

McGarry

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REVISION OF PART 35

PLANNED OUTLINE OF COMPLETE PACKAGE THAT WILL BE FORWARDED TO MR. DAVIS
FOR TRANSMITTAL TO MR. DIRCKS.

1. Notes of general interest and clarification for reviewers.
2. Davis to Dircks memo. One-paragraph summary.
3. Commission Paper (Dircks to Commission memo). Lengthy summary.
 - a. Overview of industry and current regulatory program.
 - b. Background, including features of SECY-83-62 and Commission instructions in response to it.
 - c. Decision 1: Revise the regulations.
 - i. Options
 - ii. Discussion
 - d. Decision 2: Revise the licensing program.
 - i. Options
 - ii. Discussion
 - e. Effects.
 - f. Recommendations.
 - g. Notes (administrative notations)

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4. Enclosure 1: Federal Register Notice.
 - a. One-paragraph Summary.
 - b. By-product Material in Medicine.
 - i. Use for Patient Care
 - ii. State and Federal Regulation
 - c. NRC's Regulatory Program
 - i. Current Licensing Practice
 - ii. Problems With Current Practice
 - d. Proposed Revision of the Regulatory Program
 - i. Overview
 - ii. Codification of Requirements in the Regulations
 - iii. License Application, Issuance, and Authority and Responsibility
 - iv. Enforcement
 - v. Amendments
 - vi. Summary of Changes Proposed in the Regulatory Program
 - e. Notes
 - i. Word Usage
 - ii. Records Retention
 - iii. Effect on Broad Licensees
 - iv. Transition Policy
 - f. Discussion of Proposed Regulations
 - g. Derivation Table
 - h. Administrative Statements (Administrivia)
 - i. Part 35-Human Use of Byproduct Material
 - j. Conforming Amendments

5. Enclosure 2: Memo Chilk to Dircks dated June 23, 1983.
6. Enclosure 3: Periodic and Systematic Review.
7. Enclosure 4: Regulatory Analysis.
 - a. Alternatives.
 - i. Current
 - ii. Proposed
 - iii. Hybrid "plan"
 - b. Cost of selected alternative to various hypothetical licensees
 - i. Private practice
 - ii. Hospital with a diagnostic service
 - iii. Hospital with a diagnostic service and radiopharmaceutical therapy
 - iv. Hospital with a diagnostic service and brachytherapy
 - v. Hospital with a diagnostic service and teletherapy
 - vi. Mobile nuclear medicine service
8. Enclosure 5: Draft Public Announcement.
9. Enclosure 6: Draft Congressional Letter.
10. Enclosure 7: Environmental Impact Analysis.
11. Enclosure 8: Summary table of Comments on content of SECY-83-62 regulation.
 - a. Suggestions for additional requirements
 - b. Drafting committee response

12. Enclosure 9: Summary of citations issued to human use licensees in 1982

- a. List of citations and their legal basis
- b. How the citations would be enforced under the proposed regulatory program

14. Enclosure 10: Regulatory Guide 10.8

- a. Instructions for application
- b. Appendices and model procedures

NOTES OF GENERAL INTEREST AND CLARIFICATION FOR REVIEWERS

1. Contrary to the Part 35 strategy plan element 1 that said "only editorial and non-substantive changes" would be made to the regulation, several changes that some reviewers may consider substantive have been made because the individuals who suggested the changes were able to support their suggestions with clear reference to health and safety.
2. I have tried to indicate where all changes were made in the draft Federal Register Notice dated 12 07 83 that some of you have seen.
3. The patient excreta exemption that is in the current Part 20 has not been included because it will require an extensive environmental impact analysis. This problem will be handled at a later date as a separate rulemaking.
4. There will be no "tie-down" license condition. The regulation requires that authorized users be named on the license. See 35.15. The regulation requires that the licensee follow his own procedures. See 35.31b2. The regulation allows licensees to modify procedures with the advice and consent of the RSO and management. See 35.31b3 and 35.32b4.
5. The 12 07 83 draft that some of you have seen indicated that there would be a conforming amendment to Part 71-Transportation. Currently DOT, and therefore NRC, exempts physicians from transportation regulations. The plan was to expand this exemption, for the sake of consistency, to supervised individuals; this would have been done as a joint rulemaking with DOT. Background meetings indicate that DOT staff is divided on the propriety of this exemption. Therefore, this issue may be handled at a later date as a separate rulemaking.
6. There is a conforming amendment to §31.11 that grandfathers human use licensees who are also doing in vitro work under §35.14(c). (Many people have thought that nuclear medicine clinics that are doing in vitro work would have to file a form NRC-483.)

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DRAFT

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: PROPOSED REVISION OF PART 35

(retitled "Medical Use of Byproduct Material")

The staff has prepared a proposed revision of 10 CFR Part 35, "Human Use of Byproduct Material" for ^{public} comment. The proposed revision is based on SECY-83-62 and the Commission's response to that proposal. Individuals from NMSS, IE, RI, RII, RIII, RIV, RV, RES, OPE, SP, ADM, ELD, and two Agreement States helped ^{to comment on} ~~prepare~~ this proposal. *The Cost Assessment Group has reviewed the regulatory analysis and their comments have been resolved.*

The following offices have concurred with the proposal, indicating that they have no objection to publishing the proposed revision for comment: [fill in]

A. Most of the Agreement States and some NRC staff is not agree with the proposed licensing system that is part of the proposal. A range of alternatives and a discussion of each is provided for the Commissioners' consideration.

John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

Encl: Proposed revision
of 10 CFR Part 35

DRAFT COMMISSION PAPER

For: The Commissioners

From: William J. Dircks, Executive Director for Operations

Subject: PROPOSED REVISION OF 10 CFR PART 35 "^{Medical}~~HUMAN~~ 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} ~~on~~ licensing ^{and regulation} of byproduct materials.

Issue: Revision of the ~~human use~~ regulations and change in the method of licensing ^{the} ~~of human~~ use of byproduct material. ^{in the practice of medicine}

Overview: The phrase "^{medical}~~human~~ 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 ~~human~~ ^{medical} use and to change the method by which persons are licensed for ~~human~~ ^{medical} use of byproduct material. The staff ~~had~~ 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 from headquarters and regional staff and the Agreement States that were received.

The NRC issues licenses to both ^{hospitals} ~~medical facilities~~ and ^{physicians in} private practice ~~physicians~~ for the use of byproduct materials in ^{medical} ~~medical~~ diagnosis and treatment of humans. ^{disease} During the past three decades, ^{of byproduct material} use has

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CP 10 CFR 35

grown annually at a rate of about 15 percent. There are currently about 2200 hospitals and ³400 ¹⁴³private practice physicians who are NRC licensees. In 198³1, NRC staff received ¹⁴³73 applications for new licenses, ⁶⁴⁷224 renewal applications, and ¹⁷⁷²1,303 amendment applications for a total of ²⁵⁶²1,620 requested licensing actions.

Most ^{hospitals} ~~medical institutions~~ and private practice physicians operate under a specific license which authorizes many types of byproduct materials ^{use} ~~procedures~~. An application is made on a standard NRC form ^{which is} and supplemented ^{by} with 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} ~~procedures~~ 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} ~~human~~ 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. ~~The drafting committee~~ ^{It} tried to incorporate into a single codified regulation all the standards that apply specifically to the ^{medical} ~~human~~ 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} ~~drafting committee~~ 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, ~~as~~ ^{was} the second key feature, ~~the drafting committee recommended~~ ^{would} that applicants 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. ^{(H)PS} The applicant would ^{have} merely certify ^{ed} that adequate procedures had been developed. Also, ~~since~~ ^{because} training and experience requirements would now appear in the regulations, applicant authorized users would ^{have} simply ~~be allowed to~~ certify ^{ed} 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 ^{en}sure 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} ~~drafting committee~~ has collected and analyzed ^{many} ~~technical comments~~ that were received from headquarters and regional staff and the Agreement States. Many ^{of them} suggestions have been incorporated in the proposed regulation. In ^{some} many cases the ~~committee~~ did not believe the suggestions could ^{not} stand the test of need based on public health and safety. ^{those have not been incorporated} A summary ~~table of technical~~ ^{of} comments and their resolution is attached ^{as} (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 ^{for the sake of consistency in the proposed regulation}, 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 & compares} that individual's qualifications ^{in comparison with} to 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} ~~these~~ experts hold certification from a specialty board that the staff proposes to recognize as evidence of adequate training and experience.

13 (A) { 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. }

"(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 public comment, or will be allowed to submit an alternative procedure for review. ~~Many new model procedures have been developed for applicants' consideration.~~) ^{In order} However, to allow each licensee to make prompt use of new safety methods and to adjust procedures to meet new needs caused by changes in need for patient care services or patient load, licensees will be free to modify their procedures without NRC review or approval as long as they meet the requirements of the regulations. At an ^{hospital} institution, the Radiation Safety Committee must review and approve a ^{change} modified procedure before it may be implemented. At ^{private practice} non-institution facilities, the ^{Radiation Safety Officer} RSO and management must review and approve ^{changes} modifications. ^{insert p 5a, b} (This may be compared to technical specifications that apply to reactor licensees. Within the context and requirements of the regulations, licensees would be free to make ~~changes in procedural detail to meet changed operating needs.~~) ^{PA} 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

4 This regulatory concept is similar to NRC's method of regulating power reactors. Regulatory guide 1.33 lists, by title, many management, facility 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 ~~how long the facility may continue to operate in case of under~~ ^{(3) which} degraded conditions require ~~must~~ shut down. 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} ~~record~~ of each ^{proposed} change. ~~The records must be retained for the duration of the license.~~

5 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) conditions that must be implemented in case of degraded conditions (for example, repair or 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 ^{norms that will be turned over for use} unrestricted areas). The licensee would be allowed to make changes in the facility and 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.

(radiation safety)

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} ~~(supported by training and experience; summaries)~~
- (b) new types of use ^(for example, adding radiopharmaceuticals therapy to a license that authorizes diagnostic radiopharmaceuticals) ~~(supported by 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) ~~(supported by the specific procedure needed for the method of use)~~ and
- (d) new locations of use ^{locations} ~~(supported by a complete new application if the base of operation changes, or simply the additional address if satellite operations were approved on the original license).~~

A ~~section on enforcement~~ policy ~~during the transition period~~ was also added.

Proposal:

The staff ^{recommends} ~~is suggesting~~ that the Commission publish for public comment a proposed revision of Part 35 and a ^{description of a} new method for licensing ^{the medical} ~~human~~ use of byproduct material. Three alternative courses for the Commission are discussed below.

Alternative 1: Take no action.

Alternative 2: Publish the proposed revision of Part 35 attached as Enclosure 1.

Alternative 3: Publish the proposed revision of Part 35 after modifying the preamble ^{and the regulations} to require that ^{applicants and} licensees submit ~~procedural modifications~~ ^{their radiation safety programs and program changes} for NRC review and approval.

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} ~~human~~ use of by-product materials. The Commission "approved the consolidation of essential safety elements" (Enclosure 2). ~~The staff is not aware of~~ *Most individuals who have reviewed the draft recommend adoption of the* ~~anyone who would recommend retaining the current Part 35 over the~~ proposed revision *of the regulatory text.*

Effect of Selecting Alternative 1:

Because the current Part 35 does not contain all the ^{essential} ~~critical~~ safety elements for ^{medical} ~~human~~ 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 alternative^s, but is more costly to both NRC and licensees than Alternative ^{2, and 3}, and denies the industry the benefit of a clear, consolidated codification of the ^{medical use requirements that is} ~~regulations~~ offered by both of the other alternatives. It is difficult to maintain standardization under this scheme because the legal basis for controlling a licensee ^{is the licensee's application} ~~is the licensee's application rather than the regulations.~~ *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~~ ^{all for pre-} ~~licensing review and approval.~~ However, ^{make changes or} ~~the licensee~~ ^{modify} would be free to facilities and procedures or replace equipment with approval of the Radiation Safety Officer (RSO) and management or, at ^{hospital} ~~an institution~~, ^{licensee's}

(B)

storage,
that described controls on the receipt, [↓] use, and disposal
of byproduct material, equipment calibrations and checks,
personnel training, ^{and} general safety measures. A license
reviewer would review the application to assure that the
applicant had adequate training and experience,
facilities and equipment, and radiation safety procedures.
Then the license would be issued.

In either case
the RSO and the Radiation Safety Committee (RSC), ~~as long as the modifications~~ conform with the requirements of the regulations.

changes would have to

do not have the training?
Proponents: The proposed licensing method provides for agency review before allowing a program to begin. The implementation of ~~a safe~~ *the* program requires the support of the individuals who have special safety training. (If ~~that training is not evident~~ *will* in the key individuals, the license ~~should not be issued.~~ *would mean*) Issuance of the license ~~should stand as evidence~~ *that* the agency has found the applicant trained to know safe from unsafe and legal from illegal, and that the applicant is ~~sufficiently~~ *equipped* to handle material safely within the scope of use permitted by the license. Licensure would connote that those key individuals are also competent to ~~recognize and implement procedure modifications~~ *make changes* that provide a level of safety consistent with the requirements of the regulations, and to select replacement equipment and to ~~modify~~ *change* facilities to the extent consistent with those requirements, ~~for purpose of~~ *or those changes which might be made for* improved patient care or safety, or reduced cost. ~~Such modifications could not be made capriciously, because they~~ *continue to* 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 new site-specific needs. License processing would be compatible with both hard copy and computer assisted information systems.

Objections Many

organizations with
Opponents: ~~Most~~ *Most* licensees are small facilities that are staffed by a few authorized user physicians, and technicians who have graduated from a two year formal training program or have been trained ~~at the facility~~ *on the job* by an authorized user or co-worker. They might employ a part-time consultant who is qualified to review changes ~~on the basis of safety~~ *radiation safety problems*, but that individual may not be aware of the ramifications implicit in a proposed ~~modification~~ *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 an ^{hospital} institution, 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 changes} modifications.

Effect of Selecting Alternative 2:

The staff recommends ^{below} 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 ^{its} those recommendations. Rather, the proposal would require some redirection of training, and other resources, and would probably be perceived as a change from the current policy of strict prescriptiveness to a policy granting more authority for the licensee who ^{must} handle material safely. ^{bears the responsibility for}

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

NRC

~~Under the decentralization program now completed, almost all human use~~
~~licensing~~ is now handled by individuals who also do ~~inspections~~. The
 training of ^{and} ~~these individuals~~ ^{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 ~~be trained to~~ recognize, in the field, ^{technical and management practices} ~~program elements~~ that do not meet the ^{regulatory} standards, required by the regulation. The inspector would have to be more thoroughly familiar with the regulation, but would no longer have to

^{be} familiarize himself with each licensee's ^{application} procedures before conducting an inspection. This would help to ensure uniformity among the regions. ^{Because} Since a major goal of the drafting committee was to prepare the statement of consideration, regulation, and regulatory guide in plain English, the staff expects fewer deficient applications.

Agreement States

Insert p 13a

~~AGREEMENT STATES: PLEASE PROVIDE TEXT FOR THIS SECTION.~~

Licensees

The requirements in the proposed regulation were taken from the current regulation, licensing policy, frequently used license conditions, and standards recommended in ~~the~~ ^{that are used} current regulatory guidance followed 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} modify their procedures. ~~Since more licensing guidance will now be available to the public,~~ licensees may have a clearer understanding of the regulatory process ^{the need for} in general and the applicable requirements.

Because of the consolidated statement of considerations that accompanies the proposed revisions

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. ~~Concerning costs or savings, since they are ultimately borne by the public,~~ 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.



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

Ref: SA/LAB

APR 26 1984

Mc Elroy
They believe that they will need to restrain inspectors, that the duration of each inspection will increase, and there may be increased worker doses.

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety
Office of Nuclear Material
Safety and Safeguards

FROM: G. Wayne Kerr, Director
Office of State Programs

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35 AND REGULATORY
GUIDE 10.8

We have reviewed the subject documents and we feel that the Agreement States' views should be summarized in the memorandum to Mr. Dircks and in the Commission paper as follows:

generally
"The Agreement States support the consolidation of various regulations and requirements pertaining to the medical use of *and* byproduct material into one document, ~~10 CFR Part 35.~~ They have provided some technical comments on the revised Part 35. The Agreement States strongly object to the ~~proposal of not requiring~~ licensees to follow the radiation safety procedures submitted with their application and permitting licensees to change radiation safety procedures without prior agency review and approval. Although the Part 35 revision would not be made a matter of *matters* compatibility because it deals with licensing ~~procedures~~, the States believe they will *be* receive pressure from their licensees to adopt the NRC system. A letter from the Chairman of the Agreement States setting forth the overall Agreement State viewpoint on this matter is enclosed (Enclosure)."

Our input for page 3 of enclosure 4 is provided in the enclosure to this memorandum along with some suggested changes to the Commission paper.

Copies of comments from individual States have been sent to Mr. McElroy as received. We expect to receive several more comments within the next week or so.

