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For: The Commissioners

From: William J. Dircks, Executive Director for Operations

Subject: PROPOSED REVISION OF 10 CFR PART 35 "MEDICAL USE OF BYPRODUCT MATERIAL"

Purpose: To obtain Commission approval of a notice of proposed rulemaking.

Category: This paper covers a significant policy question concerning the licensing and regulation of byproduct materials.

Issue: Revision of the regulations and change in the method of licensing the use of byproduct material in the practice of medicine.

Overview: The phrase "medical use" is used to refer to the intentional irradiation of humans by medical practitioners in the practice of the healing arts. The staff is proposing to revise the regulations governing medical use and to change the method by which persons are licensed for human use of byproduct material. The staff prepared an earlier proposal which was circulated as SECY-83-62. This new proposal reflects guidance from the Commission to the staff on that earlier proposal (Enclosure 2), and additional comments that were received from headquarters and regional staff and the Agreement States.

The NRC issues licenses to both hospitals and physicians in private practice for the use of byproduct materials in diagnosis and treatment of human disease. During the past three decades, medical use of byproduct material has grown annually at a rate of about 15 percent. There are currently about 2200 hospitals and 300 physicians in private practice who are NRC licensees. In 1983, NRC staff received 143 applications for new licenses, 647 renewal applications, and 1,772 amendment applications for a total of 2,562 requested licensing actions.

Most hospitals and private practice physicians operate under a specific license which authorizes many types of byproduct materials use. An application is made on a standard NRC form which is supplemented by

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detailed descriptions of radiation safety procedures, personnel qualifications, and facilities and equipment. Each application is reviewed in detail before a license is issued. There are also a few nuclear medicine uses authorized by general license. A general license authorizes physicians to use small quantities of certain prepackaged radiopharmaceuticals, and is obtained simply by filing a registration form. Current ~~section~~ § 35.31 specifies safety measures and possession limits. The NRC staff does not perform a technical review of the registration form but only validates it.

The staff is proposing to simplify the regulatory program for medical licensees. The specific objectives are to:

- Make regulations consistent with well established technology and standards,
- Write all prescriptive requirements in simple English and codify them in the regulations, and
- Assure uniformity among the regions in licensing and inspection.

Key features of the proposed rule change designed to meet these objectives include:

- Consolidation of the requirements that apply to medical use that are now dispersed throughout existing regulations, branch policy positions, standard conditions of licenses, and regulatory guidance into a concise and coherent set of regulations, and
- Allowance for greater flexibility under the license, thereby reducing the number of amendment requests.

In preparing this proposal, the staff has taken direction from the Commission's policy (Policy and Planning Guidance, 1984, NUREG-0885, Issue 3, page 7 item 2, and page 8 item 3) that "...NRC regulations should allow individual licensees the flexibility to select the most cost-effective ways to satisfy NRC safety objectives...Existing regulatory requirements that have a marginal importance to safety should be eliminated..."

Background: The previous proposal, SECY-83-62, had two key features. It tried to incorporate in a single codified regulation all the standards that apply specifically to the medical use of byproduct material. The current Part 35, current Regulatory Guide 10.8, and a list of frequently used license conditions served as the principal references. The staff believed that the proposed regulation was sufficiently stringent and specific to provide clear guidance and a basis for enforcement action that was not based on statements made by the licensee during the application process. Therefore, the second key feature was that applicants would no longer be required to submit

for agency review and approval the detailed, site-specific radiation safety procedures that would be followed to effect compliance with the regulations. These procedures describe the Radiation Safety Committee charter and by-laws, survey instrument calibration, package receipt and opening, general laboratory safety measures, area surveys, waste disposal, etc. The applicant would have merely certified that adequate procedures had been developed. Also, because training and experience requirements would now appear in the regulations, applicant authorized users would have simply certified that they met the training and experience requirements.

Some individuals on the NRC staff and most of the Agreement State program directors opposed the proposal. Some felt that the regulatory text was incomplete. Many felt that, to ensure the public health and safety, it was necessary to review an applicant's radiation safety procedures for completeness and adequacy.

The Commission directed the staff (Enclosure 2) to revise the proposal, keeping in mind four general directives that are discussed in the following paragraphs.

"(1) The Commission approves the consolidation of the essential safety elements ... into a Part 35 rule." The staff has received many technical comments from headquarters and regional staff and the Agreement States; many of them have been incorporated in the proposed regulation. In some cases the suggestions could not stand the test of need based on public health and safety; those have not been incorporated. A summary of comments and their resolution is attached (Enclosure 8).

"(2) The Commission has decided to continue the pre-licensing review of physicians' qualifications ..." The Enclosure 1 preamble has been revised to reflect this directive. The Commission should note that NRC would also require pre-licensing review of Radiation Safety Officer qualifications (consistent with current practice), and Qualified Teletherapy Calibration Expert qualifications (contrary to current practice, in which the licensee evaluates that individual's qualifications in comparison with the standards in current Part 35). This new requirement should not impose a significant burden on the industry because informal contact with regional inspectors indicated that roughly 70% of teletherapy experts hold certification from a specialty board that the staff proposes to recognize as evidence of adequate training and experience.

"(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. (Consistent with current practice, an applicant will be allowed to simply certify that he will follow a model procedure supplied in Regulatory Guide 10.8 that was developed by NRC with

change its procedures, facilities, and equipment for improved patient care, safety, or reduced cost,

public comment, or will be allowed to submit an alternative procedure for review.) In order to allow each licensee to ~~make prompt use of new safety methods and to adjust procedures to meet new needs caused by changes in need for patient care services or patient load~~, licensees will be free to ~~modify their procedures~~ without NRC review or approval as long as they meet the requirements of the regulations. At a hospital, the Radiation Safety Committee must review and approve a procedure change before it may be implemented. At private practice facilities, the Radiation Safety Officer and management must review and approve changes.

make changes

continue to

This regulatory concept is similar to NRC's method of regulating power reactors. Regulatory guide 1.33 lists, by title, many management, facilty operation, and radiation safety procedures that may be needed depending on the facility configuration. The technical specifications for the reactor facility, which actually comprise part of the operating license but are standardized for the various reactor designs, identify: (1) essential elements of normal operating procedures; (2) procedures that must be implemented in case of degraded conditions; and (3) which degraded conditions require shutdown. The regulations, at 10 CFR 50.59, allow the operating licensee to make changes in the facility and procedures that were described in the safety analysis report without NRC approval except for changes in the technical specifications or changes that might have major safety implications. The licensee is required to make a safety evaluation of each proposed change.

X

This proposed revision of Part 35 is similar to the reactor regulatory concept because the staff has codified, in the regulations rather than in technical specifications, the following: (1) essential elements of normal operating procedures (for example, survey frequency, equipment calibration, and safety precautions); (2) procedures that must be implemented in case of degraded conditions (for example, repair and recalibration of equipment that isn't working properly); and (3) which degraded conditions require shutdown (for example, limits on trace radioactive contaminants in radiopharmaceuticals, removable contamination from sealed sources, contamination in rooms that will be turned over for unrestricted use). The licensee would be allowed to make changes in the facility and radiation safety procedures as long as they were consistent with the requirements of the regulations. The licensee would have to make a safety evaluation of each proposed change.

management oversight,

A licensee will be cited for 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), failure to have the written procedures required by the regulations, failure to follow those procedures, failure to have the records required by the regulations, or failure to follow technically valid procedures.

"(4) The staff should clarify how it will implement the proposed requirements regarding license amendments, while continuing to ensure safety in the licensee's operations." The Enclosure 1 preamble has been clarified to indicate when a license amendment request must be submitted and what information will be needed to support it. Amendment requests will be required for--

(a) new users--supply summary of training and experience;

(b) new types of use (for example, adding therapy radiopharmaceuticals to a license that authorizes diagnostic radiopharmaceuticals)--supply all procedures needed for that type of use;

(c) a new method of use (for example, adding a new kind of diagnostic radiopharmaceutical to a license that authorizes currently available diagnostic radiopharmaceuticals)--supply the specific procedure needed for the new method of use; and

(d) new locations of use--supply a complete new application if the base of operation changes, or simply the additional address if satellite locations were approved on the original license.

A transition policy was also added.

Proposal: The staff recommends that the Commission publish for public comment a proposed revision of Part 35 and a description of a new method for licensing the medical use of byproduct material. Three alternative courses for the Commission are discussed below.

Alternative 1: Take no action. add P35(A)

Alternative 2: Publish the proposed revision of Part 35 attached as Enclosure 1. add P35(B)

Alternative 3: Publish the proposed revision of Part 35, but ~~after modifying the preamble to~~ require submission of ~~that applicants and licensees submit their~~ radiation safety programs and program changes. ~~for NRC review and approval.~~ add P35(C)

Discussion of Alternative 1:

Almost all the individuals who commented on the proposed revision that was submitted in SECY 83-62 agreed that the current Part 35 was in need of revision because it is difficult to read and does not contain all the requirements necessary for radiation safety in the medical use of byproduct materials. The Commission "approved the consolidation of essential safety elements" (Enclosure 2). Most individuals who have reviewed the draft recommend adoption of the proposed revision of the regulatory text.

Effect of Selecting Alternative 1:

Because the current Part 35 does not contain all the essential safety elements for medical use, the NRC would have to continue to review detailed applications and require that licensees follow radiation safety procedures that were reviewed and approved by NRC. This alternative does not provide any greater degree of safety than the other alternatives, but is more costly to both NRC and licensees than Alternatives 2 and 3, and denies the industry the benefit of a clear, consolidated codification of the medical use requirements that is offered by both of the other alternatives. It is difficult to maintain standardization under this scheme because the legal basis for controlling a licensee's use of byproduct material is the licensee's application. Because each application is different, the result is a regulatory regime that is different for each licensee.

Discussion of Alternative 2:

The NRC would publish in the Federal Register for comment the proposed regulations and licensing method described in Enclosure 1. An applicant would submit: (1) evidence of training and experience, (2) a description of facilities and equipment and (3) radiation safety procedures that described controls on the receipt, storage, use, and disposal of byproduct material, equipment calibration and checks, personnel training, and general safety measures. A license reviewer would review the applicant tion to assure that the applicant had adequate training and experience, facilities and equipment, and radiation safety procedures. Then the license would be issued. The licensee would be free to make changes in facilities and procedures or replace equipment with approval of the licensee's Radiation Safety Officer (RSO) and management or, at a hospital the RSO and the Radiation Safety Committee (RSC). In either case the changes would have to conform with the requirements of the regulations.

Proponents: The proposed licensing method provides for agency review before allowing a program to begin. Then, the implementation of a safe program requires the support of the individuals who have special safety training. (If the key individuals do not have the training, the license will not be issued.) Issuance of the license would mean that the agency has found the applicant trained to know safe from unsafe and legal from illegal, and that the applicant is equipped to handle material safely within the scope of use permitted by the license. Licensure would also connote that those key individuals are ~~also~~ competent to make minor radiation safety programs changes that continue to provide a level of safety consistent with the requirements of the regulations, and to select replacement equipment and to change facilities to the extent consistent with those requirements. These changes, which might be made for improved patient care, ~~or~~ safety, or reduced cost, would have to be approved by the RSO and management or the RSO and RSC before being implemented. ~~This method allows the licensee the flexibility to meet~~

The licensee would not be authorized to significantly redirect the medical radiation safety program because all the essential elements are clearly codified in the regulations. Independent review of minor changes by a governmental agency will not provide a significant ~~impact on~~ public health and safety benefit, but is expensive.

~~new site-specific needs.~~ License processing would be compatible with both hard copy and computer assisted information systems.

Objections: Many licensees are small organizations with a few authorized user physicians, and technicians who have graduated from a two year formal training program or have been trained on the job by an authorized user or co-worker. They might employ a part-time radiation safety consultant who is qualified to review changes for safety problems, but who ~~that individual~~ may not be aware of the ramifications implicit in a proposed change because he is not thoroughly familiar with the day-to-day operations. On a private practice license, the authorized user may also be the RSO and management, and therefore would be reviewing his own handiwork for safety considerations. At a hospital the only two individuals on the RSC who are required to have had radiation safety training are the authorized user and RSO, who may be the ones proposing the change. Therefore, in either case there would be no independent agent required to review proposed licensee changes. The proposal would place more authority in the hands of management; and many medical escalated enforcement actions are necessitated by inadequate management control. The agency would not have the opportunity to circumvent ill-advised changes.

Effect of Selecting Alternative 2:

The staff recommends that the Commission select Alternative 2. The staff does not expect any change in worker or public dose or significant costs or savings to any entity if the Commission follows this recommendation. The proposal would probably be perceived as a change from the current policy of strict prescriptiveness to a policy granting more authority for the licensee who bears the responsibility for handling material safely.

For the four groups that would be affected a short textual analysis follows. A more complete regulatory analysis is attached as Enclosure 4.

NRC

The training of licensing and inspection staff would have to be redirected because it now stresses checking the application for completeness and adequacy and then inspecting the licensee for compliance with the application. Under the proposal the inspectors would have to recognize, in the field, technical and management practices that do not meet the regulatory standards. The inspector would have to be more thoroughly familiar with the regulation, but would no longer have to be familiar with each licensee's application before conducting an inspection. This would help to ensure uniformity among the regions. However, some NRC inspectors believe an increase in field time will be necessary in order to review procedure changes. Because a major goal was to prepare the statement of consideration, regulation, and regulatory guide in plain English, the staff expects fewer deficient applications, and leaner, more succinct inspection reports.

Agreement States

The Agreement States generally support the consolidation of various regulations and requirements pertaining to the medical use of byproduct material into one document, and have provided some technical comments on the revised Part 35. The Agreement States strongly object to permitting licensees to change radiation safety procedures without agency review and approval. They believe that they will need to retrain inspectors, that the duration of each inspection will increase, and there may be increased worker doses. Although the Part 35 revision would not be made a matter of compatibility because it deals with licensing matters, the States believe they will be pressured by their licensees to adopt the NRC system.

Licensees

The requirements in the proposed regulation were taken from the current regulation, licensing policy, frequently used license conditions, and standards recommended in current regulatory guides that are used by many licensees. Therefore, the staff does not expect any increase or decrease in worker dose or any significant cost increase. There may be some insignificant savings in amendment fees for those licensees who need to change their procedures. Because of the consolidated statement considerations that accompanies the proposed revision, licensees may have a clearer understanding of the regulatory process in general and the need for the requirements.

The Public

Most man-made non-occupational dose is the result of intentional irradiation of individuals for their own medical benefit under the prescription of a state-licensed physician. Therefore an attempt to reduce public dose would, except in rare circumstances, be a clear intrusion into the practice of medicine. Because the staff does not foresee any significant changes in day-to-day operations within NRC, the Agreement States, or licensees, the staff does not expect any significant cost or savings for the public.

staff resources needed for

Discussion of Alternative 3:

The NRC would retain the current licensing method under which an applicant submits for review: 1. evidence of training and experience, 2. a description of facilities and equipment, and 3. radiation safety procedures. When licensed, the licensee must use byproduct material in accordance with the statements made in the application. The licensee would have to submit all changes in facilities, equipment, and procedures for NRC review and approval.

Proponents: The requirement that licensees use material in accordance with the procedures in the application provides assurance that licensees have safe procedures available, and provides a clear basis for enforcement action in cases of noncompliance. If the adequacy or completeness of a procedure is questioned, the license reviewer can consult reference works or co-workers rather than having to make a quick technical judgment during a field inspection. This also allows the license reviewer to exercise a certain amount of flexibility to meet each licensee's specific needs. Most Agreement State program directors believe this method of licensing is necessary in order to answer any questions that the applicant or reviewer has, and to resolve any differences of opinion on what is required for compliance. This method may require less extensive training for field inspectors because the inspection is based on compliance with a site-specific step-by-step radiation safety program.

Objections: Because the licensee is required to use material in accordance with the application and letters written in its support, to remain in compliance the licensee may not replace any equipment or service contractor or change any facility described, or change any radiation safety procedure without requesting a license amendment. This expensive, time-consuming detailed review of applications and amendments does not assure safe use, but rather simply existence of adequate facilities, equipment, and radiation safety procedures. Safe use can only be ensured by the licensee's continued, active commitment to safety. The unannounced inspection provides the best measure of that commitment.

add P35D-2 Most citations are not issued for failure to exactly follow a certain procedure or to have a particular production model piece of equipment available, but rather for doing nothing when something is clearly required, or doing something that is clearly forbidden. The essential elements of a medical radiation safety program are well defined and easily codified. Therefore, there is generally no need to continue with case-by-case regulation. That kind of licensing policy requires more extensive training for reviewers, is prone to backlog due to the bulk of material submitted for review and the number of license amendments needed, and results in a regulatory regime that is different for each licensee. X

Effect of Selecting Alternative 3:

The industry would benefit by having a clear, consolidated set of regulations. The requirement to submit changes in facilities, equipment, and radiation safety procedures for NRC review and approval would be costly to both NRC and licensees, but would not be likely to result in a higher degree of safety than that provided by Alternative 2 and would not provide any stronger or clearer basis for enforcement actions. Furthermore, if the licensee made a determination that

a change would result in safer or more efficient operations, the agency review and approval requirement would prohibit its prompt adoption.

Recommendation: The Commission:

1. Select Alternative 2.

2. Approve publication of a notice of proposed rulemaking (Enclosure 1) that would describe a new licensing method and would consolidate all human use requirements into 10 CFR Part 35.

   Certify that this rule, if promulgated, will not have a significant economic impact on small entities. This certification is necessary to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

   a. The rulemaking would be published in the Federal Register for 120-day public comment period;

   b. The staff conclusions, set forth in Enclosure 3, provide the analysis called for by the Periodic and Systematic Review of Regulations;

   Insert P35 E

   c. Neither an environmental impact statement nor a negative declaration need be made in connection with this rulemaking because it is nonsubstantive and insignificant from the standpoint of environmental impact (Enclosure 7);

   d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it as required by the Regulatory Flexibility Act;

   e. The proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

   f. A draft regulatory analysis (Enclosure 4) has been developed for this proposed rule;

   g. A public announcement (Enclosure 5) will be issued when the proposed rule is filed with the Office of the Federal Register;

h. The appropriate Congressional Committees will be informed (Enclosure 6); and

i. Copies of the Federal Register notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties on request.

William J. Dircks
Executive Director for Operations

Enclosures:
1. Federal Register Notice of Proposed Rulemaking
2. Memo Chilk to Dircks dated June 23, 1983.
3. Periodic and Systematic Review
4. Regulatory Analysis
5. Draft Public Announcement
6. Draft Congressional Letter
7. Environmental Impact Analysis
8. Summary of unresolved comments ~~on SECY-83-62 and this proposal~~
9. Summary ~~table~~ of ~~medical~~ human use licensee citations issued in 1982

Commissioners' comments or consent should be provided directly to the Office of the Secretary by ______________.

Commission Staff Office comments, if any, should be submitted to the Commissioners ______________ with an information copy to SECY. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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NUCLEAR REGULATORY COMMISSION

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

MEDICAL 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 and regulating the medical use of radioactive byproduct material. The proposed revision would primarily affect hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential radiation safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the proposed regulation provides a single source of requirements for medical use of byproduct materials. The proposed regulation also provides flexibility for licensees to update their day-to-day radiation safety procedures. The revision of the regulations would provide a more efficient method for regulating the medical uses of byproduct material.

DATE: Comment period expires (insert 120 days after FRN). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date.

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

Copies of the preliminary regulatory analysis and the comments received may be examined at the Commission's Public Document Room at 1717 H Street NW, Washington, DC. Single copies of the preliminary regulatory analysis and environmental impact assessment are available from

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

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

SUPPLEMENTARY INFORMATION:

BYPRODUCT MATERIAL IN MEDICINE

Use for Patient Care

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 15 to 20 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 2 million teletherapy treatments are performed annually by NRC licensees. Smaller, less radioactive sealed sources are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of

the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

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

NRC'S REGULATORY PROGRAM

Current Licensing Practice

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for general and specific licenses for medical use. The general license in current § 35.31 authorizes physicians to use small quantities of prepackaged, individual dosages of byproduct materials. Physicians simply submit a registration Form NRC-48$\overset{2}{3}$ to NRC. A validated copy with a registration number is returned to the applicant.

Most medical institutions and physicians who use byproduct material need more byproduct material than can be permitted under the general license program. A specific license, which authorizes a larger inventory of byproduct material and a wider variety of uses, may be issued for one or more of six types of medical use, defined as Groups I-VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar physician training and radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. Applications for a specific license are much more detailed than a general license application and actually contain the

applicant's step-by-step radiation safety procedures, which are reviewed and approved individually by NRC.

The NRC has issued 650 general licenses, and in 1983 received seventeen new applications. NRC currently has about 2500 specific medical licensees (2200 hospitals and 300 physicians in private practice). In 1983, the NRC received 143 new applications for specific licenses, 647 license renewal applications, and 1,772 license amendment requests for a total of 2,562 licensing actions.

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

Problems with Current Practice

The General License. The general license program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. The NRC believes it is no longer efficient to issue medical general licenses. The tests authorized under § 35.31 have been superseded by newer procedures with greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for general licenses. As noted above, although NRC has on file 650 in-vivo general licenses under § 35.31, only seventeen new applications were received by NRC in 1983.

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

The Specific License. Because of the potential radiation hazard to workers and the public, the specific license program incorporates three

regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and in conditions attached to individual licenses. Suggestions for good practice are contained in NRC regulatory guides and technical reports (NUREG's). For example, Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable," contain many recommendations that the NRC believes are important for the safe use of byproduct material. The revision of Part 35 incorporates those recommendations, and also corrects the piecemeal fashion in which the regulations have been amended over the years to address specific problems.

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

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

application and license comprise the basis for regulatory control. Deficiency letters are costly for the NRC and the applicant and greatly increase the time needed to complete licensing actions.

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

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

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

PROPOSED REVISION OF THE REGULATORY PROGRAM

Overview

NRC intends to modify its regulation of the medical use of byproduct material. The Commission plans to revise the regulations to provide a single source of requirements specifically related to medical use of byproduct materials, and within the boundaries set by the regulations, allow medical licensees to modify their radiation safety procedures, facilities, and equipment so they can make prompt use of new safety

methods and also meet new needs caused by changes in demand for various patient care services or in patient load. The proposed revision of 10 CFR Part 35 is consistent with the Commission's general policy on medical use of byproduct material issued February 9, 1979 (44 FR 8242). It 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."

Codification of Requirements in the Regulations

NRC proposes to simplify regulation of medical licensees by incorporating all medical use requirements in 10 CFR Part 35. These regulations would become the primary means of regulating the medical use of byproduct material. General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also continue to apply to Part 35 licensees. The current license application process will be unchanged. The applicant prepares a complete Form NRC-313. That form asks for the following information: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; what materials are requested; the purpose (in this case, "medical use"); the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management. Licensees would not face significant new regulatory burdens because, in most cases, these requirements are currently imposed as license conditions. Under the proposed revision, the license would authorize medical use of byproduct materials for specified types of use. A licensee's day-to-day uses would be controlled by the regulations. This would simplify inspections for NRC because inspectors would only need to be familiar with one set of regulations rather than a different set of license conditions and radiation safety procedures at each facility.

License Application, Issuance, and Authority and Responsibility

A new revision of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," will contain instructions on the X

and Draft Regulatory Guide TM 608-4, "Guide for the Preparation of Licenses in Medical Teletherapy Programs,"

type and extent of information that must be submitted based on what byproduct materials the applicant has requested. ~~It~~ will also contain model procedures that the applicant can use to develop site-specific procedures. (Consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow the model procedure developed by NRC staff and published in Regulatory Guide ~~10.8~~ to meet a certain requirement.) The applicant mails the completed application, with application fee, to the NRC office identified on the form.

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

To allow each licensee to make prompt use of new safety methods and to adjust radiation safety procedures to meet new needs caused by changes in demand for patient care services or patient load, licensees will be free to modify their procedures without NRC review or approval. An internal review and approval process would be required instead. The right to modify procedures does not relieve the licensee from the requirement to comply with the regulations. At medical institutions, the Radiation Safety Committee would review and approve a modified procedure before it could be implemented. At non-institution facilities, the Radiation Safety Officer (RSO) and management would review and approve changes. This regulatory scheme would <u>not</u> incorporate the current requirement that licensees use byproduct material in accordance with the statements made in the application.

This proposed regulatory program, which gives more discretionary authority, and concomitant responsibility, to the licensee, represents a change in the policy that has guided NRC's regulation of medical licensees for several years. The NRC particularly invites comment on whether this change is appropriate at this time, and whether or not it will benefit licensees, workers, and the public. The proposed regulations require specific training and experience for the use of material in each use

Clarify this sentence - violation
of the act.

group. Proposed authorized user ~~(AU)~~ physicians, and qualified tele-therapy calibration experts (~~QTCE;~~ identified in current Part 35 as ~~the~~ Qualified Expert) will have to submit summaries of their training and experience. This is currently required for ~~AU's~~ authorized users and ~~RSO's~~ Radiation Safety Officers, but would be a new requirement for ~~QTCE's~~ qualified teletherapy calibration experts, whose credentials are currently reviewed by the licensee. The staff will review those individuals' training and experience against the standards in the regulation before authorizing them to work ~~as an AU, RSO, or QTCE~~ under the license. (Also consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individual's training and experience with the assistance of its Advisory Committee on the Medical Use of Isotopes, and may issue the exemption as a license condition.)

