliciting comments on the misadministration requirements of the proposed Part 35 because they are identical to the requirements of the current Part 35. On October 29, 1982, the Commission in SECY 82-388 disapproved the staff's recommendation to propose withdrawal of this requirement.

§ 35.38 Supervision.

The authorized user is qualified to use byproduct material in the practice of medicine. Frequently, specific tasks may be delegated

(under § 35.2(b)) to individuals with less training and experience. However, it is necessary that a qualified individual instruct them, oversee their work on a frequent basis, and be available to promptly respond in unusual or emergency situations. When using byproduct material, supervised individuals must comply with instructions, procedures, and the regulations.

§ 35.49 Suppliers.

In order to ensure the use of pure materials, authorized users may use only byproduct material manufactured and distributed under procedures that were reviewed for safety by the NRC, the Food and Drug Administration (FDA), or an Agreement State. In certain institutions, the FDA has vested in a Radioactive Drug Research Committee (RDRC) (pursuant to 21 CFR 361.1) the right and responsibility to review for safety certain new radiopharmaceuticals that are in the research stage. It is the Commission's judgment that the review criteria established by the FDA are, when followed by the RDRC, sufficient to assure the health and safety of the public and workers.

Subpart C--General Technical Requirements

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

A dose calibrator is needed to ensure that the dosage of material given is the dosage that was prescribed. It must be tested for accuracy, the ability to exactly measure a specified quantity, and linearity, the ability to exactly measure a range of quantities. The American National Standards Institute (ANSI) recommends the required test frequencies to assure the proper operation of dose calibrators. (See ANSI N42.13-1978. In the interest of economy and efficiency, the NRC uses voluntary national standards in its regulatory program if they provide adequate assurance of safety.) The activity levels of the accuracy check sources were chosen because a lower activity would invalidate the accuracy test due to expected statistical fluctuations. To choose a higher activity would present an unnecessary source of radiation exposure to workers. The geometry test assures that the shape of the syringe or vial containing

the byproduct material does not affect the dosage measurement. The daily constancy check assures that the dose calibrator has worked consistently since it was last tested.

Licensees whose level or scope of use does not indicate need for a dose calibrator may request an exemption from this section. The request should be supported by a description of an alternative method that the licensee will use to measure radiopharmaceutical dosages.

§ 35.51 Calibration and check of survey instruments.

The 1000 mR/hr limit was chosen because that is the highest radiation exposure rate that is likely to be encountered in the medical environment. The calibration frequency and the other prescriptive and performance requirements in this section are consistent with ANSI N323-1978.

§ 35.53 Measurement of radiopharmaceutical dosages.

This section requires that the licensee assay the radioactivity of each radiopharmaceutical dosage before it is administered to a patient and keep a record of the assay results. This is required to ensure that the patient receives the intended dosage. The time at which the measurement must be made has been purposefully omitted to allow for flexibility in licensee's procedures.

A similar requirement was published as a proposed rule on September 1, 1981 (46 FR 43840). The comment period on the proposed rule expired November 30, 1981. The NRC is incorporating the dosage measurement proposal in this revision. The proposed Part 35 dosage measurement requirement differs from the 1981 proposal in its recordkeeping requirement. The Part 35 proposal requires the dosage measurement record to include the patient's name, and identification number if one has been assigned. This information is not required by the 1981 proposal. NRC invites comment on the requirement that dosage measurement records include patient information. NRC is not soliciting comment on other portions of the dosage measurement requirements because they are substantively the same as the 1981 proposal. Comments received in response to the 1981 dosage measurement proposal will be addressed in the statement of consideration published with the final rule revising Part 35.

§ 35.58 Authorization for calibration and reference sources.

These sources are needed to check and test radiation instruments and to mark images. They represent a small radiation hazard in relation to the amount of radioactivity used in patient care. The activity level was chosen to allow licensees to have a range of sources with several energies and half-lives available.

§ 35.59 Requirements for possession of sealed sources.

The user must follow the manufacturer's instructions because they have been reviewed for safety considerations by the Commission or an Agreement State. The six-month test interval has been recommended by the National Council on Radiation Protection and Measurements (NCRP)[1] in Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection." More frequent testing is inconsistent with ALARA considerations governing worker exposure because it would cause occupational exposure with a negligible probability of finding a leaking source. Less frequent testing does not adequately assure safety. The test procedures described maximize the probability of detecting contamination from a leaking source. Report No. 57, Section 3.3.5.3 recommends minimum detectable limit of 0.005 microcuries for equipment used to measure leak test samples. This level is consistent with the requirements of other parts of the current regulations (see, for example, §§ 31.5 and 34.25), and is only slightly higher than the minimum detectable activity exhibited by instrumentation available to licensees. The Commission has made a judgment that this level provides the most conservative detection level technically achievable at a reasonable cost. It is noted that this requirement would reduce the current permissible amout of detectable contamination from teletherapy sources ten-fold, from 0.05 microcuries to 0.005 microcuries. The Commission has made a judgment that the exempted sources do not present a contamination hazard because of the small amount

[1]The National Council on Radiation Protection and Measurements (NCRP) is a nonprofit corporation chartered by Congress in 1964 to draft proposed recommendations on protection against radiation and radiation measurements, quantities, and units, particularly those concerned with radiation protection.

of radioactivity in the sources, the method in which they are constructed, the short half-life of the byproduct material, or the small hazard of the byproduct material. The Commission has made a judgment that records retention for 3 years is sufficient to show the existence of a working sealed source leak test program. To conduct a physical inventory more frequently than quarterly is inconsistent with ALARA exposure goals. To inventory less frequently may, in case of a misplaced source, allow an unacceptable radiation exposure to go on for too long without detection.

§ 35.60 Syringe shields.

Syringes that contain byproduct material are an external radiation hazard and should therefore be shielded at all times. In some cases the use of a shield when making an injection could interfere significantly with the injection. Since this would jeopardize patient benefit, in such cases the higher radiation exposure to the hands that is received by the technician who does not use a shield is warranted. For example, a shield need not be used when the risk of extravasation is greater than the benefit of reduced worker exposure.

§ 35.61 Vial shields.

A vial radiation shield can significantly reduce the radiation exposure to the fingers and hands of an individual handling a vial of byproduct material.

§§ 35.62 Syringe labels, and 35.63 Vial labels.

Some misadministrations have been caused by accidentally transposing vials or syringes. The proper labelling of containers will help to avoid this type of mistake.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

Since radiopharmaceuticals are frequently handled, it is plausible that a syringe or some radioactive waste may be mislaid. This would result in unnecessary radiation exposure to workers and the public. The exposure rate survey will bring this problem to the attention of workers. The weekly exposure rate survey of waste storage areas will ensure that exposure rates in that area will be monitored so that special steps can

be taken if greater than average use of radiopharmaceuticals results in higher than average exposure rates in the waste storage area.

The Commission knows that a wipe test made several days after spillage of a short-lived radiopharmaceutical will probably not detect any contamination. The periodic contamination survey serves as a check of workers' physical control of radiopharmaceuticals. If contamination is found, it indicates that controls or safety measures may be inadequate or are not always being used.

The Commission has made a judgment that records retention for one year is sufficient to show the existence of a working survey program.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

A patient whose body contains byproduct material is a potentially hazardous source of radiation. The Commission proposes to allow release limits based on residual activity in the patient or exposure rate at a specified distance from the patient at the licensee's option. The 30 mCi limit is based on a recommendation of the NCRP and current licensing practice. The 6 mR/hr limit is based on the exposure rate from 30 mci of iodine-131, the most commonly used therapeutic radiopharmaceutical. The Commission is considering allowing the option because the 30 mCi limit is consistent with NCRP guidance, but some individuals believe that the exposure rate is more relevant and easier to measure. The Commission believes that either limit provides an adequate measure of safety for the general public, and has made a judgment that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement.

§ 35.80 Mobile service technical requirements.

The Commission has limited radiopharmaceutical transportation by mobile service licensees to unit dosages because they appear to be inherently safer under accident conditions and there does not appear to be sufficient need for bulk radiopharmaceuticals in mobile service. The mobile service must remove all radioactive waste generated during the

use of byproduct material at a client facility because it is unlikely that the client facility has a license to receive and process radioactive waste. The mobile service licensee must constantly control byproduct material because client facilities should be considered as unrestricted areas since there is no assurance that the licensee can control access to areas of use while working in a facility that is under another person's administrative control.

Equipment checks are needed to assure the proper function of safety instrumentation and other equipment after transport and before byproduct material is handled. A survey is needed to assure that all byproduct material has been removed from the location of use. The mobile nuclear medicine service must carry a calibrated survey meter to monitor exposure and contamination in case of any accident that may result in a release of byproduct material. The Commission has made a judgment that records retention for one year is sufficient to show the existence of a working exit survey program.

§§ 35.90 Storage of volatiles and gases.

Some radiopharmaceuticals present an inhalation or immersion hazard (e.g., iodine-131 and xenon-133). That hazard can be minimized by storing those in a fume hood or double airtight barrier (such as a folded plastic bag within a folded plastic bag), and by using them with a collection or ventilation system.

§35.92 Decay-in-storage.

For most hospital radiopharmaceutical waste, decay to background levels is essentially complete over a period of days or months. The requirements of § 20.301, directed primarily at longer half-lived material, are not necessary for short half-lived radiopharmaceutical waste. Because the special handling required for long half-lived material is usually not needed for radiopharmaceutical waste, short half-lived waste would be exempted from the requirements of § 20.301. A decay period of ten half-lives was chosen because such a time period will assure that, in most cases, byproduct material will have decayed to levels below those in § 30.71, which are quantities that, under certain ordinary conditions, are exempt from a requirement for a specific

license. A half-life of 65 days was chosen as the decay in storage half-life cutoff limit because storage in excess of 650 days is more appropriately considered as permanent storage. Waste must be monitored to assure that long-lived waste was not accidentally mixed with short-lived waste and that no waste has been added to the container since it was sealed. When the waste is monitored, neither the waste nor the survey instrument may have any radiation shielding because it might hide the presence of long-lived byproduct material in the waste. The requirement to remove or obliterate radiation labels is in §20.203(f)(4) and is included here for completeness. Generator columns must be individually monitored because they contained larger amounts of radioactivity and also may have small amounts of long-lived contaminants. The Commission has made a judgment that records retention for two years is sufficient to show the existence of a working decay-in-storage program.