We recommend that you prepare a point by point analysis of the comments from the States showing which comments were accepted, which were

10a 16

Discussion of Alternative 3:

The NRC would retain the current licensing method under which an applicant submits: 1. evidence of training and experience, 2. a description of facilities and equipment, and 3. ^{radiation safety} procedures, ^{for review} all for review, and, ^{the licensee must} when licensed, ~~is required to~~ 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 accord^{ance} 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. This is the only way to assure public health and safety. ^{If the} When a question ^{is questioned} of a procedure's adequacy or completeness arises, the license reviewer ^{can} is able to 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

Opponents: The applicant has no public notice beforehand of whether a conservative or liberal reviewer will handle his application or how many rounds of deficiency letter responses will be needed to convince the reviewer that the applicant can handle material safely. ^{Because} Since the licensee is required to use material in accord^{ance} with the application and letters written in its support, to remain in compliance, ^{the licensee} he may not replace any equipment or service contractor or change any facility

described, or ^{change} modify any ^{radiation safety} procedure without requesting a license amendment. ^{This expensive, time-consuming} Such a detailed review of ^{re and amendments} an application does not assure safe use, but rather simply existence of adequate facilities, equipment, and ^{radiation safety} procedures. ^{safe} safe use can only be ^{assured} assured by ^{unannounced inspection} unannounced inspection. ^{The licensee's continued, active commitment to safety. This provides the best measure of that commitment.}

Most citations are not issued for failure to ^{to} 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. ~~Many experts believe that the critical~~ ^{essential} elements of a medical radiation safety program are well defined and easily codified. Therefore, ~~except in peculiar circumstances~~ ^{generally} there is ^{no} need to continue with case-by-case regulation.

^{That kind of} This licensing policy ^{may} require more extensive training for reviewers, ^{and} 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.}

Effect of Selecting Alternative 3:

The industry would benefit by having a clear, consolidated set of regulations. The ~~additional~~ ^{radiation safety} 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} ~~modification~~ would result in safer or more efficient operations, the ^{agency} ~~review~~ and approval requirement would prohibit ^{its} prompt adoption ~~of the modification~~.

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} ~~negative~~ 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 ~~60~~¹²⁰-day public comment period; X
- b. The staff conclusions, set forth in Enclosure 3, provide the analysis called for by the Periodic and Systematic Review of Regulations;
- 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} ~~contains~~ information collection requirements that are subject to review by OMB. Upon Commission affirmation, formal request for OMB review and clearance will be initiated;

→ The Paperwork Reduction Act of 1990 (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.

The Commissioners

- 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 upon request.

William J. Dircks
Executive Director for Operations

Enclosures:

1. Federal Register Notice of Proposed Rulemaking
Memo Chilk to Dircks dated June 23, 1983.
2. Periodic and Systematic Review
3. Regulatory Analysis
4. Draft Public Announcement
5. Draft Congressional Letter
6. Environmental Impact Analysis
7. Summary table of comments on content of SECY-83-62 regulation *and this proposal*
8. Summary table of human use licensee citations issued in 1982
9. Draft Regulatory Guide 10.8 *medical*

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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02/09/84

CP 10 CFR 35

~~1 - changed from 12 07 83 draft that was
distributed to cognizants - nrm~~

2 13 84
[7590-01]

DRAFT

NUCLEAR REGULATORY COMMISSION

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

MEDICAL
~~HUMAN~~ USES OF BYPRODUCT MATERIAL

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

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

By clarifying and consolidating all the essential ^{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 of byproduct materials.} human use, ~~thereby reducing the administrative burden on the licensee.~~ The proposed regulation also provides ~~the basis for allowing more~~ flexibility ^{for} in licensees' ^{to} updating ^{of} their day-to-day ^{radiation safety} procedures ~~that would conserve licensee and NRC resources.~~ The ~~proposed~~ ^{of} revision ^{to} the regulations would provide a more efficient method for regulating the medical uses of byproduct material.

DATE: Comment period expires (insert ¹²⁰60 days after FRN). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date.

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

Copies of the preliminary regulatory analysis and the comments received may be examined at the Commission's Public Document Room at 1717 H Street NW, Washington, D.C. Single copies of the preliminary regulatory analysis and environmental impact ^{assessment} are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)427-4052.
4108

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301)427-4052.
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 ~~and blood clots~~^{of}, assess organ function, or monitor the effectiveness of a treatment. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 15 to 20 million nuclear medicine procedures are performed in this country annually.

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

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a 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^{which} ~~which~~^{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.

and
State Federal Regulation

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

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 human use. The general license in ^{current} § 35.31 authorizes physicians to use small quantities of prepackaged, individual doses of ^{byproduct} radioactive materials. Physicians simply submit a registration form NRC-483 to NRC, *and* ^a validated copy with an ~~assigned~~ registration number is returned to the applicant.

Most medical institutions and physicians who use byproduct material need more byproduct material than can be ~~safely~~ ^{under the} permitted by a 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 ^{medical} types of human use, defined as Groups I-VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar ^{physician training and} radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. ~~All these~~ license ^{for a specific} applications, which 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.

NRC currently has about ^(2200 hospitals and 300 private practices) 2600 ^{physicians} medical licensees. In 1981, the NRC received ¹⁴³ 73 new applications for specific licenses, ⁶⁴⁷ 244 license renewal applications, and ¹⁷⁷² 1,303 license amendment requests for a total of ²⁵⁶² about 1,600 licensing actions. The NRC has issued 650 general licenses, and in 1981 ³ received ^{seventeen} five new applications.

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

Problems with Current Practice

The General License. ^{re} This program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. Issuing a general license for all in-vivo use of radioisotopes to qualified applicants would be the simplest approach for the NRC and licensees. Unfortunately, it would not assure an acceptable level of safety in the regulated industry.

→ The NRC ^{also} believes it is no longer ^{efficient} productive to issue ^{human use} ~~human use~~ ^{medical} general licenses. The tests authorized under § 35.31 have been superseded by new ^{or} in-vitro procedures with ~~more specificity~~ and greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for the general license. As noted

above, although NRC has on file 650 in-vivo general licenses under § 35.31, only ^{seventeen} ~~five~~ new applications were received by NRC in 1981³.

To determine the status of general license use, the staff performed a telephone survey ~~by attempting to contact~~ ^{2 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 NRC license. Because of the low level of use of the general license, the NRC has concluded that it no longer serves a useful role in licensing the ^{medical} ~~human~~ use of byproduct material.

The Specific License. Because of the ^{increased} potential radiation hazard to workers and the public, the specific license program incorporates three regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and ^{as 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} ~~critical~~ for the safe use of byproduct material. The revision of Part 35 incorporates those

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. [7590-01]
Application review practice must be conservative because the applications and license comprise the basis for regulatory control.

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} for NRC reviewers ~~to conclude~~ that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step ^{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 phone call for additional information. ²
~~because of the conservative licensing and review practices needed due to the incompleteness of the regulations.~~ Deficiency letters are costly for the NRC and the applicant and greatly increase the time ^{needed} ~~required~~ to complete licensing actions.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for ^{medical} ~~human~~ use of byproduct material in accordance with the ^{program} ~~procedures submitted with~~ ^{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 ~~adding authorized users~~ ^{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 ~~medical~~ regulatory process was appropriate during the evolution of the use of byproduct material in medicine. Radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, and physician training curricula had not been established, ^{and there were no formal training programs for nuclear medicine technologists.} Therefore, it was necessary ^{to regulate by} to review 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} human 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} need for various patient care services or ^{patient} patient load. The proposed revision of 10 CFR Part 35 is consistent with the Commission's general policy on ^{medical} human use of byproduct

General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also apply to Part 35 licensees. [7590-01]

material issued February 9, 1979 (44 FR 8242) ^{continue to} which ^{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} human use requirements in 10 CFR Part 35. These regulations would become the primary ^{means} ^{regulating} source of requirements for the ^{medical} human use of byproduct material, and would serve to regulate the day-to-day uses of radioisotopes for patient care. Licensees would not face significant new regulatory burdens because, in most cases, these requirements ^{are} currently ^{imposed} appear as license conditions, which must be met. Under the proposed revision, the license would authorize ^{medical} human use of byproduct materials for specified types of use. Licensees would be ~~regulated by the requirements for use codified in~~ ^{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

4 The NRC staff will continue to review the ^{applications} ~~procedures submitted by~~ the applicant in order to determine whether ^{the applicant's radiation safety program is} they are sufficient to meet the requirements of the regulations. A new revision of Regulatory

Guide 10.8, "Guide for the Preparation of Applications for Medical

Programs," will contain ^{Op 9a} model procedures that the applicant can use to

develop site-specific procedures, ^{Op 10 - Op 9a} to meet the requirements in the regulations. If the applicant's program is ^{appears} incomplete or inadequate, NRC

After completing the review,

(A)

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 training program; facilities and radiation safety equipment; the radiation safety program; and waste management.

(B)

instructions on the type and extent of information that must be submitted based on what byproduct materials the applicant has requested. It will also contain

(C)

If the applicant's response to the deficiency letter is satisfactory (or if no deficiency letter was needed), the license will be issued.

(E)

^{application}
(The applicant mails the completed application, with fee, to the NRC office identified on the form. ^{hp}

will ~~stop processing the application and will~~ issue a deficiency letter that describes ^{the} apparent shortcomings in the applicant's program and requests clarification. ^{or correction} Also ^{2 p 9} 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.) ^{to p 9}

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} need for patient care services or ⁱⁿ patient load, licensees will be free to modify their procedures without NRC review or approval, ~~after following 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} an institution, the Radiation Safety Committee ^{would} ~~must~~ review and approve a modified procedure before it ^{could} ~~may~~ be implemented. At non-institution facilities, the ^{RSO} and management ^{would} ~~must~~ review and approve ^{changes} ~~procedure modifications~~. This regulatory scheme would not incorporate the current requirements that licensees use byproduct material in accordance with the statements made in the application. This change would bring the regulatory scheme into accord with the general licensing requirements in §30.33(a) which address equipment and facilities and training and experience, but not procedures.

^{Insert p. 10a} The proposed regulations require specific training and experience for the use of material in each use group. Proposed authorized user (AU) physicians, ^{and} ^{FRSO's} Radiation Safety Officers (RSO) and qualified teletherapy calibration experts (QTCE; identified in current Part 35 as the Qualified Expert) will have to submit summaries of their training and experience. This is currently required for AU's and RSO's, but

This ^{proposed} ~~method~~ of 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.

would be a new requirement for QTCE's, 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. (Also consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individuals' training and experience with the assistance of its Advisory Committee on the Medical Use of Isotopes, and may issue the exemption as a license condition.)

(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)

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. ^{above} Use of material without authorization, either by license or by virtue of working under supervision, would be a violation of the regulations ^{that a} which would subject the ^{person} individual to an enforcement action.

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} operating procedures. Since the regulations will now contain sufficient prescriptive and performance criteria on which to base enforcement actions, the NRC would allow licensees to modify their procedures. This would eliminate the licensee's need to prepare a formal amendment request for the NRC and pay an amendment fee in order to make ^{changes} modifications in procedures. 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.} Title 10.

Four types of ^{program changes} amendments will still be required: ^{formal license} :

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

(3) New method of use. ^{Developments may occur but only one} Two types of ^{license} amendments will be needed:

(a) If a new radioactive material (RAM) 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} RAM will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail

publish date along with chemical

17 DTPA 18 Sulf Col 19 Xe for licenses issued
after 9 17 82 20 Disoferrin...

limit by grandfather date,

to licensees a notice that says those who are authorized to use material in that group may begin using the new ^{material} RAM on the effective date of the final rule that adds the new ^{material} RAM to the regulations. ~~No individual licensing action will be taken.~~

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

(i) The new ^{material} RAM 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}. ~~These persons would have submitted the new RAM procedure for review in their application packages.~~

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

(4) New location of use. 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} ~~does~~ generally not authorize licensees to perform therapies at satellite locations. ^{this type of} ~~Such~~ requests will be handled on a case-by-case basis.)

Invent 14a

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 procedures that were submitted in support of the application if the Radiation Safety Committee, or management and RSO outside an ^{medical} institution, approves the modification. However, the right to modify procedures does not relieve the licensee from the requirement to comply with the regulations. Amendments will generally be reviewed just as new applications are reviewed, but they may incorporate by reference the original application and any previous amendments.

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material the license must be renewed.

~~When preparing~~ The renewal applications must completely describe the ~~entire~~ 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, ^{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, request authorization for new types or methods of use.

① is using different areas of use,

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 responsible in case of non-compliance. [7590-01]

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.

^{Insert A above}
2 X. 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 X. 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} therapy, 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 3. Dose and dosage. In pharmacy, the word dose is used to indicate the amount of chemical administered; in radiation biology it is used to indicate the amount of ionizing energy absorbed; ^{per unit mass} and in radiation safety ^{as a shorthand term} it is used 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, ^{and 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 4. Record and report. A record is a user-retrievable notation or complete document. It may consist of something as small as a check-mark on a form or something as 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 5. 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} operable. 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."

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

76. 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.

87. 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 has a diagnostic sealed source in a device (see § 35.500) usually only

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 ^{also} every day so the user knows what reading to expect from the instrument. [7590-01]
The source may be used for other purposes.

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.

108. Operable. The word "operable" is, ^{not used in} ~~to some people, conspicuous~~ in its absence from the proposed regulation. If a ~~survey instrument,~~ ^{piece of equipment or reliable} room monitor, gas trap, or fume hood is not operable, whether due to ^{old} dead, or absent batteries, or incomplete or improper maintenance, ^(damage, inappropriate use, or improper use) it is ~~no~~ longer a working survey instrument, room monitor, gas trap, or fume hood, and is more appropriately described, for safety purposes, as an ~~assemblage of metal and plastic that once served a useful purpose.~~

~~cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used. Therefore, every piece of~~
Records Retention ^{equipment must be operable. add p10a.}

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, ~~the Commission has made a judgment that~~

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

12. Promptly. This word is used with its ordinary definition, which is "performed readily or immediately."

records retention for one year provides adequate evidence of compliance with requirements:

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

2b. In a few cases a record is only created once or the Commission considers the record to be critical evidence of compliance with regulations that, if not followed, might cause an immediate discernible impact on a worker or member of the public. See, for example, requirements for the geometry test for a dose calibrator and the teletherapy dosimetry equipment calibration, respectively. 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.

In a separate project the ^{NRC planning} staff is ~~beginning to develop~~ a comprehensive records retention policy that may conflict with the policy reflected in this proposed rulemaking. Readers should note that, ~~for~~ ^{for} sake of uniformity, some records retention requirements may be changed ~~if~~ ^{if} when the comprehensive policy is implemented.

Effect on Broad Licensees

In addition to the more common "group" licenses 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} ~~human~~ use. There are two types, a pure broad license and a hybrid broad license.

About 50 pure ^{medical} ~~human use~~ broad licenses have been issued. They are issued to large academic institutions that have had several years experience using radioactive materials, ^{these licenses} and invest in each institution's Radiation Safety Committee (RSC) the authority to permit medical practitioners to use byproduct material for ~~human use~~ in both patient care and medical research, ^{to permit} and individuals to use byproduct material for research in test tubes and animals, and to review the facilities and ^{radiation} safety procedures all these individuals will use. Before NRC issues a pure broad license it reviews the applicant's administrative and ^{radiation} safety procedures, the training and experience of the RSO and each individual member of the RSC, and the standards and ^{management} procedures the RSC 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 e} of proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500.

About 50 ^{medical} ~~human use~~ hybrid broad licenses have also been issued. They are similar to the pure broad license described above, except that the RSC only has the authority to permit individuals to use material in test tube and animal research, and only authorizes ^{medical} ~~human~~ use in accordance with the groups in current § 35.100. The NRC continues to review the training and experience of medical practitioners before allowing them to use material for human use. ^{Because} Since the control of human 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}
~~Since~~, whether at a group or broad license facility, teletherapy is separately licensed "for treatment of humans" and 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 ← Insert @ p 23

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} ~~Since~~ the requirements in the proposed revision were taken from commonly used license conditions and regulatory guidance that most licensees have incorporated in their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants who apply after the effective date of the proposed regulations. Therefore, current licensees will be cited if they do not comply with the new regulations. However, if there is ^{an} inconsistency between a license and the regulation (for example a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually) with the license less stringent than the regulation, the license would be considered ~~as~~ ^{an} exemption from the regulation. ^{Because} ~~Since~~ the less stringent license requirement was reviewed for safety considerations and approved by the NRC, ^{the} ~~such~~ ^{if} inconsistencies 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 license requirement elsewhere that is less stringent than the proposed regulation.

In the case of records retention, the regulation will take precedence because, in the past, the Commission has not offered much guidance on this topic, ~~and~~ 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 ~~has been created and it~~ ^{is the same as} is substantively identical to a record described in the proposed regulation and no ~~clear and specific~~ retention requirement has been stated for that record, licensees could ^{adopt} follow the retention ^{period} guidance in the final rulemaking. Licensees would still have to comply with any record retention requirement for a particular 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.)

p22a The NRC particularly requests public comments 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} ~~human~~ use of byproduct material.

NRC does not currently review ^{qualified} teletherapy
calibration ^(QTCE) expert credentials, and does not identify
on the license. The Radiation Safety Officer (RSO)

Under this proposal, NRC would begin
to review ^{their credentials} and identify both just as it does
now for authorized users. To add ~~new~~ ^{teletherapy} current
licensees to this new scheme, licensees would
be required to submit the for review and
approval the credentials of the ~~teletherapy~~
~~exp~~ QTCE whenever an ~~licensing action~~ ^{request} is the
next amendment or renewal is required. The
RSO and QTCE would be identified on the
next license amendment.

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.

top 21
The general license in current §35.31 has been eliminated from the proposed regulations, *and all medical use will be specifically licensed. In the future*
Current ~~human use~~ general licensees will *receive a specific license and will* be incorporated in 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* ~~those provisions of the proposed Part 35~~ that are more burdensome than the current *general license* ~~requirements for human use general licensees~~.
The only action they will need take is to respond affirmatively 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, ~~amendment~~, or renewal fees as long as their *programs are* ~~material uses~~ *are* limited to that *described in current §35.31. Below* ~~that~~ described in current §35.31. *Below* 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 *as a line item on their applications.* have to specifically request this authorization. Part 31 will be amended to continue this authorization for current in vitro licensees. *In either case, the use of § 31.11 materials will only be subject to the requirements of § 31.11.*

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

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. [7590-01]

through I contain the additional technical requirements that apply to licensees for each of the six ^{new} types of human use. Subpart J lists the training and experience requirements, and Subpart K lists the penalties for violations of the regulations.

