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8/18/83

NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30, 31, 32, 35, and 40
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 essential safety ~~needs~~ now contained in license conditions, regulatory guides, and staff positions, the proposed regulation provides a single source requirements for human use. ~~This would~~ reduce the administrative burden on the licensee. The proposed regulation also provides the basis for a more ~~efficient license application and review process~~ that would conserve licensee and NRC resources. The proposed revision to the regulations ~~is needed to~~ provide a more efficient method for ~~licensing~~ the medical uses of byproduct material.

DATE: Comment period expires (insert 60 days after FRN. ~~For purposes of Federal Register publication, the date computation formula is removed. This language should be included in the cover memo that accompanies the document when it is submitted for publication. SECY will insert the actual date based on the FR pub. date~~). 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.

Enclosure 1

Copies of the preliminary value/impact 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 value/impact statement are available from Norman L. McElroy, Office of Nuclear ~~Regulatory Research~~, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)443-7970.

FOR FURTHER INFORMATION CONTACT: ~~Dr. William Walker~~, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)427-~~4232~~.

SUPPLEMENTARY INFORMATION:

Uses of Byproduct Material in Medicine

Radioactive materials are used in drugs ~~and sealed sources~~ in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. Patients receive these materials by injection, inhalation, or oral administration. Physicians use ~~specialized~~ detecting equipment to visualize the distribution of a radioactive drug within ~~an organ system in the body~~. Using this technology, it is possible to locate tumors and blood clots, ~~measure physiological~~ function, ~~and~~ monitor the effectiveness of treatment. Larger quantities of radiopharmaceuticals are administered ~~therapeutically~~ 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 ~~tele~~therapy ~~units~~ to treat cancer. Teletherapy units provide shielding ~~and collimation to~~ direct the radiation beam to the ~~affected~~ part of the patient's body. An estimated 2 million teletherapy treatments are performed annually by NRC licensees. ~~Much~~ smaller sealed sources are designed to be implanted directly into a tumor or applied on the surface of an area to be treated. This procedure, known as brachytherapy, ~~limits the radiation field to the affected area and spares healthy tissue from radiation damage~~. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

NRC's Role

Twenty-six states have assumed responsibility for regulating certain radioactive materials by agreement with the NRC. They issue licenses for human uses of byproduct material. The NRC issues licenses to medical facilities and individual physicians in non-Agreement States. These licenses ~~define the~~ use of radioactive materials for diagnostic and therapeutic medical procedures in humans. ~~During the past three decades, the medical use of radioactive material has grown about 15 percent per year.~~ NRC currently has ~~2,631~~ medical licensees. In 1981, NRC ~~staff~~ received 73 applications for new licenses, 244 license renewal applications, and 1,303 license amendment ~~applications~~ for a total of 1,620 licensing actions.

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 (§ 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 ~~engaged in nuclear medicine~~ need more byproduct material 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 ~~groups~~ of human use (Groups I-VI, defined in the current § 35.100). These license applications are reviewed individually by NRC. Each group ~~contains~~ related diagnostic or therapeutic procedures. A separate specific license ~~is~~ also issued for use of teletherapy units.

NRC has published many NUREG reports and regulatory guides that contain radiation ~~protection procedures~~ applicable to specific licensees. 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 ~~these procedures~~, the human uses of byproduct material generally ~~do not~~ pose a hazard to workers and the public.

Problems with Current Practice

The General License. Issuing a general license for all in-vivo medical use of radioisotopes to qualified applicants would be the simplest approach for NRC and licensees. It would not achieve the objective of maintaining an acceptable level of safety for the regulated industry. The concept of a general license assumes that the quantities and forms of the licensed material present such a low level of hazard that a case-by-case review of applications, on-site inspections, and periodic license renewals are unnecessary. The concept of a specific license, on the other hand, incorporates all three of these features. For these reasons, materials that are now specifically licensed could not be adequately regulated under a general license.

It is no longer necessary to have an in-vivo medical general license. 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 the medical community's use of the in-vivo general license.

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. Less than 9 percent of the current registrants still use material under a general license. Many have moved, are deceased or otherwise could not be located.

The staff has concluded that the general license no longer serves a useful role in licensing the human use of byproduct material.

The Specific License. A major problem with current licensing procedures is that radiation protection requirements are not located in one document. Currently guidance is scattered among several regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, regulatory guides, technical reports (NUREGs), and as conditions attached to individual licenses.

Suggestions for good practice contained in Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and

its 16 appendices and the bulletins issued by the NRC Office of Inspection and Enforcement have come to be incorrectly perceived as regulations. The revision of Part 35 would correct 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 procedure, the applicant must include sufficient information for NRC reviewers to conclude that all safety requirements for human use will be met. In addition, the applicant must describe the procedures that will be used to meet the requirement of the regulations. Therefore, applicants include copies of their procedures with their application package. 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 experience, facility, equipment, and procedures in detail. If the application is found to be deficient, a "deficiency letter" is sent to the applicant explaining what specific additional information is required. Review of the application is not resumed until the 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. However, in many cases, because of the conservative licensing and review practices, the letters frequently request clarification of information that does not involve significant matters of safety. Deficiency letters greatly increase the time required to complete licensing actions.

When the application, including any additional information, is approved, the NRC issues a specific license that grants the authority for human use of byproduct material. Requirements in addition to those contained in the regulations may be incorporated in the license as conditions of use. Since the licensee must conform with conditions specified in the license, the license also serves to regulate radiation safety in the day-to-day use of byproduct material.

The specific license is valid for five years. Before uses, personnel, or procedures may be changed, the license must be amended. 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.

Proposed ~~Procedural Approach and Supporting Rationale~~

NRC intends to modify its regulation of the medical use of byproduct material. The Commission ~~has a two-step~~ plan: ~~(1)~~ revise the regulations to provide a single source of the requirements specifically related to human use of byproduct materials, and ~~(2) revise the~~ medical license ~~review process. The~~ latter step would allow use of an automated ~~management~~ information system (MIS).