Subpart D--Uptake, dilution, and excretion (Group General/I)

§§ 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.

Drugs approved for human use by the FDA have a label or package insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when it is used according to the package insert. By restricting the physician to the FDA-approved physical form, route of administration, and dosage range, NRC assures the safety of the public while allowing the physician flexibility regarding the choice of the clinical procedure. The FDA also authorizes the Radioactive Drug Research Committee (RDRC) at an institution to review and approve the use of radioactive materials for human use for research purposes. The Commission believes that the guidelines used by the FDA when reviewing the credentials of the RDRC members, and the guidelines that the FDA requires the RDRC to use when evaluating research proposals, are adequate to assure the safety of workers and the public without unduly restricting medical research.

The radiopharmaceuticals listed in §35.100 were taken from those listed in the current §§35.31 and 35.100(a). Those listed in §35.200 were taken from current §§35.100(b) and (c). Mercury-203 was not included in the proposed revision because the Commission believes that there are other radiopharmaceuticals available that provide equivalent diagnostic information with much less radiation dose to the patient.

Manufacturers are currently distributing generally licensed radiopharmaceuticals under a license issued pursuant to §32.70. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute radiopharmaceuticals pursuant to §32.72.

§35.120 Possession of survey instrument.

A low level survey instrument is needed to check areas of use for contamination. Since the total amount of radioactivity used for uptake, dilution, and excretion studies is relatively small, the Commission does not believe the licensee needs an ionization survey instrument to measure dose rates.

Subpart E--Imaging and localization (Group II/III)

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

Xenon-133 as a gas or saline solution has been added to this group. Manufacturers are currently distributing the product under a license issued pursuant to Part 30. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute xenon pursuant to §32.72.

Through continuing medical research, new uses may be found for existing approved radiopharmaceuticals. These new uses, which may require a different dosage, route of administration, or physical form, may not appear on the manufacturer's label or package insert instructions. It was such a situation that resulted in a petition filed by Dr. George V. Taplin (Docket No. PRM-35-1) requesting an exemption for Tc-99m pentetate as an aerosol for lung function studies. A proposed rule was published on April 13, 1982 (47 FR 15798). The comment period on this proposed rule expired June 14, 1982, and 35 comments were received. The NRC

adopted the rule in final form without change on February 4, 1983 (48 FR 5217). The NRC is incorporating this regulation into this revision of Part 35 without soliciting public comment because there are no substantive changes to the rule as adopted.

§ 35.204 Permissible molybdenum-99 concentration.

When molybdenum-99 undergoes radioactive decay, clinically useful technetium-99m is produced. Occasionally, unwanted molybdenum appears in the technetium solution. The permissible concentration of molybdenum-99 was chosen to be consistent with the permissible concentration listed in the United States Pharmacopeia (USP), the nationwide standard for all pharmaceuticals used in the practice of medicine. It is the judgment of the Commission that the USP standard provides an adequate level of safety and to require a different standard would be confusing and unproductive. Since diagnostic dosages of technetium-99m are generally 30 millicuries or less, the maximum permissible level of molybdenum-99 in such a dosage would result in a patient receiving an undesired 4.5 microcuries of molybdenum-99. The molybdenum would be taken up primarily by the liver. The dose to the liver would be about 0.2 rads as a result of the molybdenum concentration. The Commission has made a judgment that this radiation dose is insignificant compared to the radiation dose which would be received by the patient due to the administration of the technetium.

§ 35.205 Control of aerosols and gases.

The Commission believes that a system that provides for the collection or controlled dispersal of aerosols and gases is needed to reduce exposure to workers and the public.

§35.220 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart F--Radiopharmaceuticals for therapy (Group IV/V)

§ 35.300 Use of radiopharmaceuticals for therapy.

The radiopharmaceuticals listed in §35.300 were taken from those listed in the current §§35.100(d) and (e).

Drugs approved for human use by the FDA have a label or package insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when used according to the package insert, and therefore would require that the licensee use the radiopharmaceuticals in accordance with the package insert.

§§35.310 Safety instruction, and 35.410 Safety instruction.

In the hospital setting, the use of byproduct material presents special training problems which are not addressed in Part 19 because they are unique to the medical environment. For example, visitor control in a hospital cannot be accomplished by physical barriers which might impede the delivery of emergency medical care. Also, after administration, the byproduct material is contained in an ambulatory human. Therefore, the Commission has made a judgment that worker instruction in addition to that required by Part 19 is necessary. (This parallels special instruction required, for example, for radiographers and radiographer's assistants pursuant to § 34.31 of this chapter.) The Commission has also made a judgment that record retention for two years is sufficient to show the existence of a working safety instruction program.

§35.320 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart G--Sources for brachytherapy (Group VI)

§ 35.400 Use of sources for brachytherapy.

This section identifies brachytherapy sources that may be used in human use. The list was taken from the current § 35.100(e). Tantalum wire has been added.

§ 35.404 Release of patients treated with temporary implants.

A responsibility of the Commission is to restrict the movement of byproduct material when the public exposure would be increased. Brachytherapy sources for temporary implants have high levels of radiation, and remain radioactive for a long period of time. Loss of control of these sources and their release to unrestricted areas may result in potentially lethal radiation exposure to members of the public. The Commission has made a judgment that temporary confinement of the brachytherapy patient is necessary to assure public safety. Section 35.404 requires that the licensee confine the patient until all temporary brachytherapy sources have been removed. The Commission has made a judgment that records retention for two years is sufficient to show the existence of a working source control program.

§35.406 Brachytherapy sources inventory.

Because of the particular hazard of brachytherapy sources due to their high activity and small size, the Commission belives that an inventory procedure that requires an entry each time a source is handled will help to assure that if a source is misplaced, this will quickly become apparent to the licensee, who can then promptly begin a search for the source.

§35.420 Possession of survey instrument.

The licensee needs a high level survey instrument to measure exposure rates in storage areas and uncontrolled areas around a patient's room, and to check to be sure all sources have been removed from the patient before release from confinement.

Subpart H--Sealed sources for diagnosis (Group VII)

§ 35.500 Use of sealed sources for diagnosis.

This is a new use group established to incorporate the recent development of medical devices which use a sealed source of byproduct material to create a beam of ionizing radiation. These devices are currently available to persons licensed to use materials listed in §35.100(f). Since the devices represent a lower level of hazard than the other sealed sources in that group, the Commission has determined that these devices should comprise a new group.

§35.520 Availability of survey instrument.

The licensee needs a survey instrument to measure the exposure rates around a packaged sealed source that is to be returned to the manufacturer, and to survey for contamination in case of an accident that might have compromised the integrity of the sealed source. However, since a source exchange is an infrequent and scheduled event, and since a hazardous accident would be a very rare occurrence, the Commission believes that it is sufficient, for safety purposes, to require the licensee to make arrangements to borrow or rent an instrument or contract with a measurement service when measurements are necessary.

Subpart I--Teletherapy (Group VIII)

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

This is a new use group established to deal with a well-established type of use. Safety measures that apply to all licensees within this group have been used over the years and are reflected in these proposed regulations.

§ 35.605 Maintenance and repair restrictions.

This section provides that only specially licensed persons may maintain, adjust, or repair teletherapy units because this type of work requires special training and equipment in order to be done safely.

§ 35.606 Amendments.

Amendments are required for items identified in paragraphs (a) through (f) because any change described in these paragraphs could result in an increase in radiation levels in excess of the levels authorized in § 20.105. The service of a qualified teletherapy calibration expert is a critical component in assuring the safe use of a teletherapy unit. The Commission has made a judgment that only an individual with proper training and experience can determine the operating characteristics of the licensee's teletherapy unit.

§ 35.610 Posted instructions.

Emergency instructions must be posted to remind individuals of the proper steps to be taken in case of an emergency and to identify individuals to be notified in an emergency. The Commission believes this is also an appropriate place to remind workers that it is important to ensure that only the patient is in the room before turning the unit on. The reminder is necessary because it is possible that when two workers are stationed on one teletherapy unit one worker may inadvertently turn the unit on when the other worker is still in the treatment room, or a worker may turn the unit on to check its operation after a patient or co-worker has entered the treatment room unbeknownst to the worker at the control console.

§ 35.615 Doors, interlocks, and warning systems.

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," on page 42, states that a survey of a new teletherapy facility must determine that ". . .All entrances into the irradiation room or other high radiation areas are provided with barriers equipped with interlocks that are not dependent on the operation of a single circuit, and that will interrupt radiation production when the barrier is opened." There have been incidents in irradiation facilities in which personnel were unnecessarily exposed to radiation because door interlocks or alarms were intentionally bypassed for convenience. See, for example, cases 19, 21, and 28 in NUREG/BR-0001, "Case Histories of Radiography Events," vol. 1, 1980.

If the interlocks and warning systems had not been bypassed, personnel would not have been irradiated. The Commission, however, has made a judgment that the dual warning system of a door interlock and a radiation monitor in the teletherapy room obviates the need for the dual circuit door interlock recommended in the report.

The beam condition indicator light will indicate to workers about to enter the room whether the unit is turned on or off.

§35.620 Possession of survey instrument.

The licensee needs a survey instrument on hand in order to measure exposure rates in case the radiation monitoring device or the teletherapy unit fails.

§ 35.621 Radiation monitoring device.

The radiation monitoring device is needed to indicate radiation levels in the teletherapy room in the event of the failure of the interlocks or the warning system. There have been a number of documented instances in which individuals have been unnecessarily exposed following the failure of the source retraction mechanism, coupled with a failure of the primary beam condition indicator system. Section 35.621 requires licensees to install a permanent radiation monitor in each teletherapy room, to check its operation before using the teletherapy unit, and to use a portable survey instrument or personal audible alarm dosimeter if the monitor is inoperable. Identical requirements were published as a proposed rule on April 28, 1982, (47 FR 18131). These requirements were adopted in a final rule published January 18, 1983 (48 FR 2116).

The NRC is incorporating the rulemaking on teletherapy monitoring and servicing in this rulemaking on the revision of Part 35. NRC is not soliciting comment on the new teletherapy requirements of the proposed Part 35 because they are identical to the requirements of the earlier 1982 rulemaking.

§ 35.622 Viewing system.

If a patient moved during a therapeutic administration, this could result in a 200 rad dose to healthy tissue. The viewing system is

needed to monitor the orientation of the patient and the teletherapy unit to assure the prescribed application of radiation.