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

Authority

*of the statutory basis for the regulations.
It also provides notice*

This listing 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} human use. The Commission uses the specific licensing process to

limit the use of byproduct material to persons who have the equipment, facilities, training, and experience needed to ensure its safe use. Individuals who are working under the supervision of an authorized user do not need a license, ^{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.

Information collection
 § 35.8 ~~Reporting, recordkeeping, and application~~ requirements: OMB

Approval.

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

§ 35.15 Definitions.

The term "Agreement State" ^{applies} ~~was included~~ to identify those states ^{entered into an agreement} that have ^{in responsibility for regulating} agreed with NRC to assure the safe use of byproduct material within their borders.

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

Insert (b) p 81a
 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.

(H) The phrase in the practice of medicine in accordance with a license was included to make it clear that NRC recognizes that [7590-01] states may have different definitions of medical practice or different levels of control and that licensees should not interpret the NRC license as pre-emption of state medical regulations or an attempt to direct the state's regulation of medical practice. 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}human use" was included to help identify the scope of this part. The word "intentional" was added to the current definition of the term "human use" to make it clear that occupational and non-occupational exposures under the regulations of Part 20, accidental exposures, and unwanted exposures from other sources of radiation (e.g., nuclear powered cardiac pacemakers, smoke detectors, and radioactive waste) are not considered ^{medical}human use. - (H)

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

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

The word "misadministration" was included to define those instances in which a mistake has been made in the ^{medical}human use of byproduct material. The definitions are ^{the same as those in} ~~consistent with~~ 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 ~~apply for a license to use~~ byproduct material in the practice of medicine.

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

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

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

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

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

§ 35.16 Application for license.

At an institution, only management may apply for a license, ~~and the~~^{on that license} individual physicians would be listed as authorized users. An individual physician may not apply for a use within an ~~institution~~^{medical} (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 outside an 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} ~~human~~ use. This requirement does not imply that the applicant should have two separate safety programs.

This section also reflects the Commission's decision to delegate to Regional Administrators some licensing functions which, until recently, were conducted in the headquarters. This program was described in a

Federal Register notice^s published April 14, 1983 (48 FR 16030), and
May 27, 1982 (47 FR 23138), *May 9, 1984 (49 FR 19430).*

§ 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.} ~~determine whether a licensee is in compliance with its regulations.~~ The Commission has determined that certain changes are potentially significant for the following reasons and thus will require an amendment:

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

(2) The use of byproduct material at an address not identified on the license would make it impossible for the Commission to make unannounced inspections. *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. ~~Except for teletherapy,~~ *(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* ~~because~~ *the NRC* would no longer *have assurance* ~~be assured~~ that the collective training and experience of the licensee's remaining personnel is adequate to ~~assure~~ *en* assure the safe use of byproduct material for all the types of use authorized by the license. The Commission has made a judgment that notification within 30 days is sufficient because technicians who have worked under the supervision of the authorized user can adequately ~~assure~~ *en* assure the safe receipt and proper storage of byproduct material, ~~for a few weeks.~~ *(This parallels the Commission's judgment that common carriers who handle byproduct material*

~~packages need not be licensed).~~ However, over a longer period of time, ^e absence of an individual to oversee a byproduct material program may increase the probability of an accumulation of unused byproduct material or unauthorized use of material. This presents an unacceptable potential hazard.

§ 35.28 License issuance.

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

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

necessary to recover operating costs. The Commission's discussion of this topic is in 36 FR 145, published January 6, 1971.

§ 35.29 Specific exemptions.

As part of an application or amendment request,

A person may ^{ask for} request an exemption from any requirement of this part.

The Commission may allow the exemption if the applicant can show that it will not compromise the health and safety of workers and the public.

The NRC occasionally receives requests for exemptions from procedural, equipment, or training standards.

Subpart B--General Administrative Requirements

§35.30 ALARA program.

An ALARA program is a management tool needed to assure that all reasonable efforts are made to assure the safe use of byproduct material ~~in institutions.~~ (See 'Management Organization and Administration for ALARA' by Kathren, Health Physics, Vol. 42, No. 2, February 1982, p. 119-131, and 'Radiation Safety in a Nuclear Medicine Department,' by Gandsman et al., Health Physics, Vol. 38, No. 3, March 1980, p. 399-408.)

Many workers from different departments within an institution might be occasionally exposed to byproduct material. The Commission has made a

judgment that a formal ALARA program is the only management tool that *ensure a cooperative effort to reduce individual and collective dose and ensure* can provide assurance that sources of radiation and work procedures in a

large facility are regularly reviewed for safety. Specific requirements

usually considered part of an ALARA program are required by §§ 35.31 and

35.32. ^(C) Since outside of an institution, the safe use of byproduct material

does not usually depend on the cooperation of individuals from several *administratively*

^{separate} different departments, and in most cases the authorized users are also

^(C) *# Non-institutional licensees, such as one or a few physicians in private practice, are not required to have a formal ALARA program because*

note: a professional body filled with
MD's is not a medical organization

the management, non-institutional licensees need not have a formal written ALARA program.

§ 35.31 Radiation Safety Officer.

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

§ 35.32 Radiation Safety Committee.

The proposed Part 35 requires institutional licensees to establish a Radiation Safety Committee to oversee the use of byproduct material. ^{pp 32a}

~~Under this proposal,~~ committee membership must include a physician identified on the institution's license as an authorized user of byproduct material for each type of use permitted by the license, the institution's Radiation Safety Officer, a representative of the institution's management and a representative of the nursing service. A similar requirement was published as a proposed rule on April 9, 1979 (44 FR 21023). ^{and} ~~(Institutions that only request a license for diagnostic sealed sources will be exempted from this requirement by license condition because the radiation safety program, due to the nature of the source and its method of use, would not depend on the cooperation of individuals from several different departments.)~~ ^Q ~~The NRC is not soliciting comments on the Radiation Safety Committee rule of Part 35 because an opportunity to comment on the rule has already been provided in the recently completed rulemaking on the Radiation Safety Committee. That rulemaking, published as a final rule on September 13, 1982 (47 FR 40149), has been incorporated in the proposed wording of Part 35.~~

^Q Packages would arrive infrequently, there would be no chance of contaminating an entire room or suite, there would be no radioactive waste, there no radioactive patients, and 32 little chance of loss of material.

(A)

The committee is required because, in an institution, staff radiation safety for all workers (users and ancillary) 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. 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.

(B)

The committee's deliberations will provide management and authorized users with information that is needed to optimize allocations of resources ^{available} for radiation safety.

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. A review more frequent than quarterly would inappropriately emphasize normal and expected statistical variations in exposure data. A less frequent review would ^{not provide for timely notice of} ~~allow an~~ unnecessary or unnecessarily high ^{doses} exposure to continue uncorrected for an unacceptably long period. The quarterly review should be guided by two trigger levels for individual ^{doses} exposures. The lower level would be a minimum level below which no action need be taken. Above the minimum level, the source of exposure should be determined and consideration given to methods of reducing the exposure rate. The higher level should trigger immediate intervention by the Radiation Safety Officer to reduce the exposure. The committee should review the appropriateness and completeness of the intervention, and should develop a permanent solution to maintain ^{doses} exposures at a lower level.

The annual review of the safety program is needed to determine its adequacy in light of the current and projected use of all byproduct material. In the Commission's judgment, a review at least once each year is adequate to assure that exposures remain ALARA considering the few program adjustments typically made during any single year. More time

between reviews might not permit the committee to make timely recommendations for avoiding unnecessary worker or patient exposures.

§ 35.33 Requirement for Authority and Statement of Responsibilities.

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

§ 35.34 ^{visiting} ~~Provisional~~ authorized user.

The uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a 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 an ^{other licensee's} NRC license that listed the visitor as a ^{visiting} 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 ^{and to remove the sixty day} time limit. In order to reduce paperwork burden, the licensee does not have to add the visitor as an authorized user until an amendment request is filed for some other purpose. Since the ^{visiting} ~~provisional~~ authorized user's training and experience has been reviewed by a regulatory agency, public health and safety will not be adversely affected. ^{by allowing this short-term authorization}

§ 35.35 Mobile nuclear medicine service administrative requirements.

Mobile nuclear medicine service has been limited to diagnostic ^{medical} human use because the inherent hazard of therapeutic amounts of byproduct

02/08/84

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} ~~list by title~~ each individual method of use authorized by their license, and 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.

34a

material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or equipment. These licensees are required to have a letter of permission from the management of each client ~~facility~~ ^{to} assure that the client management is aware of and in agreement with the ~~human~~ ^{medical} use of byproduct material within the facility.

(2) The Commission did not authorize transportation of ~~multi-dose vials~~ ^{daily} or generators because ~~physicians are exempted in § 71.9 from transportation requirements, and these materials cannot be safely transported unless they are properly packaged.~~ ^{they needed by persons who do not have access to prepared radiopharmaceuticals. That lack of access would be contrary to the geographic proximity required by § 35.38.}

^{top 43} Mobile service may ^{not} be provided to ~~both unlicensed and licensed~~ clients, the former because ^{in case of a spill or unlawful dose rates, the} they have no other access to services and the latter because ^{responsibility for corrective action may be clouded.} they may occasionally need assistance during periods of high patient load or technologist absence.

Insert p 35a

§ 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 36} is in 45FR 31701, published May 14, 1980. ~~NRC is not soliciting comments on the misadministration requirements of the proposed Part 35 because they are the same as the requirements of the current Part 35. On October 29, 1982, the Commission, in SECY 82-388, disapproved the staff's recommendation to propose withdrawal of this requirement, and concluded that it should~~ ^{considered} *not be withdrawn at this time.*

if the changes are within the requirements
of the regulations.

§ 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. The purpose of this authorization is to allow the licensee to respond to changes in staffing levels, available equipment, or patient load that may require re-allocation 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 ~~by NRC inspectors~~ to determine whether the licensee has made changes that are contrary to the ^{regulations, license conditions, or orders,} ~~regulatory requirements~~, and during termination surveys ^{an indication} to provide a list of every area where material was used.

during un-announced inspections

→ H 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 un-announced inspection.

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 [7590-01]
Medical services must also be responsive to each community's particular needs. The NRC does particularly regulate on this resolution, comment and on whether special training elements should be identified for certain tasks that are delegated or whether the general guidance is sufficient.
§ 35.38 Supervision. *clearly*

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

A above
§ 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. In certain institutions, the FDA has vested in a Radioactive Drug Research Committee (RDRC) (pursuant to 21 CFR 361.1) the right and responsibility to review for safety research projects that involve the administration of radiopharmaceuticals to humans for medical research. It is the Commission's judgment that the review criteria established by the FDA are, when followed by the RDRC, sufficient to assure the health and safety of the public and workers.

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. [©]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 insure 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 in a dose calibrator because they are so tiny; such dosages also present only a trivial risk to depleting the clinic inventory for the day. The geometry test assures the patient. Therefore, they 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} ~~is~~ not required by the 1981 proposal. ~~NRC invites comment on the requirement that dosage measurement records include patient information. NRC is not soliciting comment on other portions of the dosage measurement requirements because they are substantively the same as the 1981 proposal. Comments received in response to the 1981 dosage measurement proposal will be addressed in the statement of consideration published with the final rule revising Part 35.~~

§ 35.58 Authorization for calibration and reference sources.

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

§ 35.59 Requirements for possession of sealed sources.

The user must follow the manufacturer's instructions because they have been reviewed for safety considerations by the Commission or an Agreement State. ~~¶~~ The six-month test interval has been recommended by the National Council on Radiation Protection and Measurements (NCRP)¹ in Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection." More frequent testing is inconsistent with ALARA

¹The 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.*

considerations governing worker exposure because it would cause workers dose when making the test but provides only a slightly greater occupational exposure with a negligible 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 ^{where} for equipment used to measure ^{risk} 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 ^{lowest} ~~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, ~~the short half-life of the byproduct material~~, 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.

§ 35.60 Syringe shields.

Syringes that contain byproduct material ^{could} are an external radiation ^{source} hazard and should therefore be shielded at all times. In some cases the

If the NRC considered requiring the use of syringe shields when drawing individual dosages from multi-dose vials, that requirement is not included on this proposed revision. However, the NRC is soliciting comments on [7590-01]

whether syringe shields should be used when drawing individual dosages. [because the increased handling required to remove the shield when measuring the dosage may actually increase radiation dose to the hands.]
use of a shield when making an injection could interfere significantly with the injection. Since this would jeopardize patient benefit; in such cases the higher radiation exposure to the hands that is received by the technician who does not use a ^{syringe} shield is warranted. ~~For example,~~ a shield need not be used when the risk of spoiling the injection is greater than the benefit of reduced worker exposure.

§ 35.61 Vial shields.

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

§§ 35.62 Syringe labels, and 35.63 Vial labels.

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

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

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

removable contamination)

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

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

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

§ 35.80 Mobile nuclear medicine service technical requirements.

The Commission has limited radiopharmaceutical transportation by these licensees to unit dosages ^{and multi-dose vials of prepared radiopharmaceuticals.} ~~because they appear to be inherently~~
^{Insert (B) p 35.} ~~safer under accident conditions and there does not appear to be sufficient need for bulk radiopharmaceuticals in mobile nuclear medicine service.~~ The service must remove all radioactive waste generated during the use of byproduct material at a client facility because it is unlikely that the client facility has a license to receive and process radioactive waste. ^{Therefore} ^{exercise physical} This licensee must constantly control byproduct material. ~~because, since~~ there is no assurance that the licensee can control access to areas of use while working in a facility that is under another person's administrative control, client facilities should be considered as unrestricted areas ^{and} ~~and~~.

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 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} hazard ^{volatile} (e.g., iodine-131 and xenon-133). ^{respectively, a chance of exposure reduced} That hazard can be minimized by ^{materials} storing these in a fume hood or ^{multiple} ~~double~~ airtight barrier (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. ~~Because the special handling required for long half-lived material is usually not needed for radiopharmaceutical waste,~~ ^{therefore} short half-lived waste ^{can} would 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.} ~~such a time period will assure that,~~ ^{thus etc.} 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 may only be used~~ for radioactive material with a half-life of 65 days or less. ~~This half-life cutoff limit was chosen~~ because storage in excess of 650 days is more appropriately considered ^(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.) as permanent storage. A 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 (Group General/I)

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

Drugs approved for human use by the FDA have a label or package insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when it is used according to the package insert. By restricting the physician to the FDA-approved physical form, route of administration, and dosage range, NRC assures the safety of the public while allowing the physician flexibility regarding the choice of the clinical procedure.⁴¹ The FDA also authorizes the Radioactive Drug Research Committee (RDRC) at an institution to review and approve the use of radioactive materials for ~~human use for~~ ^{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
 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.

④ Radiopharmaceuticals authorized by an RDRC in accordance with FDA regulations. This authorization was not included in the regulations because only a few licensees request it.

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

§35.120 Possession of survey instrument.

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

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

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

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

Through continuing medical research, new uses may be found for existing approved radiopharmaceuticals. These new uses, which may require a different dosage, route of administration, or physical form, may not appear on the manufacturer's label or package insert instructions. It was such a situation that resulted in a petition filed by Dr. George V. Taplin (Docket No. PRM-35-1) requesting an exemption for

74

See for example PNO III 84 48 June 11 1984

Syncor @ Blue Ash

Lic No 34 18309 01MD

My calc \rightarrow 22 rad/uli Mo

Henny Ford calc \rightarrow 33 rad/uli Mo. close enough.

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 rule making and because} there are no substantive changes to the rule as adopted.

§ 35.204 Permissible molybdenum-99 concentration.

When molybdenum-99 undergoes radioactive decay, ^{clinically useful} technetium-99m is produced. ^{(D) below} 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. ^{by holding the permissible concentration to the required level} The Commission has made a judgment that ^{the resulting} this radiation dose is insignificant compared to the radiation dose which would be received by the patient due to the administration of the technetium.

(D) When the technetium is ^{separated} from the molybdenum,

The person who 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 ^{§ 20.106 and} § 20.106, which limits the amount of radioactivity in the effluent stream.

Insert p 43a

§ 35.220 Possession of survey instruments.

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

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

§ 35.300 Use of radiopharmaceuticals for therapy.

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

→ The Drugs ^{have been} approved for ^{medical} ~~human~~ use by the FDA, ~~have a label or package~~ insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when used according to the package insert, and therefore would require that the

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 required exhaust calculation, the licensee must assume that the largest single gas container is completely spilled, and may use either ambient or emergency air exhaust rates.

handled in the area

licensee use the radiopharmaceuticals in accordance with the package insert.

§§35.310 Safety instruction, and 35.410 Safety instruction.

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

§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 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.

no FDA pkg insert. Just safe
handling. Dye

Subpart G--Sources for brachytherapy (Group VI)

§ 35.400 Use of sources for brachytherapy.

This section identifies brachytherapy sources that may be used ^{for} in ~~human~~ ^{medical} use. The list was taken from the current § 35.100(e), which is a list of sources commonly used for patient care. ~~Tantalum wire has been added.~~

§ 35.404 Release of patients treated with temporary implants.