~~NRC's current license review~~ process was appropriate ~~for the early stage of technological development~~ in ~~nuclear~~ medicine. ~~At that time,~~ radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, and training curricula had not been established. Therefore, it was necessary to review each individual program to ensure that the applicant had adequate personnel, facilities, and equipment. The current review process is now becoming unnecessarily burdensome for both licensees and NRC. In ~~deciding on~~ the proposed action, the staff recognized that past NRC policy has been to issue general licenses for materials in forms or quantities that present little or no hazard to the user or public. Specific licenses are issued when there is a need for continuing regulatory surveillance. The proposed revision of the licensing process also takes into consideration the following: (1) the safety technology is now more fully developed, (2) safety requirements are well defined and (3) several professional boards, which require extensive academic and clinical experience prior to certification, have become established.

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." In proposing this revision, NRC seeks to ensure that the degree of regulation is commensurate with the risk posed to health and safety by the various medical uses of byproduct material.

The procedural revisions primarily address problems that complicate the licensing process. They do not directly address radiation protection issues. NRC believes that the health and safety of people involved in human use of byproduct material are being adequately protected at present. Since most radiation protection practices will be unaffected by the revision, NRC fully expects the current level of health and safety protection required of medical licensees to be maintained under the revised regulations.

NRC proposes to simplify ~~the licensing process for~~ medical licensees by ~~transferring~~ all human use requirements ~~to~~ 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 ~~daily~~ uses of radioisotopes ~~at medical facilities. However,~~ licensees would not face new regulatory burdens because, in most cases, these requirements currently appear as license conditions which must be met.

In conjunction with this effort the staff will revise Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs." The revised guide will contain ~~a~~ model ~~and~~ procedures that the applicant can use to develop ~~a~~ site-specific ~~plan and~~ procedures to meet the requirements in the proposed regulations. ~~for human use.~~

NRC further proposes to simplify current licensing practice by eliminating the requirement that applicants submit for review detailed procedures describing how they intend to meet requirements in the regulations. (Licensees will still be required ~~by the regulations, however,~~ to establish and implement these written procedures and have copies available for NRC inspections.) Instead, applicants would submit descriptions of ~~their~~ radiation safety plans. The detailed procedures would have to reflect commitments made in the plan, and would also contain whatever additional requirements the applicant believes necessary to ensure that byproduct material will be used safely.

Since procedures would no longer be submitted to NRC for review, the practice of including these procedures as conditions of use on the license would be eliminated. This simplification would permit licensees to modify procedures to meet NRC requirements without obtaining a license amendment. In its inspection and enforcement role, NRC would be concerned with whether the requirements in the regulations are being met, not with

the details of the procedures used to meet them. A license amendment would still be required for changes in types of medical use or any change in professional staff. Overall, the number of amendment requests is expected to decrease substantially as a result of this simplification.

Because lengthy procedural descriptions are presently affixed to licenses as conditions of use, applications can be 50 pages or more in length. Under the proposed approach, the licensee would operate the facility according to the requirements for human use in the regulations and the commitments made in the radiation safety plan submitted with the application. Day-to-day practices would be essentially unchanged under this scheme, but the volume of paperwork transferred between NRC and its medical licensees and the volume of the license itself would be greatly reduced. Institutions that have broad licenses authorizing research and development of human uses of byproduct material in addition to medical uses that are generally recognized as safe will still have to submit appropriate procedures for review. Each will be exempted by license condition from those sections of Part 35 that would unduly inhibit its medical research program. Broad license applicants who wish to be authorized for in-vitro and animal research under the authorization of the Radiation Safety Committee and for human use as described in Part 35 will also continue to be required to submit appropriate descriptions of procedures for review in accordance with 10 CFR Part 33.

To summarize, placing all human use requirements in the regulations and eliminating submittal of specific procedures would expedite the licensing review process. NRC estimates that eliminating staff review of procedures would decrease the necessary review time by about 50 percent. NRC estimates that the proposed simplifications would decrease the rate of deficiency letters for medical applicants by greater than 95 percent. This would result in a reduced process burden for NRC and faster turn-around time for licensees. Since the NRC processing time would be reduced, NRC staff would have time to conduct postlicensing inspections of medical applicants shortly after the start of operations.

NRC plans to modify an existing MIS to further increase the efficiency of the review process. The MIS would be designed to decrease delays in the licensing process caused by paperwork processing. It would aid the staff in their review of applications. Furthermore, the

3. "The Commission has decided to continue the pre-licensing review of applicants' operating procedures . . . " The staff will continue to review procedures submitted in support of an application in order to determine whether they are sufficient to meet the requirements of the regulations, and will issue a deficiency letter if procedures are incomplete or inadequate. (Consistent with current practice, applicants will be allowed to simply certify that they will follow the model procedure supplied in Regulatory Guide 10.8, or they will be allowed to submit their own alternative procedures for review.) A licensee will be cited for failure to have the written procedures required by the regulations, failure to follow those procedures, 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). 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, licensee's 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 modifications.

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DRAFT PLAN FOR REVISING PART 35

The Commissioners unanimously directed the staff to revise SECY-83-62 in accordance with four directives. The directives and the planned responses follow.

1. "The Commission approves the consolidation of the essential safety elements . . . into a Part 35 rule." Except as noted below, the regulation the staff will only make editorial and other non-substantive changes such as adding recently approved drugs and a recently approved sealed source device, adding definitions for podiatrists and dentists, and updating the regionalization information.

2. ~~"The Commission has decided to continue the pre-licensing review of physicians' qualifications . . ."~~ The proposed regulations ~~will~~ require specific training and experience for the use of material in ~~any particular~~ use group. ~~The regulation and licensing method will be revised to require~~ each proposed authorized user (AU) physician, and Radiation Safety Officer (RSO) and Qualified Teletherapy Calibration Experts (QTCE) to submit summaries of their training and experience ~~on a form similar to 313M Supplements A and B~~. The staff will review those individuals' training and experience before authorizing them to work as an AU, RSO, or QTCE. Use, or supervision of use, of material without ~~the specified training and experience~~ 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 enforcement 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, consisting of representatives of the R.S. and license management, have reviewed and approved the modifications. 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.

~~4. "The staff should clarify how it will implement the proposed requirements regarding license amendments . . ." The staff foreseas four types of amendments.~~

1 a. New users. The ~~staff~~ NRC will review the training and experience of each proposed AU, RSO, and QTCE as described ~~in item 2.~~ above.

