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

APR 26 1983

MEMORANDUM FOR: Samuel J. Chilk, Secretary
Office of the Secretary

FROM: Patricia G. Vacca
Joseph DeMedico
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: STAFF REQUIREMENTS--BRIEFING ON SECY 83-62

This is in reference to Item 2 of your memorandum dated April 19, 1983 (M 830419), requesting that we mark up the staff proposal with changes that would satisfy our concerns. Enclosure 1 is the requested mark-up. In preparing this document, NMSS management requested that we:

- Consider only substantive concerns of health and safety significance as opposed to philosophical issues.
- Complete the project within 4 - 5 working days.
- Devote primary attention to the regulation as opposed to the application form.

Because of the short turn-around time, this document is more concept than polished product and represents only one approach to the problem. The task force could refine this concept or develop a viable alternative with input from the Commission, ELD, other NRC Offices, and the Agreement States.

In the interest of time we had to make some assumptions about the application form. We envision a form that would incorporate features similar to pages 2, 5, 6, and 7 of the current Form NRC 313 (Enclosure 2). The information on this form would allow a pre-licensing determination of the adequacy of:

- Radiation safety procedures and instructions.
- Training and experience of non-board certified physicians.
- Facilities and equipment.

Although the application form would request this information and NRC would review it, the regulation incorporates the Chairman's suggestion that licensees be given the flexibility to change their procedures without amending the license. (See the proposed Section 35.26a.)

Also in the interest of time, we removed xenon 133 from Subpart E (Section 35.200). Xenon requires special ventilation, equipment, calculations, and procedures. Our quick repair would require the applicant to apply for specific authorization by submitting information similar to that requested in Appendix I of the current Regulatory Guide 10.8 (Enclosure 3). It may be possible to establish a new subpart for radioactive gases and place all of the necessary requirements directly into the regulation, but this effort would take more time than we have been allotted.

Enclosure 4 is a list of additional items that should be examined before the rule is published in proposed form. While these are perhaps less "substantive" than the issues that our mark-up addresses, we believe that they should be resolved before publication.

Patricia C. Vacca

Joseph DelMedico

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Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Marked-up revision of
   10 CFR 35
2. Form NRC-313M
3. Appendix A of Regulatory Guide 10.8
4. Recommendations for other changes
   to the regulation

cc w/encl:
GJWalker, NMSS
VLMiller, NMSS
DRChapell, NMSS
TECunningham, NMSS
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35.31(a)(4) and (a)(5), 35.32(f)-(i), 35.34(c), 35.37(a)-(d), 35.50(d), 35.51(e), 35.53(c), 35.59(d) and (e), 35.59(g) and (i), 35.70(d), 35.80(f), 35.92(b), 35.204(c), 35.304, 35.404(b), 35.405, 35.610, 35.621(e), 35.630(c), 35.632(g), 35.633(j), 35.641(c), 35.642(c), 35.644, and 35.645(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A -- General Information

§ 35.1 Purpose and scope.

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

§ 35.2 License required.

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

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

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

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

(1) The OMB control number is _____.

(2) OMB approval expires _____.

(b) The apporved information collection requirements include the application, recordkeeping, and reporting requirements contained in §§ 35.16, 35.18, 35.30(d), 35.31(a), 35.32(f), (h) and (i), 35.33(b), 35.34(c), 35.35(b), 35.37(a)-(d), 35.50(d), 35.51(e), 35.53(c), 35.59(c), 35.59(d) and (f), 35.70(c), 35.80(e), 35.92(b), 35.204, 35.304(b), 35.404(b), 35.405, 35.604, 35.610, 35.621(d), 35.630(c), 35.632(g), 35.633(e) and (j), 35.641(c), 35.642(c), 35.644, and 35.645(c).

§ 35.15 Definitions.

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

"ALARA" means as low as reasonably achievable.

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

"Human use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings.

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

"Management" means the chief administrative officer of a licensee.

"Misadministration" means the administration of:

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

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

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

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

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

(6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry

result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

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

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

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

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

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

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

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

§ 35.16 Application for license, amendment, or renewal.

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

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

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

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

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

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

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

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

§ 35.17 License Amendments.