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} ~~brachy~~ therapy patient is necessary to ^{en}sure public safety. Section 35.404 requires that the licensee confine the patient until all temporary ~~brachytherapy~~ ^{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} ~~source~~ count and ^{a radiation survey log} ~~line~~ entry each time a source ^{is} ~~is~~ handled will help to ^{en}sure that if a source is misplaced,

^{its absence}
 This will quickly become apparent to the licensee, who can then promptly begin a search for the source.

§ 35.415 Safety precautions.

Because of the high exposure rates around ^{implant}~~brachytherapy~~ patients, a private room is needed to protect the public, who might be visiting nearby patients, from unnecessary exposure^u to radiation. The RSO must be notified in case of the patient's death or medical emergency to ensure that control of ~~brachytherapy~~^{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 use group established to incorporate the recent development of medical devices ^{Hat} which use a sealed source of byproduct material to create a beam of ionizing radiation. These devices are ~~now~~ ^{currently} available to persons licensed to use materials listed in

§ 35.100(f). Since the devices represent a lower level of hazard than the other ~~sealed~~ sources in that group, the Commission has determined that these devices should comprise a new group.

§ 35.520 Availability of survey instrument.

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

Subpart I--Teletherapy (Group VIII)

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

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

§ 35.605 Maintenance and repair restrictions.

This section provides ^{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.

§ 35.606 Amendments.

Amendments are required for items identified in paragraphs (a) through (f) because any change described in these paragraphs could

easy
 result in an increase in radiation levels in excess of the levels authorized in § 20.105. The service of a qualified teletherapy calibration expert is a ~~critical component~~ ^{an essential element} in ~~ensuring~~ ^{ens} the safe use of a teletherapy unit. The Commission has made a judgment that only an individual with proper training and experience can determine the operating characteristics of the licensee's teletherapy unit.

§ 35.610 Posted instructions.

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

§ 35.615 Doors, interlocks, and warning systems.

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," on page 42, states that a survey of a new teletherapy facility must determine that ". . . All entrances into the irradiation room or other high radiation areas are provided with barriers equipped with interlocks that are not dependent on the operation of a single circuit, and that will interrupt radiation production when the

barrier is opened." There have been incidents in irradiation facilities in which personnel were unnecessarily exposed to radiation because door interlocks or alarms were intentionally bypassed for convenience. See, for example, cases 19, 21, and 28 in NUREG/BR-0001, "Case Histories of Radiography Events," vol. 1, 1930. If the interlocks and warning systems had not been bypassed, personnel would not have been irradiated. The Commission, however, has made a judgment that the dual warning system of a door interlock and a radiation monitor in the teletherapy room obviates the need for the dual circuit door interlock recommended in the report.

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

§ 35.620 Possession of survey instrument.

The licensee needs a survey instrument on hand ~~in order to measure~~ ^{as a backup ^{room} monitoring device} ~~exposure rates~~ in case the radiation monitoring device ~~or the teletherapy unit~~ fails.

§ 35.621 Radiation monitoring device.

The radiation monitoring device is needed to indicate radiation levels in the teletherapy room in the event of the failure of the interlocks or the warning system. ~~There have been a number of reported incidents in which individuals have been~~ ^{may} 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

note stop w
note repair edge of on
new direction
done @ 35.632

unit, and to use a portable survey instrument or personal audible alarm dosimeter if the monitor is inoperable.

~~Identical~~ ^{Similar} requirements were published as a proposed rule on April 28, 1982, (47 FR 18131), ^{and} ~~These requirements~~ were adopted in a final rule published January 18, 1983 (48 FR 2116). The NRC is incorporating the rulemaking on teletherapy monitoring and servicing in this rulemaking on the revision of Part 35. ~~NRC is not soliciting comment on the new teletherapy requirements of the proposed Part 35 because they are identical to the requirements of the earlier 1982 rulemaking.~~

§ 35.622 Viewing system.

If a patient moved during a therapy administration, this could result in a ^{radiation} 200 rad 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.} ~~assure that the dose prescribed is the dose actually given.~~ In order to help ^{the equipment} ensure accuracy ^{as} it must be calibrated. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the proposed resolution of the petition filed by the American Association of Physicists in Medicine, Petition Docket No. PRM 35-2 (see 47 FR 4311; January 29, 1982). Currently, regulations require that primary dosimetry equipment be calibrated every two years. The petitioner requested ^{that} this two year requirement be relaxed to four years if, two years after calibration, the primary dosimetry system is compared with a system that was cali-

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

§ 35.632 Full calibration measurements.

Full calibrations are needed to ensure that the dose given is the *same as the* ~~dose that was~~ prescribed. The required frequency of full calibrations remains unchanged from that of the current Part 35. The test for timer accuracy has been clarified to include on-off error. The accuracy of localization devices ^{which} are used to position the teletherapy patient *↳ that*

The NRC proposes to allow licensees to use either the currently required calibration procedure or a new procedure that was recently [7590-01] 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.

has been added to minimize the risk of unintentionally irradiating

healthy tissue. The function of mechanical and electrical interlocks

~~which~~ *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} ~~measurement~~ systems that ~~cannot be~~ *are capable of making precise relative measurements but are not suitable* easily shipped for calibration. *for making absolute output measurements.*

The exposure rate from a radioactive source goes down as time

progresses due to source radioactive decay. To ^{en} ~~assure~~ accurate dose

delivery, the regulation requires that licensees mathematically take

this into account in calculating patient doses. The regulation requires

that the licensee use time periods of not longer than one month when

making decay calculations. This will ^{en} ~~assure~~ that the actual dose does

not differ from the calculated dose by more than one percent due to this

decay error.

§§ 35.633 Periodic spot-checks, and 35.642 Safety checks for teletherapy facilities.

A monthly spot-check is required by § 35.22 of the current regu-

lations 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 localiza-

Error in either may result in incorrect administration of radiation. tion devices has been added. The qualified teletherapy calibration

expert must review the results of the spot-check measurements within

A The required location of the collimators during the head leakage survey is a real specification. It is based on the fact that, for individuals who receive 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. [7590-01]

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. ⁹¹ A requirement to check certain safety systems in the teletherapy facility has been added. These checks, which 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 the safety of the teletherapy facility.

→ In case of failure of the viewing systems, the regulation would allow the physicians to decide whether treatments should be interrupted, this would not relieve the licensee from the requirement to promptly repair the viewing systems. add @ below.
§ 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. *(Above)*

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

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

E The regulation would require shutdowns of the facility 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 supervisions would provide an acceptable balance of worker safety and medical use needs.

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

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

§ 35.645 Five-year inspection.

Many licensees replace teletherapy sources at five year intervals. Requiring a mechanical check at five year intervals helps to assure ^{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. *A. 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} constitutes proof of adequate training and experience because the criteria which must be met to attain certification are more stringent than the training and experience required by the Commission.

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

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

72 Recency of Training.
~~§ 35.900(c) Training within the last five years or continuous involvement.~~

A
 Radiation safety regulations and practices may be expected to change with time. The Commission has made a judgment that training

received within the preceding five years is sufficiently up-to-date to assure the safe use of byproduct material. If an individual received training more than five years prior to the application and has not had continuing involvement in the field, training must be repeated.

to p 2
 §§ 35.900(d), 35.910(b), 35.920(b), 35.930(b), 35.940(b), 35.941(b), 35.950(b), 35.960(b), and 35.961(b) Training and experience.

The criteria identified in these sections were developed by the staff with the assistance of the ACMUI over the past several years. The Commission has made a judgment that, for each type of use, the training and experience described is necessary to ^{en} assure 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 ^{radio} pharmaceutical manufacturer, ~~as private tutored~~ *(NRC will carefully review this information before listing an individual on a license.)* instruction, or elsewhere. Supervised work experience must be received at an institution under an ^{authorized user} ~~appropriate~~ preceptor because usually only such an individual is qualified to teach the ^{clinical} ~~field~~ 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.

Physician training exception.

§ 35.971 ~~Three month training program.~~

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

Insert App 60-61

Hal Peterson: that's a weak excuse.
alm- agreed.

§ 35.990 Violations.

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

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

^{proposed} This conforming amendment grandfathers ^{many} human use licensees ^{now} who are ~~also~~ using byproduct material for in vitro work under the provisions of §§ 31.11 and 35.14(c). ^{there} 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, ^{other} so that the Commission will know how many persons are doing in vitro testing. The use of materials listed in § 31.11 will only be subject to the requirements of that section;

Consistent with current regulatory ^{ions} practice, 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 identifies 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 NUMBERORIGINSubpart 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
	<i>Medical</i> Human use	35.3(a) revised
	<i>Medical</i> Institution	new term
	Management	new term
	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

	<i>Visiting</i> Provisional 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
<u>Subpart B--General Administrative Requirements</u>		
35.30	ALARA program.	new text; see RG 10.8 Appendix 0 revised
35.31	Radiation Safety Officer.	RG 10.8
35.32	Radiation Safety Committee.	35.11(b) revised
35.33	Requirements for authority and statement of responsibilities.	new text
35.34	<i>Visiting</i> Provisional authorized user.	license condition
35.35	Mobile nuclear medicine service administrative requirements. ✓	licensing policy
35.36	<i>Radiation safety programs changes.</i>	<i>new text</i>
35.37	Records and reports of misadministrations.	35.42 verbatim
35.38	Supervision.	expanded from RG 10.8 p. 3
35.49	Suppliers.	35.14 revised

Subpart C--General Technical Requirements

- | | | |
|-------|--|--|
| 35.50 | Possession, use, calibration,
and check of dose calibrators. | RG 10.8 Appendix D2 revised,
and new text |
| 35.51 | Calibration and check of
survey instruments. | RG 10.8 Appendix D1 revised,
and new text |
| 35.53 | Measurement of radio-
pharmaceutical dosages. | proposed rulemaking 35.15
(46 FR 43840; September 1,
1981) |
| 35.58 | Authorization for calibration
and reference sources. | 35.14(d) revised |
| 35.59 | Requirements for possession
of sealed sources. | 35.14(e)(1)(i), 35.14(f)
revised |
| 35.60 | Syringe shields. | Inspection and Enforcement
letter April 16, 1979 |
| 35.61 | Vial shields. | Inspection and Enforcement
letter April 16, 1979 |
| 35.62 | Syringe labels. | new text |
| 35.63 | Vial labels. | new text |
| 35.70 | Surveys for contamination
and ambient radiation
exposure rate. | RG 10.8 Appendix I revised |
| 35.75 | Release of patients containing
radiopharmaceuticals or
permanent implants. | new text |

- 35.80 Mobile nuclear medicine service licensing policy
technical requirements.
- 35.90 Storage of volatiles and gases. RG 10.8 Appendix M revised
- 35.92 Decay-in-storage. license condition

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

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

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

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

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

- 35.300 Use of radiopharmaceuticals 35.100 (IV) and (V) revised
for therapy.
- 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

Subpart G--Sources for brachytherapy (Group VI) ²

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 (Group VII) ²

35.500 Use of sealed sources for diagnosis. new text

35.520 Availability of survey instrument. new text

Subpart I--Teletherapy (Group VIII) ²

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.	<u>Revision of Federal Register</u> <i>new text</i> Notice (47 FR 53476; December 2, 1982)

- | | | |
|--------|--|---|
| 35.920 | Training for imaging
and localization studies. | Revision of Federal Register
Notice (47 FR 53476; December 2,
1982) |
| 35.930 | Training for therapeutic use
of radiopharmaceuticals. | Revision of Federal Register
Notice (47 FR 53476; December 2,
1982) |
| 35.940 | Training for therapeutic
use of brachytherapy sources. | Revision of Federal Register
Notice (47 FR 53476; December 2,
1982) |
| 35.941 | Training for ophthalmic
use of strontium-90. | Revision of Federal Register
Notice (47 FR 53476; December 2,
1982) |
| 35.950 | Training for use of sealed
sources for diagnosis. | new text |
| 35.960 | Training for teletherapy. | <div style="border: 1px solid black; padding: 5px; display: inline-block;"> Revision of Federal Register
Notice (47 FR 53476 December 2, 1982) </div> |
| 35.961 | Training for qualified
teletherapy calibration
expert. | 35.24 revised |
| 35.970 | Experienced physician training
exception. | new text |
| 35.971 | New physician training
exception. | new text |
| 35.972 | <i>Recency of training.</i> | <i>copy © here</i> |

Subpart 5--Enforcement

35.990 Violations.

new text

ADMINISTRATIVE STATEMENTS*Insert p. 71a*Environmental Impact - Negative Declaration

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

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

Paperwork Reduction Act Statement

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

Insert
2/A

New
page

l.c. → FINDING OF NO SIGNIFICANT ENVIRONMENTAL IMPACT: AVAILABILITY

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The 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.} ~~(insert name, address, and telephone number of staff contact).~~

l.c. → 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.

l.c. → 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.} ~~(insert name, address, and telephone number of staff contact).~~

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 ~~adverse~~ economic impact on a substantial number of small entities. The NRC has issued approximately ⁵2600 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately ³400 by individual physicians. Most of the institutional licensees are community hospitals, that range in size from 75 bed facilities to 750 bed facilities. The Small Business Administration size standards, 13 CFR Part 121, ^(49 FR 5037; February 9, 1984) classify a hospital ^{or physician's office} as a small entity if ~~its capacity is less than 150 beds or if its~~ ^{average} gross annual receipts do not exceed \$³1.5 million. Under these size standards, ~~a substantial number of~~ ^{some} NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

Although ^{the} number of medical licensees that would fall into the small entity category ^{does not} constitutes a substantial number for purposes of the Regulatory Flexibility Act, ^{significant} there should not be a ~~negative~~ economic impact on these small entities. ⁴ The primary objective of the proposed rule is to simplify the medical licensing process by consolidating requirements without lessening the protection necessary ^{for} ~~to preserve~~ public health and safety. This will be accomplished through incorporation of frequently used license conditions into the regulations and the elimination or modification of requirements that are not essential to the protection of public health and safety. These steps will make it easier for a licensee to determine what is required to obtain a license and what is required of licensees. *Therefore,*

The Commission has prepared a preliminary ^{regulatory analysis} ~~value/impact~~ statement 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~~ cost 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.} ~~Norman L.~~ McElroy, ^{li} ~~Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC Telephone: (301)427-4052.~~

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

- (1) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;
- (2) How the proposed regulation would result in a significant economic burden on the licensee as compared to that on a larger licensee;
- (3) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;
- (4) The benefits that would be gained or the detriments that would be avoided to the licensee, if the proposed regulations were modified as suggested by the commenter; and
- (5) How the regulation, as modified, would still adequately protect public health and safety.

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

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

General Domestic Licenses for Byproduct Material

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

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

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

Human Use Of Byproduct Material

Health professions, Incorporation by reference,
Medical devices

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

Domestic Licensing of Source Material

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

Under the authority of
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy
Reorganization Act of 1974, as amended, and ^{5 U.S.C.} ~~section 553 of title 5 of~~
~~the United States Code~~, ^{of the NRC proposing to} notice is hereby given that adoption of the
following revision of 10 CFR Part 35 and the following amendments to
10 CFR Parts 30, 32, and 40, ~~is contemplated.~~

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

MEDICAL
PART 35--~~HUMAN~~ USE OF BYPRODUCT MATERIAL

Sec.

Subpart A--General Information

- 35.1 Purpose and scope.
- 35.2 License required.
- 35.8 ^{*Information collection*} ~~Reporting, recordkeeping, and application requirements:~~
OMB approval.
- 35.15 Definitions.
- 35.16 Application for license, amendment, or renewal.
- 35.17 License amendments.
- 35.18 Notifications.
- 35.28 License issuance.
- 35.29 Specific exemptions.

Subpart B--General Administrative Requirements

- 35.30 ALARA program.
- 35.31 Radiation Safety Officer.
- 35.32 Radiation Safety Committee.
- 35.33 Requirement for authority and statement of responsibilities.

- 35.34 Visiting authorized user.
- 35.35 Mobile nuclear medicine service administrative requirements.
- 35.36 *Radiation safety program changes.*
- 35.37 Records and reports of misadministrations.
- 35.38 Supervision.
- 35.49 Suppliers.

Subpart C--General Technical Requirements

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

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

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

35.120 Possession of survey instrument.

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

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

35.204 Permissible molybdenum-99 concentration.

35.205 Control of aerosols and gases.

35.220 Possession of survey instruments.

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

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 (~~Group VI~~) X

35.400 Use of sources for brachytherapy.

35.404 Release of patients treated with temporary implants.

35.406 Brachytherapy sources inventory.

35.410 Safety instruction.

35.415 Safety precautions.

35.420 Possession of survey instrument.

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

35.500 Use of sealed sources for diagnosis.

35.520 Availability of survey instrument.

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

- 35.600 Use of a sealed source in a teletherapy unit.
- 35.605 Maintenance and repair restrictions.
- 35.606 Amendments.
- 35.610 Safety instruction.
- 35.615 Doors, interlocks, and warning systems.
- 35.620 Possession of survey instrument.
- 35.621 Radiation monitoring device.
- 35.622 Viewing system.
- 35.630 Dosimetry equipment.
- 35.632 Full calibration measurements.
- 35.633 Periodic spot-checks.
- 35.641 Radiation surveys for teletherapy facilities.
- 35.642 Safety checks for teletherapy facilities.
- 35.643 Modification of teletherapy unit or room before beginning treatment program.
- 35.644 Reports of teletherapy surveys, checks, tests, and measurements.
- 35.645 Five-year inspection.

Subpart J--Training and experience requirements

- 35.900 Radiation Safety Officer.
- 35.901 Radiation Safety Officer training exception.
- 35.910 Training for uptake, dilution, and excretion studies.
- 35.920 Training for imaging and localization studies.
- 35.930 Training for therapeutic use of radiopharmaceuticals.
- 35.940 Training for therapeutic use of brachytherapy sources.