§ 35.630 Dosimetry equipment.

Dosimetry equipment is needed to assure that the dose prescribed is the dose actually given. In order to help ensure accuracy it must be calibrated. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the proposed resolution of the petition filed by the American Association of Physicists in Medicine, Petition Docket No. PRM 35-2 (see 47 FR 4311; January 29, 1982). Currently, regulations require that primary dosimetry equipment be calibrated every two years. The petitioner requested this two year requirement be relaxed to four years if, two years after calibration, the primary dosimetry system is compared with a system that was calibrated within the past two years, and the results of the comparison indicate that the calibration factor used to convert an instrument reading to a dose measurement had not changed by more than two percent. (Intercomparison meetings are occasionally scheduled by several qualified teletherapy calibration experts within a geographic area. Each expert takes a dosimetry system to the meeting, where each dosimetry system in turn is exposed to the same radiation dose from a teletherapy unit. The response of each dosimetry system can then be compared to the response of the other systems. If each system measures the same radiation dose in rads, this provides assurance that each system is working properly.) This suggestion has been incorporated into these proposed regulations. The petitioner also asked that the licensee be required to make quarterly constancy checks to assure the consistency of operation of the dosimetry system. The Commission did not incorporate this suggestion because the apparent exposure rate of constancy check devices as indicated by the dosimetry system may vary by as much as two percent even though the calibration factor for the dosimetery equipment has not changed. Therefore, the Commission does not believe that periodic constancy checks would necessarily provide increased assurance of proper operation.

§ 35.632 Full calibration measurements.

Full calibrations are needed to ensure that the dose given is the dose that was prescribed. The required frequency of full calibrations remains unchanged from that of the current Part 35. The test for timer accuracy has been clarified to include on-off error. The accuracy of localization devices which are used to position the teletherapy patient has been added to minimize the risk of unintentionally irradiating healthy tissue. The function of mechanical and electrical interlocks which are used to limit the directions in which the beam can be aimed, and thereby reduce the exposure rate in uncontrolled areas, has also been added. The licensee need no longer perform all measurements with a calibrated dosimetry system. Instead, the calibrated dosimetry system need only be used for one representative measurement, and then a relative exposure rate system can be used to complete the calibration. This would allow for use of computerized or automated measurement systems that cannot be easily shipped for calibration.

The exposure rate from a radioactive source goes down as time progresses due to source radioactive decay. To assure accurate dose delivery, the regulation requires that licensees mathematically take this into account in calculating patient doses. The regulation requires that the licensee use time periods of not longer than one month when making decay calculations. This will assure that the actual dose does not differ from the calculated dose by more than one percent due to this decay error.

§§ 35.633 Periodic spot-checks, and 35.642 Facility checks following installation of a source.

A monthly spot-check is required by § 35.22 of the current regulations to ensure that the teletherapy unit is giving the expected radiation dose. The following changes have been made. Timer accuracy has been clarified to include on-off error. The accuracy of localization devices has been added. The qualified teletherapy calibration expert must review the results of the spot-check measurements within fifteen days, and must notify the licensee in writing of the results of the monthly check, to assure the licensee and the Commission that the check results were reviewed by a qualified individual. The Commission has made a

judgment that a response period of less than fifteen days would be unreasonably expensive. A requirement to check certain safety systems in the teletherapy facility has been added. These checks are needed to assure that safety systems required by other sections of the regulations are working properly. These checks need not be performed by the qualified teletherapy calibration expert. Devices that are not working must be promptly repaired in order to assure the safety of the teletherapy facility.

§ 35.641 Radiation measurements following installation of a source.

The Commission has used these maximum and average permissible source leakage radiation levels for several years as license conditions. They are consistent with guidance from the NCRP in its Report No. 33, "Medical X-ray and Gamma-ray Protection for Energies up to 10 MeV - Equipment Design and Use," Section 4.2.2. The Commission has made a judgment that they are sufficiently restrictive to keep exposures as low as reasonably achievable.

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

The section is needed to require that licensees take prompt action to reduce exposure rates in uncontrolled areas that may be caused by errors in design or construction.

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

Given the potential for high exposure to workers and the public, the radiation survey information required by §35.644 is needed to assure that teletherapy sources have been properly installed and are sufficiently shielded to assure compliance with the exposure limits of Part 20.

§ 35.645 Five-year inspection.

Many licensees replace teletherapy sources at five year intervals. Requiring a mechanical check at five year intervals helps to assure the source exposure mechanism is in good working order and will not stick in the exposed position. The mechanic who exchanges sources and inspects

units can remove the source, inspect the drawer mechanism, and then install the new source. More frequent checks would require greater time near a very radioactive source. Less frequent checks would not be sufficient to assure the continuous proper operation of the exposure mechanism. The identification information in the record is needed to establish which unit was inspected, when, and by whom. The remaining information is needed so the Commission may determine that the inspection was of sufficient depth to assure the health and safety of workers and the public.

Subpart J--Training and Experience Requirements

A combination of theoretical and practical training and experience is necessary to assure the safe use of byproduct material. The criteria in this subpart were developed by the staff with the advice of the Advisory Committee on the Medical Use of Isotopes (ACMUI). The requirements for the Radiation Safety Officer have not been published before. The requirements for authorized users are similar to those published as an amendment to Appendix A of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," in the Federal Register on December 2, 1982 (47 FR 54376). The requirements for the qualified teletherapy calibration expert are similar to those required of a qualified expert pursuant to the current § 35.24.

§§ 35.900(a), 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.941(a), 35.950(a), 35.960(a), and 35.961(a) concerning certification.

The Commission has made a judgment that in some cases, certification by an appropriate professional board constitutes proof of adequate training and experience because the criteria which must be met to attain certification are more stringent than the training and experience required by the Commission.

§ 35.900(b) Authorized user as a Radiation Safety Officer.

The training and experience required by the Commission includes safety considerations for the byproduct material that the authorized user may use. Therefore an authorized user is qualified to oversee the

safe use of byproduct material that he is authorized to use pursuant to the conditions of the license.

§ 35.900(c) Training within the last five years or continuous involvement.

Radiation safety regulations and practices may be expected to change with time. The Commission has made a judgment that training received within the preceding five years is sufficiently up-to-date to assure the safe use of byproduct material. If an individal received training more than five years prior to the application but has had continuing involvement in the field, conformance with Section 19.12, Instructions to Workers, assures that the individual has had continuing instruction in radiation safety.

§§ 35.900(d), 35.910(b), 35.920(b), 35.930(b), 35.940(b), 35.941(b), 35.950(b), 35.960(b), and 35.961(b) Training and experience.

The criteria identified in these sections were developed by the staff with the assistance of the ACMUI over the past several years. The Commission has made a judgment that, for each type of use, the training and experience described is necessary to assure the safe use of byproduct material.

§§ 35.910(c) and 35.920(c) Integrated programs.

The Accreditation Council for Graduate Medical Education (ACGME) reviews and approves training programs for physicians. Approval of these training programs is based, in part, on adequate radiation safety content. The Commission has made a judgment that individuals who have successfully completed an approved training program have received sufficient training and experience to use byproduct material safely.

§§ 35.901 and 35.970 Current radiation safety officers and authorized users.

The staff has reviewed and found acceptable the training and experience of each individual who is currently listed as a radiation safety officer or an authorized user. Further review of the credentials of these individuals is unnecessary.

§ 35.971 Three month training program.

In addition to the ACGME, the American Board of Radiology, the American Board of Osteopathic Radiology, and the American Board of Nuclear Medicine review and approve nuclear medicine training programs for physicians. These three boards independently arrived at the conclusion that, while currently acceptable, a three month training program may not allow sufficient time in the future to provide the training and experience needed to develop a satisfactory level of expertise in nuclear medicine, including radiation safety. All three boards and the ACGME are therefore planning to require that, by August 31, 1987, training programs be of six months duration. The Commission has made a judgment that, in the meantime, individuals who have successfully completed an approved three month training program have received sufficient training and experience to use byproduct material safely.

§ 35.990 Violations.

This section gives notice that the Commission will initiate legal proceedings if necessary to enforce requirements.

DERIVATION TABLE

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

NEW SECTION NUMBER		ORIGIN
Subpart A--General Information		
35.1	Purpose and scope.	35.1 revised
35.2	License required.	35.2 revised
35.8	Reporting, recordkeeping, and application requirements: OMB Approval.	new text
35.15	Definitions.	
	Agreement State	20.3
	ALARA	acronym
	Authorized users	term used on licenses
	Dentist	new term
	Human use	35.3(a) revised
	Institution	new term
	Management	new term
	Misadministration	35.41
	Mobile service	new term
	Output	new term
	Physician	35.3(b) revised
	Podiatrist	new term
	Qualified teletherapy calibration expert	new term
	Radiation Safety Officer	term used on licenses
	Sealed source	30.4(r) verbatim
	Visiting authorized user	new term
35.16	Application for license, amendment, or renewal.	35.4 revised
35.17	License amendments.	new text; compare 30.38
35.18	Notifications.	new text
35.28	License issuance.	new text, compare 30.36
35.29	Specific exemptions.	new text; compare 30.11

Subpart B--General Administrative Requirements		
35.30	ALARA program.	new text; see RG 10.8 Appendix O revised
35.31	Radiation Safety Officer.	RG 10.8
35.32	Radiation Safety Committee.	35.11(b) revised
35.33	Requirements for authority and statement of responsibilities.	new text
35.34	Visiting authorized user.	license condition
35.35	Mobile service administrative requirements	licensing policy
35.37	Records and reports of misadministrations.	35.42 verbatim
35.38	Supervision.	expanded from RG 10.8 p. 3
35.49	Suppliers.	35.14 revised
Subpart C--General Technical Requirements		
35.50	Possession, use, calibration, and check of dose calibrators.	RG 10.8 Appendix D2 revised, and new text
35.51	Calibration and check of survey instruments.	RG 10.8 Appendix D1 revised, and new text
35.53	Measurement of radio-pharmaceutical dosages.	proposed rulemaking 35.15 (46 FR 43840; September 1, 1981)
35.58	Authorization for calibration and reference sources.	35.14(d) revised
35.59	Requirements for possession of sealed sources.	35.14(e)(1)(i), 35.14(f) revised
35.60	Syringe shields.	Inspection and Enforcement letter April 16, 1979
35.61	Vial shields.	Inspection and Enforcement letter April 16, 1979
35.62	Syringe labels.	new text
35.63	Vial labels.	new text
35.70	Surveys for contamination and ambient radiation exposure rate.	RG 10.8 Appendix I revised