2 b. New type of use. ~~Amendment~~ 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 c. New method of use. Two types of amendment ~~may~~ and be needed:

i. 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 intravenously by 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 ~~letter~~ notice that says they may begin using the new RAM on the effective date of the final rule that adds the new RAM. No individual licensing action will be taken. to the regulations

go to 7d

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b

~~ii~~. 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

~~1~~. 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, ~~when applying for amendment,~~ would have submitted the new RAM procedure for review, in their application packages.

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~~2~~. NRC will mail to current licensees a notice ~~letter~~ that says they may apply for authority to use the new RAM. With that notice ~~letter~~, NRC will also supply a model procedure, which would become a new appendix in ~~an addition to~~ Regulatory Guide 10.8, ~~)~~ 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. ~~This review will include review of procedures for the new RAM.~~

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~~d~~. 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 will only have to identify the new location. for diagnostic studies

Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC does not authorize licensees to perform therapies at satellite locations. (Jim is this correct?)

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In summary, the regulat~~ory text proposed earlier~~ion will ~~not~~ be amended to require that licensees meet standards that are currently imposed by license condition. ~~substantively modified (except for subsequent rule changes that have been made to accomodate new RAM's and uses).~~ The ~~staff~~ NRC will continue to review user training and experience, ~~and issue deficiency letters if necessary~~. The ~~staff~~ NRC will review site-specific procedures for completeness and adequacy and issue deficiency letters if necessary, but will ~~not require~~ allow licensees to ~~follow the specific~~ 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.

7e

MIS can be used to compare application data with licensees of similar type and size. Unusual variations will automatically be brought to the attention of the reviewer. This prelicensing audit capability would identify conditions that may warrant further evaluation of the applicant's program by the reviewer. The MIS would provide for: (1) automated screening of applications for completeness and (2) an automated data base management system that would permit preparation of descriptive statistics and evaluation of trends. These are impractical with the current manual processing and hard copy filing systems. The MIS would also benefit licensees by reducing delays in the review process.

Although the MIS would enhance the improvements of the proposed revisions, definite gains in efficiency would be made in the licensing review process without modifying the existing MIS. However, it is estimated that review time could be reduced by an additional 10 days per application by using the MIS combined with the other processing revisions. The time gained by NRC staff through the proposed simplifications would be focused on reducing the backlog of medical licensing actions and on evaluation of other safety issues.

Under the proposed revisions, 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 ~~conditions~~ 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.

Scope of Revision of Human Use Regulations (10 CFR Part 35)

NRC is proposing a revision of the human use regulations to (1) provide the necessary changes to clarify and simplify the medical licensing process and (2) include staff resolutions of recent issues and of a petition for rulemaking that pertains to medical licensees (PRM-35-2). Most of the changes involve a transfer of a recommended practice or requirement from another NRC document to the regulations without modification of the requirement itself.

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 ~~procedures~~ 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 provision for~~ general licenses has been eliminated from the proposed regulations, and all human use will be specifically licensed. (Current general licenses will be incorporated in the specific license system. ~~General licensees~~ will be limited to the methods of use described in the current § 35.31, and relieved from those provisions of the proposed Part 35 that are unnecessarily burdensome for those authorized amounts and methods of use.) ~~The~~ The proposed specific licenses differ from the current licenses because they would not specify additional requirements except in unusual cases.

Items of general information, general administrative requirements, and general technical requirements are addressed first. ~~These are found~~ in Subparts A through C, respectively, ~~of the proposed regulations.~~ 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 ~~for each type of use~~, 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, ~~and~~ 40. 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:

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 who handle byproduct material have a license issued by the Commission or an Agreement State. The Commission uses the specific licensing process to limit the use of byproduct material to ~~applicants~~ 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 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 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,

The term "dentist" was added to identify a group of practitioners 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

~~current definition of the~~ term human use to make it clear that occupational and nonoccupational 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 policy 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 to practice medicine and therefore eligible to apply for a license to use byproduct material in the practice of medicine.

The term "podiatrist" was added to identify a group of practitioners 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 ~~that~~ individual.

The term "Radiation Safety Officer" was added to identify the individual ~~identified by~~ name 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.

§ 35.16 Application for license, and § 35.17 License amendments.

The criteria that will be used by the staff to evaluate requests for licenses, amendments, and exemptions are identified in § 35.28, License issuance, of this discussion of proposed regulations.

§ 35.16 Application for license.

A physician in private practice may apply for a license. An individual physician may not apply for a license if his use of material is in connection with the provisions of nuclear medicine services by an institution, i.e., an organization which provides various medical services. At an institution, only management may apply for a license. 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-313MH because it elicits information in an orderly, readable manner. It will also allow for uniformity in Commission information handling systems.

This section also reflects the Commission's decision to delegate to Regional Administrators some of the 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 believes that, since exposures should be kept as low as reasonably achievable (ALARA), the licensee must obtain an amendment for any changes to the license that might increase the potential for radiation to workers and the general public. The Commission has determined that certain changes are potentially significant for the following reasons and thus will require an amendment:

(1) A change in type of human use or receipt of byproduct material may increase radiation exposure.

(2) The use of byproduct material at an address not identified on the license ~~may allow an increase in unmonitored radiation exposure levels~~.

(3) ~~A change in either the individual listed as the~~ Radiation Safety Officer, ~~as an~~ authorized user, ~~or as the~~ qualified teletherapy calibration expert ~~requires an amendment request so that~~ the Commission ~~may determine~~ that the training and experience of ~~the new individual is~~ sufficient to ensure safe use of byproduct material.

(4) Any other program changes that might result in an increase of radiation exposure 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. 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. ~~(For the purpose of this statement of consideration, the term "type of use" refers to titles of Subparts D through I. For example, uptake, dilution, and excretion is a type of use.~~ Imaging is a type of use.) The Commission has made a judgment that notification within 30 days is sufficient. 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 program ~~responsibilities~~ may increase the probability of an accumulation of unused byproduct material or unauthorized use of ~~restricted areas~~. 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 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. Over a longer term, the descriptive information submitted on the application may no longer accurately describe the scope of the byproduct material program and resources available.

The applicant must use Form NRC-313MH because it was specifically designed to elicit the information the Commission needs to complete a safety review of the applicant. The Commission will apply certain standards when reviewing an application to assure 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 found in 36 FR 145, published January 6, 1971.

§ 35.29 Specific exemptions.