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

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

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

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

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

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

(f) Before making any changes in the licensed program that could result in a reduction of radiation safety.

§ 35.18 Notifications.

The licensee shall notify the Commission in writing on Form NRC-313M (revised) within thirty days when an authorized user, Radiation Safety Officer, or qualified teletherapy calibration expert, permanently discontinues performance of duties under the license. The licensee shall mail the form to the appropriate address identified in § 35.16.

§ 35.28 License issuance.

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

(a) The applicant has filed Form NRC-313M "Application for Materials License--Human Use";

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

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

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

→ §35.28a. See attached - p. 51a

§ 35.29 Specific exemptions.

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

Subpart B--General Administrative Requirements

§ 35.30 ALARA program.

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

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

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

35.28a. Changes in procedures and instructions.

Without prior Commission approval, the licensee may make changes to the procedures and instructions described in the license application, provided that the revised procedures and instructions continue to fulfill the requirements of this part.

35.29a This proposed change would place the staff in the role of providing, and requiring the use of, free consultation whether needed or not. Furthermore, it would not provide the regulatory restraint that the TP ideas is desired by Vacca and DeMedico because a disingenuous applicant could submit conservative procedures for review and then, on receipt of his license, revise them.

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(2) The program must include a periodic review of byproduct material use, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The review and education must assure that individuals make every reasonable effort to maintain individual and collective occupational dose equivalent as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

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

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

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

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

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

§ 35.31 Radiation Safety Committee.

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

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

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

(2) The committee must meet at least quarterly.

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

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

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations;

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

(vi) ALARA program reviews.

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

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

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

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

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

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

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

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

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

§ 35.32 Radiation Safety Officer.

Each ~~institutional~~ licensee ~~organization~~ shall appoint a Radiation Safety Officer who is responsible for establishing and maintaining the radiation safety policies designated by management. The Radiation Safety Officer must be a member of the Radiation Safety Committee and responsible to the licensee's management for ensuring that radiation safety activities are being correctly performed in the daily operation of the licensee's radiation safety program including:

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

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

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

§ 35.33 Administrative Requirements for Authority and Responsibilities.

(a) The licensee shall provide the Radiation Safety Committee and Radiation Safety Officer sufficient authority and organizational freedom to: (1) identify radiation safety problems; (3) initiate, recommend or provide solutions; and (3) verify implementation of solutions.

(b) The licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Committee and Radiation Safety Officer. To satisfy the requirements of this section, in addition to the functions specified in §§ 35.31 and 35.32, the Radiation Safety Committee or Radiation Safety Officer must perform or ensure performance of the following functions:

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

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

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

(i) Emergency actions;

(ii) Periodic radiation surveys;

(iii) Periodic inventory of byproduct material;

(iv) Safety during use of byproduct material;

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

(vi) Training of personnel.

Replace with attached – page 55a

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

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

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

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

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

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

§ 35.34 Visiting authorized user.

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

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

35.33. Administrative requirements for authority and responsibilities.

(b)(4) Establishing and implementing a radiation safety education program for personnel working in or frequenting areas where byproduct material is used and stored. To satisfy this requirement, the radiation safety education program shall provide training:

(i) upon employment and at least annually thereafter; and

(ii) in the items specified in §19.12 of this chapter; and

(iii) in those procedures and instructions developed by the licensee to comply with the requirements of this part that are applicable to the employee's duties.

p55 35.3354 The TP believes the licensee is best qualified to determine the necessary training freqiency. For procedures that are done only once every several months, training should precede each procedure. For procedures that are done each day and audited by the authorized user or RSO, there is no need for periodic training. V&D b4ii and b4iii simply restate current 19.12 and are superflucus.

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

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

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

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

§ 35.35 Mobile service administrative requirements.

See new text, p.56a

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

(b) Mobile service licensees shall maintain a letter authorizing use of byproduct material signed by the management of each location where services are rendered.

§ 35.37 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

35.35. Mobile service administrative requirements.

(a) The Commission will only license mobile services in accordance with Subparts D, E and H of this part and §31.11 of this chapter, except that the license will authorize neither elution of generators nor the preparation of radiopharmaceuticals from reagent kits at locations serviced by the mobile service.