35.75	Release of patients containing radiopharmaceuticals or permanent implants.	new text
35.80	Mobile service technical. requirements.	licensing policy
35.90	Storage of volatiles and gases.	RG 10.8 Appendix M revised
35.92	Decay-in-storage.	license condition

Subpart D--Uptake, dilution, and excretion (Group General/I)

35.100	Use of radiopharmaceuticals, for uptake, dilution, and excretion studies.	35.31 and 35.100 (I) revised
35.120	Possession of survey instrument.	RG 10.8 page 5

Supart E--Imaging and localization (Group II/III)

35.200	Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.	35.100 (II) and (III) revised
35.204	Permissible molybdenum-99 concentration.	US Pharmacopeia
35.205	Control of aerosols and gases.	RG 10.8 Appendix M revised
35.220	Posession of survey instruments.	RG 10.8 page 5

Subpart F--Radiopharmaceuticals for therapy (Group IV/V)

35.300	Use of radiopharmaceuticals for therapy.	35.100 (IV) and (V) revised
35.310	Safety instruction.	19.12 revised
35.320	Possession of survey instruments.	RG 10.8 page 5

Subpart G--Sources for brachytherapy (Group VI)

35.400	Use of sources for brachytherapy.	35.100 (VI) revised
35.404	Release of patients treated with temporary implants.	35.14(b)(5)(vii) revised

35.406	Brachytherapy sources inventory.	RG 8.18 page 8
35.410	Safety instruction.	19.12 revised
35.420	Possession of survey instruments.	new text

Subpart H--Sealed sources for diagnosis (Group VII)

35.500	Use of sealed sources for diagnosis.	new text
35.520	Availabilty of survey instrument.	new text

Subpart I--Teletherapy (Group VIII)

35.600	Use of a sealed source in a teletherapy unit.	new text
35.605	Maintenance and repair restrictions.	license condition
35.606	Amendments.	new text
35.610	Posted instructions.	license condition and new text
35.615	Doors, interlocks, and warning systems.	license condition
35.620	Possession of survey instrument.	
35.621	Radiation monitoring device.	35.25 (48 FR 2115; January 18, 1983)
35.622	Viewing system.	license condition
35.630	Dosimetry equipment.	35.22, 35.23 revised
35.632	Full calibration measurements.	35.21 revised
35.633	Periodic spot-checks.	35.22 revised and license condition
35.641	Radiation measurements following installation of a source.	license condition
35.642	Facility checks following installation of a source.	license condition
35.643	Modification of teletherapy unit or room before beginning a treatment program.	new text

35.644	Reports of teletherapy surveys, checks, tests and measurements.	license condition
35.645	Five-year inspection.	license condition

Subpart J--Training and experience requirements

35.900	Radiation Safety Officer.	new text
35.901	Radiation Safety Officer training exception.	new text
35.910	Training for uptake, dilution, and excretion studies.	Revision of Federal Register Notice (47 FR 53476; December 2, 1982)
35.920	Training for imaging and localization studies.	Revision of Federal Register Notice (47 FR 53476; December 2, 1982)
35.930	Training for therapeutic use of radiopharmaceuticals.	Revision of Federal Register Notice (47 FR 53476; December 2, 1982)
35.940	Training for therapeutic use of brachytherapy sources.	Revision of Federal Register Notice (47 FR 53476; December 2, 1982)
35.941	Training for ophthalmic use of strontium-90.	Revision of Federal Register Notice (47 FR 53476; December 2, 1982)
35.950	Training for use of sealed sources for diagnosis.	new text
35.960	Training for teletherapy.	Revision of Federal Register Notice (47 FR 53476 December 2, 1982)
35.961	Training for qualified teletherapy calibration expert.	35.24 revised
35.970	Experienced physician training exception.	new text
35.971	New physician training exception.	new text

Subpart §--Enforcement

35.990 Violations. new text

Environmental Impact - Negative Declaration

The proposed rule, if adopted, would not result in any activity that significantly affects the quality of the human environment. The Commission has determined that under the National Environmental Policy Act, and the criteria in 10 CFR Part 51, an environmental impact statement is not required for this proposed rule.

The environmental impact appraisal forming the basis for this determination is available for inspection at the NRC Public Document Room, 1717 H Street NW., Washington, DC, and as noted in the "Addresses" section.

Paperwork Reduction Act Statement

The Nuclear Regulatory Commission will submit this proposed rule to the Office of Management and Budget (OMB) for any review that may be necessary under the Paperwork Reduction Act, Public L. 96-511. The SF-83 "Request for Clearance," the Supporting Statement, and any other documentation submitted to OMB, have been placed in the NRC Public Document Room at 1717 H Street NW., Washington, DC 20555, for inspection, and copying for a fee.

Regulatory Flexibility Certification

Based on the information available at this stage of the rulemaking proceeding, in accordance with Section 605(b) of the Regulatory Flexibility Act of 1980, the Commission certifies that this proposed rule, if promulgated, will not have a significant adverse economic impact on a substantial number of small entities. The NRC has issued approximately 2600 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 400 by individual physicians. Most of the institutional licensees are community hospitals that range in size from 75 bed facilities to 750 bed facilities. The Small Business Administration size standards, 13 CFR Part 121, classify a hospital as a small entity if its capacity is less than 150 beds or if its gross annual receipts do not exceed $1.5 million. Under these size standards, a substantial number of NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

Although the number of medical licensees that would fall into the small entity category constitutes a substantial number for purposes of the Regulatory Flexibility Act, there should not be a negative economic impact on these small entities. The primary objective of the proposed rule is to simplify the medical licensing process by consolidation of requirements without lessening the protection necessary to preserve public health and safety. This will be accomplished through incorporation of frequently used license conditions into the regulations and the elimination or modification of requirements that are not essential to the protection of public health and safety. These steps will make it easier for a licensee to determine what is required to obtain a license and what is required of licensees.

The Commission has prepared a preliminary value/impact statement for this proposed regulation. The preliminary value/impact statement contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the proposed regulation would result in cost savings to all licensees. The preliminary value/impact statement is available for public inspection in the NRC Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the preliminary value/impact statement are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC Telephone: (301)427-4052.

Because of the widely differing conditions under which licensees covered by this proposed regulation operate, the Commission specifically seeks public comment from small entities. Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates:

(1) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(2) How the proposed regulation would result in a significant economic burden on the licensee as compared to that on a larger licensee;

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

(4) The benefits that would be gained or the detriments that would be avoided to the licensee, if the proposed regulations were modified as suggested by the commenter; and

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

List of Subjects in 10 CFR Parts 30, 31, 32, 35, 40, and 71 Rules of General Applicability to Domestic Licensing of Byproduct Material

Part 30 - Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting requirements.

General Domestic Licenses for Byproduct Material

Part 31 - Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Scientific equipment.

Specific Domestic License to Manufacture or Transfer Certain Items Containing Byproduct Materials

Part 32 - Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting requirements.

Human Use Of Byproduct Material

Part 35 - Byproduct material, Drugs, Health devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Domestic Licensing of Source Material

Part 40 - Government contracts, Hazardous materials - transportation, Nuclear materials, Penalty, Reporting requirements, Source material, Uranium.

Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions

Part 71 - Hazardous materials - transportation, Nuclear materials, Packaging and containers, Penalty, Reporting requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 32, 40, and 71 is contemplated.

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

PART 35--HUMAN USE OF BYPRODUCT MATERIAL

Sec.

Subpart A--General Information

35.1 Purpose and scope.

35.2 License required.

35.8 Reporting, recordkeeping, and application requirements: OMB approval.

35.15 Definitions.

35.16 Application for license, amendment, or renewal.

35.17 License amendments.

35.18 Notifications.

35.28 License issuance.

35.29 Specific exemptions.

Subpart B--General Administrative Requirements

35.30 ALARA program.

35.31 Radiation Safety Officer

35.32 Radiation Safety Committee

35.33 Requirement for authority and statement of responsibilities.

35.34 Visiting authorized user.

35.35 Mobile service administrative requirements.

35.37 Records and reports of misadministrations.

35.38 Supervision.

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.

35.58 Authorization for calibration and reference sources.

35.59 Requirements for possession of sealed sources and brachytherapy sources.

35.60 Syringe shields.

35.61 Vial shields.

35.62 Syringe labels.

35.63 Vial labels.

35.70 Surveys for contamination and ambient radiation exposure rate.

35.75 Release of patients containing radiopharmaceuticals or permanent implants.

35.80 Mobile service technical requirements.

35.90 Storage of volatiles and gases.

35.92 Decay-in-storage.

Subpart D--Uptake, dilution, and excretion (Group General/I)

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

35.120 Possession of survey instrument.

Subpart E--Imaging and localization (Group II/III)

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 (Group IV/V)

35.300 Use of radiopharmaceuticals for therapy.

35.310 Safety instruction.

35.320 Possession of survey instruments.

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); §§ 35.2, 35.17, 35.30(a) and (c), 35.31(a) and (b), 35.32, 35.33, 35.34(a), 35.38, 35.49, 35.50(a)-(d), 35.51(a)-(d), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.62, 35.63, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.100, 35,120, 35.200, 35.204(a) and (b), 35.205, 35.220, 35.300, 35.310(a), 35.320, 35.400, 35.404(a), 35.406(a), 35.410(a), 35.500, 35.520, 35.600, 35.605, 35.606, 35.610, 35.615, 35.620, 35.621(a)-(d), 35.621(f) and (g), 35.622, 35.630(a) and (b), 35.632(a)-(f), 35.633(a)-(i), 35.641(a) and (b), 35.642(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.940, 35.941, 35.950, 35.960, and 35.961 are issued under sec. 161b, instructions criminal enforcement, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.18, 35.30(c), 35.31(b), 35.33(b), 35.34(c), 35.35(b), 35.37(a)-(d), 35.50(e), 35.51(e), 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), 35.304, 35.310(b), 35.404(b), 35.405, 35.406(b), 35.410(b), 35.621(e), 35.630(c), 35.632(g), 35.633(j), 35.641(c), 35.642(c), 35.643(c), 35.644, and 35.645(c) are issued under sec. 161o records, criminal enforcement, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A -- General Information

§ 35.1 Purpose and scope.