Enforcement

Under this regulatory scheme, a licensee will be cited for 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), failure to have on hand the written procedures required by the regulations, failure to follow the procedures on hand, failure to have the records required by the regulations, or failure to follow technically valid procedures (examples: using an instrument that doesn't work, not determining instrument detection efficiency, not allowing an instrument enough time to respond, or making unsubstantiated assumptions in calculations). Use of material ~~without~~ can be authoriz~~ation,~~ed either by license or by virtue of working under supervision; ~~,~~ would be a violation of the regulations ~~that~~ and the Act, which would subject the ~~person~~ user to an enforcement action. Use without authorization

Amendments

As mentioned above, under the current regulatory scheme, the licensee is required to handle material exactly according to the radiation safety procedures submitted with the application. The NRC frequently receives requests for permission to modify day-to-day radiation safety procedures.

authorized user, Radiation Safety Officer, and qualified teletherapy calibration expert

Since Because the regulations will now contain sufficient prescriptive and performance criteria on which to base enforcement actions, the NRC would allow a licensee~~s~~ to change ~~modify their~~ its radiation safety procedures. ~~This would eliminate the licensee's need to~~ without prepare ing a formal amendment request ~~for the NRC and~~ paying an amendment fee ~~in order to make changes in procedures.~~ and awaiting NRC approval. This would not relieve the licensee from the regulatory requirement to comply with the regulations in Part 35 or other parts of 10 CFR Chapter I.

Four types of program changes will still require formal license amendments:

(1) New users. The NRC will review the training and experience of each proposed ~~AU, RSO, and QTCE~~ as described above before listing the individual on a license.

(2) New type of use. A licensee's request to add a type of use (for example, adding radiopharmaceutical therapy to a license that authorizes radiopharmaceuticals for imaging) to an existing license will be handled as a new application. The ~~AU's~~ authorized user's training and experience will be reviewed for adequacy with respect to the new type of use, and procedures that must be submitted in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

(3) New method of use. Two developments may occur but only one type of license amendment will be needed:

(a) If a new radioactive material becomes available, and the radiation safety procedures needed for its safe use are identical to the procedures already established for an already established and authorized use (for example, a new imaging agent administered by intravenous injection), no license amendment will be required. Instead, the new material will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail to licenseas a notice that says those who are authorized to use material in that group may begin using the new material on the effective date of the final rule that adds the new material to the regulations.

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

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

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

(4) New location of use. Two types of amendment may be needed:

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

(b) Some licensees receive packages, prepare radiopharmaceuticals, and package waste at a central facility, but actually use the byproduct material at satellite locations. This might be a mobile nuclear medicine service that provides diagnostic services at clients' facilities such as clinics, small hospitals, or nursing homes, or it may be a licensee that has a principal facility and outlying clinics. If the licensee has been approved to offer service at satellite locations, a request to add another satellite location will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC will generally not authorize licensees to perform therapies at satellite locations. This type of request will be handled on a case-by-case basis.)

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material the license must be renewed. The renewal application must completely describe the entire radiation safety program just as a new application does. If a previously submitted radiation

safety procedure, facility description, or equipment list still accurately reflects that part of the licensee's program, the renewal applicant may simply make a clear reference to the previous submission. If the licensee has changed a procedure, is using different areas of use, or is using different equipment, a complete new description of the particular procedure, area of use, or equipment must be submitted. The licensee may also take this opportunity to identify new authorized users or request authorization for new types or methods of use.

Summary of Changes Proposed in the Regulatory Program

In summary, the regulation will be amended to require that licensees meet standards that are currently imposed by license conditions. The NRC will continue to review user training and experience. The NRC will review site-specific radiation safety procedures for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to ~~modify~~ change procedures that were submitted in support of the application after conducting an internal radiation safety review of each change. ~~if the Radiation Safety Committee, or management and RSO outside a medical institution, approves the modification~~. However, the right to ~~modify~~ change procedures does not relieve the licensee from the requirement to comply with the regulations. Amendment~~s~~ requests will generally be reviewed just as new applications are reviewed, but they may incorporate by reference the original application and any previous amendments.

NOTES

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Word Usage

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

1. Licensee. The person (individual, partnership, corporation, or agency) ~~who is~~ listed on the license as the "licensee" is responsible for compliance with regulations and license conditions. The licensee may effect compliance through full-time or part-time employees, contracts with consultants or service organizations, or other business arrangements. The word "licensee" is used throughout the regulation to stress the fact that,

no matter which method is used, the licensee is legally responsible in case of non-compliance.

2. Type of use and group. In the current Part 35 there are six "groups" of use described in § 35.100. Each group is comprised of a set of medical procedures that require similar training and equipment for radiation safety purposes. The word "group" has not been used in the proposed revision in order to avoid confusion between the old and new Part 35. The revision uses the phrase "type of use" for this concept. Some types of use are amalgamations of old groups, and some types are new. The six types of use are: (1) uptake, dilution, and excretion -- Subpart D; (2) imaging and localization -- Subpart E; (3) radiopharmaceutical therapy -- Subpart F; (4) brachytherapy -- Subpart G; (5) sealed sources for diagnosis -- Subpart H; and (6) teletherapy -- Subpart I.

3. Method of use and procedure. The word "procedure" is frequently used in supporting documentation for byproduct materials programs. Sometimes it refers to a specific set of steps that must be taken to effect an end, for example a procedure for ordering and receiving packages. Sometimes it is used to indicate a type of medical examination or treatment, for example a thyroid uptake study or a cesium implant therapy, without indicating the amount of byproduct material used or the specific steps taken in handling it. The word may also be used to indicate the number of patients cared for over a period of time, for example an average workload of fifteen procedures each day. In order to avoid confusion, the phrase "method of use" appears in the proposed revision. Each type of use is comprised of several methods of use. Each method of use should identify, explicitly or by context, the radionuclide, its chemical and physical form, method of administration, and purpose (diagnosis or therapy).

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

indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit rad or rem.

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

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

7 ~~6~~. Location of use, facility, and area of use. The phrase "location of use" is used to describe the building or buildings (typically identified by a single street address) where byproduct material is used. The word ~~phrase~~ "facility" connotes a room or contiguous rooms where byproduct material is used, such as a nuclear medicine clinic comprised of an office, an imaging room, and a dosage preparation and waste storage room. The ~~word~~ phrase "area of use" connotes the space used by a worker when performing a specific task connected with receiving, handling, or storing byproduct material. X

8 ~~7~~. Chemical form. The current regulation requires that if a radiopharmaceutical is used for indications other than those described in the package insert, the user must never-the-less follow instructions on chemical and physical form, dosage, and route of administration. The proposed revision has deleted the word chemical in its restatement of this requirement because to change the chemical form would be to create a radiopharmaceutical other than the one received from the authorized distributor.

Deletion of this word in the proposed revision does not authorize Part 35 licensees to manufacture radiopharmaceuticals.

9 ~~8~~. Available for use. In many cases the regulation states an equipment possession requirement because the piece of equipment is considered by experts to be an integral part of the radiation safety program. In a few cases the need for a piece of equipment is sporadic and normally scheduled weeks in advance. For example, a licensee ~~who~~ that a has a diagnostic sealed source in a device (see § 35.500) usually only needs a survey instrument when receiving or returning a radioactive source; there is no need to have the instrument on hand every day. The phrase "available for use" is intended to connote that the licensee either may possess equipment or contract for measurement services, but is not required to have regular day-to-day possession of the described equipment.

10 ~~9~~. Dedicated check source. A long-lived radioactive source can be used to check the day-to-day constancy of an instrument. The same source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

1~~0~~1. Operable. The word "operable" is not used in the proposed regulation. If a piece of equipment is not operable or reliable, whether due to old or absent batteries, incomplete or improper maintenance, damage, inappropriate use, or improper use, it cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used. ~~Therefore,~~ Because every piece of equipment must be operable.

1~~1~~2. Implement. This verb is used with its ordinary definition, which is "to carry out, accomplish, or ensure fulfillment of."

1~~2~~3. Promptly. This word is used with its ordinary definition, which is "performed readily or immediately."

Record Retention

The Commission requires that licensees make and retain records as evidence of compliance with regulations and license conditions. A review of records during inspections is the least burdensome way that the Commission may be assured that the licensee has developed and implemented a radiation safety program. However, permanent retention of all required

records, or retention between inspections, would be unreasonable and would run counter to recent guidance to regulatory agencies that was issued by the Office of Management and Budget. Therefore the Commission has, in the proposed revision, generally adhered to the following policy.

1. For recurring records that are created on a daily basis, for example end-of-day surveys, and for most non-recurring, sporadic, or periodic records, such as individual patient dosage measurements or survey instrument calibrations, the Commission has made a judgment that records retention for two years provides adequate evidence of compliance with requirements.

2. In a few cases a record is only created once or the Commission considers the record to be essential ~~critical~~ evidence of compliance with regulations that, if not followed, might cause an immediate discernible impact on a worker or member of the public. ~~See~~ (for example, requirements for the geometry test for a dose calibrator and the teletherapy dosimetry equipment calibration, respectively). In those cases the Commission has made a judgment that retention for the duration of use of the equipment or of the license is necessary.

Effect on Broad Licensees

In addition to the more common "group" licenses which the NRC issues that authorize byproduct material for uses described in the groups, the NRC has also issued about 100 "broad" licenses under Part 33 that include medical use. There are two types, a "pure" broad license and a "hybrid" broad license.

About 50 "pure" medical use broad licenses have been issued. They are issued to large academic institutions that have had several years experience using radioactive materials. These licenses vest in each institution's Radiation Safety Committee ~~(RSC)~~ the authority to permit medical practitioners to use byproduct material for both patient care and medical research, to permit individuals to use byproduct material for research in test tubes and animals, and to review the facilities and radiation safety procedures that ~~all~~ these individuals will use. Before NRC issues a pure broad license it reviews the applicant's administrative and safety procedures, the training and experience of the ~~RSO~~ Radiation Safety Officer and of each

individual member of the Committee ~~RSC~~, and the standards and management procedures ~~the RSC~~ it will use when ~~it~~ reviews permit requests. This type of license is needed to allow for the orderly evolution of the medical sciences. The NRC will continue to review ~~RSO and RSC~~ committee member qualifications on a case-by-case basis because the size and individuality of each broad license program precludes the preparation of generic prescriptive qualifications. These licensees would be required to comply with the proposed prescriptive and performance criteria of Part 35, but would be exempted from the training and experience requirements of Subpart J and the authorized materials and authorized use restrictions in proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500.

About 50 medical "hybrid" broad licenses have also been issued. They are similar to the ~~pure broad~~ license described above, except that the Committee ~~RSC~~ only has the authority to permit individuals to use material in test tube and animal research, and only authorizes medical use in accordance with the groups in current § 35.100. The NRC would continues to review the training and experience of medical practitioners before allowing them to use material for medical use. Because control of medical use in these cases is the same as that exercised over the more common group licensees, the basis for a determination of compliance will be the same as that described below for group licensees.

Because, whether at a group or broad license facility, teletherapy is separately licensed "for treatment of humans" and because the NRC reviews qualifications of proposed users and safety procedures, no significant inconsistencies with current teletherapy programs or new teletherapy programs are expected.

Transition Policy For General Licensees

The general license in current § 35.31 has been eliminated from the proposed regulations. In the future, all medical use will be specifically licensed. Current general licensees will receive a specific license ~~and~~ that will be incorporated into NRC's filing system for keeping track of specific licensees, but they will be limited to the methods of use described in the current § 35.31, and relieved, by license condition, from the requirements that are more burdensome than the current general licensee requirements. The only action ~~they~~ a general licensee will need to take is to respond affirmatively

because Part 20 reg. applicable to $\geq$ 200 uCi

clarify 0-200, > 200 then P20 applies.

For now, draft so $\leq$ 200 - Genl lic

"3 mCi tape" requires disposal of rad waste

(*) because each licensee's radiation safety program was reviewed individually and license conditions were tailored to meet the licensee's individual needs,

to a notice that asks if they want to continue to have an NRC license that is limited to the methods of use authorized by the current general license. They will not be assessed application or renewal fees as long as their programs are limited to the material uses described in current §35.31. General licensees ~~who~~ that want to make any changes in their programs will have to apply under the new licensing scheme and will be subject to all the fees that apply to specific licensees.

The current Part 35 also grants a general license for in vitro work described in §31.11 to group licensees without requiring that they submit an in vitro registration form. Under the proposed regulation, applicants would have to specifically request this authorization as a line item on their application. Part 31 will be amended to continue the in vitro authorization for current medical licensees until their licenses are renewed. In either case, the use of § 31.11 materials within the inventory limits of that section will only be subject to the requirements of § 31.11.

Transition Policy for Specific Licensees

Under the current regulatory program, the license document with the appended application is used to regulate each individual licensee. Because the requirements in the proposed revision were taken from commonly used typical license conditions and regulatory guidance that most licensees have incorporated into their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants ~~who~~ that apply after the effective date of the proposed regulations. Therefore, current licensees will be cited if they do not comply with the new regulations. However, (*) above ~~if~~ there may be occasional ~~is an~~ inconsistency between a license condition and the regulation (for example, a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually). (**) below with the license less stringent than the regulation, the license would be considered an exemption from the regulation. Because the less stringent license requirement was reviewed for safety considerations and approved by the NRC, the inconsistency would not result in an increased risk to workers or the public. ~~On the other hand,~~ If the license requirement is more stringent than the regulation, the license requirement will stand in place of the regulation because it may serve to balance another

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(**) There is no health and safety reason to undo these licenses to effect compliance with the regulation. To impose the regulations in addition to the license conditions would not provide significant additional health and safety. Therefore, in case of inconsistency

of the final rule and the expiration date of each license.

license requirement elsewhere that is less stringent than the proposed regulation. The Commission proposes to resolve this temporary regulatory inconsistency by granting a general exemption during the transition period between the effective date

p35 (J)

In the case of record retention, the regulation will generally take precedence because, in the past, the Commission has not offered much guidance on this topic. Many applicants have either not specified a period of retention or have incorporated a single, all encompassing record retention phrase "until the Commission authorizes their disposal," rather than shouldering the burden of justifying to NRC a shorter period. If a record is substantively the same as a record described in the proposed regulation and the licensee ~~no~~ retention ~~requirement~~ period has not ~~been~~ stated a for that specific record, licensees could adopt the retention period stated in the final rulemaking. However, ~~L~~licensees would still have to comply with any record retention period required ~~ment for a particular~~ by a topic ~~that is specifically stated or referenced in a~~ license condition or another Part (for example Part 20) of the regulations. (For example, surveys that provide the basis for occupational dose records or measurements of effluent release are governed by Part 20.)

NRC does not currently review qualified teletherapy calibration expert ~~(QTCE)~~ credentials, and does not identify the Radiation Safety Officer ~~(RSO)~~ on the license. Under this proposal, NRC would begin to review their credentials and identify both just as it does now for authorized users. To add current licensees to this new scheme, ~~teletherapy~~ licensees would be required to submit for review and approval the credentials in ~~of the QTCE~~ when the next amendment or renewal request is required. The ~~RSO and QTCE~~ use individuals would be identified on the next license amendment.

The NRC particularly requests public comment on this transition policy and would like to know if licensees envision problems of interpretation or compliance that the staff might not foresee.

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 medical use of byproduct material. Radiation protection standards now contained in several existing regulations, Inspection and Enforcement orders that modify a single license or group of licenses, technical reports (NUREGs), standard conditions of

licenses, and regulatory guides would be consolidated into a concise set of regulations. The requirements that apply to all licensees appear first, followed by the specific requirements for each of the six basic types of use.

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

In order to maintain consistency among the various parts of NRC's regulations, conforming amendments have been made to the affected sections of Parts 30, 31, 32, 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.

Title

The title of Part 35 has been changed from "Human Use of Byproduct Material" to "Medical Use of Byproduct Material" to better reflect the scope of the part.

Authority

This listing provides notice of the statutory basis for the regulations. It also provides notice that the NRC may initiate criminal prosecution of persons who knowingly and willfully do not comply with the prescriptive requirements issued under sec. 161b or the recordkeeping and reporting requirements issued under sec. 161o.

Subpart A--General Information

§ 35.1 Purpose and scope.

The regulations in this part apply to all persons licensed by the Commission to intentionally administer byproduct material or the radiation from byproduct material to humans, and to individuals working under their supervision.

§ 35.2 License required.

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

§ 35.8 Information collection requirements: OMB Approval.

This section provides notice 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" applies to those states that have entered into an agreement with NRC to assume responsibility for regulating the 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 "Area of use" was added to identify a place on which ~~that is within a physical structure and that is allocated to the~~ byproduct materials are received, used, or stored. ~~program,~~ The term is used in § 35.36 to authorize licensees to use byproduct materials in rooms, suites, or building wings not identified in the application.

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

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

The term "medical use" was included to help identify the scope of this part. The word "intentional" was included in ~~added to~~ the ~~current~~ definition ~~of the term "human use"~~ to make it clear that occupational and non-occupational exposures under the regulations of Part 20, accidental exposures, and unwanted exposures from other sources of radiation (e.g., nuclear powered cardiac pacemakers, smoke detectors, and radioactive waste) are not considered medical use. The phrase "in the practice of medicine in accordance with a license" was included to make it clear that NRC recognizes that states may have different definitions of medical practice or different levels of control and that licensees should not interpret the NRC license as a pre-emption of state medical regulations or an attempt to direct the states' regulation of medical practice.

The word "medical institution" was added to identify organizations in which the radiation safety program depends on the cooperation of individuals from several different departments.

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

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

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

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

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

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

The term "qualified teletherapy calibration expert" was included to replace the term "qualified expert" which is used in the current § 35.24.

The new term better reflects the training, experience, and responsibilities of the individual who is responsible for calibrating a licensee's teletherapy unit.

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

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

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

§ 35.16 Application for license, amendment, or renewal.

At an institution, only management may apply for a license; individual physicians would be listed on that license as authorized users. An individual physician may not apply for use within a medical institution (an organization that provides various medical services). This requirement reflects the need for coordination with other employees who may not be under the administrative control of the authorized user. For use ~~based~~ sited outside an a medical institution, such as for private practice or mobile service, any person may apply. An application must be filed on Form NRC-313 because it elicits information in an orderly manner that will allow for uniformity in application review procedures.

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

This section also reflects the Commission's decision to delegate to Regional Administrators some licensing functions which, until recently, were conducted in the headquarters. This program was described in Federal Register notices published May 27, 1982 (47 FR 23138), April 14, 1983 (48 FR 16030) and May 9, 1984 (49 FR 19630).

§ 35.17 License amendments.

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

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

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

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

§ 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. Without this notice the NRC would not have assurance that the collective training and experience of the licensee's remaining personnel is adequate to ensure the safe use of byproduct material for all the types of use authorized by the license. The Commission has made a judgment that notification within 30 days is sufficient because technicians who have worked under the supervision of the authorized user can adequately ensure the safe receipt and proper storage of byproduct material. However, absence of an individual to oversee a byproduct material program may increase the

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probability of an accumulation of unused byproduct material or unauthorized use of material. This presents an unacceptable potential hazard.

§ 35.28 License issuance.

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

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

Concerning fees, ~~it is the sense of~~ Congress has directed that agency services, such as licensing and inspection, must be self-sustaining to the extent possible.

§ 35.29 Specific exemptions.

As part of an application or amendment request, a person may request an exemption from any requirement of this part. The NRC occasionally receives requests for exemptions from procedural, equipment, or training standards. The Commission may allow the exemption if the applicant can show that it will not compromise the health and safety of workers and the public.

Subpart B--General Administrative Requirements

§35.30 ALARA program.

An ALARA program is a management tool needed to assure that all reasonable efforts are made to assure the safe use of byproduct material. (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.) In an institution many workers from different departments 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 ensure a cooperative effort to reduce individual and collective dose and ensure regular safety reviews. Specific requirements usually considered part of an ALARA program are required by §§ 35.31 and 35.32.

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Non-institutional licensees, such as one or a few physicians in private practice, are not required to have a formal ALARA program because the safe use of byproduct material does not usually depend on the cooperation of individuals from several administratively separate departments

§ 35.31 Radiation Safety Officer.

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

§ 35.32 Radiation Safety Committee.

The proposed Part 35 requires institutional licensees to establish a Radiation Safety Committee to oversee the use of byproduct material. The committee is required because, in an institution, radiation safety for all workers (users and ancillary staff) and the public depends on the cooperation of employees from administratively separate departments. Without the benefit of committee discussion, authorized users may not be aware of radiation safety problems outside their own department that are caused by their patients, packages, or waste. The committee's deliberations will provide management and authorized users with information that

is needed to optimize allocation of resources available for radiation safety. A committee is not required for licensees that are not medical institutions because such organizations generally do not have the multi-armed, multi-tiered management structure typical of medical institutions. In non-institutions the authorized user is likely to be part of management and a line supervisor for ancillary workers; therefore a formal committee structure would serve no useful purpose. A similar requirement was published as a proposed rule on April 9, 1979 (44 FR 21023), and as a final rule on September 13, 1982 (47 FR 40149).

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.

Institutions that only request a license for diagnostic sealed sources will be exempted from this requirement by license condition because the radiation safety program would not depend on the cooperation of individuals from several different departments. Packages would arrive infrequently, there would be no chance of contaminating an entire room or suite, no radioactive waste, no radioactive patients, and little chance of loss of material.

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

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 not provide for timely notice of unnecessary or unnecessarily high doses. The quarterly review should be guided by two trigger levels for individual doses. The lower level would be a minimum level below which no action

need be taken. Above the minimum level, the source of exposure should be determined and consideration given to methods of reducing the exposure rate. The higher level should trigger immediate intervention by the Radiation Safety Officer to reduce the exposure. The committee should review the appropriateness and completeness of the intervention, and should develop a permanent solution to maintain do~~ese~~ses at a lower level.

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

§ 35.33 Requirement for Authority and Statement of Responsibilities.

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

§ 35.34 Visiting authorized user.

The uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a host licensee when its permanent staff may be unable to do so. This was allowed in the past by a standard license condition. If the licensee had a copy of another licensee's NRC license that listed the visitor as an authorized user, the visitor could work under the license for sixty days each year without requesting a license amendment. The scope of this concept has been expanded to allow NRC licensees to employ Agreement State authorized users. ~~Since~~ Because the visiting authorized user's training and experience has been reviewed for health and safety considerations by a regulatory agency, will not pose an undue risk to public health and safety ~~will not be adversely affected by allowing~~ this short-term authorization. The purpose of written permission is to assure that the required records have been reviewed and found complete.

When exercising this privilege, host licensees should identify each individual method of use authorized by their license, each individual method of use authorized by the visitor's license, and each individual method of use that the visitor will be allowed to do at the host facility. Note that in some cases the Agreement States' groups, schedules, or subparts do not correspond to those of the NRC. The visitor can only do those procedures authorized by both licenses.

§ 35.35 Mobile nuclear medicine service administrative requirements.

Mobile nuclear medicine service has been limited to diagnostic medical use because the inherent hazard of therapeutic amounts of byproduct material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or P35© equipment. These licensees are required to have a letter of permission from the management of each client to assure that the client management is aware of and in agreement with the medical use of byproduct material within the facility.

Mobile service may not be provided to licensed clients because, in case of a spill or ~~unlawful~~ dose rates above regulatory limits, the responsibility for corrective action may be clouded.

§ 35.36 Radiation safety program changes.

This section allows the licensee to make changes in the radiation safety program that was described in the application if the changes are within the requirements of the regulation. The purpose of this authorization is to allow the licensee to respond to changes in staff levels, available equipment, or patient load that may require reallocation of floor space, or to make changes that may be necessary for patient care, administrative, ~~new~~ radiation safety, or economy needs. Before implementing any change, the licensee must make a record of safety matters that were considered when planning the change. The record will be used during unannounced inspections to determine whether the licensee has made changes that are contrary to the regulations, license conditions or orders, and during termination surveys to provide an indication of every area where material was used.

This section does not allow the licensee to use byproduct material at addresses different from those listed on the license because the Commission would not be able to conduct an unannounced inspection.

§ 35.37 Records and reports of misadministrations.

The proposed Part 35 retains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. A discussion of these requirements appears at 45 FR 31701, published May 14, 1980. ~~The Commission, in SECY 82-388, considered withdrawal of this requirement and concluded that it should not be withdrawn at this time.~~

§ 35.38 Supervision.

The authorized user is allowed ~~qualified~~ to use byproduct material in the practice of medicine. Frequently, specific tasks may be delegated (under §§ 35.2(b) and 35.38) to individuals with less training and experience. However, it is necessary that a qualified individual instruct them, oversee their work on a frequent basis, and be available to promptly respond in unusual or emergency situations. The regulation requires that supervised individuals comply with instructions, procedures, and the regulations.

The NRC has not specified which tasks may be delegated to whom because the practice of medicine is regulated differently in each state and because medical services must also be responsive to each community's particular needs. The NRC particularly requests comment on whether special training elements should be clearly identified for certain tasks that are delegated or whether the general guidance is sufficient.

§ 35.49 Suppliers.

In order to authorize only the use of materials reviewed by the government for safety and effectiveness considerations, authorized users may use only byproduct material that has been manufactured and distributed under procedures that were reviewed for safety by the NRC, the Food and Drug Administration (FDA), or an Agreement State.

The NRC will continue its current practice of allowing, on a case-by-case basis, re-transfer of radiopharmaceuticals between Part 35 licensees if an applicant specifically requests an exemption from this section and shows the exemption is in the public interest.