The Commission may allow exemptions from the requirements of this part if the applicant can show the exemption will not compromise the health and safety of the worker and 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 assure that sources of radiation and work procedures are regularly reviewed for safety. Specific ~~duties~~ usually considered part of an ALARA program are required by §§ 35.31 and 35.32.

§ 35.31 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).

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), will be incorporated in the ~~final~~ wording of Part 35.

The Committee must review (1) the qualifications of each individual to be listed as an authorized user, and (2) each proposed method of use. ~~This is~~ to assure the safety of workers and the public. 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 quarterly. A more frequent review 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 ~~based on~~ 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 reducing the exposure. 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 ~~should include the status of~~ current 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 ~~changes~~ 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.

§ 35.32 Radiation Safety Officer.

An individual with special expertise is needed to coordinate the safe use of byproduct material in accordance with the license and regulations. ~~This is~~ the Radiation Safety Officer (RSO). ~~In § 35.32, paragraphs (a) through (e) specify the RSO's safety responsibilities.~~

§ 35.33 ~~Administrative~~ Requirements for Authority and Responsibilities.

To assure that ~~proper records are kept, responsibility for record-~~ keeping required by this part rests with the RSO and the committee. Records ~~that describe~~ the licensee's receipt, use, and disposal of byproduct materal, equipment checks, and surveys must be kept. The licensee must also keep records that show that the RSO, the authorized users, and qualified teletherapy calibration expert meet the training and experience requirements of Subpart J. These records may be either copies of certifications by certifying bodies listed in that subpart, or a transcript of appropriate training courses and a narrative of experience which together meet the appropriate requirements of Subpart J. For RSO's, authorized users, and qualified teletherapy calibration experts who do not have a certification, the preceptor's statement, form NRC-313M Supplements A and B which is appended to Regulatory Guide 10.8, constitutes an adequate record.

§ 35.34 Visiting authorized user.

In the Commission's judgment, the uninterrupted provision of ~~necessary~~ medical ~~services~~ 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 at the visited medical facility. Visits of more than 60 days in one year suggest that the visiting authorized user is an integral part of the institution's health care delivery system, and should be identified as an authorized user on the medical facility's license.

§ 35.35 Mobile service administrative requirements.

Mobile service licensees are required to have a letter of permission from the management of each client facility. ~~This will~~ 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 maintains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. ~~No changes have been made to these requirements.~~ 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. ~~Therefore~~, 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.

~~The~~ authorized users may use only ~~radiopharmaceuticals that have been~~ 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 ~~and~~ followed by the RDRC ~~are~~ 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.

Accuracy ~~means~~ the ability to exactly measure a specified quantity, and Linearity ~~means~~ the ability to exactly measure a range of quantities. A dose calibrator must be tested for ~~these characteristics~~ to assure that the ~~amount~~ of material given is the prescribed ~~amount~~. The American National Standards Institute (ANSI) recommends these test frequencies to assure the proper operation of dose calibrators. (See ANSI N42.13-1978.) 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.

§ 35.51 ~~Possession, use,~~ 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. This calibration frequency ~~is~~ consistent with ANSI N323-1978. ~~Section 4.7.1.~~

§ 35.53 Measurement of Radiopharmaceutical Dosages.

This section requires that the licensee assay each radiopharmaceutical dosage before it is administered to a patient and keep a record of the assay results. This procedure is currently required ~~by all specific licenses for medical use of byproduct material~~ to ~~a~~ssure that the patient receives the intended dose.

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. Eighteen comments were received.

The NRC is incorporating the dosage measurement proposal in this revision. The proposed Part 35 dosage measurement requirement differs from the 1981 proposal only in its recordkeeping requirement. The Part 35 proposal requires the dosage measurement record to include the patient's name and identification number. 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 Part 35 revision and 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 test ~~the proper function of~~ radiation ~~safety~~ instrumen~~tation~~. 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. ~~to fully test their equipment.~~

§ 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 ~~is in the current regulations and~~ 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 a ~~maximum permissible removable contamination~~ limit of 0.005 microcuries for ~~sealed sources.~~ 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. 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 is inconsistent with ALARA exposure goals. To inventory less frequently may allow an unacceptable radiation exposure to go on for too long without detection. The Commission has made a judgment that the exempted sources do not present a contamination hazard because of the small amount 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.

§ 35.60 Syringe shields.

Syringes that contain byproduct material ~~present~~ an external radiation hazard and should therefore be shielded at all times. In some cases the use of ~~the~~ shield could interfere significantly with the injection ~~of the material.~~ Since this would ~~limit~~ patient benefit, the higher

[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.

radiation exposure received by the technician ~~in the absence of~~ a shield is warranted. Where the ~~harm from~~ extravasation, for example, is greater than the benefit of reduced worker exposure, a shield need not be used.

§ 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 ~~two~~ 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 survey will bring this problem to the attention of workers. The weekly survey of waste storage areas will ensure that exposure ~~to workers~~ in that area ~~and to uncontrolled areas~~ will be monitored ~~and~~ that special steps ~~will~~ be taken if greater than average use of radiopharmaceuticals results in higher than average exposure ~~levels~~ in the waste storage area. 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. ~~While~~ 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. ~~For~~ iodine-131, the most common therapeutic radiopharmaceutical, the 6 mR/hr limit ~~would result in a whole body dose equivalent to a co-worker or family member of about 500 millirem, assuming~~

that individual spends eight hours per day at an average distance of 1 meter from the patient. The Commission considered a lower limit that would require a longer period of patient confinement. The Commission has made a judgment that further reductions in public exposure are not reasonably achievable considering the potential for detrimental effect of an unnecessarily long hospital confinement.

§ 35.80 Mobile service technical requirements.

The Commission has limited mobile service licensees to transporting byproduct material as unit dosages because, at this time, there is insufficient assurance that the facilities and equipment needed to prepare bulk radiopharmaceuticals and perform quality control measurements can be frequently transported and still work reliably. 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 consider client facilities as unrestricted areas because 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.

The equipment check required by § 35.80(d) is necessary to assure the proper function of safety instrumentation and equipment after transport and before byproduct material is handled. The survey required by § 35.80(e) is 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 a traffic or other 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, and 35.205 Control of aerosols and gases.

Some radiopharmaceuticals present an inhalation or immersion hazard (e.g., iodine-131 and xenon-133). That hazard can be minimized by

storing these in a fume hood or double airtight barrier, and by using them with a collection or ventilation system.