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

§ 35.2 License required.

(a) No person shall manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for human use except in accordance with a specific license issued by the Commission or an Agreement State and 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 § 35.38, unless prohibited by license condition.

§ 35.8 Reporting, recordkeeping, and application requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget for approval as required by the Paperwork Reduction Act (Pub. L. 96-511). OMB approved the information collection requirements on _____.

(1) The OMB control number is _____.

(2) OMB approval expires _____.

(b) The approved information collection requirements include the application, recordkeeping, and reporting requirements contained in §§ 35.16, 35.17, 35.18, 35.30(c), 35.31(b), 35.32(a), 35.33(b), 35.34(c), 35.35(b), 35.37(a)-(d), 35.50(e), 35.51(e), 35.53(c), 35.59(d), (e), (g),

and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310, 35.404(b), 35.406, 35.410(b), 35.606, 35.610, 35.621(e), 35.630(c), 35.632(g), 35.633(e) and (j), 35.641(c), 35.642(c), 35.643(c), 35.644, and 35.645(c).

§ 35.15 Definitions.

"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" means as low as reasonably achievable.

"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 human use of byproduct material.

"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 the art of dentistry on humans.

"Human 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 in the art of medicine.

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

"Management" means the chief executive officer.

"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 therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or

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

"Mobile service" means the transportation and use of byproduct material for human use and for checks and tests of equipment used in conjunction with human use by the licensee.

"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.

"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 the art of podiatry on humans.

"Qualified teletherapy calibration expert" means the individual identified as the qualified teletherapy calibration expert on a Commission license.

"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.

"Visiting authorized user" means an authorized user who participates in the human use of byproduct material at a location other than that identified on the license that identifies the physician as an authorized user.

§ 35.16 Application for license, amendment, or renewal.

(a) For use in an institution, only management may apply. For use outside an institution, any physician, dentist, or podiatrist, may apply.

(b) An application for a license, a license amendment, or the renewal of a license for human 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 Form NRC-313, "Application for Materials License." For guidance in completing the form refer to the instructions contained in Regulatory Guide 10.8 Revision 2, "Guide for the Preparation of Applications for Medical Programs."

(c) An application for a license, a license amendment, or the renewal of a license for human use of byproduct material as described in §35.600 of this part must be made by filing Form NRC-313. For guidance in completing the form refer to the instructions contained in Regulatory Guide 10.X, "Guide for the Preparation of Applications for Teletherapy Programs."

(d) The applicant shall mail the completed application form as directed below.

(1) If the applicant is not a Federal agency and is located in Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, the applicant shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region I, Material Program Section No. 2, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(2) If the applicant is not a Federal agency and is located in Virginia or West Virginia, the applicant shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region II, Material Licensing Section 101 Marietta Street, Suite 3100, Atlanta, Georgia 30303.

(3) If the applicant is not a Federal agency and is located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, the applicant shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

(4) If the applicant is not a Federal agency and is located in Montana, South Dakota, Utah, or Wyoming, the applicant shall mail or deliver the completed application form to U. S. Nuclear Regulatory Commission, Region IV, Material Licensing Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

(5) If the applicant is not a Federal agency and is located in Alaska, Hawaii, or a U.S. territory or possession in the Pacific, the applicant shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region V, Material Licensing Section, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

(e) If the applicant is a Federal agency, if the applicant is an agency of the District of Columbia, or if the applicant is located in a

State, territory, or possession that is not mentioned in paragraphs (d)(1) through (5), of this section, the applicant shall:

(1) Mail the completed application form to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or

(2) Deliver the completed application form to the Commission offices at:

(i) 1717 H Street NW., Washington, DC, or

(ii) 7915 Eastern Avenue, Willste Building, Silver Spring, Maryland.

§ 35.17 License amendments.

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

(a) Before using byproduct material for a method or type of human use not permitted by the license issued under this part;

(b) Before the licensee permits anyone, except a visiting authorized user described in § 35.34, to work as an authorized user under the license;

(c) Before the licensee permits an individual not listed on the license to perform the duties of the Radiation Safety Officer or Qualified Teletherapy Calibration Expert;

(d) Before receiving byproduct material in excess of the amount authorized on the license;

(e) Before adding to or changing the location or locations of use identified on the license; and

(f) Before making any changes in the licensed program.

§ 35.18 Notifications.

The licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or qualified teletherapy calibration expert, permanently discontinues performance of duties under the license. The licensee shall mail the form to the appropriate address identified in § 35.16.

§ 35.28 License issuance.

The Commission shall issue a license for the human 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 §35.16;

(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 for the protection of the public health and safety; and

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

§ 35.29 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.

Subpart B--General Administrative Requirements

§ 35.30 ALARA program.

(a) Each institutional licensee shall establish a program to maintain individual and collective dose equivalents as low as reasonably achievable.

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

(1) Management, the Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program.

(2) The program must include an annual review by the Radiation Safety Committee of the types and amounts of byproduct material used, occupational dose reports or summaries, 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 individuals make every reasonable effort to maintain individual and collective occupational dose as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(c) The licensee shall keep a written description of the ALARA program for the duration of the license. The written description must include:

(1) A commitment by management to keep individual and collective occupational dose as low as reasonably achievable;

(2) A requirement that the Radiation Safety Officer brief management once each year on the byproduct material program;

(3) Personnel exposure investigational levels that, when exceeded, will initiate an investigation of the cause of the exposure by the Radiation Safety Officer; and

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

§ 35.31 Radiation Safety Officer.

(a) Each licensee shall appoint a Radiation Safety Officer who is responsible for implementing the radation safety program. The Radiation Safety Officer must be reponsible to the licensee's management for ensuring that radiation safety activities are being correctly performed in accordance with approved procedures in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate known instances of deviation from good practice and implement corrective actions as necessary;

(2) Establish and implement written policy and procedures for:

(i) authorizing the purchase and receipt of byproduct material;

(ii) Receiving byproduct material;

(iii) Storing byproduct material;

(iv) Performing a periodic inventory of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action in the event of loss of control of byproduct material;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material safely;

(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 regulations, a copy of the reguations, a copy of the license application and license and amendments, and the written policy and procedures required by the regulations.

(3) For use not at an institution, approve modifications of procedures with the advice and consent of management; and

(4) For use at an institution, ist the Radiation Safety Committee in the performance of its duties.

§ 35.32 Radiation Safety Committee.

Each institutional licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material. Management may establish more than one committee to meet these responsibilities, but each committe that is established shall meet the administrative requirements. To satisfy this requirement:

(a) The committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user for each type of use permitted by the license the Radiation Safety Officer, a representative of the nursing service, if there is one, 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 a least quarterly.

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

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in §35.30(b)(2)

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

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

(1) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(2) Review on the basis of safety and approve or disapprove any individual who is to be listed as an authorized user or the Radiation Safety Officer before submission of the license application or application for amendment;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of byproduct material;

(4) Review on the basis of safety and approve or disapprove procedures and modifications of procedures for the safe use of byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with byproduct material;

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

(7) Review annually, with the assistance of the Radiation Safety Officer, the byproduct material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

§ 35.33 Requirement for authority and statement of responsibilities.

(a) The licensee shall provide the Radiation Safety Officer, and at an institution the Radiation Safety Committee, sufficient authority and organizational freedom to:

(1) identify radiation safety problems;

(2) initiate, recommend, or provide solutions; and

(3) verify implementation of solutions.

(b) The licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at an institution the Radiation Safety Committee.

§ 35.34 Visiting authorized user.

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

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

(2) The licensee has a copy of a Commission or Agreement State license that lists the visiting authorized user as an authorized user for human use; and

(3) The visiting authorized user performs only those procedures for which the visiting authorized user is specifically authorized by a Commission or Agreement State license.

(b) The licensee need not apply for a license amendment authorizing the short-term use described in paragraph (a) of this section.

(c) The licensee shall retain for two years copies of the records specified in paragraph (a)(1) of this section and of the license specified in paragraph (a)(2) of this section.

§ 35.35 Mobile service administrative requirements.

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

(b) Mobile service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of byproduct material.

§ 35.37 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring

physician personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) 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 shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report 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 licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September and December) in which they occur. These written reports must include the licensee's name; the referring physician's name; a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information that could lead to identification of the patient.

(d) Each licensee shall maintain for Commission inspection a record of each misadministration. 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, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. The licensee shall preserve misadministration records until the Commission authorizes their disposition.

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

§ 35.38 Supervision.

The licensee who permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as authorized by § 35.2(b) shall:

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

(2) Review the supervised individual's use of byproduct material and the records kept to reflect such use;

(3) Require the authorized user to be immediately available by telephone to the supervised individual; and

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice. The supervising authorized user need not be present for each use of byproduct material.

(b) Require the supervised individual receiving, possessing, using or transferring byproduct material under § 35.2(b) to:

(1) Follow the instructions of the supervising authorized user;

(2) Follow the procedures established by the Radiation Safety Officer and

(3) Comply with the regulations of this part and the license conditions with respect to the use of byproduct material.

§ 35.49 Suppliers.

The licensee may use for human 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 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 preparation of radiopharmaceuticals for human use; and

(c) Radiopharmaceuticals authorized by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration pursuant to 21 CFR 361.1.

Subpart C--General Technical Requirements

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

(a) Each human use licensee who is authorized to administer radiopharmaceuticals shall have in his possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) The licensee shall:

(1) Check each dose calibrator for constancy 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, and whose activity is at least 10 microcuries for radium-226, and 50 microcuries for any other photon-emitting radionuclide;

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

(d) The licensee shall mathematically correct dosage readings for any error in excess of 10 percent if the dosage is greater than 10 microcuries.

(e) The licensee shall retain a record of each check and test required by this section for two years unless directed otherwise.

(1) The record required in paragraph (b)(1) of this section must include 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) The record required in paragraph (b)(2) of this section must include 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) The record required in paragraph (b)(3) of this section must include 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.

(4) The record required in paragraph (b)(4) of this section must include 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) The licensee shall calibrate survey instruments before first use, annually, and following repair;

(b) To satisfy the requirements of paragraph (a) of this section, the licensee shall:

(1) Calibrate all scale readings up to 1000 milliroentgens per hour;

(2) Calibrate two 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.