Subpart C--General Technical Requirements

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

A dose calibrator is needed to ensure that the dosage of material given is the dosage that was prescribed. It must be tested for accuracy, the ability to exactly measure a specified quantity, and linearity, the ability to exactly measure a range of quantities. The requirements are generally consistent with the recommendations of the American National Standards Institute. (See ANSI N42.13-1978. Copies may be purchased by contacting Sales Department, American National Standards Institute, 1430 Broadway, New York, NY 10018. In the interest of economy and efficiency, the NRC uses voluntary national standards in its regulatory program if they provide adequate assurance of safety.) The activity levels of the accuracy check sources were chosen because a lower activity would invalidate the accuracy test due to expected statistical fluctuations, and a higher activity would present an unnecessary source of radiation exposure to workers. The radionuclides required reflect the fact that dose calibrators are not as accurate as might be expected for the photon energies commonly used for imaging (see "Joint NCDRH and State Quality Assurance Surveys in Nuclear Medicine," HHS Publication FDA 83-8209). The linearity test should only be done over the range between highest individual dosage measured and 10 microcuries to ensure that the dosage given is the dosage that was prescribed. It is not necessary to test for linearity for all amounts that might be measured, for example the first elution from a fresh generator or a multidose vial, because this would subject the worker to unnecessary radiation dose. Dosages below 10 microcuries cannot be accurately measured on a conventional dose calibrator becase they are so tiny. Also, ~~such~~ these dosages present only a trivial risk to the patient and therefore need not be so accurately measured. The geometry test assures that the shape of the syringe or vial containing the byproduct material does not affect the dosage measurement. The daily constancy check assures that the dose calibrator has worked consistently since it was last tested.

Licensees whose level or scope of use does not indicate need for a dose calibrator may request an exemption from this section. The request

should be supported by a description of an alternative method that the licensee will use to measure radiopharmaceutical dosages.

§ 35.51 Calibration and check of survey instruments.

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

§ 35.53 Measurement of radiopharmaceutical dosages.

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

A similar requirement was published as a proposed rule on September 1, 1981 (46 FR 43840). The comment period on the proposed rule expired November 30, 1981. The NRC is incorporating the dosage measurement proposal in this revision. The proposed Part 35 dosage measurement requirement differs from the 1981 proposal in its recordkeeping requirement. The Part 35 proposal requires the dosage measurement record to include the patient's name, and identification number if one has been assigned, and prescribed dosage. This information was not required by the 1981 proposal.

§ 35.58 Authorization for calibration and reference sources.

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

and brachytherapy sources

§ 35.59 Requirements for possession of sealed sources.

The user must follow the manufacturer's instructions because they have been reviewed for safety considerations by the Commission or an Agreement State.

The six-month test interval has been recommended by the National Council on Radiation Protection and Measurements (NCRP)[1] in Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection." More frequent testing is inconsistent with ALARA considerations because it would cause worker dose when making the test but provides only a slightly greater probability of finding a leaking source. The test procedures described are intended to maximize the probability of detecting contamination from a leaking source. Report No. 57, Section 3.3.5.3 recommends a minimum detectable limit of 0.005 microcuries for equipment used to measure leak test samples. This level is also consistent with the requirements of other parts of the current regulations (see, for example, §§ 31.5 and 34.25), and is only slightly higher than the minimum detectable activity exhibited by instrumentation available to licensees. The Commission has made a judgment that this level provides the most conservative detection level technically achievable at a reasonable cost. It is noted that this requirement would reduce the current permissible amount of detectable contamination from teletherapy sources ten-fold, from 0.05 microcuries to 0.005 microcuries for purpose of consistency.

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, or the small hazard of the byproduct material. To conduct a physical inventory more frequently than quarterly is inconsistent with ALARA exposure goals. To inventory less frequently may, in case of a misplaced source, allow an unacceptable radiation exposure to go on for too long without detection. The radiation survey assures that sources are safely stored.

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[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. Copies of reports may be purchased by contacting NCRP Publications, P.O. Box 30175, Washington, DC 20014.

§ 35.60 Syringe shields.

Syringes that contain byproduct material can be an external radiation source and should therefore be shielded at all times. In some cases the use of a shield when making an injection could interfere significantly with the injection. This would jeopardize patient benefit. In such cases the higher radiation exposure to the hands that is received by the technician who does not use a syringe shield is warranted. A shield need not be used when the risk of spoiling the injection is greater than the benefit of reduced worker exposure.

The NRC considered requiring the use of syringe shields when drawing individual dosages from multi-dose vials. That requirement is not included in this proposed revision because it appears that the increased handling required to remove the shield when measuring the dosage may actually increase radiation dose to the hands. However, the NRC is soliciting comments on whether syringe shields should be used when drawing individual dosages.

§ 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 shield labels.

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

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

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

The patient should not be released from the clinic or hospital until the residual radioactivity in the patient is at an acceptable level.

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

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

A patient whose body contains byproduct material is a source of external radiation and can be a source of radioactive contamination. The Commission proposes to allow patient 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 millicuries burden limit is based on a recommendation of the NCRP and current licensing practice. The 6 mR/hr at one meter limit is based on the exposure rate from 30 millicuries of iodine-131, the most commonly used therapeutic radiopharmaceutical. ~~The Commission is considering allowing the option because the 30 millicurie limit is consistent with NCRP guidance, but~~ some individuals believe that the exposure rate is more relevant and easier to measure. The Commission believes that either limit provides an adequate measure of safety for the general public, and ~~has made a judgment~~ that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement.

§ 35.80 Mobile nuclear medicine service technical requirements.

The Commission has limited radiopharmaceutical transportation by these licensees to unit dosages and multi-dose vials of prepared radiopharmaceuticals.

The Commission did not authorize transportation of generators because they are needed by persons who do not have daily access to prepared radiopharmaceuticals. That lack of access would be contrary to the geographic proximity required by § 35.38.

The service must remove all radioactive waste generated during the use of byproduct material at a client location of use ~~facility~~ because the Commission has no assurance ~~it is unlikely~~ that the client is equipped to safely ~~facility has a license to~~ receive and process radioactive waste. 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, client facilities should be considered as unrestricted areas, and the licensee must therefore constantly exercise physical control of byproduct material.

Equipment checks are needed to assure the proper function of equipment after transport and before byproduct material is handled. A survey is needed to assure that all byproduct material has been removed from the client location of use. The mobile nuclear medicine service must carry a calibrated survey meter to monitor exposure and contamination in case of any accident that may result in a release of byproduct material.

§ 35.90 Storage of volatiles and gases.

Some radiopharmaceuticals present an inhalation or immersion source (e.g., volatile iodine-131 and xenon-133 respectively). The chance of exposure can be reduced by storing these materials in a fume hood or multiple barriers (such as a folded plastic bag within a folded plastic bag).

§ 35.92 Decay-in-storage.

For most hospital radiopharmaceutical waste, decay to background levels is essentially complete over a period of days or months. The waste disposal requirements of § 20.301, directed primarily at longer half-lived material, are not necessary for short half-lived radiopharmaceutical waste. Therefore, short half-lived waste can be exempted from the requirements of § 20.301. A decay period of ten half-lives was chosen because it represents a thousand-fold reduction in radioactivity. This ensures that, in most cases, byproduct material will have decayed to levels below those in § 30.71, which are quantities that, under certain ordinary conditions, are exempt from a requirement for a specific license. The regulation would only allow decay-in-storage for radioactive material with a half-life of 65 days or less because storage in excess

of 650 days is more appropriately considered permanent storage. (Consistent with current practice, the Commission will consider, on a case-by-case basis, requests to decay longer-lived material or to decay for fewer half-lives.) Waste must be monitored to assure that long-lived waste was not accidentally mixed with short-lived waste and that no waste has been added to the container since it was sealed. When the waste is monitored, neither the waste nor the survey instrument may have any radiation shielding because it might hide the presence of long-lived byproduct material in the waste. The requirement to remove or obliterate radiation labels is in § 20.203(f)(4) and is included here for completeness. Generator columns must be individually monitored because they contained larger amounts of radioactivity and also may have small amounts of long-lived contaminants.

Subpart D--Uptake, dilution, and 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. (§ 35.200 is also discussed later).

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.

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The FDA also authorizes the Radioactive Drug Research Committee (RDRC) at an institution to review and approve the use of radioactive materials for medical use 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. Therefore, the Commission will continue to allow, on a case-by-case basis,

licensees to administer radiopharmaceuticals authorized by an RDRC in accordance with FDA regulations. This authorization was not included in the regulation because only a few licensees request it.

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

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

§ 35.120 Possession of survey instrument.

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

Subpart E--Imaging and localization

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

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

Through continuing medical research, new uses may be found for existing approved radiopharmaceuticals. These new uses, which may require a different dosage, route of administration, or physical form, may not appear on the manufacturer's label or package insert instructions. It was such a situation that resulted in a petition filed by Dr. George V.

√ L3: mention how to get new exceptions.

; the preamble of the final rule also described how to apply for future exemption requests.

Taplin (Docket No. PRM-35-1) requesting an exemption for Tc-99m pentetate as an aerosol for lung function studies. A proposed rule was published on April 13, 1982 (47 FR 15798). The comment period on this proposed rule expired June 14, 1982, and 35 comments were received. The NRC adopted the rule in final form without change on February 4, 1983 (48 FR 5217). The NRC is incorporating this regulation into this revision of Part 35 without soliciting public comment because of the recentness of the rulemaking and because there are no substantive changes to the rule as adopted.

§ 35.204 Permissible molybdenum-99 concentration.

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

The ~~person who~~ licensee that elutes the generator must measure and keep a record of the molybdenum concentration. Persons who receive prepared radiopharmaceuticals do not have to make this measurement because the person who prepared it would have made the measurement (see the conforming amendment to § 30.34).

§ 35.205 Control of aerosols and gases.

The Commission believes that a system that provides for the collection or controlled dispersal of aerosols and gases is needed to reduce exposure to workers and the public. If control is by dispersal in the atmosphere, licensees should note §§ 20.105 and 20.106, which limit the amount of radioactivity in the effluent stream.

Unlike solid and liquid byproduct materials authorized by this part, gases usually cannot be contained or recovered after a spill. To reduce exposure to workers and the public after a spill, exhaust and dispersal in the atmosphere is commonly used. However, because conventional room ventilation rates are seldom sufficient to clear spilled gas in a timely fashion, the licensee must follow special, room-specific safety measures in case of a gas spill. When making the requied exhaust calculation, the licensee must assume that the largest single gas container handled in the area is completely spilled, and may use either ambient or emergency air exhuast rates.

§ 35.220 Possession of survey instruments.

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

Subpart F--Radiopharmaceuticals for therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

The radiopharmaceuticals listed in § 35.300 were taken from those listed in the current §§ 35.100(d) and (e). The drugs have been approved for medical use by the FDA.

§§ 35.310 Safety instruction, and 35.410 Safety instruction.

In the hospital setting, the use of byproduct material presents special training problems which are not addressed in Part 19 because they are unique to the medical environment. For example, visitor control in a hospital cannot be accomplished by physical barriers which might impede the delivery of emergency medical care to patients. ~~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 the Commission's regulations.)

§ 35.315 Safety precautions

Because of the special contamination hazards of radiopharmaceutical therapy patients, a private room with private sanitary facilities is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency in order to determine whether special contamination control procedures must be implemented.

§ 35.320 Possession of survey instruments.

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

Subpart G--Sources for Brachytherapy ~~(Group VI)~~

§ 35.400 Use of sources for brachytherapy.

This section identifies brachytherapy sources that may be used for medical use. The list was taken from the current § 35.100(e), which is a list of sources commonly used for patient care.

§ 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 implant patient is necessary to ensure public safety. Section 35.404 requires that the licensee ~~confine~~ prevent the patient from leaving the hospital or clinic until all temporary implant sources

have been removed. The records required by this section may be amalgamated with the records required by § 35.406; there is no need for duplication.

§ 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 a physical count and a radiation survey log entry each time sources are handled will help to ensure that if a source is misplaced~~,~~ its absence will quickly become apparent to the licensee, ~~who~~ which can then promptly begin a search for the source.

§ 35.415 Safety precautions.

Because of the high exposure rates around implant patients, a private room is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency to ensure that control of implant sources is retained.

§ 35.420 Possession of survey instrument.

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

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

§ 35.500 Use of sealed sources for diagnosis.

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

§ 35.520 Availability of survey instrument.

The licensee needs a survey instrument to measure the exposure rates around a packaged sealed source that was just received or 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, because a source exchange is an infrequent and scheduled event, and because a hazardous accident would be a very rare occurrence, the Commission believes that it is sufficient, for safety purposes, to require the licensee to make arrangements to borrow or rent an instrument or contract with a measurement service when measurements are necessary.

Subpart I--Teletherapy ~~(Group VIII)~~

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

This is a new type of use group established to deal with a well-established type of use. Safety measures that now apply to all licensees within this group have been used over the years and are reflected in these proposed regulations. , and § 35.645 five-year inspection (§ 35.645 is also discussed later).

§ 35.605 Maintenance and repair restrictions.

Th~~is~~ese section~~s~~ provide~~s~~ notice that only specially licensed persons may maintain, adjust, or repair teletherapy units because this type of work requires special training and equipment in order to be done safely. This work is licensed under Part 30 of the Commission's regulations.

§ 35.606 Amendments.

Amendments are required for items identified in paragraphs (a) through (~~f~~e) because any change described in these paragraphs could easily 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 an essential element in ensuring the safe use of a teletherapy unit. The Commission has made a judgment that only an individual with ~~proper~~ special training and experience can determine the operating characteristics of the licensee's teletherapy unit and should therefore be identified on the license.

X

§ 35.610 ~~Posted~~ Safety instructions.

Emergency instructions must be posted to remind individuals of the proper steps to be taken in case of an emergency and to identify individuals to be notified in an emergency. The Commission believes this is also an appropriate place to remind workers that it is important to ensure that only the patient is in the room before turning the unit on. The reminder is necessary because it is possible that when two workers are stationed on one teletherapy unit one worker may inadvertently turn the unit on when the other worker is still in the treatment room, or a worker may turn the unit on to check its operation after a patient or co-worker has entered the treatment room without telling the worker at the control console.

P35(M)

§ 35.615 Doors, interlocks, and warning systems.

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

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

§ 35.620 Possession of survey instrument.

The licensee needs a survey instrument on hand as a backup room monitoring device in case the radiation monitoring device fails.

§ 35.621 Radiation monitoring device.

The radiation monitoring device is needed to indicate radiation levels in the teletherapy room ~~in the event of the failure of~~ if the interlocks or the warning system fail. Individuals may be unnecessarily exposed following the failure of the source retraction mechanism coupled with a failure of the primary beam condition indicator system. Therefore, § 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. Similar requirements were published as a proposed rule on April 28, 1982, (47 FR 18131), and were adopted in a final rule published January 18, 1983 (48 FR 2116).

§ 35.622 Viewing system.

If a patient moved during a therapy administration, this could result in a radiation dose to healthy tissue and no dose to the treatment area. Therefore, a viewing system is needed to monitor the orientation of the patient and the teletherapy unit to assure the prescribed application of radiation.

§ 35.630 Dosimetry equipment.

Dosimetry equipment is needed to measure radiation output. In order to help assure accuracy the equipment must be calibrated. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the proposed resolution of the petition filed by the American Association of Physicists in Medicine, Petition Docket No. PRM 35-2 (see 47 FR 4311; January 29, 1982). Currently, regulations require that primary dosimetry equipment be calibrated every two years. The petitioner requested that this two year requirement be relaxed to four years if, two years after calibration, the primary dosimetry system inter is compared with a system that was calibrated within the past two years, and the results of the inter comparison indicate that the calibration factor used to convert an instrument reading to a dose measurement had not

of similar metrological quality

changed by more than two percent. (Intercomparison meetings are occasionally scheduled by several qualified teletherapy calibration experts within a geographic area. Each expert takes a dosimetry system to the meeting. ~~where~~ Each dosimetry system in turn is exposed to the same radiation dose from a teletherapy unit. The response of each dosimetry system can then be compared to the response of the other systems. If each system measures the same radiation dose in rads, this provides assurance that each system is working properly.) This suggestion has been incorporated into these proposed regulations. The petitioner also asked that the licensee be required to make quarterly constancy checks to assure the consistency of operation of the dosimetry system. The Commission did not incorporate this suggestion because the apparent exposure rate of constancy check devices as indicated by the dosimetry system may vary by as much as two percent even though the calibration factor for the dosimetery equipment has not changed. Therefore, the Commission does not believe that periodic constancy checks would necessarily provide increased assurance of proper operation.

Note that when instruments of different metrological quality are exposed to the same radiation dose, it is referred to as a comparison rather than an intercomparison.

§ 35.632 Full calibration measurements.

Full calibrations are needed to ensure that the given dose is the same as the prescribed dose. 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 that 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 that are used to limit the directions in which the beam can be aimed, and thereby reduce the exposure rate in uncontrolled areas, has also been added. The licensee need no longer perform all measurements with a calibrated dosimetry system. Instead, the calibrated dosimetry system need only be used for one representative measurement, and then a relative exposure rate measurement system can be used to complete the calibration. This would allow for use of computer-controlled dosimetry systems that are capable of making precise relative measurements but are not suitable for making absolute output measurements.

The ~~NRC~~ Commission proposes to allow licensees to use either the currently required calibration procedure or a new procedure that was recently published. The new procedure is generally considered more scientifically rigorous, but the Commission believes that either procedure provides an adequate measure of teletherapy dose rate.

The exposure rate from a radioactive source goes down as time progresses due to source radioactive decay. To ensure 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 ensure 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 Safety checks for teletherapy facilities.

A monthly spot-check is required by § 35.22 of the current regulations to ensure that the teletherapy unit is giving the expected radiation dose. The following changes from current requirements have been made. Timer accuracy has been clarified to include on-off error. The accuracy of localization devices has been added. Error in either may result in incorrect administration of radiation. The qualified teletherapy calibration expert must review the results of the spot-check measurements within fifteen days, and must notify the licensee in writing of the results of the monthly check, to assure the licensee and the Commission that the check results were reviewed by a qualified individual. The Commission has made a judgment that a response period of less than fifteen days would be unreasonably expensive.

A requirement to check certain safety systems in the teletherapy facility has been added. These checks are needed to assure that safety systems required by other sections of the regulations are working properly. They need not be performed by the qualified teletherapy calibration expert. Devices that are not working must be promptly repaired in order to assure safety in the teletherapy facility. In case of failure of the viewing system, the regulation would allow the physician to decide whether treatments should be interrupted. This would <u>not</u> relieve the licensee from the requirement to promptly repair the viewing system.

The regulation would require ~~shutdown of the facility~~ that the teletherapy unit not be used in case of door interlock failure because that is the mechanism that protects workers and the public from unintentional irradiation. However, the Commission invites comment as to whether additional administrative procedures or personal supervision would provide an acceptable balance of worker safety and medical use needs.

§ 35.641 Radiation surveys for teletherapy facilities.

The Commission has used these maximum and average permissible source leakage radiation levels for several years as license conditions. They are consistent with guidance from the NCRP in its Report No. 33, "Medical X-ray and Gamma-ray Protection for Energies up to 10 MeV-Equipment Design and Use," Section 4.2.2. The Commission has made a judgment that they are sufficiently restrictive to keep exposures as low as reasonably achievable. The required location of the collimators during the head leakage survey is a new specification. It is based on the fact that, for individuals who recieve most of their radiation dose from working around a source in the "off" position, the collimators will normally be at the setting used for the last treatment.

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

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

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

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

§ 35.645 Five-year inspection.

Many licensees replace teletherapy sources at five year intervals. Requiring a mechanical check at five year intervals helps to assure that the source exposure mechanism is in good working order and will not stick in the exposed position. The mechanic who exchanges sources and inspects units can remove the source, inspect the drawer mechanism, and then install the new source. More frequent checks would require greater time near a very radioactive source. Less frequent checks would not be sufficient to assure the continuous proper operation of the exposure mechanism. The identification information in the record is needed to establish which unit was inspected, when, and by whom. The remaining information is needed so the Commission may determine that the inspection was of sufficient depth to assure the health and safety of workers and the public.

Subpart J--Training and Experience Requirements

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

Consistent with current practice, if individuals do not meet the training and experience standards, the NRC will review their credentials with regard to the materials requested and these standards and make authorizations on a case-by-case basis.

§§ 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 provides 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(c) 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 s ~~is~~ are qualified to oversee the safe use of byproduct material that ~~he is~~ they are authorized to use pursuant to the conditions of the license.

§§ 35.900(b), 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 ensure the safe use of byproduct material. The duration of training and experience is usually specified in classroom (not credit) hours. Training may be received as part of a formal program at an accredited university, at a proprietary school, from an equipment or radiopharmaceutical manufacturer, or elsewhere. NRC will carefully review this information before listing an individual on a license. Supervised work experience must be received at an institution under an authorized user preceptor because usually only such an individual is qualified to teach the clinical use of byproduct material, and, if the experience were not received at an institution, the student would be less likely to receive experience with all the methods of use commonly used or all the management problems associated with the safe handling 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 Physician training exception.

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 th~ CGME have therefore extended their training programs to six months uration. 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.

§ 35.972 Recentness of Training.

submittal of an application

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 before ~~prior to~~ the application and has not had continuing involvement in the field, training must be repeated.

Subpart K--Enforcement

§ 35.990 Violations.

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

Insert P35 (K)

Conforming amendment

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

Many ~~human~~ medical use licensees now use byproduct material for in vitro work under the provisions of current §§ 31.11 and 35.14(c). The proposed conforming amendment grandfathers them. In the future, new and renewal applicants will have to specifically request permission to use § 31.11 materials as a separate line item on their applications. The use of materials listed in § 31.11 within the inventory limits of that section will only be subject to the requirements of that section; consistent with current regulations, the use of materials listed in § 31.11 will not be subject to the requirements of Parts 19, 20, 21, and 35 except for the Mock Iodine-125 disposal, loss or theft, and notification clause of § 31.11(f).

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, current regulatory guides (RG), Office of Inspection and Enforcement bulletins, the United States Pharmacopeia, and new text prepared by staff.

NEW SECTION NUMBER		ORIGIN
Subpart A--General Information		
35.1	Purpose and scope.	35.1 revised
35.2	License required.	35.2 revised
35.8	Reporting, recordkeeping, and application requirements: OMB Approval.	new text
35.15	Definitions.	
	Agreement State	20.3
	ALARA	acronym
	Authorized users	term used on licenses
	Dentist	new term
	Medical institution	new term

	Management	new term
	Medical use	35.3(a) revised
	Misadministration	35.41
	Mobile nuclear medicine service	new term
	Output	new term
	Physician	35.3(b) revised
	Podiatrist	new term
	Qualified teletherapy calibration expert	new term
	Radiation Safety Officer	term used on licenses
	Sealed source	30.4(r) verbatim
	Visiting authorized user	new term; similar to "visiting authorized user" license condition
35.16	Application for license, amendment, or renewal.	35.4 revised
35.17	License amendments.	new text; compare 30.38
35.18	Notifications.	new text
35.28	License issuance.	new text, compare 30.36
35.29	Specific exemptions.	new text; compare 30.11

Subpart B--General Administrative Requirements

35.30	ALARA program.	new text; see RG 10.8 Appendix O revised
35.31	Radiation Safety Off[illegible]	RG 10.8
35.32	Radiation Safety Comm[illegible]tee.	35.11(b) revised
35.33	Requirements for authority and statement of responsibilities.	new text
35.34	Visiting authorized user.	license condition
35.35	Mobile nuclear medicine service administrative requirements.	licensing policy
35.36	Radiation safety program changes.	New text
35.37	Records and reports of misadministrations.	35.42

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 C2 revised, and new text
35.51	Calibration and check of survey instruments.	RG 10.8 Appendix D1 revised, and new text
35.53	Measurement of radio pharmaceutical dosages.	proposed rulemaking 35.15 (46 FR 43840; September 1, 1981)
35.58	Authorization for calibration and reference sources.	35.14(d) revised
35.59	Requirements for possession of sealed sources.	35.14(e)(1)(i), 35.14(f) revised
35.60	Syringe shields.	Inspection and Enforcement letter April 16, 1979
35.61	Vial shields.	Inspection and Enforcement letter April 16, 1979
35.62	Syringe labels.	new text
35.63	Vial shield 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 nuclear medicine 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

<u>Subpart D--Uptake, dilution, and excretion</u>		
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
<u>Supart E--Imaging and localization</u>		
35.200	Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.	35.100 (II) and (III) revised
35.204	Permissible molybdenum-99 concentration.	US Pharmacopeia
35.205	Control of aerosols and gases.	RG 10.8 Appendix M revised
35.220	Posession of survey instruments.	RG 10.8 page 5
<u>Subpart F--Radiopharmaceuticals for therapy</u>		
35.300	Use of radiopharmaceuticals for therapy.	35.100 (IV) and (V) revised
35.310	Safety instruction.	19.12 revised
35.315	Safety precautions.	RG 10.8 Appendix K
35.320	Possession of survey instruments.	RG 10.8 page 5
<u>Subpart G--Sources for brachytherapy</u>		
35.400	Use of sources for brachytherapy.	35.100 (VI) revised
35.404	Release of patients treated with temporary implants.	35.14(b)(5)(vii) revised
35.406	Brachytherapy sources inventory.	RG 8.18 page 8
35.410	Safety instruction.	19.12 revised
35.415	Safety precautions.	RG 10.8 Appendix L
35.420	Possession of survey instruments.	new text

Subpart H--Sealed sources for diagnosis

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

Subpart I--Teletherapy (Group VIII)

35.600	Use of a sealed source in a teletherapy unit.	new text
35.605	Maintenance and repair restrictions.	license condition
35.606	Amendments.	new text
35.610	Safety instruction.	license condition and new text
35.615	Doors, interlocks, and warning systems.	license condition
35.620	Possession of survey instrument.	new text
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 surveys for teletherapy facilities	license condition
35.642	Safety checks for teletherapy facilities.	license condition
35.643	Modification of teletherapy unit or room before beginning a treatment program.	new text
35.644	Reports of teletherapy surveys, checks, tests and measurements.	license condition
35.645	Five-year inspection.	license condition

Subpart J--Training and experience requirements

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

X

Subpart K--Enforcement

35.990 Violations. new text
35.999 General exemption during transition period. new text

ADMINISTRATIVE STATEMENTS

The Commission is proposing to completely revise the regulations governing the medical use of byproduct material.