§35.92 Decay-in-storage.

For most hospital 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 ~~human use~~ waste. Because the special handling required for long half-lived material is ~~typically~~ not needed for ~~human use~~ waste, ~~§ 35.92 exempts this~~ waste from the requirements of § 20.301. 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. Ten half-lives was chosen as a decay period 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 ~~specific~~ conditions, are exempt from a requirement for a specific license. Waste must be monitored to assure that long-lived waste was not accidentally mixed with short-lived waste. When the waste is monitored, neither the waste nor the survey instrument may have any radiation shielding. ~~Shielding of the waste or detector~~ might hide the presence of long-lived byproduct material in the waste. 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--~~Group~~ General/I (uptake, dilution, excretion)

§§ 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.

Manufacturers are currently distributing general license radiopharmaceuticals under a license issued pursuant to section 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 section 32.72.

Subpart E--Group II/III (imaging)

§ 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 section 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 aerosol ~~used~~ 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.

§ 35.120 Possession of survey instrument.

A low level survey instrument is used to check areas 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

(RDRC) (FDA)
The Food and Drug Administration also authorizes the Radioactive Drug Research Committee 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.

§ 35.220 Possession of survey instruments.

(c) 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.

The permissible concentration of molybdenum-99 was chosen to be consistent with the permissible concentration listed in the United States Pharmacopeia (USP). ~~The USP is~~ the nationwide standard for all pharmaceuticals used in the practice of medicine. It is the judgment of the Commission that to ~~introduce~~ a different standard would, ~~in this case~~, 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. ~~Add text.~~

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

§ 35.300 Use of radiopharmaceuticals for therapy.

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,

§§35.304 Safety instruction, and 35.405 Safety instruction.

In the hospital setting, the use of byproduct material presents special training problems which, ~~in the judgment of the Commission~~, 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.

Subpart G--~~Group VI~~ (sources for brachytherapy)

§ 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 ~~Schedule A Group VI~~. 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.

Subpart H--~~Group VII~~ (sealed sources for diagnosis)

§ 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 ~~under Group VI of the current Part 35~~. 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.

§ 35.406 Brachytherapy sources inventory.

Because of the particular hazard of brachytherapy sources due to their high activity and small size, the Commission believes 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 patients room, and to check to be sure all sources have been removed from the patient before release from confinement.

§ 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 ~~does not believe~~ that it is sufficient, for safety purposes, to require the licensee to make arrangements to borrow or rent an instrument or contract with a service measurement who makes measurements are necessary.

Subpart I--Group VIII (teletherapy)

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

This is a new use group established to ~~acknowledge~~ a well established ~~medical procedure~~. Safety measures that apply to all licensees within the group have been used over the years and are reflected in these proposed regulations.

§ 35.604 Information to be submitted with application.

This requirement identifies the information needed to describe the unique characteristics of a teletherapy installation. The plans, elevations, and shielding are needed to assure that the requirements of § 20.105 will be met. The interlock information is needed to assure against accidental exposure of workers and members of the general public. The viewing system is needed to monitor the orientation of the patient and the teletherapy unit, thereby assuring the ~~safe exposure to~~ radiation.

§ 35.605 Maintenance and repair restrictions.

This section provides that only specially licensed persons may maintain, adjust, or repair teletherapy units.

§ 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 ~~Emergency~~ instructions.

Emergency instructions must be posted to remind individuals of the proper ~~tasks~~ to be ~~completed~~ in case of an emergency and to identify individuals to be notified in an emergency.

§ 35.620 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.

§ 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.

~~Occasionally~~ a patient moves 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, ~~thereby~~ assuring the ~~safe~~ application of radiation.

§ 35.630 Dosimetry equipment.

Dosimetry equipment is needed to assure that the dose prescribed is the dose actually given. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the 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, ~~at the two year mark~~, the primary dosimetry system is compared with a system ~~which~~ 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. Each dosimetry system is ~~then~~ 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 exposure rate indicated by constancy check devices may vary by as much as two percent even though the calibration factor for the dosimetery equipment has not changed. ~~As a result, monthly~~ constancy checks would ~~not~~ necessarily provide increased assurance of proper operation.

§ 35.632 Full calibration measurements.

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 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.

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. 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, ~~The purpose of this notification requirement is~~ to assure the licensee and the Commission that the check results were reviewed by a qualified individual. The Commission has made a judgment that ~~the risk to the public health and safety over~~ fifteen days ~~is~~ minimal. 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 ~~which~~ 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, ~~See NCRP~~ in NCRP 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.

§ 35.644 Reports of teletherapy carriage, checks, tests, and measurements ~~following installation of a source~~.

Given the potential for higher exposure to workers and the public, the radiation survey information required by Section 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 ~~keep occupational exposures as low as reasonably achievable~~ 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 ecord 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.

§ 35.643 Modifications of teletherapy unit or rooms before beginning a treatment programme.

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.

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 individual 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) ~~and (e)~~, 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, and 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. (keep?)	35.2 revised
35.8	Reporting, recording, and application requirements: OMB Approval.	new text
35.15	Definitions. (Document Style)	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 klotherapy 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, amendments 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 Committee.	35.11(b) revised
35.32	~~Responsibilities of the~~ Radiation Safety Officer.	RG 10.8
35.33	~~Administrative~~ requirements for authority and responsibilities.	new ~~term~~ 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	~~Possession, use,~~ calibration, and check of survey instruments.	RG 10.8 Appendix D1 revised, and new text
35.53	Measurement of radiopharmaceutical 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--Group General/I (uptake, diluton, excretion)

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
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	Possession of survey instruments.	RG 10.8 page 5

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

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

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

Subpart G--Group VI (sources for brachytherapy)		
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
35.405	Safety instruction.	19.12 revised
35.406	Brachytherapy source inventory.	RG 8.18 page 6
35.420	Possession of survey instrument.	new text
Subpart H--Group VII (sealed sources for diagnosis)		
35.500	Use of sealed sources for diagnosis.	new text
35.520	Availability of survey instrument.	new text
Subpart I--Group VIII (teletherapy)		
35.600	Use of a sealed source in a teletherapy unit.	new text
~~35.604~~	~~Information to be submitted with application.~~	~~30.33(a)(2) revised~~
35.605	Maintenance and repair restrictions.	license condition
35.606	Amendments.	new text
35.610	~~Emergency~~ posted instructions.	license condition and new text
35.620	Doors, interlocks, and warning systems.	license condition
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, ~~and~~ 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 ~~diagnostic~~ use of Sealed sources	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 St, NW., Washington, D.C.