- 35.941 Training for ophthalmic use of strontium-90.
- 35.950 Training for 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 ~~New~~ ^{physician} physician training exception.
- 35.972 *Recertification of training.*

Subpart K--Enforcement

- 35.990 Violations.

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

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.2, 35.17, 35.30(a) and (c), 35.31(a) and (b), 35.32, 35.33, 35.34(a), 35.38, 35.49, 35.50(a)-(d), 35.51(a)-(d), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.62, 35.63, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.100, 35.120, 35.200, 35.204(a) and (b), 35.205, 35.220, 35.300, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a), 35.410(a), 35.500, 35.520, 35.600, 35.605, 35.606, 35.610(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, and 35.961 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), 35.33(b), 35.34(c), 35.35(b), 35.37(a)-(d), 35.32(b), (b) and 35.36(b), 35.970, and 35.971

35.50(e), 35.51(e), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i),
 35.70(g), 35.80(f), 35.92(b), 35.204(c), ~~35.304~~, 35.310(b), 35.404(b),
 35.405, 35.406(b) and (c), 35.410(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. 1610, 68 Stat. 950 as amended
 (42 U.S.C. 2201(o)).

Subpart A -- General Information

§ 35.1 Purpose and scope.

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

§ 35.2 License required.

(a) No person shall manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for ~~human~~ ^{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.

Information collections
 § 35.8 ~~Reporting, recordkeeping, and application requirements:~~

OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget ^(OMB) for approval as required by the Paperwork Reduction Act ^{of 1980} (~~Pub. L. 96-511~~) ^(44 U.S.C. 3501 et seq.). OMB ^{has} approved the information collection requirements ~~on~~ *in this part under control number 3150*.

(1) The OMB control number is _____.

(2) OMB approval expires _____.

(b) The approved information collection requirements ~~include the~~ application, recordkeeping, and reporting requirements contained in *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.

Insert (B) p 31a
 "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} ~~human~~ use of byproduct material.

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

-A for p 81

"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.

-B for p 25

The term "Area of use" was added to identify the ~~concept of floor space~~^{a place that is} within a physical structure ~~(a building, a temporary building, or a mobile van)~~ that is allocated to the byproduct materials 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.

^{Medical}
 "Human use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the ^{art} 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.~~

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

"Management" means the chief executive officer.

"Misadministration" means the administration of:

- (1) A radiopharmaceutical or radiation from a sealed source other than the one intended;
- (2) A radiopharmaceutical or radiation to the wrong patient;
- (3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;
- (4) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;
- (5) A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or
- (6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

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

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

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

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

^{Visiting}
"Provisional authorized user" means an authorized user who is not identified on the license of the person for whom he is working.

"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.

§ 35.16 Application for license, amendment, or renewal.

(a) For use ^{based medical} in an institution, only ^{the violations} management may apply. For use ^{not based on medical} outside an institution, any person may apply.

(b) An application for a license for human use of byproduct material as described in §§35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing ^{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 ^{so original and one copy} in letter format.

(c) An application for a license for human 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 10.1, "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 applicant shall mail the completed ^{request} application form as directed below.

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

(2) If the applicant is not a Federal agency and is located in Virginia, ^{Puerto Rico, or the Virgin Islands,} or West Virginia, the applicant shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region II, Material Licensing Section, 101 Marietta Street, Suite ²⁹⁰⁰ 3100, Atlanta, Georgia 30303.

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

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

this wording from P20 App D
changed to P20 wording.

Glenn RI note

Note: The typed wording may be ^{mis}interpreted either: don't clean or survey
when P20 occurs; or Alt "listed on the license" can be ATCE. I considered
"assumes the position of" but that didn't get rid of all surveying
as ATCE.

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

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

(1) Mail the completed ^{request} ~~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 offices at:

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

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

§ 35.17 License amendments.

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

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

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

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

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

(e) Before adding to or changing the location or locations of use or mailing address identified on the license.

§ 35.18 Notifications.

The licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or qualified teletherapy calibration expert, permanently discontinues performance of duties under the license. The licensee shall mail the 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} institutional licensee shall ^{implement} ~~establish~~ a program to maintain individual and collective dose equivalents as low as reasonably achievable.

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

(1) Management, the Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program 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} ~~keep~~ a written description of the ALARA program for the duration of the license. The written description must include:

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

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

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

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

§ 35.31 Radiation Safety Officer.

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

(b) The Radiation Safety Officer shall:

- (1) Investigate ^{below} ~~known instances of~~ ^{approved radiation safety} deviation from ~~good 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;

overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and others

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

(vii) Performing periodic radiation surveys;

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

(ix) Disposing of byproduct material *safely*;

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

(xi) Keeping a copy of all records and reports required by the regulations, a copy of the regulations, a copy of ^{*each licensing request*} ~~the license application~~ and license and amendments, and the written policy and procedures required by the regulations.

(3) For use not at ^{*a medical*} ~~an~~ institution, approve or disapprove ^{*radiation safety program*} ~~modifications~~ ^{*changes*} ~~of procedures~~ with the advice and consent of management; and

(4) For use at ^{*a medical*} ~~an~~ institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.32 Radiation Safety Committee.

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

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

(1) Membership must consist of at least three individuals and must include an authorized user ^{*for*} ~~for~~ each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service,

~~if there is one~~, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The committee must meet at least quarterly.

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

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

- (i) The date of the meeting;
- (ii) Members present;
- (iii) Members absent;
- (iv) Summary of deliberations^{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 ^{or} maintain one copy for the duration of the license.

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

- (1) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;
- (2) Review, ^{and with regard to the training and experience standards in Subpart J of this part,} on the basis of safety, ^{or Qualified Self Therapy Calibration Expert,} and approve or disapprove any individual who is to be listed as an authorized user, or the Radiation Safety Officer, before submission of the license application or application for amendment;

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

(4) Review on the basis of safety and approve, or disapprove with the advice and consent of the Radiation Safety Officer and the management representative, procedures and ^{radiation safety program changes} ~~modifications of procedures~~ for the safe use of byproduct material;

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

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

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

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

§ 35.33 Requirement for authority and statement of responsibilities.

(a) The licensee shall provide the Radiation Safety Officer, and at an ^{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 an ^{medical} institution the Radiation Safety Committee.

visiting
 § 35.34 ~~Provisional~~ authorized user.

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

(1) The ~~provisional~~ *visiting* authorized user has the prior written permission of the licensee's management and, if ~~such~~ *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* ~~lists~~ *visiting* the ~~provisional~~ authorized user as an authorized user for *medical* ~~human~~ use; and

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

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

~~(c) The licensee must request that the provisional authorized user be listed as an authorized user the next time the licensee applies for a license amendment or renewal.~~

(d) The licensee shall retain *for two years after the* ~~provisional~~ *visiting* authorized user's last use of licensed material copies of the records specified in this section unless the ~~provisional~~ *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 an NRC or Agreement State license for the materials listed in those Subparts.*

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

Insert p 93a

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

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report ^{*must*} ~~shall~~ include the

§ 35.36 Radiation safety program changes.

(a) The licensee may change the ^{radiation safety} procedures and equipment that are used to meet regulatory requirements and that were described in the application for licence, 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 applications for licence, renewal, or amendment.

^{The effective date of the change,}
The record must include a copy of

(b) The licensee shall retain for the duration of the license a record of each change, the old and new radiation safety procedures, equipment descriptions, or areas ^{plans}, the reasons 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 management or, in an institution, the Radiation Safety Committee chairman and the management representative.

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 ^{re}maintain for ^{ten years}~~the duration of the license~~ 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.

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} ~~authorized~~ by § 35.2(b) shall:

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

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

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

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

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

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

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

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

§ 35.49 Suppliers.

The licensee may use for ^{medical} ~~human~~ use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in

Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or ^{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) Radiopharmaceuticals authorized by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration pursuant to 21 CFR 361.1; and

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

Subpart C--General Technical Requirements

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

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

(b) The licensee shall:

(1) Check each dose calibrator for constancy 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 licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) The licensee shall mathematically correct dosage readings for any 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 licensee shall retain a record of each check and test required by this section for two years unless directed otherwise.

(1) The record required in paragraph (b)(1) of this section must include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

(2) The record required in paragraph (b)(2) of this section must include the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer.

(3) The record required in paragraph (b)(3) of this section must include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer.

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

§ 35.51 Calibration and check of survey instruments.

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

(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} ~~may~~:

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

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

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

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

(1) A description of the calibration procedure; and

(2) A description of the source, ~~radionuclide~~ ⁹ used and ~~its certified activity~~ 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 licensee shall:

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

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

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

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration date; ^{and ^{the} radionuclide;}

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

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

(4) Date and time of the measurement; and

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

§ 35.58 Authorization for calibration and reference sources.

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

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

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

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half life longer than 100 days in individual amounts not to exceed 200 microcuries each; *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 *such* instructions in a legible form convenient to users of the source.

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

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

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

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

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

(2) Take teletherapy 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 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 Parts 20 and 30 of this chapter; and

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

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

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

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

ADM record retention rule

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

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

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

~~(6) Sources containing only hydrogen-3;~~

~~(7) Wires of iridium-192; and~~

~~(8) Wires of tantalum-182.~~

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

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

(i) The licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in

millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields.

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

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

require each individual who prepares a radiopharmaceutical kit to use a syringe shield and shield radiation

§ 35.61 Vial shields.

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

§ 35.62 Syringe labels.

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

§ 35.63 Vial labels.

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

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

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

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

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

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

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

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

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

ADM rulemaking

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

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

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

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

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

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

§ 35.80 Mobile nuclear medicine service technical requirements.

A licensee providing mobile service shall:

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

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

ADM submodeing

(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 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 facility,} survey for ~~ambient radiation~~ ^{all areas} exposure rate with a low range survey meter ~~prior to departure from the location of radiopharmaceutical use~~ to ensure that all radiopharmaceuticals and all associated waste have been removed; and

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

§ 35.90 Storage of volatiles and gases.

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

§ 35.92 Decay-in-storage.

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

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

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

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

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

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

(a) The 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), ~~or which has been authorized by a Radioactive Drug Research Committee that has been approved by the FDA pursuant to 21 CFR 361.1.~~

(b) The licensee using a radiopharmaceutical listed in paragraph (a) of this section for a clinical procedure other than one specified in the product 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 licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in his possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour.

Subpart E--Imaging and Localization (~~Group II/III~~) X§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) The 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;
- (xi) Oxidronate sodium;
- (xii) Disofenin; and
- (xiii) Succimer.

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

- 5 (5) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;
- 6 (6) Iodine-125 as sodium iodide or fibrinogen;
- 7 (7) Chromium-51 as human serum albumin;
- 8 (8) Gold-198 in colloidal form;
- 9 (9) Mercury-197 as chlormerodrin;
- 10 (10) Selenium-75 as selenomethionine;
- 11 (11) Strontium-85 as nitrate;
- 12 (12) Ytterbium-169 as pentetate sodium;
- ~~13 (13) Indium-113m as chloride;~~
- 14 (14) Xenon-133 as a gas or saline solution;
- 15 (15) 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) ^{or which has been} authorized by a Radioactive Drug Research Committee that has been approved by the FDA pursuant to 21 CFR 361.1.

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

(c) The 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 paragraphs (a) ^e and (b) of this section:

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

§ 35.204 Permissible molybdenum-99 concentration.

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

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

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

§ 35.205 Control of aerosols and gases.

(a) The licensee who administers 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.

(e) Before receiving, using, or storing a radioactive gas, ~~in a room,~~ the licensee shall calculate, based on the highest activity of gas handled in a single container and the measured available air exhaust rate, the amount of time needed after a spill to reduce the concentration ^{in the area of use} to the occupational limit ~~permitted by Part 2~~ listed in Appendix B to Part 20 of this chapter.

The calculations must be ^{at the area of use}

(f) The licensee shall post the calculated time and require that, in case of a gas spill, individuals evacuate the room ~~until~~ until:

- (1) The posted time has elapsed; or
- (2) A survey of the room indicates that the concentration in the room is ^{less than} ~~within~~ the occupational limit listed in Appendix B to Part 20 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 licensee shall only administer radioactive aerosols and gases in rooms that are at negative pressure compared to surrounding rooms.

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

[insert p 112 a]

§ 35.220 Possession of survey instruments.

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

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

§ 35.300 Use of radiopharmaceuticals for therapy.

The licensee 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} ~~authorized by~~ 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 licensee shall provide oral and written radiation safety instructions for all personnel caring for the patient undergoing radiopharmaceutical therapy. To satisfy this requirement, the instructions must describe ^{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 licensee shall keep for two years a list of individuals receiving instructions required by paragraph (a) of this section, a description of the instructions, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) The licensee shall provide each individual hospitalized for radiopharmaceutical therapy a private room with ^{private} sanitary facilities.

(b) The licensee shall notify the Radiation Safety officer immediately in case of the patient's death or medical emergency.

(c) 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 ^{Radiation Safety Officer} RSO 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} its 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} it 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. ~~each second~~

(g) ^{Within three days after administering therapeutic dosage of iodine-131, the licensee shall measure the thyroid burden of each individual who helped prepare or administer the dosage, B.B.S.W.}
§ 35.320 Possession of survey instruments.

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

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 measurement.

Subpart G--Sources for brachytherapy ~~(Group VI)~~ X§ 35.400 Use of sources for brachytherapy.

The 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; *and*
- ~~(g) Tantalum-182 as wire.~~

§ 35.404 Release of patients treated with temporary implants.

- (a) The licensee shall not release from confinement for medical care a patient treated by *Immediately after removing the last* the temporary implant *of a source listed in from a patient* ~~§ 35.400, until~~ *the licensee shall make* a radiation survey of the patient *is made to confirm that* all sources have been removed. *temporary implant until all sources have been removed.*

- (b) The 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 *and* 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.*

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

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§ 35.406. Brachytherapy sources inventory.

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

^{Insert p 117a} (c) The licensee shall retain the record required in paragraph (b) and (c) ^{is} of this section for two years.

§ 35.410 Safety instruction.

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

- (1) Size and appearance of the brachytherapy sources;

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

(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 in case of the patient's death or medical emergency.

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

§ 35.415 Safety precautions.

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

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

(c) 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 must specifically authorize visits by individuals under age 18 on a case-by-case basis.

§ 35.420 Possession of survey instrument.

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

Subpart H--Sealed sources for diagnosis (Group VII) *e* X§ 35.500 Use of sealed sources for diagnosis.

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.

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

Subpart I--Teletherapy (Group VIII) *e*§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units ^{*for medical use*} that contain the following sources: ~~for the treatment~~ of humans:

- (a) Cobalt-60 as a sealed source; and
- (b) Cesium-137 as a sealed source.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the ^{Nuclear Regulatory Commission} NRC 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 licensee shall apply for and must receive a license amendment prior to:

- (a) Making any change in the treatment room shielding;
- (b) Making any change in the location of the teletherapy unit within the treatment room;
- (c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- (d) Relocating the teletherapy unit;
- ~~(e) Removing the teletherapy unit; or~~
- ^e (f) 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 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*

~~(ii)~~ any other abnormal operation occurs; and

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

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

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

§ 35.615 Doors, interlocks, and warning systems.

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

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

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

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

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

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

§ 35.620 Possession of survey instrument.

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

§ 35.621 Radiation monitoring device.

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

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

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

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

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

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

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

§ 35.622 Viewing system.

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

§ 35.630 Dosimetry equipment.

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

(1) The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine, ^(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 ~~American Association of Physicists in Medicine~~ (AAPM). The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. The licensee shall use a teletherapy unit with a cobalt-60 source when intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, and a teletherapy unit with a cesium-137 source when intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units. *the licensee shall use*

(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 instrument^{rs} that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factors that were deduced, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

(a) Any licensee authorized to use a teletherapy unit for ~~treating~~^{medical use} ~~humans~~ shall perform full calibration measurements on each teletherapy unit:

- (1) Before the first ^{medical} use of the unit ~~for treating humans~~; and
- (2) Before ^{medical use} ~~treating humans~~ under the following conditions:

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

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

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

(3) At intervals not exceeding one year.

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

(1) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used ^{for medical use} ~~in radiation therapy~~;

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

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

(4) Timer accuracy;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices used for ^{medical use} ~~treating humans~~.

(c) The licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The ^{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 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. ~~These procedures~~ ^{that} are

or Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics [7590-01] Vol. 10, No. 6, 1973, pp. 741-771.

described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, ^{*Both of these references have*} which ~~has~~ been approved for incorporation by reference by the Director of the Federal Register. Copies of the document ^{*are*} are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW, Washington, D.C. 20555. ^{*are*} A copy of the document is also on file at the Office of the Federal Register, 1100 L Street NW, Room 8301, Washington, D.C. 20408. A notice of any change in the material will be published in the Federal Register.

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

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by a qualified teletherapy calibration expert.

(g) The licensee shall retain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance

measuring or localization device, and the signature of the qualified teletherapy calibration expert.

§ 35.633 Periodic spot-checks.

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

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

- (1) Timer accuracy;
- (2) On-off error;
- (3) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (4) The accuracy of all distance measuring and localization devices used for ^{medical use} ~~treating~~ humans;
- (5) The output for one typical set of operating conditions; and
- (6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

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

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

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

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

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

- (1) Electrical interlocks at each teletherapy room entrance;
- (2) ~~The function of~~ ^{of} electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
- (3) ~~Any~~ ^{of} beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
- (4) ~~The~~ ^{of} viewing system;
- (5) ~~Operability of~~ ^{of} treatment room doors from inside and outside the treatment room; and
- (6) ~~Operability of any~~ ^{of} electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

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

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

change to "regular" someday
"recurring at fixed or uniform intervals"

ref Jack Krichmer. use a cubic pre, \therefore avg over 100 cm²

(j) The licensee shall retain a record of each spot-check required by paragraphs (a) and (f) of this section for two years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before ^{medical} human 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} when in the off position ^{and the collimator is 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 licensee shall ^{not} ~~maintain~~ a record of the radiation measurements made following installation of a source for the duration of the license.