Finding of no Significant Environmental Impact: Availability

The Commission has determined under the National Evnironmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. insert P55(7) The environmental assessment and finding of no significant impact on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the environmental assessment and finding of no significant impact are available from Mr. McElroy. (see "For further information contact:" heading)

Paperwork Reduction Act Statement

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

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the analysis may be obtained from Mr. McElroy.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted as indicated in the ADDRESSES heading.

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 economic impact on a substantial number of small entities. The NRC has issued approximately 2500 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 300 by individual physicians. Most of the institutional licensees are community hospitals. The Small Business Administration size standards, 13 CFR Part 121, (49 FR 5037; February 9, 1984) classify a hospital or physician's office as a small entity if its average gross annual receipts do not exceed $3.5 million. Under these size standards, some NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

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

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

The Commission has prepared a preliminary regulatory analysis for this proposed regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the proposed regulation would not result in significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room at 1717 H Street NW, Washington, DC. Single copies are available from Mr. McElroy.

Because of the widely differing conditions under which licensees covered by this proposed regulation operate, the Commission specifically

Insert (*) p 58

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.

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

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

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

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

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

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is proposing to adopt the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

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

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Sec.

Subpart C--General Technical Requirements

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

Subpart D--Uptake, Dilution, and Excretion

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

Subpart E--Imaging and Localization

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

Subpart F--Radiopharmaceuticals for Therapy

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

Subpart G--Sources for Brachytherapy

Subpart H--Sealed Sources for Diagnosis

Subpart I--Teletherapy

Subpart J--Training and Experience Requirements

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 use of sealed sources for diagnosis.

35.960 Training for teletherapy.

35.961 Training for qualified teletherapy calibration expert.

35.970 Experienced authorized user training exception.

35.971 Physician training exception.

35.972 Recentness of training.

Subpart K--Enforcement

35.990 Violations.

35.999 General exemption during transition period.

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

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.2, 35.17, 35.30(a) and (b), 35.31(a) and (b), 35.32, 35.33, 35.34(a), 35.36(a), 35.38, 35.49, 35.50(a)-(d), 35.51(a)-(d), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.62, 35.63, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.100(b), 35,120, 35.200(b) and (c), 35.204(a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610(a) and (b), 35.615, 35.620, 35.621(a)-(d), 35.621(f) and (g), 35.622, 35.630(a) and (b), 35.632(a)-(f), 35.633(a)-(i), 35.641(a) and (b), 35.642(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.18, 35.30(c), 35.31(b), 35.32(b), 35.33(b), 35.34(a) and (c), 35.35(b), 35.36(b), 35.37(a)-(d), 35.50(e), 35.51(e), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406(b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.621(e), 35.630(c), 35.632(g), 35.633(j),

35.641(c), 35.642(c), 35.643(c), 35.644, and 35.645(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A -- General Information

§ 35.1 Purpose and scope.

the medical use of byproduct material and for

This part prescribes requirements and provisions for issuance of specific licenses authorizing the medical use of this ~~byproduct~~ material. ~~This part also prescribes~~ These requirements and provisions ~~for the medical 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, others ~~requirements of~~ in this chapter. The requirements and provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 License required.

(a) No person shall manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State and as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.38, unless prohibited by license condition.

§ 35.8 Information collection 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 (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-______.

(b) The approved information collection requirements contained in this part appear in §§ 35.16, 35.17, 35.18, 35.30(c), 35.31(b), 35.32(a), 35.33(b), 35.34(c), 35.35(b), 35.36, 35.37(a)-(d), 35.50(e), 35.51(e), 35.53(c), 35.59(d), (e), (g), and (i), 35.70(g), 35.80(f), 35.92(b),

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

§ 35.15 Definitions.

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

"ALARA" means as low as reasonably achievable.

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

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

"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.

"Management" means the chief executive officer.

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

"Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in ~~art~~ the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Misadministration" means the administration of:

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

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

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

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

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

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

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

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

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

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

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

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

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

"Visiting authorized user" means an authorized user who is not identified on the license of the host ~~person for whom he is working~~.

§ 35.16 Application for license, amendment, or renewal.

(a) For use sited ~~based~~ in a medical institution, only the institution's management may apply. For use not sited ~~based~~ in a medical institution, any person may apply.

(b) An application for a license for medical ~~human~~ use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions ~~contained~~ in Regulatory Guide 10.8 Revision 2, "Guide

for the Preparation of Applications for Medical Programs." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for ~~human~~ medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions contained in Regulatory Guide 10.--, "Guide for the Preparation of Applications for Teletherapy Programs." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) ~~The~~ An applicant shall mail the completed request as directed below.

(1) If the applicant is not a Federal agency and is located in Connecticut, the District of Columbia, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, ~~the applicant~~ it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region I, Material Licensing, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(2) If the applicant is not a Federal agency and is located in Virginia, West Virginia, Puerto Rico, or the Virgin Islands, ~~the applicant~~ it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region II, Material Licensing Section, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323.

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

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

(5) If the applicant is not a Federal agency and is located in Alaska, Hawaii, or Guam ~~the applicant~~ it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region V, Material

Licensing Section, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

(e) If the applicant is a Federal agency or ~~if the applicant~~ it is located in a State, territory, or possession that is not mentioned in paragraphs (d)(1) through (5) of this section, ~~the applicant~~ it shall:

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

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

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

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

<u>§ 35.17 License amendments</u>.

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

(a) Before it us~~ing~~es byproduct material for a method or type of medical use not permitted by the license issued under this part;

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

(c) Before ~~the licensee~~ it changes Radiation Safety Officers or Qualified Teletherapy Calibration Experts;

(d) Before it receiv~~ing~~es byproduct material in excess of the amount authorized on the license; and

(e) Before it add~~ing~~s to or chang~~ing~~es the location or locations of use or mailing address identified on the license.

<u>§ 35.18 Notifications</u>.

The licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Qualified Teletherapy Calibration Expert, permanently discontinues performance of duties under the license. ~~The licensee~~ It shall mail the report to the appropriate address identified in § 35.16.

§ 35.28 License issuance.

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

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.16;

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

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission for the protection of the public health and safety; and

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

§ 35.29 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.30 ALARA program.

(a) Each medical institution licensee shall implement 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 as required by the regulations or requested by the Radiation Safety Committee.

(2) The program must include an annual review by the Radiation Safety Committee of the types and amounts of byproduct material used, occupational dose reports or summaries, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain individual and collective occupational

dose as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

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

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

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

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

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

§ 35.31 Radiation Safety Officer.

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

(b) The Radiation Safety Officer shall:

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

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

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if ~~in the event of loss of~~ control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

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

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission's regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) For medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and

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

§ 35.32 Radiation Safety Committee.

Each medical institution 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 of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The committee must meet a least quarterly.

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

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

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

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

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

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

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

(1) 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 with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Qualified Teletherapy Calibration Expert before submissi~~on of the~~ ng a license application or ~~application~~ request for amendment or renewal;

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

(4) Review on the basis of safety, and approve, or with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes;

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

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

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

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

§ 35.33 Requirement for authority and statement of responsibilities.

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

(1) Identify radiation safety problems;

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

(3) Verify implementation of solutions.

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

§ 35.34 Visiting authorized user.

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

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

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

(3) The visiting authorized user ~~performs~~ only those procedures for which ~~he~~ is specifically authorized by a Commission or Agreement State license. are performed by that individual.

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

(c) ~~The~~ A licensee shall retain copies of the records specified in this section for two years after the visiting authorized user's last use of licensed material unless the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.35 Mobile nuclear medicine service administrative requirements.

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

of this chapter to serve clients who do not have a~~n~~ ~~NRC~~ Commission or Agreement State license for the materials listed in those Subparts.

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

§ 35.36 Radiation safety program changes.

(a) ~~The~~ A licensee may change the radiation safety procedures and equipment that are used to meet regulatory requirements and that were described in the application for license, renewal, or amendment. The licensee may also receive, use, and store licensed material (except teletherapy sources) in areas of use that were not identified in the application for license, renewal, or amendment.

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

§ 35.37 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician ~~personally informs the licensee either that he will~~ agrees to inform the patient or believes, based on ~~that, in his~~ medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian

cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

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

(c) When a misadministration involves a diagnostic procedure, the 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 retain for ten years 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.

(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.

A ~~The~~ licensee who permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed 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 this use;

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

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

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

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

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

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

§ 35.49 Suppliers.

~~The~~ A licensee may use for medical use only:

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

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant

to § 32.73 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for human use; and

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

Subpart C--General Technical Requirements

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

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

(b) ~~The~~ A licensee shall:

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

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

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

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

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

The records required in paragraphs (b)(1) through (b)(4) of this section must include:

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

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

(1) For ~~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) For ~~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) For ~~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~~.~~; and

(4) For ~~The record required in~~ paragraph (b)(4), ~~of this section must include~~ the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

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

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

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

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

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

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

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

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

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

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

(1) A description of the calibration procedure; and

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

§ 35.53 Measurement of radiopharmaceutical dosages.

~~The~~ A licensee shall:

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

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

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

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

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

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

(4) Date and time of the measurement; and

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

§ 35.58 Authorization for calibration and reference sources.

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

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

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

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

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

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

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

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

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before ~~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 label or brochure that accompanies the source.

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

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

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

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

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

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

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

(2) File a report within five days of the leakage test with the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter, with a copy to Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.

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

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

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

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

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

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

(6) Wires of iridium-192.

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

(h) ~~Any~~ A licensee in possession of a sealed source or brachytherapy source shall survey with a low range survey meter quarterly all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) ~~The~~ A licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured 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~~ A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) ~~The~~ A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield and 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.

A ~~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.

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

§ 35.63 Vial shield labels.

A ~~The~~ licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) ~~The~~ A 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~~ A 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~~ A 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~~ as low as than 0.1 milliroentgen per hour.

(d) ~~The~~ A licensee shall establish radiation exposure rate action levels for the surveys required by paragraphs (a) and (b) of this section

clarify 100 cm^2 Witten, withdrawn after conversation

may - defer to ADM p 25)

and shall require that the individual ~~who is~~ performing the survey immediately notify the Radiation Safety Officer if an exposure rate exceeds an action level.

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

(f) ~~The~~ A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute.

(g) ~~The~~ A 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.

(h) ~~The~~ A licensee shall retain a record of each survey for two years. The record must include the date of the survey, a plan of each area ~~that was~~ surveyed, the action level established for each area, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

<u>§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.</u>

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

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

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

(b) ~~The~~ A licensee ~~shall~~ may 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.

nuclear medicine

§ 35.80 Mobile nuclear medicine service technical requirements.

A licensee providing mobile service shall:

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

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

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

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before ~~administering byproduct material to humans~~ medical use at each location of use;

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

(f) Retain a record of each survey required in paragraph (e) of this section for 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 of use 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.

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

§ 35.92 Decay-in-storage.

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

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

(2) Monitors byproduct material at the container surface ~~prior to~~ before 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 with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level ~~prior to~~ before disposal.

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

Subpart D--Uptake, Dilution, and Excretion

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

(a) ~~The~~ A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:

(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

for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

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

§ 35.120 Possession of survey instrument.

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

Subpart E--Imaging and Localization

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

(a) ~~The~~ A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:

(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;

"may" defer to ADM p251

(xi) Oxidronate sodium;

(xii) Disofenin; and

(xiii) Succimer.

(4) 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;

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

(6) Chromium-51 as human serum albumin;

(7) Gold-198 in colloidal form;

(8) Mercury-197 as chlormerodrin;

(9) Selenium-75 as selenomethionine;

(10) Strontium-85 as nitrate;

(11) Ytterbium-169 as pentetate sodium;

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

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

(b) ~~The~~ A licensee using the radiopharmaceuticals listed in paragraph (a) of this section for clinical procedures other than those specified in the product label or package insert shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.

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

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

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

§ 35.204 Permissible molybdenum-99 concentration.

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

(2) removed. Few FB's, TLD's, survey mtrs adequate

See HP 42 6 837 6 82

44 5 5798582

46 3 627

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

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

§ 35.205 Control of aerosols and gases.

(a) ~~The~~ A licensee ~~who administers~~ administering radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter.

(b) 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.

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

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

(e) ~~The~~ A licensee shall post the calculated time at the area of use and require that, in case of a gas spill, individuals evacuate the room until

~~(1)~~ the posted time has elapsed. ~~; or~~

~~(2) A survey of the room indicates that the concentration in the room is less than the occupational limit listed in Appendix B to Part 20 of this chapter.~~

(f) ~~The~~ A licensee shall check the operation of collection and ventilation systems each six months.

§ 35.220 Possession of survey instruments.

~~Each~~ A licensee authorized to use byproduct material for imaging and localization studies shall have in ~~his~~ its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable ~~high level~~ ion~~ization~~ ~~type~~ chamber radiation survey instrument that has a scale with a full scale deflection of 1 roentgen per hour.

Subpart F--Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

~~The~~ A licensee may use the following prepared radiopharmaceuticals:

(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 for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA).

§ 35.310 Safety instruction.

(a) ~~The~~ A licensee shall provide oral and written radiation safety instruction~~s~~ for all personnel caring for the patient undergoing radiopharmaceutical therapy. To satisfy this requirement, the instruction~~s~~ must describe the licensee's procedures for:

(1) Patient control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

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

§ 35.315 Safety precautions.

(a) ~~The~~ A licensee shall provide each individual hospitalized for radiopharmaceutical therapy a private room with a private sanitary facility.

(b) ~~The~~ A licensee shall notify the Radiation Safety Officer immediately if ~~in case of~~ the patient~~'s~~ ~~death~~ dies or has a medical emergency.

(c) ~~The~~ A licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) ~~The~~ An authorized user and Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

(e) The licensee shall either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a low range survey meter set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(f) The licensee shall survey the patient's room and private sanitary facility for removable contamination before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

(g) Within three days after administering a therapeutic dosage of iodine-131, the licensee shall measure the thyroid burden of each individual who helped prepare or administer the dosage, and retain for the period

required by § 20.401(c)(1) a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

§ 35.320 Possession of survey instruments.

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

Subpart G--Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

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

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon or as wire for interstitial treatment of cancer;

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

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

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient to confirm that all sources have been removed. The licensee ~~shall~~ may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

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

§ 35.406. Brachytherapy sources inventory.

A ~~The~~ licensee shall maintain a record of receipt, use, transfer, and disposal of brachytherapy sources.

(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count the number returned to ensure that all sources taken from the storage area have been returned.

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

(1) The names of the individuals permitted to handle the sources,

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

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

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

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

personnel

§ 35.410 Safety instruction.

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

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if ~~in case of~~ the patient~~'s death~~ dies or has a medical emergency.

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

§ 35.415 Safety precautions.

(a) The licensee shall provide to each individual hospitalized for implant therapy a private room.

(b) The licensee shall notify the Radiation Safety Officer immediately if ~~in case of the~~ a patient~~'s death~~ dies or has a medical emergency.

(c) A ~~The~~ licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) The authorized user and ~~RSO~~ Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

§ 35.420 Possession of survey instrument.

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

Subpart H--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

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

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

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

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

§ 35.520 Availability of survey instrument.

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

Subpart I--Teletherapy

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

A ~~The~~ regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain the following sources.

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

(b) Cesium-137 as a sealed source.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the ~~Nuclear Regulatory~~ Commission or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or 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~~ A licensee shall apply for and must receive a license amendment ~~prior~~ before 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; or

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

§ 35.610 Safety instruction.

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

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

(2) The procedure to be followed if:

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

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

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

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

§ 35.615 Doors, interlocks, and warning systems.

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

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

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

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

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

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

§ 35.620 Possession of survey instrument.

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

§ 35.621 Radiation monitoring device.

(a) ~~The~~ A 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 results 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.

A

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

(f) If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.

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

§ 35.622 Viewing system.

A ~~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) 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 (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned

by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee ~~shall~~ may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

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

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction 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~~ The licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

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

(2) Before medical use under the following conditions:

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

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

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

(3) At intervals not exceeding one year.

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

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

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

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

(4) Timer accuracy;

(5) On-off error; and

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

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

(d) ~~The~~ A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771. Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW, Washington, DC 20555. Copies of the documents

same will use flatness scanner trace
instead of film. see 35.2162 L.J. RI

are also on file at the Office of the Federal Register, 1100 L Street NW, Room 8301, Washington, DC 20408. A notice of any change in the material will be published in the Federal Register.

(e) ~~The~~ A 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~~ A licensee shall retain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a ~~radio-graph of a single field with the location of the light~~ determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, ~~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 medical use 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 medical use;

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

(f) ~~The~~ A licensee authorized to use a teletherapy unit for medical use shall perform spot-checks of each teletherapy facility ~~at intervals not exceeding one~~ once in each calendar 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) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

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

(4) Viewing systems;

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

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

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

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

(j) ~~The~~ A licensee shall retain a record of each spot-check required by paragraphs (a) and (f) of this section for two years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a determination of the coincidence of the radiation field and the ~~radiograph of a single field with the location of the light~~ field indicated by the light beam localizing device ~~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 surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606(a)-(d),the licensee shall perform radiation surveys to verify that:

(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 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 scattering 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~~ A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

§ 35.642 Safety checks for teletherapy facilities.

(a) ~~The~~ A licensee shall promptly check all systems listed in § 35.633(g) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606(a)-(d).

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

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

viewing system, and doors, and the signature of the Radiation Safety Officer.

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

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

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

(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~~,~~ made to comply with paragraph (a) of this section and the results of the second survey; or

(d) Request and receive a license amendment under § 20.105(a) of this part that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.105(b).

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

A ~~The~~ licensee shall mail an original and a copy of the records required in §§ 35.641, 35.642, 35.643, and the output from the teletherapy source expressed as Roentgens per hour at a distance of one meter from the source and determined during the full calibration required in § 35.632, to the appropriate ~~U.S. Nuclear Regulatory~~ Commission Regional Office listed in § 35.16 of this part within thirty days following completion of the action that initiated the record requirement.

§ 35.645 Five-year inspection.

(a) 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.

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(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 manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

(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) Have had 200 hours of classroom and laboratory training and one year of 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 radiation safety at a medical institution under the supervision of the individual identified

as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

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

§ 35.901 Radiation Safety Officer training exception.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license on (***insert effective date of final rule***) who oversees only the use of byproduct material for which the licensee was authorized on that date need not comply with the training requirements of § 35.900.

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

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

(a) Is certified in:

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

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

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

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and 40 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, the classroom and laboratory instruction 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;

(iv) 10 hours of radiation biology; and

(v) 10 hours of radiopharmaceutical chemistry.

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical 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 suitable radiopharmaceuticals and calculating and measuring the dosages;

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

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

(v) Patient followup; or

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

§ 35.920 Training for imaging and localization studies.

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

(a) Is certified in:

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

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

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

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

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

(i) 100 hours of radiation physics and instrumentation;

(ii) 30 hours of radiation protection;

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

(iv) 30 hours of radiopharmaceutical chemistry; and

(v) 20 hours of radiation biology.

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

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

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient dosages;

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

(v) Using emergency procedures to 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 a medical 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 suitable radiopharmaceuticals and calculating and measuring the dosages;

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

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

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory

training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

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

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

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has 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 a medical 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 iodine-131 for treatment of thyroid carcinoma in 3 individuals; and

(iv) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

§ 35.940 Training for therapeutic use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user using a brachytherapy source listed in § 35.400 for therapy to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

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

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

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

(b) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of 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;

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

(v) Using emergency procedures to 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 or the Committee on Postdoctoral Training of the American Osteopathic Association, and an

additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience must include:

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

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

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

(b) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(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 a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user using a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;

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

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

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

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

(2) 3 hours of radiation biology; and

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

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user using a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

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

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

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

(b) Is in the active practice of therapeutic radiology, and has 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 a minimum of three years of supervised clinical experience.

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

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

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

(iv) 25 hours of radiation biology.

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

(i) Review of the full calibration measurements and periodic spot checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent misadministrations;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) Checking and using survey meters.

(3) To satisfy the requirement for 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 Acreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience 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 doses 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 qualified teletherapy calibration expert as to:

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

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

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

§ 35.970 Experienced authorized user training exception.

~~A~~ physicians, dentists, or podiatrists identified as ~~an~~ authorized users for the human use of byproduct material on a Commission or Agreement State license on (*** insert effective date of final rule ***) who perform~~s~~ only those methods of use for which they were ~~he was~~ authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 Physician training exception.

A physician who, before July 1, 1984, began a three month nuclear medicine training program ~~that was~~ approved by the Accreditation Council

for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recentness of training.

The training and experience specified in this ~~support~~ subpart must have been obtained within the five years preceding the date of application or the individual must have had continuing experience since the required training and experience was completed.

Subpart K--Enforcement

§ 35.990 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of:

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) Any rule, regulation, or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed for violation of:

(1) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 under section 234 of the Atomic Energy Act of 1954;

(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 rule, 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.

P35(L)

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 (y) and (z) as follows:

§ 30.4 Definitions.

*   *   *   *   *

(h) "Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico 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;

*   *   *   *   *

(y) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice ~~the art of~~ dentistry on humans.

(z) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice ~~the art of~~ podiatry on humans.

3. Section 30.34 is amended by revising paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

*   *   *   *   *

(g) A licensee may prepare technetium-99m radiopharmaceuticals only with technetium-99m that contains less than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m. The licensee shall perform tests and maintain the records required by § 35.204.

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

4. Section 31.11 is amended by revising paragraph (b) to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory listing. te

*   *   *   *   *

(b) No person shall receive, acquire, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section: unless that person

(1) ~~Until he~~ has filed Form NRC-483, "Registration Certificate-In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and received from the Commission a validated copy of Form NRC-483 with a registration number assigned;

(2) ~~Unless he~~ has a license that authorizes the medical use of byproduct material and that expires before [*** insert five years after effective date of final rule ***]; or

(3) ~~Unless he~~ has a license that authorizes the medical use of byproduct material and also authorizes the use of byproduct material consistent with the requirements of this section.

*   *   *   *   *

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 radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material listed in §§ 35.100, 35.200, or 35.300, 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, or 35.500 as appropriate 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 ____________ 1984.

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For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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Enclosure 2

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

OFFICE OF THE
SECRETARY

June 23, 1983

Action: Davis, NMSS
Cys: Dircks
Roe
Rehm
Stello
GCunningham
Minogue
DeYoung
Kerr, SP
Regions I-V
Walker, NMSS
Felton
Philips

MEMORANDUM FOR: William J. Dircks, Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-83-62 (10 CFR PART 35)

This is to advise you that the Commission (with all agreeing) has made the following decisions with respect to the staff's proposed changes to 10 CFR Part 35 (SECY-83-62):

(1) The Commission approves the consolidation of the essential safety elements from regulations, guides and branch positions into a Part 35 rule.

(2) The Commission has decided to continue the pre-licensing review of physicians' qualifications in processing applications for human use of byproduct material in nuclear medicine and instructs the staff to amend the draft Part 35 accordingly.

(3) The Commission has decided to continue the pre-licensing review of applicants' operating procedures by NRC licensing staff. The Commission instructs the staff to make the changes as needed to reflect its decision that operating procedures are to be reviewed prior to licensing.

(4) The staff should clarify how it will implement the proposed requirements regarding license amendments, while continuing to ensure safety in the licensee's operations.

(5) The staff should provide the Commission with a proposed Part 35, revised as directed above, by August 30, 1983.

(EDO Suspense: August 23, 1983)

cc: Chairman Palladino
Commissioner Gilinsky
Commissioner Ahearne
Commissioner Roberts
Commissioner Asselstine
OGC
OPE

Rec'd Off. EDO
Date 6-24-83
Time 6:15

PERIODIC AND SYSTEMATIC REVIEW - 10 CFR PART 35

Introduction

Task IV G.2 of the TMI Action Plan directed the staff to review all existing regulations for content, quality and clarity. SECY 81-435 and 435A established specific review criteria and created the Regulations Coordinating Committee (RCC) to plan, schedule, and coordinate the review. Under the RCC charter, one guideline for setting the priority of specific regulations for review was a Commission or staff initiative for a major revision of an existing rule. The Periodic and Systematic Review of 10 CFR Part 35 is in response to a staff decision that a substantial revision of the human use licensing requirements of Part 35 was necessary.

It should be noted that the re-evaluation of Part 35 does not address the misadministration sections of the current rule (§§ 35.41 - 35.44). When these provisions were first promulgated, the Commission established a specific time period for their evaluation. Due to this separate time period and the unique nature of the misadministration issue, the proposed revision to Part 35 and this Periodic and Systematic Review do not include this subject within their scope of analysis.

Analysis

1. The Need for the Regulation.

Under 10 CFR Part 35, the NRC issues licenses to hospitals and physicians for the use of radioactive materials for diagnostic and therapeutic purposes. The NRC currently has approximately 2500 medical licensees, and 15 to 20 million nuclear medicine procedures are performed in the United States each year. The proposed facilities, personnel, program controls, and equipment used in these procedures are carefully reviewed during the licensing process to ensure the safety of the public, patients, and occupationally exposed workers.

2. Direct and Indirect Effects.

The nuclear medicine field has grown substantially over the past three decades, as evidenced by the increase in license applications, renewals, and

amendments. In addition to this numerical growth, the scope of use has expanded dramatically over the years. In order to adequately regulate new developments, many safety measures were added as license amendments or recommended in regulatory guides, rather than being incorporated in the regulations. However, over the past few years nuclear medicine procedures have stabilized, and uniform and comprehensive safety requirements can now be codified in the regulations in order to establish a more coherent regulatory program.