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, D.C. 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 300 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 Commission believes that the proposed rule would result in cost savings to almost all licensees. The primary objective of the proposed rule is to eliminate unnecessary administrative paperwork burdens on medical licensees by simplifying the licensing process without lessening the protection necessary to preserve public health and safety. This will be accomplished through incorporation of existing licensing amendments into the regulations, the elimination or modification of requirements that are not essential to the protection of public health and safety, by simplification of the licensing application form, and by establishment of a computerized licensing information system. These steps will not only make it easier for a licensee to determine what is required to obtain a license but should also substantially reduce the economic burden on medical licensees that is associated with the present licensing system.

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 Maureen Moriarty, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. Telephone: (301)427-4232.

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, and 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.

Packaging of Radioactive Materials for Transport and Transportation of Radioactive Material Under Certain Conditions.
Part 71 - Hazardous materials - transportation, Nuclear materials, Packaging and containers, Penalty, Reporting requirements.

[7590-01]

Domestic Licensing of Source Material

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

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, ~~and~~ 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 Committee.

35.32 Radiation Safety Officer.

35.33 ~~Administrative~~ requirements for authority and responsibilities. (statement of)

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

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

Subpart E--Group II/III (imaging)

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

Subpart G--Group VI (sources for brachytherapy)

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

35.500 Use of sealed sources for diagnosis.

Subpart I--Group VIII (teletherapy)

35.600 Use of a sealed source in a teletherapy unit.

~~35.604 Information to be submitted with application.~~

35.605 Maintenance and repair restrictions.

35.606 Amendments.

35.610 ~~Emergency~~ instructions.

35.620 Doors, interlocks, and warning systems.

35.621 Radiation monitoring device.

35.622 Viewing system.

35.630 Dosimetry equipment.

35.632 Full calibration measurements.

35.633 Periodic spot-checks.

35.641 Radiation measurements following installation of a source.

35.642 Facility checks following installation of a source.

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

35.644 Reports ~~following installation of a source.~~

35.645 Five-year inspection.

Subpart J--Training and experience requirements

35.900 Radiation Safety Officer.

35.901 Radiation safety officer training exception.

35.910 Training for uptake, dilution, and excretion studies.

35.920 Training for imaging ~~and localization~~ studies.

35.930 Training for therapeutic use of radiopharmaceuticals.

35.940 Training for therapeutic use of brachytherapy sources.

35.941 Training for ophthalmic use of strontium-90.

35.950 Training for diagnostic sealed sources.

35.960 Training for teletherapy.

35.961 Training for qualified teletherapy calibration expert.

35.970 Experienced ~~physician~~ training exception.

35.971 New physician training exception.

Subpart K--Enforcement

35.990 Violations.

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)-(c), 35.31(a)~~(1)-(a)(3)~~, 35.31(b), 35.32, 35.33, 35.34(a), 35.38~~(a)~~, ~~35.38(c)-(e)~~, 35.49, 35.50(a)-(c), 35.51(a)-(d), 35.53(a) and (b), 35.59(a)-(c), (e)(1), and (h), 35.60, 35.61, 35.62, 35.70(a)-(c), 35.75, 35.80(a)-(e), 35.90, 35.92(a)~~(1)-(4)~~, 35.100, 35.200, 35.204(a) and (b), 35.205, 35.300, 35.400, 35.404(a), 35.500, 35.600, 35.605, 35.606, 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), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.940, 35.941, 35.960, and 35.961 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.18, 35.30(d), 35.31~~(a)(4) and (a)(5)~~, ~~35.32(f)-(i)~~, 35.34(c), 35.37(a)-(d), 35.50(d), 35.51(e), 35.53(c), 35.59(d) and (e), 35.59(g) and (i), 35.70(d), 35.80(f), 35.92(b), 35.204(c), 35.304, 35.404(b), 35.405, ~~35.610,~~ 35.621(e), 35.630(c), 35.632(g), 35.633(j), 35.641(c), 35.642(c), 35.644, and 35.645(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A -- General Information

§ 35.1 Purpose and scope.

This part prescribes requirements 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 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, 35.18, 35.30(d), 35.31(a), 35.32(f), ~~(h) and (i)~~, 35.33(b), 35.34(c), 35.35(b), 35.37(a)-(d), 35.50(d), 35.51(e), 35.53(c), ~~35.59(c),~~ 35.59(d) and (f), 35.70(c), 35.80(e), 35.92(b), 35.204, 35.304(b), 35.404(b), 35.405, ~~35.604~~, 35.610, 35.621(d), 35.630(c), 35.632(g), 35.633(e) and (j), 35.641(c), 35.642(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 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 in 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 ~~administrative~~ executive officer ~~of a licensee~~.

"Misadministration" means the administration of:

(1) A radiopharmaceutical or radiation from a sealed source other than the one intended:

(2) A radiopharmaceutical or radiation to the wrong patient;

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

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

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

"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, 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.

An application for a license, a license amendment, or the renewal of a license for human use of byproduct material as ~~provided by~~ this part must be made by filing Form NRC-313M ~~Revision 1~~, "Application for Materials License ~~Human Use~~." For use by an institution, only management may apply. For use outside an institution, any physician may apply. The applicant shall mail the completed application form as directed below.

(a) If the applicant is a Federal agency, if the applicant is an agency of the District of Columbia, if the applicant is located in a State that is not mentioned in paragraph (b), (c), (d), (e), or (f) of this section, ~~or if the application is only for a teletherapy unit~~, the applicant shall:

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

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

(i) 1717 H Street, N.W., Washington, D.C., or

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

(b) If the applicant is not a Federal agency and is located in Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, ~~and the application is not only for a teletherapy unit,~~ 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.

(c) If the applicant is not a Federal agency and is located in Virginia or West Virginia, ~~and the application is not only for a teletherapy unit,~~ 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.

(d) If the applicant is not a Federal agency and is located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, ~~and the application is not only for a teletherapy unit,~~ 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.