The record must include the date of the measurements, the 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} ~~radiation level~~ measured around the teletherapy source while in the off position and the average of all measurements, a plan of ^{the area surrounding the treatment room} ~~each area~~ that ^{was} surveyed, the measured ^{dose} ~~exposure~~ rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

§ 35.642 Safety checks for teletherapy facilities.

(a) The licensee shall promptly ^{check}~~test~~ 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}~~test~~ the malfunctioning system.

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

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

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

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

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

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

(a) 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(a).

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

The licensee shall mail an original and a copy of ~~the results 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 which initiated the record requirement.

§ 35.645 Five-year inspection.

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

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

(c) The licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the 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) Be an authorized user for those byproduct material uses that come within the Radiation Safety Officer's responsibilities; or

(c) 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 ^{medical} radiation safety at an ^{medical} institution under the supervision of the individual ^{identified} ~~listed~~ as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the ^{medical} human use of byproduct material. ^{or}

Insert (b) p 134 →

(d) The training and experience specified in ~~paragraph (c)~~ of this ^{support} ~~section~~ must have been obtained within the five years preceding the date of application or the ^{individual} ~~Radiation Safety Officer~~ must have had ^{continuing} experience ^{since the required training and experience was completed,} equivalent to one year of full time employment in medical radiation safety within the last five years.

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§ 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 (***) ^e, who oversees only the use of byproduct material for which the licensee was authorized on that date, ^e need not comply with the training requirements of § 35.900.

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

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

(a) Is certified in:

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

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

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

(b) Has completed 80 hours of ^{instruction} ~~training~~ 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} ~~training~~ requirement, the ~~training must include~~ ^{must include:} classroom and laboratory instruction ~~and supervised experience in a nuclear medicine laboratory~~ as follows:

(1) 25 hours of radiation physics and instrumentation;
 (2) 25 hours of radiation protection;
 (3) 10 hours of mathematics pertaining to the use and measurement of radioactivity;

(4) 10 hours of radiation biology; and

(5) 10 hours of radiopharmaceutical chemistry; ^{or} ~~or~~ ^{Insert 136a}

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section. within five years of the date of application for a license, or have had experience equivalent to one year of full time employment in nuclear medicine within the last five years.

§ 35.920 Training for imaging and localization studies.

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

of byproduct material;

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

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

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

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

(ii) Selecting the ^{suitable} ~~proper~~ radiopharmaceutical^s and calculating^{ing} the dosage^s;

(iii) Administering dosages to patients and ~~making proper use of~~ ^{ring} syringe radiation shields;

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

(v) Patient followup; or

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

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(a) Is certified in:

- (1) Nuclear medicine by the American Board of Nuclear Medicine; or
- (2) Diagnostic radiology with special competence in nuclear radiology

by the American Board of Radiology; or

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

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

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

- (i) 100 hours of radiation physics and instrumentation;
- (ii) 30 hours of radiation protection;
- (iii) 20 hours of mathematics pertaining to the use and measurement of radioactivity;
- (iv) 30 hours of radiopharmaceutical chemistry³ 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 an ^{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 meter⁵;
- (iii) Calculating and safely preparing patient dosages;
- (iv) Using administrative controls to prevent the misadministration

of byproduct material;

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

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

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

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

(ii) Selecting the ^{suitable} ~~proper~~ radiopharmaceutical and calculating ^{and measuring} the dosage;

(iii) Administering dosages to patients and ~~making proper~~ ^{ring} use of syringe radiation shields;

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

(v) Patient followup; or

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

the date of application for a license, or have had experience equivalent to one year of full time employment in nuclear medicine within the last five years. }

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

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

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

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

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

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

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

(iv) 20 hours of radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at 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 colloidal ^{chromic} phosphorus-32 for intracavitary treatment of malignant effusions in 3 individuals;

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

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

§ 35.940 Training for therapeutic use of brachytherapy sources.

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

(a) Is certified in:

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

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

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

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

(b) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and ^{Is in the active practice of therapeutic radiology with 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 safely;
- (iv) Using administrative controls to prevent the misadministration of byproduct material; and
- (v) Using emergency procedures to ~~handle~~ and control byproduct material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education, *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 an institution. *The supervised clinical experience must include:*

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§ 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:

- (i) 110 hours of radiation physics and instrumentation;
- (ii) 40 hours of radiation protection;
- (iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and
- (iv) 25 hours of radiation biology.

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

- (i) Review of the full calibration measurements and periodic spot checks;
- (ii) Preparing treatment plans and calculating treatment times;
- (iii) Using administrative controls to prevent misadministrations;
- (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
- (v) ~~Checking and using survey meters.~~

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

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

(ii) Selecting the proper ^{brachytherapy sources and} dose and ^{method of} ~~how it is to be~~ administered; ^{on}

(iii) Calculating the ~~teletherapy~~ doses and collaborating with the ⁱⁿ authorized user, in the review of patients' progress and consideration of the need to modify originally prescribed dose as warranted by patients' reaction to radiation; and

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

§ 35.961 Training for qualified teletherapy calibration expert.

The licensee shall require the individual calibrating or checking the radiation output of a teletherapy unit as a condition of

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

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

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

- (i) 6 hours of radiation physics and instrumentation;
- (ii) 6 hours of radiation protection;
- (iii) 4 hours of mathematics pertaining to the use and measurement of radioactivity; and
- (iv) 8 hours of radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at an ^{medical} institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals ^{that} ~~and~~ ^{must include:} ~~the~~ examination of each individual to be treated; ⁽ⁱ⁾ calculation of the dose to be administered; ⁽ⁱⁱ⁾ administration of the dose; ⁽ⁱⁱⁱ⁾ ~~post-administration~~ ^(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

re (3), this phrasing needed because of practice of
medicine & dentistry & pathology

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

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

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

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

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

(2) 3 hours of radiation biology; and

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

§ 35.960 Training for teletherapy.

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

(a) Is certified in:

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

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

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

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

(b) Has completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and three years of supervised clinical experience. *Is in the active practice of therapeutic radiology, and (a minimum of)*

(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.

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

- (i) 110 hours of radiation physics and instrumentation;
- (ii) 40 hours of radiation protection;
- (iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and
- (iv) 25 hours of radiation biology.

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

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Checking survey meters for proper operation;
- (iii) Preparing, implanting, and removing sealed sources safely;
- (iv) Using administrative controls to prevent the misadministration of byproduct material; and
- (v) Using emergency procedures to handle and control byproduct material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education, *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 an institution. *The supervised clinical experience must include:*

§ 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:

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

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed dose ^{as} as warranted by patients' reaction to radiation; and

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

§ 35.961 Training for qualified teletherapy calibration expert.

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

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

- (1) Therapeutic radiological physics; *or*
- (2) Roentgen ray and gamma ray physics; *or*
- (3) X-ray and radium physics; or
- (4) Radiological physics; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a qualified teletherapy calibration expert at an ^{medical} institution, ~~where teletherapy is performed~~. To satisfy this requirement, the neophyte qualified teletherapy calibration

expert must have performed the tasks listed in §§ 35.59, 35.632, 35.633, and 35.641 of this part under the supervision of a qualified teletherapy calibration expert during the year of work experience.

§ 35.970 Experienced authorized user training exception.

A physician, dentist, or podiatrist identified as an authorized user for the human use of byproduct material on a Commission or Agreement State license on (***) insert effective date of final rule (***) who performs only those methods of use for which he was authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 ^{New} physician training exception.

A physician who, ^{and} ~~by August 31, 1987,~~ ^{He programs} has successfully completed a three month nuclear medicine training program ^{that was} approved by the Accreditation Council for Graduate Medical Education ^{Before July 1, 1984, began a} need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recency of training.

Insert @ p 135

Subpart K--Enforcement

§ 35.990 Violations.

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

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974; or
- (3) Any regulation or order issued under these Acts.

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

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

(2) Section 206 of the Energy Reorganization Act of 1974;

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

(4) Any term, condition, or limitation of any license issued under these Acts; or

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

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any regulation or order issued under the requirements of the Act may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both as provided by law. Regulations issued under the Act include regulations issued under sec. 161, and cited in the authority citation at the beginning of this part for the purposes of sec. 223.

2 blank lines

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 ⁴(x) and ^z(y) as follows:

§ 30.4 Definitions.

*

*

*

*

*

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

* * * * *

(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;

* * * * *

⁴
(x) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice the art of dentistry on humans.

²
(y) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice the art of podiatry on humans.

* * * * *

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

§ 30.34 Terms and conditions of licenses.

* * * * *

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

For the license

May be used on phys, vet, lab, or hosp:

License

6. BPM

any BPM in § 31.11

7. Chem and for phys form
Pres phy limits in 31.11a

8 max amt.

Per 31.11(c) Total

Ind. units per 31.11a,
in any room ^①

9. For use per 31.11a LAH 31.11b-f

① basis 2-125 0.7 Rem² in Ci hr

$$0.2 \text{ mCi} \times \frac{0.7 \text{ Rem}^2}{\text{mCi hr}} \times \frac{50 \times 50 \text{ cm}^2}{2000 \frac{\text{hr}}{\text{yr}}} = 112 \frac{\text{mR}}{\text{yr}}$$

by rule to P.V. 6 20 84

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

§ 31.11 [Amended]

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

* * * *

4. Section 31.11(b) ^{is amended by moving paragraph} ~~is revised~~ to read as follows:

(b) No person shall receive, acquire, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section; ⁽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, D.C. 20555 and received from the Commission a validated copy of Form NRC-483 with registration number assigned ⁽²⁾ ~~or~~ unless he has a license that authorizes the ^{medical} ~~human~~ use of byproduct material and that expires before [*** insert five years after effective date of final rule ***] ⁽³⁾ ~~or~~ unless he has a license that authorizes the ^{medical} ~~human~~ 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;

* * * * *

21
Dated at Washington, D.C. this ____ day of _____ 198⁴₃.

For the Nuclear Regulatory Commission.

55

Samuel J. Chilk,
Secretary of the Commission.



OFFICE OF THE
SECRETARY

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

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.....6:15A

Enclosure 2

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 2⁵/₆00 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. X

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 ^{Regulatory Analysis} of the effects of the proposed revision to Part 35, see the ^{Value/Impact} Statement prepared as ^{part of the rulemaking} package.
Enclosure 4

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} ~~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.

X

The staff finally proposed in SECY-83-62 that, ^{because} 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 SECY-83-62 alternative is therefore no longer reasonable.

The staff also considered that, ^{because} 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 ^{medical} ~~primary~~ 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
REVISION OF PART 35

→ Introduction ← Insert p 1c

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 c.c.

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.

CRESS fill in

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page

- INTRODUCTION
- 1. STATEMENT OF PROBLEM
- 2. OBJECTIVES
- 3. ALTERNATIVES
- 4. CONSEQUENCES
- 5. DECISION RATIONALE
- 6. IMPLEMENTATION — SECTION-BY-SECTION
- 7. BURDEN OF PROPOSED REVISION OF PART 35
- 8. TOTAL ^{Industry} BURDEN TO ~~HYPOTHETICAL LICENSEES~~
- 9. COST TO WORKERS AND THE PUBLIC
- 10. COST TO NRC
- 11. COST OF ALTERNATIVES 1 AND 3

L.C.

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 *l.c.*

The purpose of this proposed rulemaking is to codify, in plain English, all radiation safety requirements specific to the ^{medical} ~~human~~ 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 *l.c.*

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 SECY-83-62 alternative is therefore no longer reasonable.~~

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 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. CONSEQUENCES *l.c.*

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 have not been analyzed. ^{in depth} A detailed burden analysis (expressed in dollars and man-hours) for the directed alternative follows the narrative portion of this regulatory analysis. *Based on the analysis,*

~~In general,~~ the staff does not believe there will be any significant ^{economic impact} increase in or relief from ^{on the} regulatory burden on licensees, NRC, or Agreement States. *e*

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} ~~may~~ be a ^{more} ~~more~~ safety-oriented inspection based on a uniform, nationwide code of standards.

2 [AGREEMENT STATES: PLEASE PROVIDE A PARAGRAPH DESCRIBING THE CONSEQUENCES OF THE PROPOSED ACTION ON YOUR OPERATIONS.]

Insert p 3a

Suggested Changes

1. Draft memo John G. Davis to William J. Dircks

"Individuals from NMSS, IE, RI, RII, RIII, RIV, RV, RES, OPE, SP, ADM, ELD and two Agreement States helped prepare this proposal."

We suggest two new sentences after "ELD" to read as follows:

Two State persons who represented the 27 Agreement States provided comments and viewpoints during the development of this proposal. In addition, the February 13, 1984 version of the Part 35 proposal with the revised regulatory guide 10.8 was sent to all Agreement States for review and comment.

2. Page 4, enclosure 1

Change 26 Agreement States to read 27.

3. Page 18, enclosure 1, item 8 Operable.

Change "an assemblage of metal and plastic" to "an instrument or device."

4. We recommend that the Commission paper and the regulations clearly state that any modification of procedures by the licensee be documented by date and signatures of those authorized to approve changes, and maintained on file for a minimum of five years.

5. Reg. Analysis (P.3 encl. 4)

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 safety procedures and changes to the procedures is necessary to ensure a proper degree of safety. They believe that failure 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 number of} 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.

radiation
(P) 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.

Enclosure 2

Encl 4p 3a201

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 *l.c.*

The staff is recommending the proposed revision because it clarifies requirements and grants some authority to licensees to modify their procedures, facilities, and equipment to meet needs caused by changing patient care needs. 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 *l.c.*

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* *Analysis*
Burden 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. X

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: 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. Note that some frequencies are specified in the regulation, and some have been assumed (superscripted "a") for purpose of estimating total cost. Codes:

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 similar, not identical requirements

DEF	FGH	M	Sec	R/O	Freq	Hrs for Records Pro	Hrs for Work Tec	Eqpt & Supplies	Contract Cost	\$/yr	Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R
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(Several footnotes follow the Table)

§35.2 License Required.

DEF	FGH	M		R	5y			190 ¹		40			R
I				R	5y			300 ¹		60			R

§35.16 Application for license, amendment, or renewal.

DEF	FGH	M		R	5y	20 ²¹	10			4		2	R
I				R	5y	40 ²¹	10			8		2	R

§35.17 License amendments.

A11			0		5y ²	2	1	40 ¹		8	0.4	0.2	R
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§35.18 Notifications.

A11			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 Officer⁵.

A11			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 misadministrations.

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
A11		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
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EFGHIM	Sec	R/O	Freq	Hrs for Records		Hrs for Work		Eqpt & Supplies	Contract		Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R
				Pro	Tec	Pro	Tec		Cost	\$/yr			
DEM		R						500 ¹¹		100			RG
DEM		R						80 ¹²		80			N
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
F	M	R	m ^a					500		6000			LC
M	d	R	2xd ^a		0.4						100		LC
	e	R	2xd ^a	0.2	0.2						100		LC
DEFM	0		m ^a	0.5		1					18		LC
	R							500	50 ¹⁹	150			RG
E	R		d ^a	.02	.04						15		R
E	ab	R						2000 ¹⁴		400			RG
E	d	R	6m	0.1	0.2						0.6		RG
E	lo							500	50 ¹⁹	150			RG
E	hi							1000	50 ¹⁹	250			RG
F	R		m ^a	0.1	0.5	3.0 ¹⁵				7	36		RG
F	a	R	m ^a					450 ¹⁶		5400			RG
F	c	R	m ^a		0.2 ¹⁵						2		RG
F	e	R	m ^a	1.0	2.0 ¹⁷					12	24 ¹⁸		RG
F	g	R	m ^a	0.2	0.3						6		RG
F	lo	R						500	50 ¹⁹	150			RG
F	hi	R						1000	50 ¹⁹	250			RG
	a	R	m ^a	0.1	0.1					1	1		RG

	DEF	GHI	M	Sec	R/O	Freq	Hrs for Records Pro Tec	Hrs for Work Pro 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
		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 ^A	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

	DEF	G	H	I	M	Sec	R/O	Freq	Hrs for Records Pro Tec	Hrs for Work Pro Tec	Eqpt & Supplies	Contract Cost	\$/yr	Pro Hrs /yr	Tec Hrs /yr	N, RG, LC or R	
I						a	R	5y ^a	0.5	← 1					0.3	N	X
I							R	5y				2000 ²⁰	← 400			LC	X

Footnotes

- ¹A fee required by Part 170.
- ²Assume one amendment for a new user or use over 5 years.
- ³Assume one key individual leaves over 5 years.
- ⁴Preparing 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.
- ⁵Assume 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.
- ⁶Typing and distributing minutes.
- ⁷Assume RSO needs three hours to prepare agenda, and five individuals attend a one hour meeting.
- ⁸Assuming 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.
- ⁹Radioactive check sources to convert wipe sample cpm to microcuries.
- ¹⁰Assume two at \$150. *each*
- ¹¹Assume five at \$100. *each*
- ¹²Assume 4000 labels per year at \$10 per 500.
- ¹³Diagnostic 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.
- ¹⁴Cost of a closed, shielded gas collection system.
- ¹⁵Assume RSO briefs six nurses for one-half hour.
- ¹⁶Assume three days in a private room at \$500 instead of a semi-private room at \$350.
- ¹⁷Assumed time needed to decontaminate room.
- ¹⁸Assume the RSO briefs two technicians each year.