The current practice of publishing the licensing requirements and guidance in several different sources has resulted in negative impacts on both the licensees and the NRC staff. The applicant is often uncertain about what must be included in a license application. This results in either an application that provides a substantial amount of extraneous information or in one that does not provide enough of the information necessary to make a licensing decision. This requires additional NRC staff time to review large amounts of unnecessary information or to write deficiency letters that request additional information or clarification. In either case, there are frequent delays in the licensing process that lead to a backlog in license applications. The existing regulations also severely limit a licensee's flexibility in selecting the most cost-effective method for complying with NRC requirements since even a minor radiation safety program change must be approved by a license amendment.

These negative effects of the existing regulatory program have initiated the reevaluation and revision of Part 35.

3. Alternative Approaches.

For a detailed analysis of the effects of the proposed revision to Part 35, see the Regulatory Analysis Statement prepared as Enclosure 4 of the package.

In developing an earlier staff proposal on the revision of Part 35, SECY-83-62, the staff considered reducing the number of requirements to a few, and simply providing guidance for good practice. Because such a regulatory scheme might not have protected the public health and safety, probably would have left the industry in a state of confusion given the very prescriptive regulatory scheme used for the past several years, and might have made enforcement actions more difficult, the staff did not consider this to be a reasonable alternative.

The staff finally proposed in SECY-83-62 that, because the safety requirements had been codified, applicants simply be allowed to certify that they had met the training and experience standards and would comply with the regulations. In its response to SECY-83-62 (Enclosure 2), the Commission directed the staff to continue pre-licensing review of physician qualifications and operating procedures.

The staff also considered that, because the safety requirements had been codified, applicants be required to submit evidence of training and experience and a radiation safety plan that described the licensee's general radiation safety policy and critical safety elements that would be incorporated in site-specific procedures. The staff decided that this alternative was inconsistent with Commission instructions.

The alternative ~~selected~~ recommended by the staff to regulate the medical use of byproduct material~~, the alternative directed by the Commission,~~ includes codification of all generic requirements and staff pre-licensing review of training and experience and procedures.

4. Public Comment.

One important reason for revising Part 35 is to allow public comment on requirements before they are imposed in final form. The existing system of imposing requirements through license conditions does not allow for public comment. Incorporating generic license conditions into the regulations will allow public comment on these requirements before they are finalized. In addition, a few representative licensees, some nuclear medicine professional associations, and Agreement State government personnel were contacted on the development of the proposed rule.

5. The Regulation Is Written in an Understandable Manner.

The revision of Part 35 has, in part, been prompted by the lack of clarity in the existing rule. The proposed revision is designed to be clear, coherent, and understandable.

6. Reporting Burdens.

Although the current reporting and recordkeeping activities, and the burdens associated with these requirements, have been cleared by the OMB under

the Paperwork Reduction Act, the proposed revision will modify many of the existing requirements. For specific information on the information collection activities of the proposed revision, see the OMB supporting statement in the rulemaking package.

7. Name, Address, and Telephone Number of a Knowledgeable Agency Official.

This information will be included as part of the Federal Register Notice that publishes the proposed rule.

8. Plan for Evaluation.

Implementation of the revised licensing system under Part 35 will be continuously monitored to determine whether the regulatory objectives are achieved. The proposed revision is itself the result of an evaluation of the existing rule. The staff does not foresee need for another evaluation before the one required as part of the Regulations Coordinating Committee schedule of priorities for review.

REGULATORY ANALYSIS FOR THE PROPOSED
REVISON OF PART 35

Table of Contents

Introduction

This regulatory analysis was prepared following instructions to Office Directors from the Executive Director for Operations, circulated December 13, 1982. Under those instructions, Part II.A, this proposed rulemaking is not subject to a mandatory regulatory analysis review. However, in the footnote on page 1 of the guidelines, the EDO directed that "... other rulemaking actions not covered by the mandatory review categories ... should also be supported by an analysis based on the guidance provided in Part III.B of the Guidelines but much less detail is required."

1. Statement of Problem

This proposed rulemaking affects all persons who are licensed by the NRC to irradiate individuals with byproduct material, or its radiation, in the practice of the healing arts. This industry is currently subject to all the general radiation safety materials regulations (Parts 19, 20, 21, and 30), Part 35, "Human Uses of Byproduct Material," licensing branch policies, a few generic orders, and many generic license conditions.

The problem with this regulatory scheme is three-fold: 1. All the regulatory criteria are not published in a single unified text, therefore the applicant or licensee must look in several places to find all the standards that apply to his program; 2. Licensing branch policy and a listing of the applicable generic license conditions are not generally available to the public, therefore the applicant cannot accurately plan for resources needed to meet regulatory burdens until the license is in hand; and 3. Since the requirements are scattered, in order to assure the public health and safety the staff requires that applicants submit for review many detailed procedures that will be followed when the license is issued. Then, they are required by license condition to conduct their programs in accord with the statements made in the application.

This proposed rulemaking may be taken at this time because the staff does not believe that dramatic new types of use that would require generic license conditions will evolve in the next decade; rather, the staff believes research will be devoted to refinement of current methods and development of new materials for which the radiation safety measures are similar to the safety measures for materials currently authorized for use. Even if we do see new

technologies that have to be handled on a case-by-case basis, that portion of any licensee's program designed to provide conventional patient care will benefit from the clarification and codification of regulations.

If no action is taken, the staff believes the industry will continue to be confused about whether a specific standard is a requirement or a suggestion. The codification of all regulations in a single document may result in fewer enforcement actions because all requirements will be in one text and all licensees will be working under the same set of requirements.

2. Objectives

The purpose of this proposed rulemaking is to codify, in plain English, all radiation safety requirements specific to the medical use of byproduct material. The staff and the industry generally agree that the requirements in the proposed rulemaking are needed to protect the public health and safety.

3. Alternatives

In developing an earlier staff proposal on the revision of Part 35, SECY-83-62, the staff considered reducing the number of requirements to a few, and simply providing guidance for good practice. Since such a regulatory scheme might not have protected the public health and safety, probably would have left the industry in a state of confusion given the very prescriptive regulatory scheme used for the past several years, and might have made enforcement actions more difficult, the staff did not consider this to be a reasonable alternative.

The staff finally proposed in SECY-83-62 that, since the safety requirements had been codified, applicants simply be allowed to certify that they had met the training and experience standards and would comply with the regulations. In its response to SECY-83-62 (Enclosure 2), the Commission directed the staff to continue pre-licensing review of physician qualifications and operating procedures.

The staff also considered that, since the safety requirements had been codified, applicants be required to submit evidence of training and experience and a radiation safety plan that described the licensee's general radiation

safety policy and critical safety elements that would be incorporated in site-specific procedures. The staff decided that this alternative was inconsistent with Commission instructions.

The alternative selected by the staff to regulate the ~~human~~ medical use of byproduct material, the alternative directed by the Commission, includes codification of all generic requirements and staff pre-licensing review of training and experience and procedures.

4. <u>Consequences</u>

Some general comments on the consequences of the proposed action are made below. ~~Since the Commission has selected an alternative,~~ the costs and benefits of the other alternatives are also ~~have not been~~ analyzed, but not in depth. A detailed burden analysis (expressed in dollars and man-hours) for the ~~directed~~ recommended alternative follows the narrative portion of this regulatory analysis. Based on the analysis, the staff does not believe there will be any significant economic impact on licensees or the NRC.

NRC would have to redirect its training effort because it currently emphasizes review of applicants' procedures at the NRC office rather than an on-site review of work methods at the licensees' facilities. However, the long-term benefit will be a safety inspection based on a uniform, nationwide code of standards.

Many Agreement States are in favor of consolidating the various regulatory requirements and support this revision of the regulations. However, the Agreement States are concerned about the impact of the proposed licensing procedures. Agreement States regulate about 4700 medical licenses. Most States feel that a prelicensing review of radiation safety procedures and changes to the procedures is necessary to ensure a proper degree of safety. They believe that to require licensees to follow the procedures submitted and permitting the licensees to make changes to procedures without prior review and approval is an unwarranted relaxation of regulatory control. The States believe that retraining of understaffed offices will be difficult, the number of items of non-compliance will increase, and that inspections will have to be longer and more frequent. Their contention is that they will be under pressure from their own licensees to adopt NRC's revised system of regulating the medical use of byproduct material, with which they don't agree.

(The NRC staff does not agree with this assessment because all the essential elements of a medical radiation safety program have been codified in the proposed regulation.)

The staff does not expect any relief from regulatory burden or significant additional burden for licensees because the requirements in the regulation have, for the most part, been taken from requirements imposed by other means. There may be fewer noncompliance citations because all the generic requirements will be published in one place.

The staff does not foresee any impact on other NRC programs or requirements. The staff does not foresee any significant transition problem because, as currently written, each license can stand by itself without reference to the current or proposed Part 35. The staff does not foresee any scheduling, enforceability, policy, institutional, or legal problems.

5. Decision Rationale

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The staff is recommending the proposed revision because it clarifies requirements and grants some authority to licensees to ~~modify~~ change their procedures, facilities, and equipment ~~to meet needs caused by changing patient care needs.~~ for improved patient care, safety, or reduced cost. The proposed revision is complete and the staff does not foresee any need for wide-ranging revisions, additions, or deletions for at least the next decade.

6. Implementation

Since they are fairly complete and site-specific, the current licenses will stand alone to provide for public health and safety. As licenses come due for renewal, they can be reviewed and issued under the proposed regulatory method. Since the equipment and procedures specified in the regulation are similar to those required of current licensees, the staff does not foresee any need for significant increase in expenditures of time or money for renewal licensees or new applicants. However, the staff has specifically requested public comment on the transition policy described in the preamble to the Notice of Proposed Rulemaking.

The staff is not aware of any relationship between this part and other existing or proposed requirements that would affect those requirements or cause a need for a reassessment of other actions, systems, or analyses.

7. Section-by-Section Burden Analysis of Proposed Revision of Part 35

On the following pages, the cost of complying with each individual section of the proposed regulation is estimated. Then, six hypothetical licensees that are representative of the medical industry are described. For each of the six licensees, the total regulatory burden is estimated by adding the burden due to each section with which the licensee would have to comply (not all sections apply to all licensees). In most cases these are not new burdens because similar requirements are currently imposed by license condition.

Explanation of column descriptors and entries

DEFGHIM: Describes which class of licensee must comply; see Subparts D through I in proposed Part 35; M refers to mobile service.

Sec: The subsection where the requirement is stated.

R/O: R denotes a requirement; O denotes a privilege (with concomitant burdens if the privilege is exercised) contained in proposed Part 35.

Freq: Some frequencies are specified in the regulation, and some have been assumed (superscripted "a") for purpose of estimating total cost. Codes: 5y-5 years; a-annually; 6m-each six months; q-quarterly; m-monthly; w-weekly (50 weeks per year); d-daily (250 days per year); 2xd-twice daily.

Hrs for Records: An estimate of hours spent preparing records, reports, and logs, either by a professional (Pro) or by a technician or secretary (Tec). For recurring actions, this is the time needed to do the action once. Cost of paper, forms, and filing space are insignificant and are not included.

Hrs for Work: An estimate of hours spent doing something, other than records generation, that is required of either a professional (Pro) or a technician or secretary (Tec). For recurring actions, this

is the time needed to do the action once. These estimates are based on the experience of staff when previously employed by licensees.

Eqpt & Supplies: An estimate of cost of capital equipment and consumable supplies needed based on catalogue prices from nation-wide retailers. Capital equipment is amortized over 5 years.

Contract cost: An estimate of the fee charged for a service by an outside contractor. Based on informal surveys.

$/yr: Dollar cost for compliance each year.

Pro Hrs/yr: Total professional time consumed per year for compliance.

Tec Hrs/yr: Total technical and secretarial hours consumed per year for compliance.

N, RG, LC, or R: N-a new requirement imposed by the proposed Part 35
RG-a recommended procedure, contained in a regulatory guide, that is frequently adopted by applicants
LC-a frequently imposed license condition, I&E order, or licensing branch policy
R-a current regulation

Note: RG, LC, and R imply <u>similar</u>, not identical requirements

second footnote

DEFGHIM (Several footnotes follow the Table)	Sec	R/O	Freq	Hrs for Records Pro	Hrs for Records Tec	Hrs for Work Pro	Hrs for Work Tec	Eqpt & Supplies	Contract Cost	$/yr	Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R
	§35.2	License Required.											
DEFGHM		R	5y					190[1, 22]		40			R
I		R	5y					300[1, 23]		60			R
	§35.16	Application for license, amendment, or renewal.											
DEFGHM		R	5y	20[21]		10					4	2	R
I		R	5y	40[21]		10					8	2	R
	§35.17	License amendments.											
All		O	5y[2]	2		1		40[1, 24]		8	0.4	0.2	R
	§35.18	Notifications.											
All		R	5y[3]	0.5		0.5					0.1	0.1	N
	§35.30	ALARA program.											
Inst		R	a			10[4]					10		RG
	§35.31	Radiation Safety Officer[5].											
All		R	m[a]			8					96		RG
	§35.32	Radiation Safety Committee.											
Inst		R	q		2[6]	8[7]					40	8	R
	§35.37	Records and reports of misadminstrations.											
DEHM	c	R	3y[8]	1	1						0.3	0.3	R
	§35.50	Possession, use, calibration, and check of dose calibrators.											
DEFM	a	R						2000		400			RG
DEFM	b1	R	d	.02		.02						10	RG
DEFM	b2	R	a	.20		.20		500		100		0.4	RG
DEFM	b3	R	q	.50		1						6	RG
DEFM	b4	R	5y[a]	1		1						0.4	RG
	§35.53	Measurement of radiopharmaceutical dosages.											
DEFM		R	15xd[a]	.02		.02						150	RG
	§35.59	Requirements for possession of sealed sources and brachytherapy sources.											
DEFM	bcd	R	6m	0.5		0.5		150[9]		30	1		R
G	bcd	R	6m	1		1		75[9]		15	2		R
HI	bcd	R	6m	0.5		0.5		75[9]		15	1		R
All	g	R	qtr	0.5		0.5					4		R
DEFGM	hi	R	qtr	0.5		0.5					4		N
	§35.60	Syringe shields.											
DEM		R						300[10]		60			RG

DEFGHIM	Sec	R/O	Freq	Records Pro	Records Tec	Work Pro	Work Tec	Eqpt & Supplies	Contract Cost	$/yr	Hrs /yr	Hrs /yr	N, RG, LC or R
	§35.61 Vial shields.												
DEM		R						500[11]		100			RG
	§35.62 Syringe labels.												
DEM								80[12]		80			N
	§35.70 Surveys for contamination and ambient radiation exposure rate.												
DEM	a	R	d		0.2		0.4					150	RG
DEM	b	R	w		0.1		0.1					10	RG
DEM	e	R	w		0.2		0.5					35	RG
	§35.75 Release of patients containing radiopharmaceuticals or permanent implants.[13]												
F	M	R	m[a]					500		6000			LC
	§35.80 Mobile nuclear medicine service technical requirements.												
M	d	R	2xd[a]				0.4					100	LC
	e	R	2xd[a]		0.2		0.2					100	LC
	§35.92 Decay-in-storage.												
DEFM		O	m[a]		0.5		1					18	LC
	§35.120 Possession of survey instrument.												
D		R						500	50[19]	150			RG
	§35.204 Permissible molybdenum-99 concentration.												
E		R	d[a]		.02		.04					15	R
	§35.205 Controls of aerosols and gases.												
E	ab	R						2000[14]		400			RG
E	d	R	6m		0.1		0.2					0.6	RG
	§35.220 Possession of survey instruments.												
E	lo							500	50[19]	150			RG
E	hi							1000	50[19]	250			RG
	§35.310 Safety instruction.												
F		R	m[a]	0.1	0.5		3.0[15]				7	36	RG
	§35.315 Safety precautions.												
F	a	R	m[a]					450[16]		5400			RG
F	c	R	m[a]				0.2					2	RG
F	e	R	m[a]	1.0			1.5[17]				12	18	RG
	g	R	m[a]		0.2		0.3					6	RG
	§35.320 Possession of survey instruments.												
F	lo	R						500	50[19]	150			RG
F	hi	R						1000	50[19]	250			RG
	§35.404 Release of patients treated with temporary implants.												
G	a	R	m[a]		0.1		0.1				1	1	RG

DEFGHIM	Sec	R/O	Freq	Hrs for Records Pro	Hrs for Records Tec	Hrs for Work Pro	Hrs for Work Tec	Eqpt & Supplies	Contract Cost	$/yr	Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R
	§35.406	Brachytherapy sources inventory.											
G	a	R	m^a				0.1					1	RG
G	b	R	m^a		0.2							2	RG
	§35.410	Safety instruction.											
G		R	m^a	0.1				0.5	3.0[15]		7	36	RG
	§35.415	Safety precautions.											
G	a	R	m^a					450[16]		5400			
G	c	R	m^a						0.2			2	RG
	§35.420	Possession of survey instrument.											
G		R						1000	50[19]	250			RG
	§35.520	Availability of survey instrument.											
H		R	q^a						100[18]	400			RG
	§35.610	Safety instruction.											
I		R	y^a	0.1		0.5	1.0[18]				1	2	RG
	§35.615	Doors, interlocks, and warning systems.											
I	b	R						200		40			LC
I	c	R						100		20			LC
	§35.620	Possession of survey instrument.											
I	hi	R						1000	50	250			RG
	§35.621	Radiation monitoring device.											
I	a	R						750		150			R
I	d	R	d		0.02		0.1					30	R
	§35.622	Viewing system.											
I		R						1000		200			LC
	§35.630	Dosimetry equipment.											
I	a	R	2y					2500	400	700			R
	§35.632	Full calibration measurements.											
I		R	a	16		16					32		R
	§35.633	Periodic spot checks.											
I	a	R	m	0.5		1					18		R
I	f	R	m		0.5		1					18	LC
	§35.641	Radiation surveys for teletherapy facilities.											
I	a1	R	$5y^a$	0.5			1				0.3		LC
I	a2	R	$5y^a$	8			4	4			12	4	LC

DEFGHIM	Sec	R/O	Freq	Hrs for Records Pro	Hrs for Records Tec	Hrs for Work Pro	Hrs for Work Tec	Eqpt & Supplies	Contract Cost	$/yr	Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R
	§35.642	Safety checks for teletherapy facilities.											
I	a	R	5y[a]		0.5		1					0.3	N
	§35.645	Five-year inspection.											
I		R	5y						2000[20]	400		LC	

Footnotes

[1]A fee required by Part 170.

[2]Assume one amendment for a new user or use over 5 years.

[3]Assume one key individual leaves over 5 years.

[4]Preparing the program is part of the application time. This cost assumes six hours to prepare an annual briefing and one hour for the RSO to deliver the briefing to three administrators.

[5]Assume eight hours once each month to investigate a deviation from good practice. Developing policy and procedures is part of the application time. Procedure modification is not required and therefore not costed. Helping the Radiation Safety Committee is costed in § 35.32.

[6]Typing and distributing minutes.

[7]Assume RSO needs three hours to prepare agenda, and five individuals attend a one hour meeting.

[8]Assuming 15 procedures per day, 250 days per year, and a frequency of 0.01% (see SECY-82-388 p 2), there will be about one misadministration every three years.

[9][illegible]active check sources to convert wipe sample cpm to microcuries.

[10]Assume two at $150 each.

[11]Assume five at $100 each.

[12]Assume 4000 labels per year at $10 per 500.

[13]Diagnostic dosages do not require patient confinement for radiation safety purposes. Assume one radiopharmaceutical therapy procedure each month with one additional day of confinement (beyond that needed for patient care) in a private room at $500 each day. Permanent implant administrations generally do not require patient confinement for radiation safety purposes.

[14]Cost of a closed, shielded gas collection system.

[15]Assume RSO briefs six nurses for one-half hour.

[16]Assume three days in a private room at $500 instead of a semi-private room at $350.

[17]Assumed time needed to decontaminate room.

[18]Assume the RSO briefs two technicians each year.

Footnotes (Continued)

[19]Calibration service.

[20]Assume two days at $750 each day, plus $500 total per diem and travel.

[21]Draft Regulatory Guide 10.8 for all applications except teletherapy, and a draft Regulatory Guide that is being developed for teletherapy, are available for use by applicants. Except for site-specific information that must be submitted, applicants can certify that they will follow the model procedures in the guides, or mark-up the model procedures to meet their site specific needs and submit clean mark-ups for staff review. This burden estimate assumes that most applicants will use most of the model procedures.

~~[22]The fees in the analysis were effective until June 19,~~

[22] Changed on June 20, 1984 to $580.

[23] Changed on June 20, 1984 to $580.

[24] Changed on June 20, 1984 to $120 for all subparts except teletherapy, which is $230.

Sections not costed

35.1 Purpose and scope.

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

35.15 Definitions.

35.28 License issuance.

35.29 Specific exemptions.

35.31 Radiation Safety Officer. Having an RSO is required by the general criteria of §30.33 which require that the applicant be qualified by training and experience. Development of procedures is costed @ §35.16.

35.33 Requirement for authority and statement of responsibilities. This is part of the management responsibility to provide a position description for <u>any</u> worker.

35.34 Visiting authorized user. This is an option, not a requirement. The review process may be conducted during the meetings costed at §35.32.

35.35 Mobile nuclear medicine service administration requirements.

36.36 Radiation safety program changes.

35.37abde Records and reports of misadministrations. Therapy misadministrations are very rare (see SECY-83-388 p 2). Investigating and making a record of a misadministration is costed @ §35.31 as part of a deviation from good practice.

35.38 Supervision. This is part of the management responsibility to supervise employees.

35.49 Suppliers.

35.50cde Dose calibrators do not break down frequently. Records are costed within the prescriptive requirements to test or check the calibrator.

35.51 Calibration and check of survey instruments. The calibration cost is included as a contract cost in the section that requires possession of the instrument. The survey instrument check (d of this section) is included in the time needed to make a survey.

35.58 Authorization for calibration and reference sources.

35.59e Leaking sources are very rare.

35.63 Vial shield labels. Vial shields can be permanently labeled in a few minutes.

35.90 Storage of volatiles and gases. A plastic bag within a plastic bag will meet the requirement of the regulation.

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

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

35.205c Control of aerosols and gases. Negative pressure in imaging rooms can be achieved by closing the door, turning off or covering supply vents, and fully opening exhaust vents.

35.300 Use of radiopharmaceuticals for therapy.

35.400 Use of sources for brachytherapy.

35.500 Use of sealed sources for diagnosis.

35.600 Use of a sealed source in a teletherapy unit.

35.605 Maintenance and repair restrictions.

35.606 Amendments. None of the changes which require an amendment request are frequently made.

35.615a Doors, interlocks, and warning systems. Doors are usually installed for compliance with Part 20.

35.643 Modification of teletherapy unit or room before beginning a treatment program. A modification for safety purposes is not usually necessary.

35.644 Reports of teletherapy surveys, checks, tests, and measurements. The licensee need only submit a copy of a record which was costed in another section.

The following sections were not costed because they are industry-specific training and experience standards generally required by §30.33(a)(3).

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 use of sealed sources for diagnosis.

35.960 Training for teletherapy.

35.961 Training for qualified teletherapy calibration expert.

35.970 Experienced authorized user training exception.

35.971 Physician training exception.

35.990 Violations.

35.999 General exemption during transition period.

8. Total Industry Burden

Because each license authorizes the particular materials requested by the applicant, the exact number of licensees that are accurately described by the "hypothetical licensee" descriptors is unknown. However, an informal analysis of license files has yielded the indicated estimate of number of licenses affected. For the purpose of estimating total industry burden and increase in the burden caused by this revision, we assume \$100 per professional hour, \$30 per technician hour, and round to two significant figures.

Case Description and Regulatory Burden per year (see following tally sheets)

1. A nuclear medicine diagnostic clinic that is not based in a hospital and conducts 15 procedures each day. Licensee's annual regulatory burden: \$1618, 110 professional hours, and 398 technician hours. Approximate number of licensees: 300. Total industry burden:
300 x (1618 + 110 x 100 + 398 x 30) = \$7,400,000
Increase: 300 x (80 + 4.1 x 100 + 0.1 x 30) = \$150,000.

2. A nuclear medicine diagnostic clinic that is based in a hospital and conducts 15 procedures each day. Licensee's annual regulatory burden: \$1618, 160 professional hours, and 406 technician hours. Approximate number of licensees: 700. Total industry burden:
700 x (1618 + 160 x 100 + 406 x 30) = \$21,000,000
Increase: 700 x (80 + 4.1 x 100 + 0.1 x 30) = \$350,000.

3. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and one radiopharmaceutical therapy procedure each month. Licensee's annual regulatory burden: \$13,018, 179 professional hours, and 466 technician hours.
Approximate number of licensees: 700. Total industry burden:
700 x (13018 + 179 x 100 + 466 x 30) = \$31,000,000
Increase: 700 x (80 + 4.1 x 100 + 0.1 x 30) = \$350,000

4. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and one brachytherapy procedure each month. Licensee's annual regulatory burden: $7033, 177 professional hours, and 448 technician hours.
Approximate number of licensees: 400. Total industry burden:
400 x (7033 + 177 x 100 + 488 x 30) = $15,000,000
Increase: 400 x (80 + 4.1 x 100 + 0.1 x 30) = $200,000

5. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and has one cobalt-60 teletherapy unit. Licensee's annual regulatory burden: $3211, 233 professional hours, and 463 technician hours.
Approximate number of licensees: 400. Total industry burden:
400 x (3211 + 233 x 100 + 463 x 30) = $16,000,000
Increase: 400 x (0 + 0.1 x 100 + 0.4 x 30) = $8,800

6. A mobile nuclear medicine service that conducts 15 diagnostic procedures each day at each of two client locations. Licensees's annual regulatory burden: $1618, 110 professional hours, and 598 technician hours.
Approximate number of licensees: 50. Total industry burden:
50 x (1618 + 110 x 100 + 590 x 30) = $1,500,000
Increase: 50 x (80 + 4.1 x 100 + 0.1 x 30) = $25,000

The total burden of the revised Part 35 on the medical industry is about $92 million dollars. However, this is not a new impact. Almost all the burden (except for §§ 35.18, 35.59h and i, 35.62, and 35.642) is currently imposed by regulation or license condition. The new burden is about $10.8 million dollars.