(c) To satisfy the requirements of paragraph (b) of this section, the licensee may:

(1) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(2) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(d) The licensee shall check each survey instrument for proper operation with the dedicated check source before and after each use. The licensee is not required to keep records of these function checks.

(e) The licensee shall retain a record of each calibration required in paragraph (a) of this section for two years. To satisfy the requirements of this paragraph, the record must include:

(1) A description of the calibration procedure; and

(2) A description of the source radionuclide used and its estimated activity, the calculated or measured 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.

The licensee shall:

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

(b) Assay before human use the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide 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 date;

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

(3) Total 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 measurement.

§ 35.58 Authorization for calibration and reference sources.

Any person authorized by § 35.2 for human use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources that were manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 6 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;

(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 use the source in accordance with the instructions supplied by the manufacturer, and shall maintain such instructions in a legible form convenient to users of the source.

(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 a licensed transferor indicating that the source was tested within six months prior to 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 supplier's 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 the test sample from a teletherapy source with the source 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) The licensee shall retain leakage test records for two 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, decontaminate, repair, transfer, or dispose of the source in accordance with Parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 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 corrective action taken.

(f) The 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 prior to any use or transfer unless it has been leakage-tested within six months prior to the date of use or transfer;

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

(6) Sources containing only hydrogen-3;

(7) Wires of iridium-192; and

(8) Wires of tantalum-182.

(g) Any licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in the licensee's possession. The licensee shall retain each inventory record for two 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 estimated activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) Any licensee in possession of a sealed source or brachytherapy source shall survey with a low range survey meter quarterly all areas where such sources are stored.

(i) The 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 exposure rate at several points in each area expressed in millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields.

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

(b) The licensee shall require each individual who administers a radiopharmaceutical by injection to use a syringe radiation shield unless the use of the shield is contraindicated for that injection.

§ 35.61 Vial shields.

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

§ 35.62 Syringe labels.

The licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe, with a radiopharmaceutical to be administered with the radiopharmaceutical abbreviation or type of diagnostic study or therapy procedure to be performed.

§ 35.63 Vial labels.

The licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical to be administered with the chemical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) The licensee shall survey with a low range survey meter at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) The licensee shall survey with a low range survey meter at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) The licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to measure exposure rates that are greater than 0.1 milliroentgen per hour.

(d) The licensee shall establish radiation exposure rate action levels for the surveys required by paragraphs (a) and (b) of this section and shall require that the individual who is performing the survey immediately notify the Radiation Safety Officer if an exposure rate exceeds an action level.

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

(f) The licensee shall establish removable contamination action levels for the surveys required by paragraph (e) of this section and shall require that the individual who is performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the action level.

(g) The licensee shall retain a record of each survey for one year. The record must include the date of the survey, a plan of each area that was surveyed, the action level established for each area, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of 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) The licensee shall not authorize release from confinement for medical care of any patient administered a radiopharmaceutical until either:

(1) The exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries.

(b) The licensee shall not authorize release from confinement for medical care of any patient administered a permanent brachytherapy implant until the exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter.

§ 35.80 Mobile service technical requirements.

A licensee providing mobile service shall:

(a) Transport to each location of use only syringes or vials containing unit dosages of prepared radiopharmaceuticals;

(b) Bring into each location 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 a location of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other equipment as recommended by the manufacturer or as prescribed by the licensee before administering byproduct material to humans at each location of use;

(e) Carry a calibrated survey meter in each vehicle that is being used to transport byproduct material, and survey for ambient radiation exposure rate with a low range survey meter prior to departure from the location of radiopharmaceutical use to ensure that all radiopharmaceuticals and all associated waste have been removed; and

(f) Retain a record of each survey required in paragraph (e) of this section for one year. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour, the model number of the instrument used to make the survey, and the initials of the individual who performed the survey.

§ 35.90 Storage of volatiles and gases.

The licensee shall store volatile radiopharmaceuticals and radioactive gases in a fume hood or in a container with two airtight barriers against release.

§ 35.92 Decay-in-storage.

(a) The 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 the licensee:

(1) Holds byproduct material for decay a minimum of ten (10) half-lives;

(2) Monitors byproduct material at the container surface prior to disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a low range survey meter set on its most sensitive scale and unshielded;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually without any shielding to ensure that it has decayed to background radiation level prior to disposal.

(b) For paragraph (a) of this section, the licensee shall retain a record of each disposal for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the model number of the survey instrument used, the background radiation exposure rate, the radiation exposure 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 (Group General/I)

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

(a) The licensee shall use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion in accordance with the product labeling or package insert instructions for use supplied by the radiopharmaceutical manufacturer, except as provided in paragraph (b) of this section:

(1) Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA);

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

(5) Chromium-51 as sodium chromate or labeled human serum albumin;

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate;

(8) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion authorized by the Food and Drug Administration (FDA), or by a Radioactive Drug Research Committee that has been approved by the FDA pursuant to 21 CFR 361.1.

(b) The licensee using a radiopharmaceutical listed in paragraph (a) of this section for a clinical procedure other than one specified in the product labeling or package insert instructions for use shall comply with the product labeling or package insert instructions regarding physical form, route of administration and dosage range.

§ 35.120 Possession of survey instrument.

Each licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in his possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour.

Subpart E--Imaging and localization (Group II/III)

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

(a) The licensee shall use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies in accordance with the product labeling or package insert or other manufacturer's instructions for use, except as provided in paragraphs (b) and (c) of this section:

(1) Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;

(2) Technetium-99m as pertechnetate;

(3) Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:

(i) Sulfur colloid;

(ii) Pentetate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphate;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin; and

(xiii) Succimer.

(4) Tin-113/indium-113m generators for the elution of indium-113m as choride;

(5) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;

(6) Iodine-125 as sodium iodide or fibrinogen;

(7) Chromium-51 as human serum albumin;

(8) Gold-198 in colloidal form;

(9) Mercury-197 as chlormerodrin;

(10) Selenium-75 as selenomethionine;

(11) Strontium-85 as nitrate;

(12) Ytterbium-169 as pentetate sodium;

(13) Indium-113m as chloride;

(14) Xenon-133 as a gas or saline solution;

(15) Any byproduct material in a radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material authorized by the Food and Drug Administration or by a Radioactive Drug Research Committee that has been approved by the FDA pursuant to 21 CFR 361.1.

(b) The licensee using the radiopharmaceuticals listed in paragraph (a) of this section for clinical procedures other than those specified in the product labeling or package insert shall comply with the product labeling or package insert regarding:

(1) Physical form;

(2) Route of administration; and

(3) Dosage range.

(c) The following radiopharmaceuticals, when used for the listed clinical procedures, are not subject to the restrictions in paragraphs (a) and (b) of this section:

(1) Technetium-99m pentetate as an aerosol for lung function studies.

§ 35.204 Permissible molybdenum-99 concentration.

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

(b) The licensee who prepares technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

(c) The licensee who must measure molybdenum concentration shall also maintain a record of the measure 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 date of the test, and the initials of the individual who performed the test.

§ 35.205 Control of aerosols and gases.

The licensee who administers radioactive aerosols or gases shall do so with a system that will prevent the unintended dispersal of the byproduct material. 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.

§ 35.220 Possession of survey instruments.

Each licensee authorized to use byproduct material for imaging and localization studies shall have in his possession a portable low level

radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable high level ionization type radiation survey instrument that has a scale with a full scale deflection of 1 roentgen per hour.

Subpart F--Radiopharmaceuticals for therapy (Group IV/V)

§ 35.300 Use of radiopharmaceuticals for therapy.

The licensee shall use the following prepared radiopharmaceuticals in accordance with the product labeling, package insert, or other manufacturer's instructions for use:

(a) Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;

(b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;

(c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(d) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(e) Any byproduct material in a radiopharmaceutical and for a therapeutic use authorized by the Food and Drug Administration.

§ 35.310 Safety instruction.

(a) The licensee shall provide oral and written radiation safety instructions for all personnel caring for the patient undergoing radiopharmaceutical therapy. To satisfy this requirement, the instructions must describe 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) The licensee shall keep for two years a list of individuals receiving instructions required by paragraph (a) of this section, a

description of the instructions, the date of instruction, and the name of the individual who gave the instruction.

§ 35.320 Possession of survey instruments.

Each licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in his possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable high level ionization type radiation survey instrument that has a scale with a full scale deflection of 1 roentgen per hour.

Subpart G--Sources for brachytherapy (Group VI)

§ 35.400 Use of sources for brachytherapy.

The licensee shall use the following sources for therapeutic purposes in accordance with the product labeling, package insert, or other manufacturer's instructions for use:

(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 or as wire for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions;

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer; and

(g) Tantalum-182 as wire.

§ 35.404 Release of patients treated with temporary implants.

(a) The licensee shall not release from confinement for medical care a patient treated by the temporary implant of a source listed in § 35.400 until a source count and a radiation survey of the patient confirm that all sources have been removed.

(b) The licensee shall keep a record of source counts and patient surveys for two years. Each record must include the name of the patient, the number of sources implanted, the number of sources removed, and the exposure rate from the patient expressed as millirem per hour and measured within one meter of the patient.

§ 35.406. Brachytherapy sources inventory.

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

(1) The number of sources in storage and their activity;

(2) The number and total activity of sources removed from storage, the room number of use or patient's name, the time and date they were removed from storage, the number and activity of the sources remaining in storage, and the initials of the individual who removed the sources from storage;

(3) The number and total activty of sources returned from use, the room number of use or patient's name, the time and date they were returned to storage, the number and activity of sources in storage, and the initials of the individual who returned the treatment sources to storage.

(b) The licensee shall retain the record required in paragraph (a) of this section for two years.

§ 35.410 Safety instruction.

(a) The licensee shall provide written radiation safety instructions to all individuals caring for the patient undergoing brachytherapy. To satisfy this requirement, the instructions must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Procedures for patient control;

(3) Procedures for visitor control; and

(4) Procedures for notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

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

§ 35.420 Possession of survey instrument.

Each licensee authorized to use byproduct material for brachytherapy shall have in his possession a portable high level ionization type radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

Subpart H--Sealed sources for diagnosis (Group VII)

§ 35.500 Use of sealed sources for diagnosis.