Footnotes (Continued)

¹⁹Calibration service.

²⁰Assume two days at \$750 each day, plus \$500 total per diem and travel.

²¹Draft 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.

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 any worker.

35.34 ^{visiting} ~~Provisional~~ 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.

~~35.36 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 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 ^gNew physician training exception.
- 35.990 Violations.

~~TOTAL INDUSTRY BURDEN~~

Because each license authorizes the particular materials the applicant, requested by ^{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 ~~industry characterization~~ estimate of licensees affected. For the purpose numbers of

of estimating total industry burden, we assume \$100 per professional hour, \$30 per technician hour, and round to two significant figures.

Industry
 2. TOTAL BURDEN *1.c.*
~~TO HYPOTHETICAL LICENSEES~~ *5 lic, antea*

Insert p 16a

Case Description and Regulatory Burden per year (see following tally sheets)

1. A nuclear medicine diagnostic clinic that is not based in a hospital, ^{*licensed*} and conducts 15 procedures each day. Annual regulatory burden: \$1618, 110 professional hours, and 398 technician hours. *Add Ep 16b*
2. A nuclear medicine diagnostic clinic that is based in a hospital and conducts 15 procedures each day. ^{*licensed*} Annual regulatory burden: \$1618, 160 professional hours, and 406 technician hours. *Add Ep 16b*
3. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and one radiopharmaceutical therapy procedure each month. ^{*licensed*} Annual regulatory burden: \$13,018, 179 professional hours, and 466 technician hours. *Add Ep 16b*
4. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and one brachytherapy procedure each month. ^{*licensed*} Annual regulatory burden: \$7033, 177 professional hours, and 448 technician hours. *Add Ep 16b*
5. A hospital with a nuclear medicine clinic that conducts 15 diagnostic procedures each day and has one cobalt-60 teletherapy unit. ^{*licensed*} Annual regulatory burden: \$3211, 233 professional hours, and 463 technician hours. *Add Ep 16b*
6. A mobile nuclear medicine service that conducts ^{*215 diagnostic*} about 5 procedures each day at each of two client locations. ^{*licensed*} Annual regulatory burden: \$1618, 110 professional hours, and 598 technician hours. *Add Ep 16b*

add Ep 16b

(A) Approximate number of licenses: 300. ^{Total industry} burden:
 $300 \times (1618 + 110 \times 100 + 398 \times 30) = \$7,400,000$
 Increase: $300 \times (80 + 4.1 \times 100 + 0.1 \times 30) = \$147,900$

(B) Approximate number of licenses: 700. ^{Total industry} burden:
 $700 \times (1618 + 160 \times 100 + 406 \times 30) = \$21,000,000$
 Increase: $700 \times (80 + 4.1 \times 100 + 0.1 \times 30) = \$345,100$

(C) Approximate number of licenses: 700. ^{Total industry} burden:
 $700 \times (13018 + 179 \times 100 + 466 \times 30) = \$31,000,000$
 Increase: $700 \times (80 + 4.1 \times 100 + 0.1 \times 30) = \$345,100$

(D) Approximate number of licenses: 400. ^{Total industry} burden:
 $400 \times (7033 + 177 \times 100 + 448 \times 30) = \$15,000,000$
 Increase: $400 \times (80 + 4.1 \times 100 + 0.1 \times 30) = \$197,200$

(E) Approximate number of licenses: 400. ^{Total industry} burden:
 $400 \times (3211 + 233 \times 100 + 463 \times 30) = \$16,000,000$
 Increase: $400 \times (0 + 0.1 \times 100 + 0.4 \times 30) = \$8,800$

(F) Approximate number of licenses: 50. ^{Total industry} burden:
 $50 \times (1618 + 110 \times 100 + 598 \times 30) = \$1,500,000$
 Increase: $50 \times (80 + 4.1 \times 100 + 0.1 \times 30) = \$24,650$

(G) The total burdens of the revised Part 35 on the medical industry is about \$92 million dollars. However, this is not a new impact. Almost all the burdens (except for §§ 35.18, 35.59h and i, 35.62, and 35.642) is currently imposed by regulation or license conditions. Since day-to-day operations will not be significantly affected, the staff does not foresee any increase in

The new burden is about \$10.7 million dollars

Grand following pgs will go after pg 17 & 18

(H) 9. COST TO WORKERS AND THE PUBLIC (C.)

CASES

Section	\$	Pro hrs	1 Tec hrs	\$	Pro hrs	2 Tec hrs	\$	Pro hrs	3 Tec hrs	\$	Pro hrs	4 Tec hrs	\$	Pro hrs	5 Tec hrs	\$	Pro hrs	6 Tech 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
35.92							6000											
35.120*	150		18	150		18										150		200
35.204			15			15												18
35.205	400		0.6	400		0.6										400		15
35.220*	250			250												250		0.6
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																		
35.633														32				
35.641														18	18			
35.642														12.3	4			
35.645															0.3			
														400				

* expenditure also meets requirements of §§ 35.320, 35.420, 35.520, and 35.620.

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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 \$	1618	1618	13018	7033	3211	1618
P-hrs	110	160	179	177	233	110
BURDEN 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 new burdens.

	1	2	3	4	5	6
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 \$	80	80	80	80	0	80
NEW P-hrs	4.1	4.1	4.1	4.1	0.1	4.1
BURDEN T-hrs	0.1	0.1	0.1	0.1	0.4	0.1

add new pages - (H) p 16b, c, d, e,
Hm p 18a-d

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 ^{L.C.}

Since there would be no significant changes in day-to-day licensee operations, NRC staff retraining would ~~only~~ be needed to explain the new method of regulating the medical industry, but not in new technology. ~~About~~ license reviewers and inspectors would need a ~~one-time~~ two day training course conducted by one headquarters worker and held in each regional office. The cost would be ~~ten~~ instructor days and ~~student~~ days. Assuming \$60 per hour, the retraining cost would be about $60 \times (10 \times 2 + \quad \times 16) = \quad$. The staff does not foresee any significant change in the amount of time needed to issue a license or conduct an inspection.

Insert, p. 16 d. 1. c.

~~The major cost to NRC is for employee training.~~ About 85 NRC employees (managers, license reviewers, and inspectors) would have to attend a two-day course on the implementation of the revision.

The first day^{of the course} would be spent discussing the

[The course would be given at headquarters and at each of the five regional offices.]

The reasons Part 35 was revised and discussing each section of the regulations. The second day would be spent discussing the licensing and inspection process under the revision.

(2da x 8hrs/da x 85 students)

The training would consume 1360 hours of student time, and 176 hours of instructor time. The latter figure is comprised of 80 hours of planning and 96 hours of teaching.

(2da x 8hrs/da x 6source)

Instructor expenses would be about 11000 for travel and 1750 per diem. (13da x 175/da)

If we assume NRC staff time costs 160/hr, the total cost to NRC is about \$94,000.

(160 x 1360 + 160 x 176 + 11750).

→ 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 lost savings to NRC is about 1000 hours, or \$60,000.

~~will~~

I.C. 2

11. ← COST OF ALTERNATIVES 1 AND 3

Assumptions

1. NRC^{will} receive 1800 amendment requests (100 new applications, 600 renewal requests, and) each year
2. Approximately 40% of all these requests are returned to the requestor, for additional information or clarification. ^{(with a} deficiency notice ^{that asks}
3. Licensee professional time^(pro) costs \$100/hr, licensee secretarial and technical time ("tec") costs \$30/hr, and NRC professional time costs \$60/hr.

✓

11

18a

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 (\$40 fee + 2 prohrs @ \$100 + 1 techr @ \$30)).

Licensees will also not be spared the cost of repairing requests that were deficient because of unclear regulatory policy. ~~the savings are negligible.~~ (P)

NRC also bears costs under Alternative 1. The major cost has to do with inspections. The NRC currently

(P) 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 \times 20\% \times \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.

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 regulation, that hour could be saved. ~~There would be~~ 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 ($1600 \times 20\% \times 60$).

NRC would save some of the retraining 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

224
180

licensee conduct 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 \$243,000 needed to generate requests for minor changes in procedures, facilities, and equipment, and \$74,000 needed to respond to deficient notices. application

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

A short public announcement, extracted from the Federal Register Notice preamble and edited with the assistance of the Office of Public Affairs, will be inserted here.

DRAFT PUBLIC ANNOUNCEMENT

NRC PROPOSES TO SIMPLIFY MEDICAL LICENSING PROCEDURES

12-14
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 health and safety procedures; personnel training and experience; and facilities and equipment. ~~However~~^{9th} 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.

ENCL 5 27

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} ~~which~~ 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.

#

ENCLOSURE 28

DRAFT CONGRESSIONAL LETTER

~~NRC PROPOSES TO SIMPLIFY MEDICAL LICENSING PROCEDURES~~

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 issues ^{has} licenses ^{to about 2200} to medical facilities and individual physicians ³⁰⁰ in private practice for the use of radioactive materials to diagnose and to treat patients. ^{Below} 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 ^{radiation safety management} 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, ^{available facilities and equipment, and key users' training and experiences}

^{agency} The Commission's radiation safety review covers three general areas: ^{the applicant's program before issuing a license.} radiological health and safety procedures; personnel training and experience; and facilities and equipment. However, ^H 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.

The NRC receives about 100 new applications, 500 renewal requests, and 1800 ^{license} amendment requests each year.

ENCL 6930

A draft regulatory guide for medical programs has been prepared. It contains a model ^{radiation safety management} 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 ^{active 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 hospital, its Radiation Safety Committee.

Some types of program changes ^{that} ~~which~~ ^{adding} would still require a formal NRC review and license amendment include new physician user^s, new medical use^s, and new location of use.

The proposed revision to Part 35 of NRC regulations ^{will} ~~is~~ being published for public comment in the Federal Register on ^⑤ ~~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.~~

The draft regulation and the draft regulatory guide will be mailed to current licensees and other interested individuals for comment.

ENCL 6231

CONGRESSIONAL ADDRESSEES

The Honorable Richard L. Ottinger, Chairman
Subcommittee on Energy Conservation and Power
Committee on Energy and Commerce
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Subcommittee on Nuclear Regulation
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United States Senate
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Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
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ENCLOSURE 6
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DRAFT CONGRESSIONAL LETTER

A short letter to congressional oversight committees, based on the Federal Register Notice preamble and edited with the assistance of the Office of Congressional Affairs, will be inserted here.

DRAFT

ENVIRONMENTAL ASSESSMENT FOR THE PROPOSED REVISION OF 10 CFR PART 35, "HUMAN 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 "human 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 ⁶2600 "human use" licensees. Each year, the NRC receives about ¹⁰⁰75 new applications, ⁵⁰⁰250 renewal applications, and ⁸1300 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.)

§ 35.80 Mobile service technical requirements. 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 unit dosages, but not multi-dose vials or 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-rem 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 shipment 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 ^g§ 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." X

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

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Author's Name:
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CRESS: delete pp 1-8, insert new Encl 8

SUMMARY TABLE OF COMMENTS ON CONTENT OF SECY-83-62 REGULATION
OVERVIEW

Many individuals recommended that commonly used general safety measures be included in the revision of Part 35 that was contained in SECY-83-62. For example, they would require use of gloves and laboratory coats for individuals handling radiopharmaceuticals, require use of whole body dose monitors for all Part 35 radiation workers and finger dose monitors for individuals who elute generators or handle brachytherapy sources, specify frequency of radiation worker training, require the use of radionuclide sources for survey instrument calibration, package ordering and opening procedures that are more stringent than required in the current Part 20, requirements that food not be stored along with byproduct material and radioactive solutions not be pipetted by mouth, and specify frequency of air sampling measurements.

The Task Force believes that if such regulations are needed to ensure worker or public protection, an identical case is easily made for placing such requirements on almost all other classes of licensees. Therefore, to assure uniformity and consistency, such requirements would be more properly placed in Parts 19 and 20. The suggested requirements have not been incorporated in the proposed revision of Part 35 because they are not specific to medicine. Generally, only requirements that are specific to the human use of byproduct material were included in the revision. The few exceptions to this statement are requirements that might apply to some other groups of licensees but are considered critical elements in a medical radiation safety program and whose absence, in light of the specificity of other Part 35 requirements, might be construed as an indication that the requirement was not meant to apply to Part 35 licensees. Examples are performance requirements for survey instruments and contamination surveys.

Many individuals also recommended that more safety measures that are specific to medicine be included in the revision. Some examples that were submitted are: 1. recalibration of imaging equipment that was transported in support of mobile service, 2. storing and preparing volatile radiopharmaceuticals and gases in a fume hood, 3. testing frequency for radioactive gas

trapping devices, 4. provision of private room with private toilet for hospitalized radiopharmaceutical and brachytherapy patients, and treating such rooms as restricted areas during therapy, 5. control of contaminated items and associated waste, 6. use of remote handling tools for manipulating brachytherapy sources, and 7. use of electrical or mechanical position limit switches on teletherapy units if the room shielding is inadequate. Many of these comments have been incorporated.

There were many suggested general and medical-specific requirements that might be good practice but are not necessary to keep worker and public doses as low as reasonably achievable below permissible limits. The goal of the drafting committee was to include only those requirements that are specific to the medical use of byproduct material and for which a clear safety need was defined.

Basis of the Table

Source documents that were reviewed to prepare this table are identified below. Most comments were keyed to a section of the SECY-83-62 regulation that is identified as a subheading. (If in parenthesis, a commenter suggested a new section not in SECY-83-62.)

The content of the suggestion is summarized in the left column, and the source document is identified by number and page. In the right column, a √ indicates that the comment was added and the new section number is given (a few sections that were in SECY-83-62 have been renumbered); a 0 indicates that the comment was not incorporated and the reason is given.

Since this is a summary table, comments have been dramatically condensed. Comments that are addressed in the new Statement of Consideration (S of C) are not included in this table. To make a critical review the reader must refer to the source documents. Copies are available from Norman L. McElroy, NMSS, (301) 427-4052.

Source Documents

1. Memo from Vacca and DelMedico (NRC staff) to Chilk dated April 26, 1983.
2. Memo from Whatley (Alabama) to Nussbaumer dated May 25, 1983.
3. Letter from Shealy (Conference of Radiation Control Program Directors) to Kerr dated October 7, 1982.

§ 35.2 License required

Clarify reference to Agreement 0 - defer to ELD.
States - 3p1

§ 35.15 Definitions

Define podiatrist, dentist - 1 Encl 4 ✓ - added. See 35.15.
Describe responsibilities of auth user - 1 Encl 4 0 - ELD recommends responsibilities in regulations, not definitions.
Define supervision - 2p10d ✓ - already in SECY-83-62 @ 35.38.
Clarify "visiting authorized user" - 3p1 ✓ - See "provisional authorized user."

§ 35.16 Application form

Clarify the wording - 1 Encl 4 ✓ - 35.16.
Reflect full regionalization - 1 Encl 4 ✓ - 35.16.
↑
Use an application form that elicits more information - 1p49 ✓ - the new form will elicit most information that is currently requested. See 35.16

§ 35.17 License amendments

Restrict "locations of use" (e) and clarify "other program changes" (f) - 3p1 ✓ - Section (e) has been restricted, (f) deleted.

§ 35.28 License issuance

Licensee may modify procedures without Commission approval - ✓ - RSO and management approval required. See S of C.

§ 35.30 ALARA program

All licensees must have an ALARA program - 1p51, Encl 4 0 - only needed at institutions. See S of C.

§ 35.31 Radiation Safety Committee

Clarify ALARA program review - 3p2 ✓ - 35.30b2.

§ 35.32 Radiation Safety Officer

All licensees must identify RSO 1p 54, 1 Encl 4 ✓ - added @ 35.31

§ 35.33 Authority and Responsibilities

Specify annual worker training and content - 1p55a 0 - frequency belongs in Part 19, suggested phrases restate Part 19 requirements.

§ 35.34 Visiting authorized users

Only NRC authorized users as visiting authorized users - 0 - No safety basis, unduly restrictive.
1 Encl 4
Retain records - 3p2 √ - 35.34d

§ 35.35 Mobile nuclear medicine service administration requirements

No generators or kits on mobile service vans -lp56a √ - Already in SECY-83-62 @ 35.80a.
Mobile services may only have non-licensees as clients -lp56a 0 - unnecessary interference with delivery of patient care. See S of C.
Mobile service must have ltr of authorization from client management -lp56a √ - already in SECY-83-62 @ 35.35b.

§ 35.50 Dose calibrator requirements

Have a dose calibrator on hand lp59a √ - 35.50a.
Calibration procedure to test dose calibrator - lp59a. 3p2 0 - much more prescriptive than ANSI standard N42.13-1978

§ 35.51 Survey meter requirements

Have a survey meter on hand - lp60a √ - 35.120, 35.220, ... 35.620 lp60a
Calibrate annually - lp60a √ - already in SECY-83-62 @ 35.51a.
Survey meter calibration procedure lp 60a, 2no10g √ - comment 1 unnecessary, 2-4 already in SECY-83-62 @ 35.51.
Performance standards for survey meters - lp60a √ - two of the three suggested elements were already in SECY-83-62, the third allowed contractor service and ELD says is unnecessary.
Check instruments before and after each use - lp60a √ - already on SECY-83-62 @ 35.51d.
Keep a record of the calibration - lp60a √ - already on SECY-83-62 @ 35.51e.