CASES

Section	1 $	1 Pro hrs	1 Tec hrs	2 $	2 Pro hrs	2 Tec hrs	3 $	3 Pro hrs	3 Tec hrs	4 $	4 Pro hrs	4 Tec hrs	5 $	5 Pro hrs	5 Tec hrs	6 $	6 Pro hrs	6 Tec hrs
35.2	40			40									60			40		
35.16		4	2		4	2								8	2		4	2
35.17	8	0.4	0.2	8	0.4	0.2							8	0.4	0.2	8	0.4	0.2
35.18		0.1	0.1		0.1	0.1								0.1	0.1		0.1	0.1
35.30					10													
35.31		96			96												96	
35.32					40	8												
35.37		0.3	0.3		0.3	0.3											0.3	0.3
35.50	500		16.8	500		16.8										500		16.8
35.53			150			150												150
35.59bcd	30	1		30	1					15	1		15	1		30	1	
35.59g		4			4						4						4	
35.59hi		4			4						4						4	
35.60	60			60												60		
35.61	100			100												100		
35.62	80			80												80		
35.70			195			195												195
35.75							6000											
35.80																		200
35.92			18			18												18
35.120*	150			150												150		
35.204			15			15												15
35.205	400		0.6	400		0.6										400		0.6
35.220*	250			250												250		
35.310								7	36									
35.315							5400	12	24									
35.404											1	1						
35.406												3						
35.410											7	36						
35.415										5400		2						
35.610														1	2			
35.615													60					
35.621													150		30			
35.622													200					
35.630													700					
35.632														32				
35.633														18	18			
35.641														12.3	4			
35.642															0.3			
35.645													400					

*This expenditure also meets requirements of §§ 35.320, 35.420, 35.520, and 35.620.

CASES (Continued)

		1	2	3	4	5	6
subtotal	$	1618	1618	11400	5415	1593	1618
	P-hrs	110	160	19	17	73	110
	T-hrs	398	406	60	42	57	598
carryover	$			1618	1618	1618	
	P-hrs			160	160	160	
	T-hrs			406	406	406	
TOTAL BURDEN	$	1618	1618	13018	7033	3211	1618
	P-hrs	110	160	179	177	233	110
	T-hrs	398	406	466	448	463	598

Note that the only sections that impose completely new burdens are 35.18, 35.59hi, 35.62, and 35.642. Now we may calculate the <u>new</u> burden caused by this revision (the cost of just those sections).

Subtotal	$	80	80				80
	P-hrs	4.1	4.1				4.1
	T-hrs	0.1	0.1				0.1
Carryover	$			80	80	0	
	P-hrs			4.1	4.1	0.1	
	T-hrs			0.1	0.1	0.4	
TOTAL NEW BURDEN	$	80	80	80	80	0	80
	P-hrs	4.1	4.1	4.1	4.1	0.1	4.1
	T-hrs	0.1	0.1	0.1	0.1	0.4	0.1

9. Cost to Workers and the Public

Since day-to-day operations will not be significantly affected, the staff does not foresee any increase or decrease in worker or public dose. Nor does the staff foresee any additional cost to the public above that borne by licensees and passed on to the public as overhead. The only government agencies that will be affected are those that provide patient care under an NRC license.

10. Cost to NRC

However, ~~Since~~ there would be no significant changes in day-to-day licensee operations, NRC staff retraining would be needed to explain the new method of regulating the medical industry ~~, but not in new~~ and no need to learn new medical use or radiation safety technology because almost all the requirements in the proposed regulation are already imposed by other means.

About 85 NRC employees (managers, license reviewers, and inspectors) would have to attend a two-day course on the implementation of the revision. The course would be given at headquarters and at each of the five regional offices. The first day of the course would be spent discussing the reasons Part 35 was revised and discussing each section of the regulation. The second day would be spent discussing the licensing and inspection process under the revision.

The training would consume 1360 hours (2da x 8hrs/da x 85students) of student time, and 176 hours of instructor time. The latter figure is comprised of 80 hours of planning and 96 hours (2da x 8hrs/da x 6courses) of teaching. Instructor expenses would be about \$1000 for travel and \$750 per diem. (10da x \$75/da)

If we assume NRC staff time costs \$60/hr, the total cost to NRC is about \$94,000 (\$60 x 1360 + \$60 x 176 + \$1750). NRC conducts about 1000 medical inspections each year. The inspector must spend about one hour reviewing a license application before he can conduct an inspection because, in many cases citations are based on statements and representations made in the application. The savings to NRC is about 1000 hours, or \$60,000.

11. Cost of Alternatives 1 and 3

Assumptions

1. NRC will receive 100 new applications, 600 renewal requests, and 1800 amendment requests each year.

2. Approximately 40% of all these requests are returned to the requestor with a deficiency notice that asks for additional information or clarification.

3. Licensee professional time ("pro") costs $100/hr, licensee secretarial and technical time ("tec") costs $30/hr, and NRC professional time costs $60/hr.

Cost of Alternative 1

Alternative 1 is the no-action option.

The major cost to licensees is the cost of preparing amendment requests that would no longer be necessary under the revision. If we assume one-half of amendment requests are for minor changes in procedures, facilities, and equipment, the industry will have to pay $243,000 each year (900 requests x ($40 fee + 2 prohrs @ $100 + 1 techr @ $30)). 315 120

Licensees will also not be spared the cost of repairing requests that were deficient because of unclear regulatory policy. After subtracting the 900 unnecessary requests, we would receive 1600 licensing actions. If deficiencies were reduced one-half, from 40% to 20%, and if it costs the requestor $230 to respond to a deficiency notice (2 prohrs @ $100 + 1 techr @$30), a potential savings of $74,000 (1600 x 20% x $230) is lost.

Licensees would save the Alternative 2 new burden of about $10.7 million, but the staff would recommend that the Commission adopt those new requirements as a separate action.

NRC also bears costs under Alternative 1. The major cost has to do with inspections. The NRC currently conducts about 1000 medical inspections each year. The inspector must spend about one hour reviewing a license application

before he can conduct an inspection. Because under the proposal all medical inspections would be made against the regualtion, that hour could be saved under the revision. The lost savings to NRC is about 1000 hours or $60,000 dollars.

NRC would also not be spared the cost of generating deficiency notices. If, of the remaining 1600 licensing requests (900 amendments + 100 new applications + 600 renewals), one half of the 40% deficiency rate can be eliminated, and if it takes one hour of professional time to generate a deficiency notice, the lost savings to NRC is about $19,000 (1600 x 20% x $60).

NRC would save some of the re-training cost of $94,000, but not all of it because some time would still have to be spent for continuing education for licensing and inspection staff.

Cost of Alternative 3

Under Alternative 3 the NRC would revise the regulations and continue to require that the licensee conduct its ~~his~~ byproduct material program in accordance with the statements made in the application.

As described in the costing of Alternative 1, licensees would lose a potential cost savings of 315 $243,000 needed to generate requests for minor changes in procedures, facilities, and equipment, and $74,000 needed to respond to deficient application notices.

Also as described under Alternative 1, NRC would lose a potential savings of about 1000 hours, or $60,000, caused by increased inspection time, and about 320 hours, or $19,000, generating deficiency notices.

DRAFT PUBLIC ANNOUNCEMENT

NRC PROPOSES TO SIMPLIFY MEDICAL LICENSING PROCEDURES

The Nuclear Regulatory Commission is proposing to revise its regulations to simplify and make more efficient the regulatory process for the medical uses of radioisotopes.

The NRC issues licenses to medical facilities and individual physicians for the use of radioactive materials to diagnose and to treat patients. Specific licenses are issued for one or more of six groups of medical uses organized in ascending order of radiation hazard potential, each containing related diagnostic or therapeutic procedures. A separate license is issued for teletherapy units. Applicants for specific licenses must submit a substantial amount of information to show that all radiation safety requirements will be met, including a description of the procedures used in meeting the requirements. The Commission's radiation safety review covers three general areas: radiological heath and safety procedures; personnel training and experience; and facilities and equipment.

Due to the rapid evolution in the medical use of radioisotopes over the last thirty years, current requirements are found throughout the regulations, regulatory guides, standard license conditions and other sources. Therefore, the primary purpose of the proposed revision is to consolidate the requirements. Under the proposal, all requirements would be clarified and published in one place, Part 35 of NRC regulations, which would serve to regulate the day-to-day uses of medical radioisotopes. The revised regulation would give both licensees and NRC staff a clearer basis for licensing, operation, and inspection activities.

A draft regulatory guide for medical programs has been prepared. It contains a model procedure acceptable to NRC for meeting each of the medical use requirements. Licensees could use the model procedure for meeting the requirements or could prepare their own procedures.

The NRC staff will continue to review the applicant's radiation safety procedures to determine whether they are adequate to meet the requirements of the regulations. However, to permit licensees to make prompt use of new safety methods and to adjust their radioisotope programs to meet new needs caused by changes in demand for patient care services or patient load, licensees would be able to modify their procedures without NRC review provided the regulations are met. Modifications would require approval of the licensee's Radiation Safety Officer, and at a hospital, its Radiation Safety Committee.

Some types of program changes that would still require a formal NRC review and license amendment include new physician user, new medical use, and new location of use.

The proposed revision to Part 35 of NRC regulations is being published for public comment in the Federal Register on ______. Comments should be submitted within 120 days to the Office of the Secretary, Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

DRAFT CONGRESSIONAL LETTER

Dear Mr. Chairman,

The Nuclear Regulatory Commission is proposing to revise its regulations to simplify and make more efficient for both licensees and the agency the regulatory process for the medical uses of radioisotopes.

The NRC has licensed about 2200 medical facilities and 300 physicians in private practice to use radioactive materials to diagnose and to treat patients. The NRC receives about 100 new applications, 500 renewal requests, and 1800 license amendment requests each year.

License applicants must submit a substanial amount of information to show that all radiation safety requirements will be met, including a description of the radiation safety management procedures used in meeting the requirements, available facilities and equipment, and key users' training and experience. The agency reviews the applicant's program before issuing a license.

Due to the rapid evolution in the medical use of radioisotopes over the last thirty years, current requirements are found throughout the regulations, regulatory guides, standard license conditions and other sources. Therefore, the primary purpose of the proposed revision is to consolidate the requirements. Under the proposal, all requirements would be clarified and published in one place, Part 35 of NRC regulations. The revised regulation would give both licensees and NRC staff a clearer basis for licensing, operation, and inspection activities.

The NRC staff will continue to review the applicant's radiation safety procedures to determine whether they are adequate to meet the requirements of the regulations. However, to permit licensees to make prompt use of new safety methods and to adjust their radioactive materials programs to meet new needs

caused by changes in demand for patient care services or patient load, licensees would be able to modify their procedures without NRC review provided the regulations are met. Modifications would require approval of the licensee's Radiation Safety Officer, and at a hopsital, its Radiation Safety Committee.

Some types of program changes that would still require a formal NRC review and license amendment include adding new physician users, new medical users, and new locations of use.

The proposed revision to Part 35 of NRC regulations will be published for public comment in the Federal Register. The draft regulation and the draft regulatory guide will be mailed to current licensees and other interested individuals for comment.

John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

CONGRESSIONAL ADDRESSEES

The Honorable Richard L. Ottinger, Chairman
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Committee on Energy and Commerce
United States House of Representatives
Washington, DC 10515
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The Honorable Alan Simpson, Chairman
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The Honorable Morris K. Udall, Chairman
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DRAFT

ENVIRONMENTAL ASSESSMENT FOR THE PROPOSED REVISION OF 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL;" FINDING OF NO SIGNIFICANT IMPACT.

1. Introduction

The Nuclear Regulatory Commission (NRC) is proposing to revise its regulations that govern the use of byproduct material for patient diagnosis and therapy. Most of the revision would consist of a clarification and consolidation of requirements that are part of the application review process or that are currently imposed on licensees as license conditions or inspection and enforcement orders. The revision would also change the method of applying for a "medical use" license.

Since some of the regulations may have a physical effect on the human environment, the staff has prepared the following Environmental Assessment.

2. Need for the Revision; Rejection of the No Action Alternative

Guidance in the safe use of byproduct material in patient care is currently scattered among the regulations, orders, license conditions, guides, and technical reports. A document that consolidates the critical elements in the guidance is needed to ensure that each individual who needs the information will receive all the information. The document could be a NUREG Report, a Regulatory Guide, or a revision of the regulations. The NRC chose a revision of the regulations in order to reduce the time needed to issue a license and to ensure uniformity of requirements throughout the NRC-licensed medical industry.

There are currently about 2500 "human use" licensees. Each year, the NRC receives about 100 new applications, 500 renewal applications, and 1800 amendment requests. In order to ensure that the applicant has made a commitment to use

byproduct material safely, the staff thoroughly reviews each procedure that an applicant proposes to use. Since some of the safety criteria that the NRC considers critical are not in the regulations, the application and license are the primary documents used to establish the licensee's responsibility for the safe use of byproduct material. In order to simplify the licensing process without compromising the safety of workers and the public, the Commission believes it is necessary to have the critical safety prescriptive and performance criteria in the regulations. (Publication of a NUREG report or a Regulatory Guide would provide a consolidated document, but neither has regulatory force.)

Therefore, the Commission has determined that, in order to make the licensing process more efficient and to reduce the amount of time needed to issue a license, amendment, or renewal, the regulations must be revised.

3. The Proposed Action and Its Impact

a. Specific Sections. Most of the proposed revision deals with the safe use of byproduct material in the workplace. The following sections deal with exposure of the public and the environment.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants. This section requires that the licensee not release a patient until the exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter. The Commission notes that a study of the radiation exposure of family members of patients who were administered 8 to 150 millicuries of I-131 indicated that the median exposure to a family member living with the patient was 19 milliroentgens (AJPHv68n3Mar78pp225-230). Currently, according to a frequently used license condition, the licensee may release a patient who contains less than 30 millicuries of radioactivity. (For I-131, the most hazardous frequently used radiopharmaceutical, this amount of activity would create an exposure rate of about 6 milliroentgens per hour at a distance of one meter from the patient.) The Commission notes that the International Commission on Radiological Protection has, for many years, recommended limits on radiation exposure of individuals. "The dose equivalent limits . . . recommended by the [ICRP] have been in effect for over 20 years. They have

been widely used internationally and have been incorporated into legislation in a number of countries and regions. Furthermore, there is no evidence to indicate that the [ICRP's] recommended system of dose limitation has failed to provide an adequate level of safety . . . The [ICRP's] recommended whole body dose equivalent of 5 mSv (0.5 rem) in a year, as applied to critical groups, has been found to provide this degree of safety. . ." [Annals of the ICRP, Pergammon Press, Oxford. ICRP Publication 26, adopted January 17, 1977, paragraphs 77 and 119.] Therefore the Commission has determined that neither the exposure to a family member nor the exposure rate to other individuals or the environment would produce any discernible effect. (See also the discussion of §§ 35.90 and 35.205 that follows.)

<u>§ 35.80 Mobile nuclear medicine service technical requirements</u>. A mobile service transports and uses byproduct material away from the licensee's base of operation. (The safe transportation of the byproduct material is regulated by the Department of Transportation.) The licensee will be authorized to transport prepared radiopharmaceuticals, but not radionuclide generators. This will ensure that only byproduct material to be used for patient care will be transported. The regulation requires that the licensee ensure, by radiation survey, that all byproduct material, except that administered to the patient, has been removed from the place of use.

Concerning the transportation of by product material, the Commission notes the following information that has been extracted from "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" NUREG-0170 v 1 USNRC Dec. 1977.

"[page iv] Radiation exposure of transport workers and members of the general public along the transportation route occurs from the normal permissible radiation emitted from packages in transport. More than half of the 9800 person-rem exposure resulting from 1975 shipments was received by transport workers associated with the shipments. The remaining 4200 person-rems was divided among approximately ten percent of the U.S. population. None of these exposures would produce short-term fatalities. On a statistical basis, expected values for health effects that may result from this exposure

are 1.7 genetic effects per year and 1.2 latent cancer fatalities distributed over the 30 years following each year of transporting radioactive material in the United States at 1975 levels (Chapter 4, Section 4.9). More than half of this effect results from the snipment of medical-use radioactive materials where the corresponding benefit is generally accepted (Chapter 1, Table 1-2).

"Transportation accidents involving packages of radioactive material present potential for radiological exposure to transport workers and to members of the general public. The expected values of the annual radiological impact from such potential exposure are very small, estimated to be about one latent cancer fatality and one genetic effect for two hundred years of shipping at 1975 rates (Chapter 5, Section 5.9). More than two-thirds of that impact is attributable to nuclear fuel cycle and other industrial shipments (Chapter 1, Table 1-2). [Only 13% of the impact is attributed to medical shipments.]. . .

"Examination of the consequences of a major accident and assumed subsequent release of radioactive material indicates that the potential consequences are not severe for most shipments of radioactive material (Chapter 5, Section 5.6). The consequences are limited by one or more parameters: short half-life, nondispersible form, low radiotoxicity. . .

"[page vii] On the basis of the analysis and evaluation set forth in this statement and after weighing the small adverse environmental impact resulting from transportation of radioactive materials and the costs and benefits of the alternatives available for reducing or avoiding the adverse environmental effects, the staff concludes that:

a. Maximum radiation exposure of individuals from normal transportation is generally within recommended limits for members of the general public (Chapter 3, Section 3.5). There are transportation operations at a few locations where some transport workers receive radiation exposures in excess of the recommended limits established for members of the general public. In most cases, these operations employ radiation safety personnel to establish safe procedures and to train and monitor transport workers as though they were radiation workers.

b. The average radiation dose to the population at risk from normal transportation is a small fraction of the limits recommended for members of the general public from all sources of radiation other than natural and medical sources (Chapter 3, Section 3.5) and is a small fraction of natural background dose (Chapter 3, Section 3.3). . .

"[Page viii] Based on the above conclusions, the NRC staff has determined that the environmental impacts of normal transportation of radioactive material and the risks attendant to accidents involving radioactive material shipments are sufficiently small to allow continued shipments by all modes."

Currently only about 30 of the Commission's 2600 human use licensees are authorized to transport byproduct material for mobile service. The NRC does not expect any significant increase in mobile service, and therefore does not expect any significant increase in risk due to transportation.

§ 35.90 Storage of volatiles and gases, and § 35.205 Control of aerosols and gases. These sections allow the storage of volatile radiopharmaceuticals and gases in a fume hood, and the venting of waste material to the atmosphere. The purpose of these sections is to protect employees from inadvertent release of byproduct material in the workplace. The release of byproduct material to the environment is regulated by Part 20, "Standards for Protection Against Radiation."

The Commission notes that the ICRP has calculated the concentration of a radionuclide in an effluent stream that would cause a member of the population at large to receive an exposure of 0.5 rem in one year. ". . .the [maximum permissible concentration] values for [the population at large] are one-tenth of the occupational values for. . .the 168 hour week." [Health Physics, v3, June 1960. "Report of Committee II on Permissible Dose for Internal Radiation (1959)", p5] The maximum permissible concentration values in 10 CFR 20 Appendix B for soluble Tc-99m, insoluble TC-99m, insoluble I-131, and Xe-133 are equal to one-tenth of the "168 hour week" values referred to in the previous sentence. The appendix B value for soluble I-131 is more restrictive than one-tenth of the "168 hour week" value. (These are the radionuclides

most frequently used in human use.) Therefore, allowing releases up to the concentration values of 10 CFR Part 20 Appendix B is not likely to be unsafe to humans.

Concerning radiation exposure of the ecosystem, the Commission notes that a National Academy of Sciences-National Research Council committee stated that "Evidence to date indicates that probably no other living organisms are very much more radiosensitive than man so that if man as an individual is protected, then other organisms as populations would be most unlikely to suffer harm. In fact, it is very difficult if not impossible to detect any effects of radionuclides in the environment even at concentrations much higher than the minimum established by regulation agencies." ["The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," Report of the Advisory Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences-National Research Council, Washington, D.C. 20006 November 1972, p34.] Since it was determined in the preceding paragraph that man as an individual will be protected, we may assume there will not be any detectable effect on other living organisms.

For these reasons, the Commission has determined that, if approved, these sections will not result in any significant impact on the environment.

<u>§ 35.92 Decay-in-storage</u>. This section allows the licensee to release decayed byproduct material to the environment. Before doing so, the licensee must survey the material to ensure that the radiation from the material cannot be distinguished from natural background radiation levels. Because there would be no detectable radiation emanating from the released material, there will be no discernible effect on the environment.

<u>§ 35.404 Release of patients treated with temporary implants</u>. This section requires that the licensee determine by source count and radiation survey that all implant sources have been removed from the patient. This will ensure that a source and the radiation emanating from it are not unintentionally released to the environment.

§ 35.604 Information to be submitted with application. This section requires that an applicant for a teletherapy license submit information that will allow the staff to make an independent estimate of the environmental exposure due to radiation that penetrates through the teletherapy room walls. This will help to ensure that the applicant will be able to comply with the requirements of § 20.105, which regulates permissible levels of radiation in unrestricted areas.

The regulations in that section require that the licensee demonstrate that it is unlikely that any individual in an unrestricted area would receive a dose in excess of 0.5 rem in one year. The Commission has determined that this provides an adequate degree of safety for humans (see the discussion of § 35.75 in this assessment). Occasionally applicants choose to minimize the exposure of individuals by physically restricting access to an area (by a fence, for example) rather than by providing additional radiation shielding. In such a case it is conceivable that, although human exposure would be kept below 0.5 rem in one year, some flora and fauna may be exposed to higher levels of radiation.

As noted in the discussion of §§ 35.90 and 35.205 in this assessment, "....it is very difficult if not impossible to detect any effects of radionuclides in the environment even at concentrations much higher than the minimum established by regulation agencies." Since it is recognized that, for purposes of radiation protection, there is no inherent difference in the effects of internal as contrasted to external radiation exposure (ICRP Publication 26, paragraph 104), that observation may be expanded to govern this discussion of external radiation exposure.

In these cases the higher levels of radiation proposed by applicants are usually not dramatically higher than the 0.5 rem per year limit, and are usually requested by applicants only when the cost of additional radiation shielding would be an unreasonable expense. The Commission notes that the potential for human benefit due to the availability of radiation therapy far outweighs the conceivable impact on the ecosystem that might be caused by the higher radiation levels. In light of all this the Commission has determined that the benefit to society outweighs any credible impact on the environment.

b. General. The Commission issues licenses that authorize the intentional irradiation of individuals by licensees. The Commission recognizes that there is a chance that the irradiation of an individual for diagnostic or therapeutic purpose may have deleterious effects. However, in a policy statement that was published February 9, 1979 (44 FR 8242), the Commission gave notice that, while it will regulate the radiation safety of patients where justified by the risk to patients, it will not intrude into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine. For each method of human use authorized by the regulations, the possibility of individual human benefit has been demonstrated by scientific research.

4. Summary

The Commission has decided that a need exists for a change in the regulations that govern the human use of byproduct material. The change will provide a clear, concise set of regulations for the affected industry. The Commission has determined that there will be no discernible impact on the environment. Therefore, it is not necessary to prepare an environmental impact statement.

SUMMARY OF COMMENTS ON PROPOSED REVISION OF
10 CFR PART 35 THAT WAS DISTRIBUTED FOR
COMMENT ON FEBRUARY 15, 1984
3

X

Commenters:

OPE	Memo Cunningham/Jupiter dated March 19, 1984
IE	Memo Cunningham/Grace dated March 21, 1984
ADM	Memo Cunningham/Norry dated March 28, 1984
RM	Memo McElroy/Clark (Cost Analysis Group) dated April 6, 1984
RES	Memo Cunningham/Goller dated May 10, 1984
SP	Memo Cunningham/Kerr dated April 26, 1984
RI	Memo Cunningham/Martin dated March 30, 1984
RII	Memo Cunningham/Stohr dated April 6, 1984
RIII	Memo Cunningham/Hind dated March 30, 1984
RIV	Memo Cunningham/Bangart dated April 2, 1984
RV	Memo Cunningham/Scarano dated April 6, 1984
M	Memo Glenn/Mallett dated January 11, 1984
G	Memo McElroy/Glenn dated January 20, 1984
P	Memo Glenn/Potter dated January 11, 1984
NV	Letter Nussbaumer/Vaden dated March 13, 1984
ND	Letter Nussbaumer/Mount dated March 22, 1984
OR	Letter McElroy/Blazek dated March 23, 1984
AL	Letter McElroy/Blazek dated March 23, 1984, with attached comments by Whatley
NM	Letter Nussbaumer/Garcia dated March 23, 1984
GA1	Letter Blazek/Connell dated March 23, 1984
GA2	Letter Nussbaumer/Rutledge dated April 2, 1984
CRCPD	Letter McElroy/Hazle, Chairman, Conference of Radiation Control Program Directors, dated March 29, 1984
TN	Letter Nussbaumer/Graves dated April 19, 1984
CO	Letter Nussbaumer/Hazle dated April 11, 1984
TX	Letter Nussbaumer/Lacker dated April 23, 1984

AZ	Letter Nussbaumer/Tedford dated April 24, 1984
RIb	Briefing Region I/McElroy held March 9, 1984
RIIb	Briefing Region II/McElroy held March 20, 1984
RIIIb	Briefing Region III/McElroy held March 23, 1984
RIVb	Briefing Region IV/McElroy held March 21, 1984
RVb	Briefing Region V/McElroy held March 22, 1984

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STAFF PAPER

Comment: In the staff paper, it appears NRC has already selected Alternative 2 and the request for comments is a perfunctory act.