(e) If the applicant is not a Federal agency and is located in Montana, South Dakota, Utah, or Wyoming, ~~and the application is not only for a teletherapy unit,~~ 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.

(f) 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.

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§ 35.17 License amendments.

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

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

(b) Before the licensee permits a physician, other than 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;

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

(e) Before ~~supplying mobile nuclear medicine service to a location not~~ identified on the license; and

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

§ 35.18 Notifications.

The licensee shall notify the Commission ~~in writing on Form NRC-313M Revision 1~~ 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-313M ~~Revision 1~~ "Application for Materials License ~~--Human Use~~";

(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 a periodic review of byproduct material use, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The review ~~and education~~ must assure that individuals make every reasonable effort to maintain individual and collective occupational dose ~~equivalent~~ 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 dose ~~equivalents~~ 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 and a consideration of actions that might be taken to reduce the probability of recurrence.

§ 35.31 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 committee 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, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, 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.

(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 ~~prior~~ to the license application or application for amendment;

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

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

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

(6) Review annually, with the assistance of the Radiation Safety Officer, the ~~radiation safety~~ byproduct material program; and

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

§ 35.32 Radiation Safety Officer.

(a) Each licensee shall appoint a Radiation Safety Officer who is responsible for implementing the radiation safety ~~plan~~ program. ~~The Radiation Safety Officer must be a member of the Radiation Safety Committee and be~~ responsible 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 ~~radiation safety~~ byproduct material program ~~including~~:

(a) Investigating known instances of deviation from good practice and implementing corrective action as necessary;

(b) Investigating, and in an institution reporting to the Radiation Safety Committee, the findings and actions taken in instances in which occupationally exposed individuals have exceeded investigational levels; and

(c) Assisting, and in an institution advising the Radiation Safety Committee, in performing those functions specified in § 35.31(b).

§ 35.33 ~~Administrative~~ requirements for authority and responsibilities.

(a) The licensee shall provide the Radiation Safety Committee, ~~and~~ Radiation Safety Officer 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 Committee and Radiation Safety Officer. ~~To satisfy the requirements of~~

(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 on or frequent areas where byproduct material is used or stored;

(3) Keeping a copy of all records and reports required by the regulations, a copy of the regulations, 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, assist the Radiation Safety Committee in the performance of its duties.

this section, in addition to the functions specified in §§ 35.31 and 35.32, the Radiation Safety Committee or Radiation Safety Officer must perform or ensure performance of the following functions:

(1) Authorizing the purchase or receipt of byproduct material and its distribution;

(2) Establishing written policy and procedures for disposal of all byproduct material;

(3) Establishing and ensuring implementation of written procedures for:

(i) Emergency actions;

(ii) Periodic radiation surveys;

(iii) Periodic inventory of byproduct material;

(iv) Safety during use of byproduct material;

(v) Performance checks of safety equipment and survey instrumentation; and

(vi) Training of personnel.

(4) Establishing and implementing a radiation safety education program for personnel working in or frequenting areas where byproduct material is used and stored;

(5) Maintaining records to show compliance with the training and experience requirements of Subpart J of this part, which includes:

(i) For the Radiation Safety Officer, a photocopy of that individual's certificate as listed in § 35.900 or a completed Form NRC-313M Revision 1 Supplement A;

(ii) For the Qualified Teletherapy Calibration Expert, a photocopy of that individual's certification as listed in § 35.961 or a completed Form NRC-313M Revion 1Supplement A; and

(iii) For each authorized user, a photocopy of that individual's license to practice medicine, and either a photocopy of a certification that is listed as appropriate for the types of use in which the authorized user is engaged, a completed Form NRC-313M Revision 1 Supplements A and B, or a photocopy of an NRC or Agreement State license issued by (**insert effective date of final rule**) that identifies the individual as an authorized user for the types of use in which the authorized user is engaged; and

~~(6) Establishing and maintaining a recordkeeping system for records required by this part, including the minutes of meetings of the Radiation Safety Committee required under § 35.31(a) and records of the Committee's review and deliberations required under § 35.31(b).~~

§ 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 ~~days~~ 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 ~~maintain~~ retain for two years copies of the ~~written permission~~ 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 ~~maintain~~ retain for the duration of service a letter ~~authorizing~~ use of byproduct material signed by the management of each location where services are rendered. Not

§ 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 ~~authorized~~ 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 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 ~~pursuant to § 35.32~~; and

(3) Comply with the regulations of this part 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 ~~daily prior to~~ 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 gamma-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 gamma-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 ~~dose~~ 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 ~~is normally~~ 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 readings for any error in excess of 10 percent if the dose is greater than 10 microcuries. ~~and the radiopharmaceutical emits a photon with an energy greater than 25 kev.~~

(e) The licensee shall ~~keep~~ retain a record of each ~~the~~ checks and tests 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 ~~Possession, use,~~ calibration and check of survey instruments.

~~(a) Each human use licensee shall have in his possession:~~

~~(1)~~ 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~~

~~(2)~~ a portable high level radiation survey instrument that has a scale with a full scale deflection of 1 roentgen per hour.

~~(b)~~ The licensee shall calibrate survey instruments before first use, annually, and following repair;

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

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

(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.

~~(d)~~ 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.

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

~~(f)~~ The licensee shall keep a record of each calibration required in paragraph ~~(b)~~ ~~above~~ for ~~the duration of use of the instrument~~. 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 radionuclide that emits electromagnetic radiation in the form of gamma rays or x-rays;

(b) Assay before human use the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a radionuclide that emits electromagnetic radiation in the form of gamma rays or x-rays to verify that the dosage ~~it~~ does not exceed 10 microcuries.

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

(1) Generic name 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; and

(4) Date and time of 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 byproduct material in the following sealed sources that were manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations for check, calibration, and reference use ~~if such sources~~ and that do not exceed 6 millicuries each;

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§ 35.59 Requirements for possession of sealed sources.

(a) A licensee in possession of a sealed source ~~for human use~~ 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) 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.

(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 suppliers' label or brochure that accompanies the source.

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

(1) Take ~~the test~~ 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;

(2) Take the test sample from a teletherapy source with the source in the "off" position; and

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

(d) The licensee shall ~~keep~~ leak test records for ~~three~~ years. The records must contain the model number and serial number of each source tested, and 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 leak 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, 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 leak 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, D.C. 20555, describing the equipment involved, the test results, and the corrective action taken.