The licensee shall use the following sealed sources for diagnostic purposes in accordance with the product labeling, package insert, or other manufacturer's instructions for use:

(a) Iodine-125 as a sealed source in a device for bone mineral analysis;

(b) Americium-241 as a sealed source in a device for bone mineral analysis; and

(c) Iodine-125 as a sealed source in a portable device for imaging.

§ 35.520 Availability of survey instrument.

Each licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable high level ionization type radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour that has been calibrated in accordance with § 35.51 of this part.

Subpart I--Teletherapy (Group VIII)

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

The regulations and provisions of this subpart govern the use of teletherapy units that contain the following sources for the treatment of humans:

(a) Cobalt-60 as a sealed source; and

(b) Cesium-137 as a sealed source.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the NRC or an Agreement State to perform teletherapy unit maintenance and repair shall 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 Amendments.

The licensee shall apply for and must receive a license amendment prior to:

(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;

(e) Removing the teletherapy unit; or

(f) Allowing an individual not listed on the licensee's license to perform the duties of the qualified teletherapy calibration expert.

§ 35.610 Posted instructions.

The licensee shall post written instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(a) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on;

(b) 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

(ii) any other abnormal operation occurs; and

(c) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted in the event of any abnormal operation of the teletherapy unit or console.

§ 35.615 Doors, interlocks, and warning systems.

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

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

§ 35.620 Possession of survey instrument.

Each licensee who is authorized to use byproduct material in a teletherapy unit shall have in his possession either a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable high level ionization type radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

§ 35.621 Radiation monitoring device.

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

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be checked for proper operation each day before the teletherapy unit is used for treatment of patients.

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

(f) If a radiation monitor is inoperable for any reason, 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 for proper operation at the beginning of each day of use.

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

§ 35.622 Viewing system.

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

§ 35.630 Dosimetry equipment.

(a) The 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. 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 American Association of Physicists in Medicine (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 shall not use the intercomparison result to change the calibration factor. The licensee shall use a teletherapy unit with a cobalt-60 source when intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, and a teletherapy unit with a cesium-137 source when intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units.

(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 maintain 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 instrument that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factors that were deduced, 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) Any licensee authorized to use a teletherapy unit for treating humans shall perform full calibration measurements on each teletherapy unit:

(1) Before the first use of the unit for treating humans; and

(2) Before treating humans 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 physical 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 in radiation therapy;

(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 accuracy;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices used for treating humans.

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

(d) The licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine. These procedures are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, which has been approved for incorporation by reference by the Director of the Federal Register. Copies of the document are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW, Washington, D.C. 20555. A copy of the document is also on file at the Office of the Federal Register, 1100 L Street NW., Room 8301, Washington, D.C. 20408. A notice of any change in the material will be published in the Federal Register.

(e) The licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month.

(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 a qualified teletherapy calibration expert.

(g) The licensee shall retain a record of each calibration for the duration of the license. 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 radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the qualified teletherapy calibration expert.

§ 35.633 Periodic spot-checks.

(a) The licensee authorized to use teletherapy units for treating humans shall perform spot-checks on each teletherapy unit once in each calendar month.

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

(1) Timer accuracy;

(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 treating humans;

(5) The output for one typical set of operating conditions; 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).

(c) The licensee shall use the dosimetry system described in § 35.630(b) to make the measurement required in paragraph (b)(5) of this section.

(d) The licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the qualified teletherapy calibration expert. That individual need not actually perform the spot-check measurements.

(e) The licensee shall have the qualified teletherapy calibration expert review the results of each spot-check within 15 days. The qualified teletherapy calibration expert 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.

(f) The licensee authorized to use a teletherapy unit for treating humans shall perform spot-checks of each teletherapy facility at intervals not exceeding one month.

(g) To satisfy the requirement of paragraph (f) of this section, checks must assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) The function of 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) All beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) The viewing system;

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

(6) Operability of any electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(h) The licensee shall lock the control console in the off position if any door interlock malfunctions, and shall not use the unit until the interlock system is repaired.

(i) The licensee shall promptly repair any system identified in paragraph (g) of this section that is not operating properly.

(j) The licensee shall retain a record of each spot-check required by paragraphs (a) and (f) 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, the measured timer accuracy, the calculated on-off error, a radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated 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.

§ 35.641 Radiation measurements following installation of a source.

(a) Before human use and after each installation of a teletherapy source, the licensee shall perform radiation surveys to verify that:

(1) The maximum and average radiation levels at one meter from the teletherapy source when in the off position do not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively; and

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

(i) Radiation quantities in restricted areas adjacent to the treatment room are not likely to cause personnel exposures in excess of the limits specified in § 20.101 of this chapter, and

(ii) Radiation quantities in unrestricted areas adjacent to the treatment room 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 quantity 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) The licensee shall maintain 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 manufacturer's name, model number and serial number of the instrument used to measure radiation levels, each radiation level measured around the teletherapy source while in the off position and the average of all measurements, a plan of each area that was surveyed, the measured exposure 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.

§ 35.642 Facility checks following installation of a source.

(a) The licensee shall promptly test all systems listed in § 35.633(g) for proper function after each installation of a teletherapy source.

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.633(g), 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 test the malfunctioning system.

(c) The licensee shall retain a record of the facility checks following installation of a source for two years. 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.

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

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:

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

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

(c) Include in the report required by § 35.644 the results of the initial survey, a description of the modification, and the results of the second survey.

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

The licensee shall mail an original and a copy of the results of the surveys and tests required at §§ 35.641, 35.642, 35.643, and the output from the teletherapy source expressed as Roentgens per hour at a distance of one meter from the source and determined during the full calibration required in § 35.632, to the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in §35.16 of this Part within thirty days following each installation of a teletherapy source.

~~(a) The Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and~~

~~(b) The appropriate U.S. Nuclear Regulatory Commission Regional Office listed in § 35.16 of this Part.~~

§ 35.645 Five-year inspection.

(a) The 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) The 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 model number and serial number of the teletherapy unit, 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.

(d) Amendments to teletherapy licenses that extended the time interval for the inspection and servicing requirement of paragraph (a) of this section that were in effect on March 4, 1983 remain in effect and are not rescinded by this section.

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:

(a) Be certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

(3) American Board of Nuclear Medicine Science in Nuclear Medicine Science; or

(b) Be an authorized user for those byproduct material uses that come within the Radiation Safety Officer's responsibilities; or

(c) Have had classroom and laboratory training and experience as follows:

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

(3) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(4) 20 hours of radiation biology;

(5) 30 hours of radiopharmaceutical chemistry; and

(6) One year of full time experience in medical radiation safety at an institution under the supervision of the individual listed as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the human use of byproduct material.

(d) The training and experience specified in paragraph (c) of this section must have been obtained within the five years preceding the date of application or the Radiation Safety Officer must have had experience equivalent to one year of full time employment in medical radiation safety within the last five years.

§ 35.901 Radiation Safety Officer training exception.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license on (*** insert effective date of final rule ***), who oversees only the use of byproduct material for which the licensee was authorized on that date, 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 listed in § 35.100(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine; or

(2) Diagnostic radiology with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 200 hours of training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals. To satisfy this requirement, the training must include classroom and laboratory instruction and supervised experience in a nuclear medicine laboratory as follows:

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

(3) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(4) 20 hours of radiation biology; and

(5) 30 hours of radiopharmaceutical chemistry; 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 within five years of the date of application for a license, or have had experience equivalent to one year of full time employment in nuclear medicine within the last five years.

§ 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 listed in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine; or

(2) Diagnostic radiology with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 100 hours of radiation physics and instrumentation;

(ii) 30 hours of radiation protection;

(iii) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(iv) 30 hours of radiation chemistry, and

(v) 20 hours of radiopharmaceutical biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(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 meter;

(iii) Calculating and safely preparing patient dosages;

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

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

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

(3) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at an institution and must include:

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

(ii) Selecting the proper radiopharmaceutical and calculating the dosage;

(iii) Administering dosages to patients and making proper use of 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 within five years of the date of application for a license, or have had experience equivalent to one year of full time employment in nuclear medicine within the last five years.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

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

(a) Is certified in nuclear medicine by the American Board of Nuclear Medicine; or

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and have had supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

(iii) 10 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 20 hours of radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at an institution and must include:

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

(ii) Use of soluble phosphorus-32 for the treatment of polycythemia vera, leukemia, or bone metastases in 3 individuals;

(iii) Use of colloidal phosphorus-32 for intracavitary treatment of malignant effusions in 3 individuals;

(iv) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals; and

(v) Use of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

§ 35.940 Training for therapeutic use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user using 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 a 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) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 25 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(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 safely;

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

(v) Using emergency procedures to handle and control byproduct material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at an institution.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

(b) Has completed 24 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 6 hours of radiation physics and instrumentation;

(ii) 6 hours of radiation protection;

(iii) 4 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 8 hours of radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at an institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals and must include the examination of each individual to be treated, calculation of the dose to be administered, administration of the dose, post-administration 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 using 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 with special competence on nuclear radiology, or therapeutic radiology by the American Board of Radiology; or

(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 completed 8 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device . To satisfy the requirement for instruction, the training must include:

(1) 3 hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) 3 hours of radiation biology; and

(3) 2 hours of radiation protection and training in the use of the device for the purposes authorized by the license.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user using 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; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(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) Has completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 25 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(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.

(3) To satisfy the requirement for supervised clinical experience, training under the supervision of an authorized user must include:

(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 dose as warranted by patients' reaction to radiation; and

(iv) Post-administration followup and review of case histories.

§ 35.961 Training for qualified teletherapy calibration expert.

The licensee shall require the individual calibrating or checking the radiation output of a teletherapy unit as a qualified teletherapy calibration expert as provided by §§ 35.632 and 35.633 to:

(a) Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen ray and gamma ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a qualified teletherapy calibration expert at an institution where teletherapy is performed. To satisfy this requirement, the neophyte qualified teletherapy calibration expert must have performed the tasks listed in §§ 35.59, 35.632, 35.633, and 35.641 of this part under the supervision of a qualified teletherapy calibration expert during the year of work experience.

§ 35.970 Experienced authorized user training exception.

A physician, dentist, or podiatrist identified as an authorized user for the human use of byproduct material on a Commission or Agreement

State license on (*** insert effective date of final rule ***) who performs only those methods of use for which he was authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 New physician training exception.