Response: The staff has decided to recommend Alternative 2 to the Commission. The staff has asked for comment because the proposal may have unintended or unknown consequences, or other persons may have additional or alternative suggestions. Each comment has been read and considered. Many valuable comments have been incorporated in the package. We have not received any comments that lead us to believe that the basic proposal is flawed.

Comment: If 40% of applications that are now received are deficient, doesn't this indicate that a lot of applicants don't have adequate training? Aren't you just turning your back on a big problem?

Response: No. Many requirements are in standard license condition and branch policy statements that are not generally available to the public. There are many ~~critical~~ essential safety elements in the application guide that are required of all licensees (despite the front-page disclaimer that "compliance with regulatory guides is not required"). ~~Since~~ Because the applicants don't know all the rules governing the review and approval of applications, it should come as no surprise that many applications are deficient.

We believe the unannounced inspection is a better proficiency test. Inspection results for 1982 are summarized in Enclosure 9. Almost all of the 1240 citations issued in 1982 are for items that are better described as early signs of safety program degradation, but that do not present a worker or public safety hazard.

Comment: Some of the "essential safety elements" are guidelines. The application is like house plans to show compliance with the building code. There is no need to standardize all houses. You are trying to make all hospitals look alike.

Response: The analogy is excellent. (Many radiation safety experts would disagree with your suggestion that in some cases we have codified "good practice." In most cases we have been chastised for leaving something out.) Once you have

a building permit for a house, you may make minor changes in room layout or design that are consistent with the building code. The "building standards" office relies on inspectors in the field to determine compliance with the code and workmanship standards, but not the architect's detail drawings or decorator items.

Comment: Are you saying that the licensing process is no longer important?
CR Response: No. We do, however, believe that the licensing process carries too much responsibility in the regulatory program. Its role in the medical industry should be reduced. The inspector is best situated to determine whether a program is operated within the requirements.

that may be identified in written procedures

DISCUSSION OF ALTERNATIVES

Comment: The proposed Alternative 2 would be acceptable if (among other things) the licensee were only allowed to modify procedures for which requirements are identified in the regulation.

cR

Response: No. ~~The listing of what could or could not be modified would constitute another administrative step.~~ The actions that require a license amendment (new users, new locations, and new types of use), are identified in the regulation. We contend that the essential safety elements of all required radiation safety procedures are identified in the regulation. Other elements are not of significant radiation health and safety concern.

Comment: Inspectors will spend more time reviewing procedures in the field. Sometimes there are evolutionary equipment or procedure changes that are better evaluated in the office. Also, in addition to having to familiarize themselves with programs on the spot, inspectors will have to spend a lot of time on followup inspections.

cR

Response: Watching a worker do something is quicker and more relevant to safety than reading what he is supposed to do. The evolutionary changes in safety equipment that you refer to are very infrequent. A detailed review and approval process is a very costly way of assuring that things won't be done incorrectly. For the level of hazard of materials that are authorized, that expense does not seem to be justified. Once something has been done incorrectly, whether in violation of regulation or procedure, a lot of inspection and licensing time is consumed.

— dele cR

Comment: Clarify that we lose a "safety valve" if there is no procedures modification review mechanism exercised by a regulatory agency.

cR

Response: The statement is the closing sentence of "Objections-Alternative 2" of the staff paper.

Comment: The regulation does not clearly provide for a citation for a failure to follow procedures.

cR

Response: Yes, it does. The licensee, through the RSO, must implement the procedures. Implement means, "to carry out, accomplish, or ensure fulfillment

of." If the procedure which was implemented to meet a requirement has not been followed, the citation may be issued for failure to comply with the regulation.

Comment: You say that savings in amendment fees under your proposed Alternative 2 are insignificant and yet you say that "the effect of selecting Alternative 3" is costly to both NRC and licensees. From these statements, it is difficult to understand why you have chosen to recommend Alternative 2 when there is no disadvantage to Alternative 3.

cR =

Response: The disadvantage of Alternative 3 is that the model procedures in the licensing guide become, for practical purposes, regulations. The savings in amendment fees is what is insignificant to both individual licensees and the industry as a whole (one or two thousand amendments per year from the entire industry, at $40 120 each). Alternative 3 is costly to NRC because the fee does not cover the expense of reviewing the request and these reviews consume staff time that could be more productively spent on other projects that have greater impact on public health and safety. The NRC review is expensive for licensees because it adds the following costs: transmittal letter, paperwork involved in issuing a check to pay for the amendment, and whatever expenses might be incurred while awaiting the authorization to make the requested changes.

X

Comment: The Commission's instruction that the staff should approve licensees' procedures has been ignored. When the Commission said, "continue the pre-licensing review of the applicants' operating procedures," it meant more than a review for the sake of reviewing.

cR =

Response: In the earlier submission the staff had proposed that the applicant merely certify that ~~he~~ had adequate procedures, not ~~that he~~ be required to submit them for review. Therefore, the word "pre-licensing" is an important modifier in the instruction.

Comment: When discussing Alternative 1 in the staff paper, you say you were not aware of anyone who would retain the current regulation over the proposed regulation. In fact, many individuals would retain the current system in favor of Alternative 2.

cR =

Response: You are correct. But most persons who disagree with this proposal recommend the proposal described in Alternative 3, which is an alternative licensing method based on the same set of regulations. Of all of the NRC, Agreement State, and informal industry comments received, only a handful of persons have clearly recommended retention of the current Part 35 over the codification provided in the proposal.

This is not to suggest we are taking votes. Rather, it appears that almost everyone who has seen the package falls into one of two camps: (1) publish the package for comment, or (2) modify the package to require NRC approval of equipment, rooms, and procedures and changes thereto (or some combination of those three), and then publish the package for comment.

There are five principal levels of regulation:

1. Registration: Send in your name and address.
2. Self-certification: Promise you will follow the regulations.
3. Commitment: To get a license, describe your program. If your needs change, you may make the changes to your program that are consistent with your license and the regulations.
4. Control by license: To get a license, describe your program. If your needs change, get NRC permission before making program changes.
5. Supervision: Operate your program under the direct personal supervision of an NRC inspector.

Level 1 does not provide an adequate assurance of public health and safety for the materials used in medical programs. The staff recommended Level 2 in the April 1983 submission and the Commissioners rejected it. Level 3 appears in this package as Alternative 2, and is recommended by the staff. Level 4 appears in the package as Alternative 3. When weighed against the benefit to society, Level 5 is too costly.

Comment: You say industry is confused about whether a specific standard is a requirement or a suggestion. If NRC selected Alternative 3, industry would no longer be confused and you would retain what many believe are necessary procedures for radiation safety.

Response: For the purpose of this discussion, we may say NRC has two kinds of standards: (1) regulations, license conditions, and orders, and (2) regulatory guides. Failure to comply with the first standards can result in citations, fines, or imprisonment. There is no penalty for not complying with a regulatory guide procedure because it is an example of a way of achieving compliance with the regulations. We contend that the essential elements of the medical radiation safety procedures have been codified in the regulation, and what has not been codified is not of great safety significance. To adopt Alternative 3 would require NRC staff to review changes that are not of great safety significance: The confusion as to the status of regulatory guide procedures would remain unresolved.

Comment: Contrary to what you say, Alternative 1 (no action) does provide more safety than Alternative 2 because in many cases the application review process is a learning experience for the applicant. It is easier to prevent a problem than it is to clean up afterward.

Response: The application review process you refer to is retained in this draft.

CHANGES IN PROCEDURES

Comment: Inspectors will have to spend more time in the field reviewing procedures because this will not be done during the licensing process. Inspectors will have neither the time nor the reference materials needed in order to make an adequate review.

CR

Response: Inspectors should not review written procedures in the field. They should watch workers working, and spot-check records for completeness. A procedure is a written description of what a worker will or will not do. The thing that is important is what a worker actually does or does not do.

Comment: Why should the licensing staff spend its time reviewing procedures if they won't be enforceable?

CR

Response: The pre-licensing review provides for a finding of acceptable training and experience, facilities and equipment, and a management commitment to safety.

{to equipment and rooms it has specifically designated

Comment: Contrary to what you say, under the current licensing system, licensees do not have to get an amendment before changing the equipment they use.

Comment: Changing rooms where byproduct material is used should not require an amendment.

Comment: Changing rooms should require a license amendment.

CR

Response: A licensee ~~may~~ might identify equipment by name and serial number and rooms by number that will be used for storage or use of byproduct material in an application. The Office of the Executive Legal Director advises that, if ~~he~~ a licensee makes changes, ~~he~~ it is no longer in compliance with the requirement to conduct ~~his~~ its program in accordance with representations in the application. Therefore under the current licensing system, the licensee must get an amendment before making chang~~ing equipment~~es. Similarly, the licensee ~~needs the authority~~ must get an amendment to use additional rooms for ~~the~~ its byproduct materials program, or to reduce the floor space associated with the program, in order to respond to changes in patient load level, available equipment, and space needs. ~~The licensee will have to keep a record of room changes. See a new Section 35.36.~~ The proposed system would allow licensees to make changes. They would have to document the changes as described in new § 35.36.

Comment: Although the draft regulation requires the implementation of written procedures, there is no standard for minimum content, nor a requirement that modified procedures be similar to those submitted for NRC review. This complicates inspection and enforcement.

cR =

Response: Minimum procedure content is specified in the regulation for almost all the procedures required. (See Sections 35.30, 35.32, 35.33, 35.34, 35.37, 35.38, 35.50, 35.51, 35.53, 35.59, 35.70, 35.75, 35.80, 35.92, 35.204, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.610, 35.621, 35.630, 35.632, 35.633, 35.641, 35.642, and 35.645.) There is no need for modified procedures to be similar to original procedures. There is a regulatory requirement that the licensee's activities be in accord with ~~his~~ its procedures and the regulations.

Comment: Licensees could follow technically invalid procedures for several years because of our low inspection frequency. Inspection time, fines, shutdowns, and possibly even worker dose will increase. Inspections will have to be more frequent.

cR =

Response: The alternative you recommend, the NRC review and approval of changes, is expensive and time consuming for both the licensee and NRC, and does not provide assurance of safe use. Only an unannounced inspection can do that. Because all inspectors will be working from a single codified 30-page regulation, inspections of compliant licensees should be quicker. Total NRC time spent on non-compliant licensees should be reduced because NRC will be looking at the end product rather than the planned process. We disagree with the perceived need for more frequent inspections.

Comment: Many citations are for not following procedures that licensees said they would follow. Why is it acceptable for applicants to say they will follow a procedure from a guide?

cR =

Response: If a ~~person~~ licensee is planning on willful negligence, the prior submission of a long application is unlikely to deter ~~him~~ it, while it unnecessarily increases the application burden on others. Almost all procedure citations are for not doing anything when something is required, or for doing something that is clearly prohibited.

Comment: You should require clear, separate documentation of ~~procedure~~ changes. What is to prevent the licensee from changing ~~his~~ its procedures even as the inspector is conducting his review?

cR =

Response: A new Section 35.36, has been added. It requires the licensee to conduct a formal review and approval process before making any procedure changes.

Comment: The internal review process that you require would not be a real review because the authorized user who is proposing the change may be the only radiation expert in the hospital.

CR = Response: This is noted in the staff paper section "Alternative 2--Objections." (6) also, see the response in "Alternative 2--Proponents."

Comment: Today, about 40% of licensing requests are deficient; yet, you say there will be no further need for deficiency letters. Do you mean to say that procedures must be accepted as valid even though they contain gross radiation and safety problems?

CR = Response: Deficiency letters currently issued are necessitated in large part because requirements are buried in Part 35, or are in license conditions and branch policy statements that are not generally available to the public, or regulatory guides that are purported to be for guidance only. By codifying all the requirements in one place, the applicant can use the regulation as a checklist to determine whether his application is complete. If it is, it is less likely that a deficiency letter will be needed. If an applicant submits an inadequate application, a deficiency letter will be issued.

Comment: You should only allow changes in procedures that will not decrease the effectiveness of the licensee's radiation safety program.

CR = Response: The phrase "if the modification does not reduce the program effectiveness and meets Title 10 requirements" has been suggested before. A licensee may design a very safe program that is too expensive or too inflexible to meet changing patient care needs. ~~He~~ It should not have to pay an amendment fee to modify ~~his~~ its program as long as it continues to meet the regulatory standards.

Comment: You should develop evaluation criteria that the licensee must use to measure the effect of proposed changes. ~~he is making in his procedure.~~

CR = Response: ~~The standards are in the regulations.~~ ~~If the licensee is doing something contrary to regulation and doesn't have an exempting license condition,~~ ~~he~~ it is subject to enforcement action. ~~A notation that procedural modifications~~ procedure changes

~~must be in accord with the regulations appears throughout the preamble.~~ A new regulatory guide appendix has been developed that lists things that should be considered when evaluating proposed changes. However, it does not have standards to actually "measure the effect of changes."

COST ANALYSIS

Comment: In the cost analysis you should estimate: how many licensees are represented by each "hypothetical licensee"; the increase in burden due to the rule; the burden of the other alternatives described in the Commission paper; and the NRC staff retraining cost.

Response: Done.

Comment: You say there is no negative impact on small entities, yet, for your hypothetical licensees, the additional costs will range from $1,600 to $13,000. Also, an extra 400 to 600 technician hours will be needed for each licensee.

Response: The numbers you cite are the total regulatory burden; they do not represent new costs. Enclosure 4 has been revised to show total burden and new burden.

RECORDS RETENTION

Comment: Licensees should be required to keep all records since the last inspection, or at least longer than just 2 years.

CR

Response: No. The Office of Management and Budget (OMB) must approve record retention requirements. In response to that requirement, the Office of Administration has prepared a draft record retention rulemaking that establishes uniform retention periods of 2, 5, or 10 years or life of the license or piece of equipment. This Part 35 draft is consistent with that policy. Your suggestion is essentially an open-ended retention period; OMB does not allow them without good cause.

Comment: Why must the licensee record patient identification information on the dosage log sheet? The dosage is recorded in the patient's treatment record.

CR

Response: Not all licensees record dosages in patients' files. The intent of the requirement is to reduce the chance of misadministrations by checking both name and identification number.

Comment: Many sections require that the radiation safety officer sign numerous records such as daily checks on dose calibrators. One of the stated objectives for the revision of Part 35 was to reduce paper work on licensees. The necessity of having the RSO sign routine, day-to-day generated documents is questioned and is likely to become a matter of routine without any meaning. A more practical approach would appear to require the person performing the test to make the record and initial it and notify the RSO of test results outside an established range. Then the RSO could review records on a weekly basis.

CR

Response: The RSO does not sign the daily checks you refer to. The individual who makes the check initials it. The RSO generally does not sign routine, day-to-day records; usually, whoever creates the day-to-day record initials it. It is the licensee's responsibility to establish whatever management mechanism is needed to ensure management intervention when trigger levels are exceeded. A specified frequency of review was considered but not included because of the range of licensee program sizes.

Comment: Your record retention period that pertains to patient dosage records may be shorter than the retention period required by State law. These records should be retained indefinitely, or as long as required by other applicable law.

Response: No. The licensee bears the burden of ensuring compliance with other laws that regulate ~~his~~ its activities. The NRC cannot tailor its regulations to suit each State's medical regulations, nor can it say, "Keep a record as long as someone else makes you," because that does not provide a clear or meaningful standard.

Comment: In listing information collection requirements, you have required more than what is reasonably needed for radiation safety. This kind of information should be mentioned in a regulatory guide, but not in a regulation.

Response: Your point is well taken, but the burden is balanced by the fact that each listing does provide an explicit check list of what the NRC considers elements of an adequate record. No changes have been made.

WORD USE

Comment: You should use the word "operable" to describe survey meters and other equipment.

Response: No. The word does not add to enforceability. The statement of consideration provides unambiguous notice that equipment that isn't working cannot be used to meet safety requirements.

Comment: Please clarify what you mean by a "dedicated" check source.

Response: Done. See the preamble section entitled "Notes."

Comment: "Management" should be defined to include "or designee."

Comment: By requiring the "licensee" to calibrate the survey meters, you preclude the use of calibration services.

Response: Legal staff advises that "designee" is implied in legal construction of the term ~~Compare the word~~ "licensee." For instance, ~~"~~A licensee may be a non-living business entity; thus, The wording of the requirement places a legal responsibility on the licensee that may be fulfilled by full- or part-time employees or perhaps by contractors. See the preamble section entitled "Notes."

Comment: Your notes on word usage should be codified in the regulation.

Response: No. The regulation contains the definitions needed to clarify the requirements. The word usage notes will be published, along with an edited statement of considerations, in the regulatory guide in case ~~of~~ a questions of regulatory intent or interpretation come~~s~~ up at a later date.

Comment: Define "promptly."

Response: No. When used with its normal definition ("performed readily or immediately"), legal staff advises that a word need not be defined in the regulations. Contrast the word "person" which is defined in Part 30 because it is used in other than its normal definition (a legal definition of a business or government entity rather than the normal "An individual human being").

LICENSEE MANAGEMENT

Comment: There should be some kind of ALARA program for all licensees, not just medical institutions. The draft Part 20 requires one.

Response: No. The ALARA program elements in the regulation may be generally characterized as steps to ensure information flow between managers with overlapping responsibilities. At a non-institutional license ce, such formalized communication is unnecessary. If Part 20 is revised, ~~the conflict~~ incompatibilities will be resolved at that time.

Comment: You should require that mobile service licensees include authorized users on the management team. This will ensure appropriate management control.

Response: For the level of hazard of materials authorized, there does not appear to be a strong need for NRC to dictate corporate organization.

RADIATION SAFETY OFFICER AND RADIATION SAFETY COMMITTEE

Comment: You should clarify the responsibilities that must be borne by the radiation safety officer and by consultant radiation safety officers.

cR = Response: Whether consultant or full-time, the regulations require the licensee's management to provide a statement of authority, a list of duties, and provision of adequate resources. The degree of specificity you suggest is inappropriate for two reasons: (1) Some safety tasks don't apply to all licensees; and (2) if you leave an important task out, the courts assume you did so purposefully since you took the time to go to such great detail.

Comment: Clarify how many physicians must be on the radiation safety committee.

cR = Response: If one physician is authorized to use all materials listed on the license, he is the only one needed. If one physician is authorized to use materials for nuclear medicine and another physician conducts teletherapy, both must be on the committee. Alternative wording is invited.

Comment: Why must committee minutes note the numerical results of ballots?

cR = Response: The requirement was suggested because it is the one quantitative measure of committee concurrence that is easily recorded.

Comment: If the radiation safety committee only reviews a user's credentials "on the basis of safety," that will be an incomplete review.

cR = Response: Agreed. The requirement has been revised to include "and in comparison to the training and experience standards in Subpart J of this part."

Comment: You could develop a more concise rule if you simply designated the private practice authorized user as the radiation safety officer and radiation safety committee.

cR = Response: Correct, but then he would have to be exempted from the formal ALARA program requirement and the committee meeting requirements. Conciseness may be purchased at the expense of clarity. No changes have been made.

DOSE CALIBRATOR

Comment: The standard of accuracy for the dose calibrator that you list in the Draft Regulatory Guide is more stringent than the requirement in the regulation. Which standard applies?

cR =

Response: The regulatory guide procedure provides a trigger level that initiates equipment repair before the licensee goes out of compliance with the regulation. If a licensee has adopted the guide standard and has not initiated repair after going outside the range allowed in the guide standard, ~~he~~ it is out of compliance because ~~he~~ it has not implemented the procedure. If ~~he~~ it has not initiated the repair after going outside the regulatory standard, ~~he~~ it is out of compliance with the regulation.

Comment: Many licensees who have pre-measured unit dosages don't believe they need a dose calibrator. Physicians don't test the potency of non-radioactive drugs that they administer to patients.

cR =

Response: Other drugs don't decay with time the way radiopharmaceuticals do. A dose calibrator only costs about $2,000. It takes only a few seconds to measure each dosage. ~~The benefit to the public appears to be worth the cost.~~ The NRC's Advisory Committee on the Medical Use of Isotopes has recommended that all radiopharmaceutical licensees be required to use a dose calibrator to measure dosages.

Comment: The dose calibrator linearity should only be tested to the highest dosage ordinarily measured, not the highest dosage ever measured.

cR =

Response: No. Therapy dosages, which are not ordinarily measured because they are not frequently administered, are ~~10~~ ten-fold higher than diagnostic dosages. The linearity test provides the only assurance that the higher measure is accurate.

X

Comment: If the dose calibrator manufacturer supplies geometry dependence test results, there is no need for the licensee to repeat the test.

cR =

Response: If the detector was internally damaged in transit from the distributor to the receiver, the manufacturer's test result would no longer be valid.

Comment: The NRC should publish a position statement on the temporary use of radiopharmaceuticals without measuring the dosage in those cases where the licensee's dose calibrator is broken.

cR =

Response: Agreed. However, it will be developed independent of this project.

Comment: You should require that the dose calibrator be tested for accuracy with sources similar in energy to the materials that will be assayed.

cR

Response: Done.

Comment: You should require that daily dose calibrator constancy checks be made with low, medium, and high energy sources. The proposed requirement is much less stringent than our current guidance.

cR

Response: The daily constancy check in this draft is based on Section 4.5.1 of the ANSI standard for dose calibrators. Our current regulatory practice goes beyond the recommended requirement.

Comment: You should require that the dose calibrator be tested for linearity from zero to the highest activity measured.

cR

Response: ANSI Section 4.2.2 says "Calibration of the equipment should cover as completely as practicable the activity ranges for which it will be used, particularly those ranges of activity of radionuclides to be administered to patients." There is no public health and safety need to check for linearity ~~from 2 curies to 10 microcuries~~ of measurement ranges that are not used to measure patient dosages. This may cause unnecessary worker dose.

The chairman of the ANSI N42.13 drafting committee indicated in conversation that the majority of the committee recommended that the calibrator only be tested for linearity up to the highest dosage administered.

SURVEY METERS

Comment: When calibrating survey meters, the licensee should be required to use a nuclide source whose activity is known within 5%.

CR =

Response: No. Survey instruments can also be calibrated with X-ray machines. When calibrating with nuclide sources, the activity is not the descriptor of interest--the dose rate at a specified distance, which depends on how the source is fabricated and encapsulated, is what is important.

Comment: Require that licensees use a low range, thin-end-window survey meter when making surveys in the nuclear medicine clinic.

CR =

Response: No. The licensee bears the responsibility of selecting equipment that is capable of making the measurements required.

Comment: Require that survey meters be calibrated on each scale at two points that are separated by 50%.

CR =

Response: No. All of the citations for survey meter calibration that were issued in 1982 (see Enclosure 9) were for failure to calibrate the instrument, not for calibrating it incorrectly. This continues to be the case with the current citations.

Comment: Why do you require the high range survey instrument to be an ionization type of survey meter?

CR =

Response: Only an ionization chamber ~~type of~~ survey instrument is actually capable of measuring exposure rates. See NCRP Report 57, Paragraph 3.2.4.1.

SYRINGE SHIELDS AND OTHER SAFETY PRECAUTIONS

Comment: You should require that the licensee use syringe shields when preparing kits.

CR =

Response: That was the intent. The wording has been clarified.

Comment: You should require that technicians use syringe shields when drawing dosages out of multidose vials. For 20 millicuries of Tc-99m in 2 cc, the finger dose rate is 0.6 rem per minute. If a technician draws 10 dosages each day, and each withdrawal takes 10 seconds, the technician will get 1 rem each day to the finger. A syringe shield will reduce this by a factor of about 100.

CR =

Response: The recommendation to use syringe shields when drawing dosages has not been included.

It appears all of your dose rates came from Barrall and Smith (B&S) AAPM Monograph 1, 1976. Nuclear medicine technicians do not hold syringes as in B&S Figure 1; common practice is to hold the back half of the barrel where there is no radioactivity; the 2 cc dosage volume they use is out of date (see HP v. 41, n. 3, p. 535, Figure 1, -- 1 cc is a more representative number).

For the dose per year to the tip of the finger, assuming 1 mR/mCi-min (HP p. 538, average value for unshielded index finger; compare B&S p. 84, position 4 measure of 1,100 mR/hr for 20 mCi that is equivalent to 0.9 mR/mCi-min), average dosages of 10 mCi (New England Nuclear catalogue: MDP 10 to 20 mCi; gluceptate 10-20 mCi; MAA 1-4 mCi; pertechnetate for brain 10-20 mCi, thyroid 1-10 mCi, blood pool 10-30 mCi), 10 dosages per day (your number), 0.2 min per dosage (12 sec, you said 10 sec), and 250 days per year, the estimated fingertip dose per year due to drawing dosages is:

$$\frac{1\ \text{mR}}{\text{mCi-min}} \times \frac{10\ \text{mCi}}{\text{dosage-draw}} \times \frac{0.2\ \text{min}}{\text{draw}} \times \frac{10\ \text{dosages}}{\text{da}} \times \frac{250\ \text{da}}{\text{yr}} = \frac{5\ \text{rem}}{\text{yr}}$$

single space (close up)

One may respond by saying that we can save the 5 rem per year dose with a one-time purchase of a $200 syringe shield. However, the first thing the technician would do after drawing the dosage is remove it from the shield to measure it. If the dosage is high or low, the next step would be to put the syringe back in the shield to return it to the vial and adjust the volume, and then remove the syringe again to remeasure it. It appears the increased handling will consume most of the projected dose savings, rendering the expenditure unproductive.

Comment: You should require that technicians who handle radiopharmaceuticals must wear laboratory coats and gloves.

cR =

Response: No. Gloves and laboratory coats do not provide a significant barrier against contamination, and sometimes actually cause the spread of contamination instead of helping to contain it.

SUPERVISION

Comment: The "supervision" section that requires the physical presence of the authorized user on one hour's notice seems unduly stringent. Other hospital personnel can take care of the patient, and the technician can clean up spills.

Comment: In addition to the authorized user, the radiation safety officer should also be immediately available and physically present on one hour's notice.