(f) The licensee need not perform a leak 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 leak-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 shall conduct a quarterly physical inventory of all ~~sealed~~ sources in the licensee's possession. The licensee shall ~~keep~~ inventory records for two years. The inventory records must contain the model and serial number of each source, 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 shall survey with a low range survey meter quarterly all areas where ~~sealed~~ sources are stored.

(i) The licensee shall ~~keep~~ a record of ~~the~~ surveys 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 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 radiaton 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 ~~keep~~ retain a record of ~~the~~ 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 ~~to~~ 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 ~~residual~~ 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 doses 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;

(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;

(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 ~~byproduct material~~ use to ensure that all ~~byproduct material~~ and all associated waste has been removed; and

(f) ~~Keep~~ a record of ~~the~~ surveys required in ~~subsection~~ (e) 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 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 ~~decay~~ that it has decayed to background radiation level prior to disposal.

(b) For paragraph (a) of this section, the licensee shall ~~keep~~ 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 ~~stored~~ placed for decay, the model number of the survey instrument used, the background radiation ~~level~~ exposure rate, the radiation ~~level~~ exposure rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

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

§ 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 ~~the licensee's~~ 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.

Subpart E--Group II/III (imaging)

§ 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 ~~the licensee's~~ 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 preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall ~~test each generator~~ eluate or extract ~~for~~ molybdenum-99 concentration.

(c) The licensee shall maintain a record of molybdenum concentration test results 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 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.

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

§ 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.

§ 35.304 Safety instruction.

(a) The licensee shall provide oral and written radiation safety instructions for all personnel caring for the patient undergoing radio-

pharmaceutical 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.

Subpart G--Group VI (sources for brachytherapy)

§ 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 ~~implants~~ 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.~~405~~ 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) patient control;

(2) visitor control; and

(3) Procedures for notification of the radiation safety officer in case of the patient's death or medical emergency; and size and appearance of the brachytherapy sources.

(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.

§ 35.406. Brachytherapy sources inventory.

~~The licensee shall establish and implement a written brachytherapy source inventory procedure. The procedure must require the maintenance of a brachytherapy source accountability ledger that gives the location of each brachytherapy source at all times.~~

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

§ 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; ~~and~~

(a) The licensee shall make a record of brachytherapy source use. To satisfy this requirement of the section, the record 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 and the initials of the individual who removed the sources from storage;

the number and activity of the sources remaining in storage;

(3) The number and total activity of sources returned from use, the room number 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.

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

Subpart I--Group VIII (teletherapy)

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

The regulations and provisions of this subpart govern the use of teletherapy units 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.

§ 35.604 Information to be submitted with application.

The applicant shall supply such information deemed necessary by the Commission to determine the safety of the teletherapy facility. This includes, but is not necessarily limited to plan and elevation drawings, shielding information and calculations, and descriptions of interlocks, viewing systems, and other safety systems.

§ 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;

(f) Changing the source; or

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

Posted

§ 35.610 ~~Emergency~~ instructions.

The licensee shall post written ~~emergency~~ 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 ~~should~~ (i) the operator ~~be~~ unable to turn the primary beam of radiation off with controls outside the treatment room or (ii) any other abnormal operation occur; 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.

§ 35.620 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.

§ 35.621 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 monitor 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 ~~outputs~~ 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 ~~keep~~ retain a record of each calibration for the duration of the license. The record must include the date of the calibration, the model manufacturer's name, number and serial number of both the teletherapy unit and the source, the model number and serial number 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 ~~a~~ the qualified teletherapy calibration expert ~~perform the spot-check measurements or~~ review the results of ~~the~~ each spot-check ~~measurements~~ within 15 days. The qualified teletherapy calibration expert shall promptly notify the licensee in writing of the results of each spot-check ~~measurement~~. 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 ~~keep~~ 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 of 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 time 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 ~~maintain~~ retain a record of the facility checks following installation of a source for ~~the duration of the license~~ 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 ~~and tests~~ checks and measurements.

The licensee shall mail copies 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 following two addresses 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 ~~Appendix D of Part 20 of this chapter~~ § 35.14 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) ~~Be~~ 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) Have 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) Have 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) ~~Be~~ 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) Have 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) 20 hours of radiopharmaceutical biology; and

(v) 30 hours of radiation chemistry.

(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 survey meter checks for proper operation;

(iii) Calculating and safely preparing patient doses;

(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 dosage;

(iii) Administering doses to patients making proper use of syringe radiation shields;

(iv) Calculating the radiation dosage and collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Have 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:

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

(b) Have 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) ~~Be~~ 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 ~~British~~ 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) Have 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:

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

(b) ~~Have~~ 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, post-administration followup, and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

The authorized user using a sealed source in a device listed in § 35.500 ~~shall~~, except as provided in § 35.951,

(a) ~~Be~~ 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) ~~Have~~ completed ~~24~~ hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. ~~and a period of supervised clinical training in its use.~~

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

(~~i~~) ~~8~~ 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 the use of the device; ~~training must include the use of the device under the supervision of an authorized user for four hours and must include the proper use of the device and the examination of patients by use of the device~~.

§ 35.951 Training exemption for use of sealed sources for diagnosis.

(a) A physician identified as an authorized user for the human use of a sealed source in a device listed in § 35.500 on a Commission or Agreement State license on (* * * insert effective date of final rule * * *) need not comply with the requirements of § 35.950, in order to use that device.

(b) A physician who has successfully completed a three-month or six-month training program in nuclear medicine that was part of a training program approved by the Accreditation Council for Graduate Medical Education need not comply with the requirements of § 35.950.

§ 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:

(a) Be 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) Have 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) 100 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 ~~the~~ misadministrations ~~of byproduct material;~~

(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 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 ~~physician~~ authorized user training exception.

A physician, 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

dentist, or podiatrist

procedures for which ~~the physician~~ 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 in 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 be 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;

* * * * *

Dated at Washington, D.C. this _____ day of _____ 1982.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

CRPS

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

Appendix A--Form NRC-313MH

Form NRC-313MH is appended for the convenience of those who may wish to comment on the proposed regulations. It is not a part of the regulations. However, the Commission does solicit comments on its content. If the proposed regulations are adopted and codified in Title 10 of the Code of Federal Regulations, the form will be used for applications for the human use of byproduct material.