A physician who, by August 31, 1987, has successfully completed a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education need not comply with the requirements of §§ 35.910 or 35.920.

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; or

(3) Any 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;

(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 violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any regulation or order issued under the requirements of 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.

The following amendments are also made to existing parts of the regulations in this chapter. The authority for these conforming amendments is: 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).

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

2. Section 30.4 is amended by revising paragraphs (h) and (l) to read as follows and by adding new paragraphs (x) and (y) as follows:

§ 30.4 Definitions.

* * * * *

(h) "Human use" means the intential 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 in the art of medicine.

* * * * *

(l) "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;

* * * * *

(x) "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 the art of dentistry on humans.

(y) "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 the art of podiatry on humans.

* * * * *

3. 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 maintain the records required by § 35.204.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

§ 31.11 [Amended]

* * * * *

4. Section 31.11(b) is amended by deleting "§35.14(c)" and inserting "Part 35."

PART 32 - SPECIFIC DOMESTIC LICENSE TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

§ 32.70 [Removed]

5. Section 32.70 is removed.

6. In § 32.72 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 group licenses.

(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 affixed to each package, or the leaflet or brochure that accompanies each package, contains a statement that the unit dosage radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to Part 35, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

7. 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 radiopharmaceutical 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 of 10 CFR Part 35 or under an equivalent license of an Agreement State.

* * * * *

8. 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 (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material identified in §§ 35.58, 35.400, and 35.500 of 10 CFR Part 35 or under an equivalent license of an Agreement State.

* * * * *

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

9. 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;

* * * * *

PART 71 - PACKAGING OF RADIOACTIVE MATERIAL FOR TRANSPORT AND TRANSPORTATION OF RADIOACTIVE MATERIAL UNDER CERTAIN CONDITIONS.

10. Section 71.9 is amended by revising the section to read as follows:

§ 71.9 Note: ELD is preparing this section - nlm

Dated at Washington, D.C. this ____ day of _____ 1983.

For the Nuclear Regulatory Commission.

_____
Samuel J. Chilk,
Secretary of the Commission.

ast: Glenn Klecsik R2-5

addendum A to: 12 07 83

[7590-01]

New Sections for Part 35 Preamble

Word usage

In preparing the proposed revision of Part 35, one goal was to remove language that might be misinterpreted. The following words used in the revision may require clarification.

1. Type of use and group. In the current Part 35 there are six "groups" of use described in § 35.100. Each group is comprised of a set of medical procedures that require similar training and equipment for radiation safety purposes. The word "group" has not been used in the proposed revision in order to avoid confusion between the old and new Part 35. The revision uses the phrase "type of use" for this concept. Some types of use are amalgamations of old groups, and some are new. The six types of use are: (1) uptake, dilution, and excretion -- Subpart D; imaging and localization -- Subpart E; radiopharmaceutical therapy -- Subpart F; brachytherapy -- Subpart G; sealed sources for diagnosis -- Subpart H; and teletherapy -- Subpart I.

2. Method of use and procedure. The word "procedure" is frequently used in supporting documentation for byproduct materials programs. Sometimes it refers to a specific set of steps that must be taken to effect an end, for example a procedure for ordering and receiving packages. Sometimes it is used to indicate a type of medical examinaton or therapy, for example a thyroid uptake study or a cesium implant or therapy, without indicating the amount of byproduct material used or the specific steps taken in handling it. The word may also be used to indicate the number of patients cared for over a period of time, for example an average workload of fifteen procedures each day. In order to avoid further confusion, the phrase "method of use" appears in the proposed revision. Each type of use is comprised of several methods of use. Each method of use should identify the radionuclide, its form, method of administration, and purpose; in many cases one or more of these identifiers are understood and not specifically stated.

X

3. 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; and in radiation safety it is used to indicate a worker's exposure to radiation. In order to avoid further confusion, the word dosage is used in the proposed revision to indicate quantities that are measured in curies and the word dose to indicate quantities that are measured in rads or rems.

4. 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 large as a survey of a newly installed teletherapy unit with appended calculations to prove compliance with the limits on exposure in uncontrolled areas. A report is a communication with an outside entity which might be made by telephone, telegram, letter, or completed form.

5. Test and check. In many cases there are standards of performance and complete calibration protocols that have been prepared for equipment by experts. If a piece of equipment is subjected to the protocol in the laboratory and meets all the standards, then the authors would agree that there is no reason to doubt the ability of the equipment to perform as expected in normal field use. In the proposed revision this concept is referred to as a "test." During field use it is common practice to subject a piece of equipment to a perfunctory examination to determine whether it has suffered catastrophic damage in transit or is otherwise inoperable. Such a procedure does not examine all parameters of equipment performance. In the proposed revision this concept is referred to as a "check."

5. Location of use, facility, and area. The phrase "location of use" is used to describe the building or buildings where byproduct material is used. The phrase "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 word "area" connotes the space used by a worker when performing a specific task connected with receiving, handling, or storing byproduct material.

6. Chemical form. The current regulation requires that if a radiopharmaceutical is used for indications other than described in the

package insert, the user must nevertheless follow instructions on chemical and physical form, dosage, and route of administration. The proposed revision has deleted the word chemical in its restatement of this requirement because changing the chemical form would be creating a radiopharmaceutical other than the one received from the authorized distributor. Excision of this word in the proposed revision does not authorize Part 35 licensees to manufacture radiopharmaceuticals for in-house use or distribution.

Records retention

The Commission requires that licensees make and retain records as evidence of compliance with regulations. A review of records during inspections is the least burdensome way that the Commission may be assured that the licensee has developed and implemented a radiation safety program. However, permanent retention of all required records would be unreasonably burdensome for licensees, and would run counter to recent guidance to regulatory agencies that was issued by the Office of Management and Budget. Therefore the Commission has, in the proposed revision generally adhered to the following policy.

1. For recurring records that are created on a daily basis, for example end-of-day surveys, the Commission has made a judgment that records retention for one year provides adequate evidence of compliance with requirements.

2. For non-recurring, sporadic, or periodic records, such as individual patient dosages or survey instrument calibrations respectively, the Commission has made a judgment that records retention for two years provides adequate evidence of compliance with requirements.

3. In a few cases a record is only created once or the Commission considers the record to be critical evidence of compliance with regulations that, if not followed, might cause an immediate discernible impact on a worker or member of the public. See, for example, requirements for the geometry test for a dose calibrator and the teletherapy dosimetry equipment calibration, respectively.

4. In a few cases, for example sealed source leak tests that are only performed biannually, the Commission believes a three year retention requirement is necessary.

Current Licensees

Under the current regulatory program the license document with the appended application is used to regulate each individual licensee. Since the requirements in the proposed revision were taken from commonly used license conditions and regulatory guidance that most licensees have incorporated in their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants who apply after the effective date of the proposed regulations. Therefore, current licensees would be required to adhere to the new regulations. However, if there is inconsistency between the license and the regulation (for example a license may require survey instrument calibration once each year, but the proposed regulation would require calibration each six months) with the license less stringent that the regulation, the license would be considered as an exemption from the regulation. Since the less stringent license requirement was reviewed for safety considerations and approved by the NRC, such inconsistencies would not result in a potential risk to workers or the public. If the license requirement is more stringent than the regulation, the license requirement will stand in place of the regulation because it may serve to balance another license requirement elsewhere that is less stringent than the proposed regulation.

In the case of records retention, the regulation will take precedence because the Commission in the past has not offered guidance on this topic and many applicants have either not specified a period or have incorporated the phrase "until the Commission authorizes their disposal" rather than shouldering the burden of justifying a shorter period. The only exception to the preceding sentence is a record requirement that is specifically described in a license condition.

New Paragraphs for Part 35 Commission Paper

Many individuals recommended that commonly used general safety measures be included in the revision. They would require use of gloves and laboratory coats for individuals handling radiopharmaceuticals, require use of whole body dose monitors for all Part 35 radiation workers and finger dose monitors for individuals who elute generators or handle brachytherapy sources, specify frequency of radiation worker training, require the use of radionuclide sources for survey instrument calibration, package ordering and opening procedures that are more stringent than required in the current Part 20, requirements that food not be stored along with byproduct material and radioactive solutions not be pipetted by mouth, and specify frequency of air sampling measurements. If such safety measures are needed to ensure worker or public protection, a similar case could be made for placing such requirements on almost all other classes of licensees. Therefore, the requirement would be more properly placed in Part 20. Therefore, such requirements do not appear in the proposed revision of Part 35 because they are not peculiar to medicine. Generally, only requirements that are peculiar to the human use of byproduct material were included in the revision. The few exceptions to this statement are requirements that might apply to some other groups of licensees but are considered critical elements in a medical radiation safety program and whose absence, in light of the specificity of other Part 35 requirements, might be construed as a tacit removal of the requirement. An example of this is performance requirements for survey instruments.

Many individuals also recommended that more safety measures that are peculiar to medicine be included in the revision. Some examples that were submitted are: 1. recalibration of imaging equipment that was transported in support of mobile service, 2. storing and preparing volatile radiopharmaceuticals and gases in a fume hood, 3. testing frequency for radioactive gas trapping devices, 4. provision of private room with private toilet for hospitalized radiopharmaceutical and brachytherapy patients, and treating such rooms as restricted areas during therapy, 5. control of contaminated items and associated waste, 6. use of remote handling tools for manipulating brachytherapy sources, and

7. use of electrical or mechanical position limit switches on teletherapy units if the room shielding is inadequate. In response it is noted that 1. calibration of imaging equipment would be contrary to NRC's medical policy statement, but checking transported safety equipment has been included, 2. a fume hood is only one of several methods for providing worker safety during storage of volatiles and gases, 4. a private room with private toilet is not a necessary safety measure for these patients and the requirements for declaring an area restricted are already stated in Part 20, 5. requirements for control of waste contained in Part 20 are adequate, 6. the amount of training required for authorization to use brachytherapy sources is sufficient to instill in the user a clear understanding of their hazard, and 7. use of limit switches is not the only way to assure that exposure rates in controlled and uncontrolled areas are within permissible limits.

In summary, many useful comments on the earlier proposed revision, SECY 83-62, were received and have been incorporated. However, in many cases there were suggested requirements that might be good practive but are not necessary to keep worker and public doses within permissible limits. The goal of the staff who prepared the proposed revision was to include only those requirements for which a clear, technically valid safety need was apparent.