CR = Response: The requirement that the authorized user be physically present given one hour's notice provides for proper response to spills and losses, and active authorized user oversight of supervised individuals by requiring geographic proximity. (This will eliminate a user in one State "supervising" someone in another State.) If there is a clear public need, for example in the more expansive western states, the license reviewer may provide relief by exemption from this requirement. There is no clear need to require both to be available.

Comment: The licensee should review the procedures that an authorized user will use for supervising workers, and the qualifications of the workers.

CR = Response: Such a requirement would represent a major policy shift with implications for other industries that are regulated by the NRC, and is therefore outside the scope of this project.

Comment: List those duties that can be delegated and those duties that cannot be delegated.

CR = Response: In an early draft, we tried to list delegable duties and found that the list was more confusing than the simple direction to exercise supervision. The listing would most probably be ~~either~~ incomplete ~~or confusing.~~ for some licensees and too permissive for others.

appropriate response in case there are medical implications involved in an emergency,

SURVEYS

Comment: Will the applicant specify contamination action levels in ~~his~~ its application?

Response: No. The Radiation Safety Officer will set the levels; see Section 35.70(d).

Comment: If high contamination levels are found during a contamination survey, the surveyer should take immediate steps to prevent the spread of contamination.

Response: No. Immediate notification of the radiation safety officer, ~~is~~ who required. ~~He~~ is best suited to oversee the control and cleanup of the spilled material, is

Comment: Many licensees use a survey instrument to assay contamination wipe samples. Provide the guidelines on converting cpm or mr/hr to dpm.

Response: Done. More information has been provided in the regulatory guide.

Comment: The permissible contamination limit in patient rooms that are about to be released for unlimited use is too high.

Response: A wording mistake was made in the earlier draft. The limit is 200 dpm/100 cm^2.

Comment: Weekly removable contamination surveys do not provide workers with adequate awareness of potential hazards. They should be made more frequently.

Response: Many of these surveys yield results that are below the NRC's recommended action levels. For the level of hazard caused by surface contamination in nuclear medicine hot labs, it is difficult to defend a more frequent survey.

Comment: Most nuclear medicine departments cannot measure DPM on wipe samples. Instead they should be required to refer their removable contamination measurements to background count rates.

Response: That kind of standard ignores the efficiency dependence of the detector used to measure the wipe sample. The proper units for surface

contamination standards are dpm/cm² and measurements must be recorded in those units.

Comment: 200 dpm/100 cm² is too restrictive a contamination limit for restricted areas.

Response: The regulation does not set a limit on contamination in restricted areas. The licensee does that. The technician is then required to notify the Radiation Safety Officer if a limit for an area is exceeded.

Comment: The end-of-day survey section should require cleanup if removable contamination is found. Otherwise we can't issue a citation.

Response: Yes, you can. The survey section requires the surveyor to notify the Radiation Safety Officer if action levels are exceeded. One of the Radiation Safety Officer's duties is to "take emergency action in the event of loss of control" of material. Either restricted access to the area or cleanup are two appropriate actions. Doing nothing is not an appropriate action. The licensee would be cited for failure to take emergency action following loss of control of material.

RADIOACTIVE GASES

Comment: Must the licensee initially open volatiles and radioactive gases in a fume hood?

Response: No. The licensee is required to store those materials in a fume hood or within a double container designed to prevent disbursement.

Comment: The Draft Regulatory Guide that you have prepared, in Appendix Q, refers to measuring xenon concentrations with a film badge. This is questionable as an acceptable monitoring procedure.

Response: The appendix talked about measuring worker dose from noble gas concentrations with a film badge. ~~The permissible concentration of xenon is based on external dose due to submersion, a quantity that is measured by a film badge.~~

Comment: Are you no longer concerned with ventilation rates in xenon rooms?

Response: A new section has been added that requires calculations to establish room evacuation times for all rooms where gas is used or stored. The requirement is needed because normal room ventilation rates are usually not sufficient to ensure a timely clearance of leaked or spilled gas.

A recent manuscript suggested that some film badges are not capable of making satisfactory measurements. Therefore, the reference has been removed.

MOBILE NUCLEAR MEDICINE SERVICES

Comment: You should allow mobile services to carry multi-dose vials. The vials are just as safe to transport as unit dosage syringes.

Response: Done. A licensee pointed out that a unit dosage may be outside the desired prescription range if the mobile van arrives early or late. If the client had an extra patient, the van would not have a dosage on hand for the patient.

Comment: You proposed to allow mobile services to have licensed hospitals as clients. Is this a change in materials licensing policy? NRC usually doesn't allow this.

Response: The permission has been withdrawn from this draft. If an inspector were to find uncontrolled material, he would not be able to determine who was responsible for its loss.

Comment: You require that the mobile service consider ~~his~~ the area of use at the client's facility to be an unrestricted area. If ~~he can't control~~ the area can't be controlled, ~~he~~ the licensee shouldn't ~~be allowed to~~ use the material.

Response: A full-time employee of the client such as a housekeeper or security guard may not be aware of the mobile service contract, and may be reluctant to follow safety instructions given by an outsider. Therefore, the mobile service must exercise greater control than that required of in-house nuclear medicine services. Thus the wording, "Client facilities should be considered as unrestricted areas." No change has been made.

Comment: The proposal requires that only the management of a client facility be allowed to request services from a mobile nuclear medicine service. However, service might be supplied if a physician at a client hospital requested service without his management's approval.

Response: This would only happen if the physician misrepresented himself as management, or if the mobile licensee ignored the regulation that requires him to have on hand an authorization letter from the client's management.

Comment: You should allow mobile services to use I-131 for treating hyperthyroidism, instead of restricting them to only diagnostic work.

Response: The drafting committee purposely omitted all radiopharmaceutical therapy procedures for mobile service licenses. If there is a need, it may be licensed on a case-by-case basis if accompanied by a license condition that exempts the licensee from Section 35.35 and also identifies the authorized therapeutic radiopharmaceuticals.

BRACHYTHERAPY

Comment: You should require that brachytherapy sources be manipulated with remote handling tools.

Response: No. The licensee is required to follow the safety and handling instructions supplied with the source and approved by NRC or an Agreement State. Not all brachytherapy sources need to be handled with a remote handling tool.

Comment: Brachytherapy sources aren't always promptly returned to storage. The licensee should count them at the time they are removed from the patient to be sure all of them have been removed.

Response: Such a requirement might be inferred to require counting them in the patient's room. It is not common practice to take a source out of one patient and immediately put it in another patient; given that, then wherever a source is taken to after removal becomes an area of storage, and a count must be made.

Comment: Why do you require licensees to survey once each quarter around brachytherapy storage areas?

Response: If the number of brachytherapy sources in the inventory increases, or if sources have not been properly stored, dose rates around the storage area may go over permissible limits.

Comment: Brachytherapy users also need a low range meter to make a quarterly storage area survey as required in the proposed Section 35.59(h).

Response: A low range survey meter is not appropriate for this kind of survey. The meter that the licensee must have on hand is needed to survey around each patient's room after the brachytherapy sources have been implanted.

Comment: Licensees should be required to survey with a low rage meter the area where low activity brachytherapy seeds are implanted in case they are lost in the surgical dressing.

Response: The survey is required, but the low range meter is not required. The lowest scale for most high range meters is either 0-1 or 0-3mR/hr. This

is sufficiently sensitive to survey the few square meters of space where sources might be lost.

TELETHERAPY

Comment: Require both low- and high-level survey meters for teletherapy licensees. If the radioactive source gets stuck in the "on" position in a teletherapy unit, a GM survey meter may saturate or pin the indicator.
Response: No. For day-to-day use, a survey meter is needed only as a go/no go indicator in case the teletherapy room monitor fails. In case of a stuck source, the dose rate near the entrance will still be low enough to be measured with either kind of survey meter. Then, the next steps are to remove the patient and secure the room, not to measure the dose rates around the teletherapy unit.

Comment: You should require that technicians continuously observe teletherapy patients.
Response: No. Such a requirement appears to be unenforceable, and better mandated by the physician for purpose of patient care.

Comment: You should require that the licensee terminate teletherapy treatments if the patient viewing system breaks.
Response: No. The viewing system allows the technologist to monitor the patient's position with respect to the treatment beam so he can terminate the treatment if the patient moves. The decision on whether to interrupt patient care because of a broken viewing system is properly placed on the physician's shoulders. If a patient is cooperative, enforcing such a requirement may place the patient at a greater, not a lesser, risk because you would be denying him his cancer treatments.

Comment: A new teletherapy calibration procedure was recently published. You should require that licensees use the new procedure.
Response: The regulation has been revised to allow licensees to use the new calibration protocol to meet the regulatory requirement. However, not all licensees have the equipment needed to follow the new calibration protocol. Therefore, either is allowed.

should be measured

<u>Comment</u>: You say that ~~to measure~~ radiation "quantities" around new teletherapy units. Don't you mean "levels"?

<u>Response</u>: No. The word "level" connotes a continous or instantaneous rate. The regulation actually limits the total amount of radiation (millirems) that has been integrated over a period of time at a point. That concept is better characterized as a quantity.

<u>Comment</u>: Licensees should mount the teletherapy radiation monitor device so that it can be seen without entering the room. Otherwise, you have to be in the room with the teletherapy beam on to check the monitor.

<u>Response</u>: The monitor should be mounted so that you see it when you enter the room and therefore know if you are entering a safe or unsafe room. The monitor can be checked each morning with a hand-held check source in those cases in which it cannot be viewed either by a closed circuit television or through a viewing window.

BYPRODUCT MATERIAL SUPPLIERS

Comment: Delete the authorization for drugs that have been approved by a Radioactive Drug Research Committee.

Response: Done. Further review has indicated that only a few licensees are currently authorized to use Radioactive Drug Research Committee authorizations. Applicants will be notified in the regulatory guide that they may be request specific authorization to use radiopharmaceuticals that have been reviewed and approved for medical use by an FDA-approved Radioactive Drug Research Committee.

Comment: Many of the listed radiopharmaceuticals are no longer used routinely. Therefore they should not be listed.

Response: Mercury-203 has been withdrawn because the radiation dose is much higher and the imaging quality much lower than for mercury-197. Otherwise, if the Food and Drug Administration has approved a radiopharmaceutical for safety and efficacy, and if the radiopharmaceutical is not hazardous to workers or the public, to not allow its use would be an unnecessary intrusion into the practice of medicine.

Comment: Since you also control suppliers, couldn't you just list permissible isotopes and type of use (i.e., "imaging"). Then, when a new pharmaceutical is developed, you would just have to amend the suppliers' package inserts.

Response: We have considered this. However, policy to date for all materials (not just medical use materials) has been to control both the distributor and the purchaser. We will continue to research the effects of the suggested change, but as a separate project. The purpose of the current project is to codify our current requirements.

Comment: Can a hospital supply other hospitals with materials without being licensed as a nuclear pharmacy?

Response: This is not the usual case. However, if the license reviewer believes the arrangement is safe and in the public interest, an exception from the authorized supplier requirement can be made.

TRAINING AND EXPERIENCE

Comment: There is no assurance of adequacy of authorized users' training. Can NRC accredit sources of instruction or examine proposed authorized users?
Response: The problem is not unique to medical users, but rather applies to all industries under NRC jurisdiction. It should be settled as a separate policy issue, not as a minor issue in this proposed rulemaking. No changes have beem made.

Comment: Can license reviewers approve new authorized users if their training meets Subpart J standards?
Response: Yes. The application instructions have been clarified.

Comment: Can physicians be authorized even though they don't meet the training and experience standards to "nth" degree?
Response: Yes. Exceptions are allowed pursuant to Section 35.29.

Comment: The 8 hours of training required of podiatrists is insufficient.
Response: For the one device they would be authorized to use, the amount of training appears to be sufficient. The 8-hour standard was developed in a separate project and was simply adopted here.

Comment: Only properly trained individuals should be allowed to transport materials.
Response: The Department of Transportation regulations apply to the transportation of byproduct material. No changes have been made.

Comment: Why do you want to list the radiation therapy physicist on the license? We don't do that now.
Response: In light of an incident a few years ago, in which several therapy misadministrations were precipitated by the physicist's inadequate training and experience, it would be inconsistent to require identification of the authorized user and radiation safety officer on the license, but not the radiation therapy physicist.

MISCELLANY

Comment: Because of the size and specificity of this proposal, a 120-day comment period is needed.

Response: Done.

Comment: You should clarify that persons who are now working under a general license authorized by Section 35.31, who you say will be exempt from fees in the future, will be restricted to the materials and uses allowed under Section 35.31 when they receive their specific license. If they want to use more material than is allowed by the general license, they should be required to pay application, amendment, renewal, and inspection fees just like everyone else.

Response: Done.

Comment: The current draft of the proposed Form NRC-313 is worded to indicate that the licensee may not change procedures without NRC approval. This conflicts with the Commission paper.

Response: The conflicting sentence on the form has been deleted.

Comment: You should provide more guidance for small research programs.

Response: No. Refer requestors to NRC Regulatory Guides 10.2, 10.5, and 10.7.

Comment: How much will it cost to convert in vitro general licenses to specific licenses? Currently, persons who hold a medical license are authorized, by the regulation, to also do in vitro work.

Response: Nothing. In vitro general licensees are unaffected by the revision. Human use licensees who are doing in vitro work under the provision of current Section 35.14(c) are grandfathered by a conforming amendment until renewal time. New and renewal applicants will have to request the in vitro materials as a separate single line item.

Comment: The February 1984 draft that was distributed for comment would allow the licensee to identify provisional authorized users (authorized users who have authorization already by virtue of being listed on another person's

license), and allow them to work as authorized users until an amendment or renewal request was submitted. A provisional authorized user might do procedures for which he has not been authorized, either by misunderstanding or intent, for several years instead of just for 60 days as permitted under the current visiting authorized user license condition. Several authorized users may come and go without notice to the regulatory agency.

Response: Ignorance of the law is not an acceptable excuse. If a physician can't understand limits on his scope of use, there is little assurance that he can understand the limits on its duration, whether he is called a provisional authorized user or a visiting authorized user. However, given the risk of loss of management control in situations where key users are regularly replaced, and given the unclear status of the occasional visiting user, who supervises use for one day, compared to the full-time user who should take an active part in the safety program, the 60 day limit has been reinstated.

Comment: In drafting a standard for release of patients who contain byproduct material, you have switched from the current requirement that patients who contain more than 30 millicuries not be released to a standard based on the dose rate at a distance from the patient. Do you mean that the dose rate at a distance is the only way to measure the residual activity in a patient who is about to be released?

Response: There are only a few ways to determine how much radioactivity is in a patient. Measuring of the amount of material that has been excreted and subtracting it from the amount administered may be more hazardous to the worker than other methods. Retention calculations are based on healthy standard man averages, not the pharmacokinetics of ~~observed in~~ the ill individual patient. The dose rate measurement at a distance is meaningful, inexpensive, easy, and relevant. The licensee may select either the dose rate at a distance or the activity retained as his release standard. Other suggestions for patient release standards are welcome.

Comment: Changes in NRC regulations will affect Agreement State and NARM State programs.

Response: The NRC is aware of the fact that the effects of its policy sometimes go beyond its own jurisdiction. However, the probability of extramural effects cannot to stay the NRC from doing its job as it sees best.

NRC also has a mandate from Congress that must be met with finite resources. Therefore,

Comment: You should require that permanent implant patients be given radiation safety instructions before they leave the hospital.
Response: No. In the two instances where there is a clear hazard to the public and the patient's family members, permanent implant and radiopharmaceutical therapy, the regulation would not allow release of the patient above specified radiation levels. Below those levels, personal circumstances and needs of the patient and his family must be balanced against the radiation dose to the family and the public. The physician is best suited to determine what instructions should be given and to whom.

Comment: In the enforcement paragraph of the statement of considerations you discuss enforcement against an individual. You normally cite the licensee. Has policy changed?
Response: No. The paragraph said that licensees may be cited for several types of infraction. The closing sentence notes that if a person uses material and is neither named on a license nor working under supervision, then that person will be cited.

Comment: For diagnostic radiopharmaceuticals, will you limit the inventory amount to a specified number of millicuries, or continue to use the phrase "as needed" on the license.
Response: We will continue to allow inventories "as needed" for diagnostic radiopharmaceuticals.

Comment: You should delete incorrect dosage as a misadministration.
Response: It appears that the Commission wants to deal with misadministration as a separate issue. The current wording was purposely retained.

Comment: Why don't you allow decay of radioactive waste with a half life longer than 65 days, or decay for fewer than 10 half lives?
Response: The 65 day, 10 half-life limit appears to have met most of the licensees' needs. A sentence has been added to the statement of considerations noting that the Commission will consider, on a case-by-case basis, applicants' requests for longer-lived material, or for a shorter decay period.

SUMMARY OF HUMAN USE LICENSEE CITATIONS ISSUED IN 1982

This table is a summary, by category, of all the citations issued to human use licensees in 1982 for violation of (1) NRC regulations, (2) NRC orders, (3) license conditions, or (4) commitments made in the license application.

The raw data was supplied by the Division of Fuel Facilities, Materials and Safeguards, Office of Inspection and Enforcement. It is routinely collected as part of their inspection and enforcement program.

The left-most column is the legal basis for the citation. It might be a violation of: a section of the regulations or clear violation of the license, for example adding authorized users without NRC approval, or using more material than is allowed by the license; an order or conditioned permission mailed to licensees in response to a generic safety problem (LTR); a violation of a standard license condition (SLC); or a violation of the license condition that requires the licensee to use material in accord with representations made in the application (APPL), that perhaps included a promise that a certain regulatory guide (RG) procedure would be used. The second column shows the legal basis for the citation under the proposed regulation. The third column is a short description of the citation topic, and the fourth column notes the number of citations issued to human use licensees in 1982.

Of the 1240 citations issued in 1982 as a result of conducting 1568 medical inspections that year, 1197 citations (96.5%) would continue to be citations under the proposed regulations. Furthermore, due to the completeness of the proposed regulation, there may be a much clearer legal basis for more types of citations that could not be issued in the past.

Note that most of the citations are not for items that present an immediate hazard to a worker or the public, but rather are early signs of safety program degradation that are easily corrected.

OLD	NEW	TOPIC	NUMBER
		LICENSE REQUIRED	
30.3	30.3	license required	2
30.34c	30.34c	use only at location on license	19
35.2	35.2	license required	1
35.14b2	35.200 et al.	use only material listed in regs	2
35.14c	35.2	unauthorized user	1
35.14d	35.58	use only calibration sources listed in regs	4
RG10.8D	35.58 et al.	use proper, authorized calibration sources	10
SLC	35.2, 35.17	license or amendment required	22
APPL	35.17	unauthorized RSO	1
SLC	35.100 et al.	use only for authorized purposes	1
APPL	35.38	unauthorized users	1
		POSTINGS	
19.11a	19.11a	post regs	12
19.11b	19.11b	post other documents	7
19.11c	19.11c	post NRC Form 5	11
19.11d	19.11d	post conspicuously	6
		TRAIN WORKERS	
19.12	19.12	train workers	31
SLC	35.610	practice teletherapy emergency plan	1
		WORKER AND PUBLIC DOSE LIMITS	
20.101a	20.101a	worker dose limits	12
20.102a	20.102a	determine prior dose	1
20.103	20.103	limit airborne concentrations	2
20.105b	20.105b	2 mR/hr and 100 mR/wk	23
20.108	20.108	make bioassays	17
20.202	20.202	supply personnel monitors	52
20.207a	20.207a	control dose in unrestricted areas	31
20.401a	20.401a	keep worker dose records	14
20.405a	20.405a	report worker overexposures	2
20.407	20.407	report worker dose summary	3
RG10.8L	20.202	supply personnel monitors	1
		EQUIPMENT	
APPL	35.120 et al.	have a survey meter	12
RG10.8D1	35.51	calibrate survey meters	39
RG10.8D2	35.50	dose calibrator geometry test	16
RG10.8D2	35.50	dose calibrator accuracy test	28
RG10.8D2	35.50	dose calibrator linearity test	128
RG10.8D2	35.50	dose calibrator constancy check	61
RG10.8D2	35.50	use proper dose calibrator test sources	1

OLD	NEW	TOPIC	NUMBER
		PACKAGE RECEIPT	
20.205b	20.205b	monitor packages	10
30.51a	30.51a	keep records of receipt and disposal	10
30.51c3	30.51c3	keep records 5 years	2
RG10.8G	35.31	establish an ordering procedure	2
		MATERIALS CONTROL	
20.207b	20.207b	watch material in unrestricted areas	9
20.402a	20.402a	report loss or theft immediately	1
20.402b	20.402b	report loss or theft in 30 days	1
20.403b	20.403b	report incidents	1
RG10.8M	35.90, 35.205	store and control gases	1
		SAFETY MEASURES	
20.203	20.203	use signs and labels	16
20.203f	20.203f	use labels for containers	3
RG10.8G	NC	wear gloves	(22)
RG10.8G	NC	monitor hands	(3)
RG10.8G	35.60	use syringe shields	16
RG10.8G	NC	wear lab coats	(4)
RG10.8G	NC	don't eat or drink in lab	(14)
		DOSAGES TO PATIENTS	
35.14b4	35.204	measure Mo-99 concentration	16
35.14b6	35.100, 35.200	follow package insert	14
35.43	35.37	report misadministrations	3
RG10.8G	35.53	measure dosages	4
APPL	35.50	use a dose calibrator	5
		SURVEYS	
20.201a	20.201a	make precautionary surveys	37
20.201b	20.201b	make necessary surveys	151
20.401b	35.401b	keep survey and monitor records	54
35.14b5iii	35.404	survey implant patients	1
35.25	35.644	survey new teletherapy units	5
RG10.8I	35.70	make daily surveys	80
RG10.8I	35.70	make weekly surveys	11
RG10.8I	35.70	keep survey records	3
		WASTE DISPOSAL	
20.301	20.301	authorized methods	21
20.302	20.302	get permission for other methods	1
20.303	20.303	sewerage release limits	1
20.305	20.305	don't incinerate	2
20.401c3	20.401c3	keep disposal records	4
RG10.8J	35.92	decay-in-storage method	2

OLD	NEW	TOPIC	NUMBER
		SEALED SOURCES	
35.14e	35.59e	test for leakage	55
35.14e	35.59c	record leakage in "microcuries"	5
35.14f	35.59g	inventory quarterly	8
		TELETHERAPY CALIBRATIONS AND CHECKS	
35.21a	35.632	calibrate if output is off 5%	2
35.21a	35.632a	calibrate after source drawer repair	4
35.21b	35.632d	calibration procedure	6
35.22	35.633	make spot checks	4
35.22	35.633	check timer accuracy	2
35.22b	35.633b	check field/light coincidence	2
35.22b	35.633b	compare measured to calculated output	3
35.25a	35.644	keep calibration records	3
		TELETHERAPY EQUIPMENT AND PERSONNEL	
35.23a	35.630a	have dosimetry equipment	1
35.24	35.961	qualified expert training	6
35.25c	35.961	qualified expert training records	1
LTR	35.615	install radiation monitor in treatment room	3
SLC	35.615	use doors and interlocks	1
		TRANSPORTATION	
71.5a	71.5a	follow DOT regulations	11
		ADMINISTRATIVE MATTERS	
RG10.8B	35.32a	have a radiation safety committee	15
RG10.80	35.30	review worker doses quarterly	2
RG10.80	35.30	review materials program annually	1
		Total citations issued in 1982:	1240
		Citations not covered (NC) in proposal:	39
		Citations covered in proposal:	1201

Document Name:
CP 10 CFR 35 MEDICAL USE

AA73-1
PDR
D.12

Requestor's ID:
JPK

Author's Name:
McELROY

Document Comments:
12/28/84 - return this sheet when submitting corrections

12/27 - 12/28: Part 35 returned from EDO for addition of "Summary" on p. 1 of CP and for concurrence copy of CP.

12/28/84 Part 35 to be {"blue-bagged" or handcarried back to EDO today.

For: The Commissioners

From: William J. Dircks
Executive Director for Operations

Subject: PROPOSED REVISION OF 10 CFR PART 35 "MEDICAL USE OF BYPRODUCT MATERIAL"

Purpose: To obtain Commission approval of a notice of proposed rulemaking.

Category: This paper covers a significant policy question concerning the licensing and regulation of byproduct materials.

Issue: Consolidation of requirements that apply to the medical use of byproduct materials, and provision for flexibility for licensees in meeting safety requirements.

Insert Summary — see attached for text

Background: The phrase "medical use" is used to refer to the intentional irradiation of humans by medical practitioners for diagnosis or treatment of disease. There are about 2200 hospitals and 300 physicians in private practice who are NRC licensees. In 1983, NRC received 143 applications for new licenses, 647 renewal applications, and 1,772 amendment applications for a total of 2,562 requested licensing actions.

In an earlier Commission Paper (SECY-83-62), the staff recommended a complete revision of Part 35, "Human Uses of Byproduct Material." The two key features of that paper were:

- Consolidation of the medical radiation safety requirements that are now dispersed throughout existing regulations, branch policy positions, standard license conditions, and regulatory guidance, and

- Allowance for greater flexibility under the license, thereby reducing the number of amendment requests.

Contact:
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Summary: The proposed rule codifies the regulations and previously-used licensing policies and practices concerning the medical uses of radioactive materials. The proposed rule has been redrafted in accordance with the ~~Commi~~ directives provided by the Commission in 1983 and is consistent with the Commission's 1984 Policy and Planning Guidance. The central issue is whether a regulatory agency must specifically approve minor changes in a licensee's day-to-day radiation safety program. NRC Offices and Regions concur with the proposed level of flexibility that would be provided to licensees. Some Agreement State representatives do not. If adopted, ~~the~~ resource requirements for both NRC and licensees are expected to be reduced.