(§ 35.52) Procedures for ordering, receiving, and opening packages

Don't order more or different than authorized - lp61a 0 - violation of license
Have written procedures for receiving material - lp61a √ - 35.31b2ii.
Train package receivers lp61a 0 - required by Part 19
Have opening procedures - lp61b 0 - required by Part 20
Critical elements for opening procedures lp61b 0 - noted in Part 20

(§ 35.52) General rules for safe use

Critical safety elements when handling material - lp61c 0 - applicable to entire nuclear industry, not peculiar to medicine.

(§ 35.57) In vitro testing per 31.11

Allows general license without registering - 1p61d 0 - grandfather current users, in future, request as a line item. See S of C.

§ 35.58 Authorization for calibration sources

← Expand list of sources - 1 Encl 4) ✓ - 35.58.

§ 35.59 Requirements for possession of sealed sources

Clarify leak test interval - 1p62 ✓ - 35.59b2.

Clarify leak test procedure - 2nol0h 0 - unduly prescriptive.

Clarify teletherapy leak test procedure - 2nol0i ✓ - 35.59c.

§ 35.62 Syringe labels

Label syringes with radiopharm abbreviation - 1p64 0 - unduly prescriptive. See 35.62.

§ 35.70 Surveys for contamination and exposure rate

Detect 0.1 mR/hr - 1p64a ✓ - 35.70c.

Establish action levels - 1p64a ✓ - 35.70d.

§ 35.75 Release of radioactive patients

30 mCi for radio pharms and 6 mR/hr @/m for perm. implants - 1p65a 0 - 30 mCi in patient can't be measured. 35.75 would allow either. See S of C.

More control over patients - 1 Encl 4 0 - not a significant public health concern.

§ 35.80 Mobile service technical requirements

Have an on-site physician - 1p65b, 1 Encl 4 0 - unnecessary hazard is comparable to giving a blood sample or having a stomach x-ray.

Take all material in, remove it all when you leave - 1p65b ✓ - already in SECY-83-62. See 35.80b

Recheck diagnostic equipment at each site - 1p65f ✓ - 35.80d.

Remove all material before leaving - 1p65b ✓ - already on SECY-83-62. See 35.80b.

Make close-out survey - 2nol0e. ✓ - already in SECY-83-62. See 35.70.

§ 35.90 Storage of volatiles and gases

Storage in a fume hood or airtight container - 1p66a ✓ - already in SECY-83-62. See 35.90

Handle therapy iodine dosages in a fume hood - 1p66a 0 - unnecessarily restrictive

Check your fume hood biannually - 1p66a 0 - belongs in Part 20.

Test trapping devices monthly - 1p66a 0 - belongs in Part 20. but see 35.205.

Pre-license review of use areas - 2nol0f ✓ - added to Regulatory Guide 10.8.

Require "operable" fume hood
with minimum face velocity
stated - 2nol0m

0 - unduly prescriptive. If its not
operable, it's not a fume hood.
See S of C.

§ 35.100 Radiopharmaceuticals for uptake

Comply with chemical form - lp67
Specify IND, NDA drugs - 1 Encl 4
RDRC's are for research, not
patient care, so delete this -
1 Encl 4

Make "any licensee's RDRC," not
just "the licensee's RDRC." -
1 Encl 4

Loosen restrictions on authorized
use - 1 Encl 4

0 - see preamble re "word usage."
√ - 35.100, 35.200.
0 - Added to clarify that, although
not for patient care, such human use
is authorized.
√ - 35.100a.

√ - 35.100, 35.200.

§ 35.200 Radiopharmaceuticals for imaging

Delete xenon gas lp68, also
RG 10.8 p51 was appended

Comply with chemical form - lp69

0 - it is a diagnostic radiopharmaceutical
used for imaging. Although it requires
some different safety procedures, the
level of user training needed and risk
to patient are similar.

0 - preamble re "word usage."

§ 35.304 Safety instruction

Confine patients to a private room
with toilet - lp70a

Keep the patient's room as a
restricted area - lp70a

Control contaminated items - lp70a

Notify RSO of emergencies - lp70a

√ - 35.315

0 - restricted area is defined in Part 20.

0 - not specific to human use.

√ - 35.315.

§ 35.400 Brachytherapy sources

Delete iridium and tantalum as
wire lp70a

0 - the drafting committee would like
public comment on these.

§ 35.405 Safety instruction

Add source description to
training - lp71a

Confine patients to a private room
with toilet - lp71a

Survey waste for displaced sources -
lp71a

Notify RSO of emergencies - lp71a

Handle sources with remote tools -
lp71a

√ - 35.410.

√ - added private room. See 35.415.
toilet not needed for safety.

0 - not needed. but see 35.406.

√ - 35.415.

0 - not specific to human use. but
See 35.400 introductory text.

(§ 35.406) Brachytherapy sources inventory

Designate a responsible individual -
lp71a

Keep an inventory - lp71a

Keep a ledger of source use - lp71a

√ - already in SECY-83-62.
See 35.33b 3iii.

§ - already in SECY-83-62 see 35.59 g, 35.406

√ - already in SECY-83-62. See 35.404.

But due to the hazard of these sources
and the extent of misunderstanding here,
suggested elements have been added.

§ 35.605 Maintenance and repair restrictions

Don't move unit or source - 1p73a ✓ - already in SECY-83-62. See 35.606.
Don't work on the unit - 1p73a ✓ - already in SECY-83-62. See 35.605.

§ 35.606 Amendments

Delete identical source exchange requirement - 1 Encl 4 ✓ - deleted. See 35.606

§ 35.610 Emergency instructions

Add an element - 1p73 ✓ - added. See 35.6106ii.
Change title - 1 Encl 4 ✓ - changed. See 35.610.

§ 35.620 Doors, interlocks

Words are misleading - 1 Encl 4 0 - no one else complained of the wording.
See re-numbered § 35.615.

§ 35.622 Viewing system

↑
Add aural communication - ↑
1 Encl 4 0 - No apparent safety need. X

(§ 35.623) Electrical and mechanical stops

Use mechanical and electrical stops to ensure compliance with limits for unrestricted areas - 1p75a 0 - stops are only one of several ways to ensure compliance with area dose rate limits.

§ 35.630 Dosimetry equipment

Add "or abnormality" - 1p73 ✓ - 35.630.
Add constancy check - 1 Encl 4 0 - AAPM is revising its recommendation on this topic.

§ 35.632 Full calibration measurements

Add "or axis distance" - 1p77 0 - the singular is among the plural.
See 35.632b1.
Add "dependence on orientation" - 1p77 ✓ - 35.632b3.
Add "manufacturer's name" - 1p77 ✓ - 35.632g.

§ 35.633 Spot checks

Add "manufacturer's name" - 1p79 ✓ - 35.633j
Delete "measured time accuracy and on-off error" - 1p79 0 - these are important spot-check items.

(§ 35.640) Circumstances requiring special survey

Events requiring special survey ✓ - added. See 35.641a.

§ 35.641 Radiation surveys

Survey record elements - 1p80b ✓ - most were already in SECY-83-62.
The other have been added.
Define scatter phantom - 2nol0o 0 - unnecessarily detailed.

Extended inspection interval § 35.644 Survey reports
authorized - 1p82a √ - 35.645d.

Training within last five years - § 35.910 Training for uptake . . .
1p83 √ - 35.910a3.

200 hours seems too stringent;
no clinical experience √ - The training requirement has been
required - 1 Encl 4 reduced to parallel training require-
ments for similar amounts of material.
See 35.910 (cf 33.15b).

Training within last five years - § 35.920 Training for imaging . . .
1p84 √ - 35.920a3.

Delete AOBRR - § 35.930 Training for radiopharmaceutical therapy
1p86 √ - deleted. See 35.930a.

Add "3 yr clinical experience" - § 35.940 Training for brachytherapy
1p87 √ - 35.940b.

Add "training at an institution" - § 35.941 Training for Sr-90
1p88 √ - 35.941b2.

No training has been specified - § 35.950 Training for diagnostic sealed sources
1 Encl 4 √ - 35.950.

Add certain certifications - § 35.960 Training for teletherapy
1p89a √ - 35.960a.
Revise classroom training - 1p89 √ - 35.960b.
More critical elements for work √ - added one, two were already in,
experience - 1p89b two are inapplicable.
More critical elements for clinical √ - 35.960b3.
experience - 1p89
Require calibration and spot-check 0 - required, in 35.961, of the more
experience - 1nol0p appropriate individual.

Delete "unit dosage" - § 32.72 Pharmaceutical distributors
1 Encl 4 √ - deleted. See 32.72a4i.
Add group numbers - 1 Encl 4 √ - 32.72.

Add group numbers - § 32.74 Source or device distributors
1 Encl 4 √ - 32.74.

Add a certain certification - § 35.961 Training for teletherapy expert
1p90 √ - added. See 35.961a4.
Clarify two years' experience - 1p90 √ - added. See 35.961b.
Training exemption request - 1p90a 0 - see 35.29.

SUMMARY OF COMMENTS ON PROPOSED REVISION OF
10 CFR PART 35 THAT WAS DISTRIBUTED FOR
COMMENT ON FEBRUARY 15, 1984

Comments

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} dated March 9, 1984
RIIb Briefing Region II/McElroy ^{held} dated March 20, 1984
RIIIb Briefing Region III/McElroy ^{held} dated March 23, 1984
RIVb Briefing Region IV/McElroy ^{held} dated March 21, 1984
RVb Briefing Region V/McElroy ^{held} dated 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 as 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 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 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} "critical 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} permits" office relies on inspectors in the field to determine compliance with the code and workmanship standards, ^{best} not the architect's ^{detail} drawings. ^{or decorator items}

Comment: Are you saying that the licensing process is no longer important?

Response: No. We do, however, believe that the licensing process ^{carries} has assumed 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.*

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.

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 are identified in the regulation. (of all required radiation safety procedures)*

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.

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. Once something has been done incorrectly, whether in violation of regulation or procedure, a lot of inspection and licensing time is consumed. A detailed review and approval process is ^avery 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. ←

Comment: Clarify that we lose a "safety valve" if there is no procedures modification review mechanism exercised by a regulatory agency.

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.

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 implemented, followed, the citation may be issued for failure to comply with the regulation.*

Comment: You say that savings ⁱⁿ and 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.

Response: The disadvantage of Alternative 3 is that the model procedures in the licensing guide become, for practical purposes, regulations. The savings ⁱⁿ and 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 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} costly to 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.

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 procedure^s," it meant more than a review for the sake of reviewing.

Response: In the earlier submission the staff had proposed that the applicant merely certify that he had adequate procedures. ^{not that he submit them for review.} Therefore, the word "pre¹licensing" is an important modifier in the instruction. ~~If the Commissioners' instructions have not been followed, they will let us know.~~

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.

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. X

There are five principal levels of regulation:

1. Registration: Send in your name and address.
2. Self-certify: ^{ication} Promise you will follow the regulations.
3. ~~Show a~~ 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. *The staff is recommending level 3.* X

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. A

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} ~~critical~~ elements of the ~~use of~~ medical radiation safety procedures have been codified in the regulation, and what has not been codified is not of great safety significance. Therefore, to adopt Alternative 3 would require NRC staff to review ^{changes} things that are not of great safety significance.

Comment: Contrary to what you say, Alternativ^e 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.

The confusion as to the status of regulatory guide procedures would remain unresolved.

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.

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?

Response: The prelicensing review provides for a finding of acceptable training and experience, facilities and equipment, and a management commitment to safety. Also, note the Commissioners' instructions in Enclosure 2.

~~Comment: Require a license amendment for use of new rooms within a licensee's facility.~~

Response: No. The licensee needs the authority to use additional rooms for the 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. *to p 11*

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. Response: Many licensees identify equipment by name and serial number and rooms that will be used for storage or use of byproduct material and their applications. The Office of the Executive Legal Director advises that, if he makes changes, he is no longer in compliance with the requirement to conduct his program in

accordance with representations in the application. Therefore under the current licensing system, the licensee must get an amendment before changing ~~either equipment, or rooms of use~~ *add App 10*

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.

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 *of changes* that the licensee's activities be in accord with his procedures and the regulations. X

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.

Response: The alternative you recommend, the NRC review *of changes* and approval, 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?

Response: If a person is planning on willful negligence, the prior submission of a long application is unlikely to deter him, while it increases the 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 procedures even as the inspector is conducting his review?

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.

Response: This is noted in the staff paper section "Alternative 2--^{Objections}~~Opponents~~."

Comment: Today, about 40% of ^{incoming requests} applications 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?

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 ^{pur} supported to be for guidance only. By codifying all the requirements in one place, the applicant can use the regulation as a check list 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 and safety program.

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 inflexible to meet changing patient care needs. He should not have to pay an amendment fee to modify his 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 the changes he is making in his procedure.

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 is subject to enforcement action. A notation that procedural modifications must be in accord with the regulations appears throughout the preamble.

A new appendix regulatory guide 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. I
X

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.

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. *The* *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.

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.

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's 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 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, which will be published in the regulatory guide, 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 ^{for} the preamble section entitled "Notes."
See

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. Compare the word "licensee"--A licensee may be a non-living business entity. The wording of the requirement places a legal responsibility on the licensee that may be fulfilled by full- or part-time employees or 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 consideration, in the regulatory guide in case of question of regulatory intent or interpretation comes 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 rather of a business or government entity ^{rather} than the normal "An individual human being").
cc, underline

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, such formalized communication is unnecessary. If Part 20 is revised, the conflict 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.

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.

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?

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.

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.

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

he is out of compliance because

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? *

Response: The regulatory guide ^{procedure provides} establishes 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 has not implemented the procedure. If he has not initiated the repair after going outside the regulatory standard, he 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.

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.

Comment: The dose calibrator linearity should only be tested to the highest dosage ordinarily measured, not the highest dosage ever measured.

Response: No. Therapy dosages, which are not ordinarily measured because they are not frequently administered, are 10-fold higher than diagnostic dosages. The linearity test provides the only assurance that the higher measure is accurate.

Comment: If the dose calibrator manufacturer supplies geometry dependence test results, there is no need for the licensee to repeat the test.

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. *

Response: Agreed. However, it will be developed independent of this project. X

Comment: You should require that the dose calibrator be tested for accuracy with sources similar in energy to the materials that will be assayed.

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.

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 0 to the highest activity measured. *zero*

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 linearity from 2 curies to 10 microcuries. 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%.

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.

Response: No. The licensee bears the responsibility of selecting equipment that is capable of making the measurements required.

Comment: You should require that survey meters be calibrated on each scale at two points that are separated by 50%.

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?

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.

Response: That was the intent. The wording has been clarified.

Comment: You should require that technicians who handle radiopharmaceuticals must wear laboratory coats and gloves.

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.

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.

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 (copy attached); 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, copy attached -- 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:

$$\frac{1 \text{ mR}}{\text{mCi-min}} \times \frac{10 \text{ mCi}}{\text{dosage-draw}} \times \frac{0.2 \text{ min}}{\text{draw}} \times \frac{10 \text{ dosages}}{\text{da}} \times \frac{250 \text{ da}}{\text{yr}} = \frac{5 \text{ rem}}{\text{yr}}$$

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. ~~I disagree.~~ *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.

Insert Op 23

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.

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.

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.

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.

SURVEYS

Comment: Will the applicant specify contamination action levels in his 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 required. He is best suited to oversee the control and cleanup of the spilled material.

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 cm².

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

contaminations 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 talks 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.

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 area of use at the client's facility to be an unrestricted area. If he can't control the area, he 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 licensed ⁹condition that exempts the licensee from Section 35.35 and also identifies the authorized therapeutic radiopharmaceuticals.

BRH

↓

$$\text{I-125} \quad \frac{700 \text{ mRem}^2}{\text{mCi hr}} \times .5 \text{ mCi} \times \frac{1}{100 \times 100 \text{ cm}^2} = .04 \frac{\text{mR}}{\text{hr}}$$

$$\text{Ia-192} \quad \frac{4800 \text{ mRem}^2}{\text{mCi hr}} \times .5 \text{ mCi} \times \frac{1}{100 \times 100 \text{ cm}^2} = .24 \frac{\text{mR}}{\text{hr}}$$

Victoreen catalogue: all ion chambers are
0-1 or 0-3 mR/hr f.s.

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: 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 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: 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: ^{low range GM} ~~A quarterly survey may be contracted out.~~ ^{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 range meter} the area where ^{low activity} brachytherapy seeds are implanted in case they are lost in the surgical dressing. *

Response: ~~Done~~ 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 0-3 mR/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} statement of considerations has been revised to ^{allow licensees} invite the teletherapy community to suggest ^{use the new} other calibration protocols that would meet the regulatory requirement. Not all licensees have the equipment needed to follow the new calibration protocol.

*However,
Therefore, either is allowed.*

Comment: You say to measure radiation "quantities" around new teletherapy units. Don't you mean "levels"?

Response: No. The word "level" connotes a continuous 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.

Comment: 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.

Response: 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: ^DNone. Further review of licensee files has indicated that only a few 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 on the public, to not allow its use would be an unnecessary intrusion into the practice of medicine. 12

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} human 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 been 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: 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^{sp} 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: 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: 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: 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: Because of the size and specificity of this proposal, a 120-day comment period is needed.

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 Guide 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

*(A) whether he is called a provisional authorized user
or a visiting authorized user.*

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. 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 standard man averages, not the pharmacokinetics observed in the ill patient. The dose rate measurement at a distance is meaningful, inexpensive, easy, and relevant. Other suggestions for patient release standards are welcome.

Comment: Changes in NRC regulations will effect 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.

*(B) The licensee may select either the dose rate at a distance
or the activity retained as his release standard.*

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 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.

as a result of conducting 1568 medical inspections that year
Of the 1240 citations issued in 1982, 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 ~~might~~ 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
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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
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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
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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