(b) The Commission will only license mobile service licensees to provide services to persons who do not hold an NRC license.

(c) Mobile service licensees shall maintain a letter authorizing use of byproduct material signed by the management of each location where services are rendered.

T.F. -Naples

p56 35.35 V&D 35.35a appears to be identical to proposed 35.80a. The TF believes that to restrict a mobile service to unlicensed clients would unnecessarily interfere with the delivery of medical care. For example, this would prohibit a mobile service from providing technical assistance to a small licensee whose sole technician is on vacation. V&D 35.35c is identical to proposed 35.35b.

(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 (1) of this section. The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report shall 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 shall include the licensee's name; the referring physician's name; a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information that could lead to identification of the patient.

(d) Each licensee shall maintain for Commission inspection records of all misadministrations of radiopharmaceuticals or radiation from diagnostic, teletherapy or brachytherapy sources or interstitial implant sources. These records shall 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. These records shall be preserved until the Commission authorizes their disposition.

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

§ 35.38 Supervision.

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

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

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

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

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

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

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

(2) Follow the procedures established by the Radiation Safety Officer pursuant to § 35.32; and

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

§ 35.49 Suppliers.

The licensee may use for human use only:

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

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

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

Subpart C--General Technical Requirements

§ 35.50 Calibration and check of dose calibrators.

See new text, pp 59a & 59b

(a) The licensee shall:

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

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

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

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and configurations for which it is normally used.

The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

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

(c) The licensee shall mathematically correct readings for any error in excess of 10 percent if the dose is greater than 10 microcuries and the radiopharmaceutical emits a photon with an energy greater than 25 kev.

(f) (d) The licensee shall keep records of the checks and tests required by this section for two years unless directed otherwise.

(1) The record required in paragraph (a)(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

Subpart C--General Technical Requirements

35.50. Requirement for dose calibrator; calibration and check of dose calibrator.

(a) Each licensee required to assay radiopharmaceutical dosages under §35.53 shall have a dose calibrator in his possession and available for use.

(b) The licensee shall:

(1) Test each dose calibrator daily for constancy of operation as follows:

(i) Assay at least one of the reference sources required under (c) below, using the appropriate instrument setting (i.e., Cs-137 on the Cs-137 setting).

(ii) Compare the net activity reading on the dose calibrator to the predicted activity of the reference source.

(2) Test each dose calibrator upon installation and at least annually for accurate response over the range of radionuclide energies to be assayed in daily operations. This test shall be conducted as follows:

(i) Assay the reference sources required under (c) below, using the appropriate instrument setting for each source.

(ii) Compare the net activity reading on the dose calibrator for each reference source to the predicted activity of that reference source.

(3) Test each dose calibrator for linearity upon installation and at least every three months as follows:

(i) Assay a vial of technetium-99m, the activity of which is equal to the highest activity of any radionuclide that is assayed in daily operations.

(ii) Using the same source or serial dilutions of the same source, repeat step (i) at known activity points over the full range of activities that are assayed in daily operations. These known activity points may be obtained by diluting the source, allowing it to decay, or surrounding the source with lead sleeves from a commercially available linearity test kit.

(iii) Compare the instrument reading at each activity point with the predicted activity of the source at that point.

(4) Unless correction factors have been supplied by the manufacturer of the instrument, test each dose calibrator upon installation for geometry dependence as follows:

(i) Assay a fixed amount of a given radionuclide in the various containers and volumes that are assayed in daily operations.

(ii) Compare the instrument reading for each container and volume with the instrument reading for the container and volume selected as the standard reference.

(c) Use the reference standards listed in Table 1 for performing accuracy and constancy tests on the dose calibrator.

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

(e) The licensee shall mathematically correct radiopharmaceutical dosage assays for any instrument error detected in (b) and (d) above if the error is in excess of 10 percent, the dose is greater than 10 microcuries, and the radiopharmaceutical emits a photon energy greater than 25 kev.

Table 1. Dose Calibrator Reference Standards

Radionuclide	Activity	Calibration Accuracy
Cesium 137	100 microcuries or more	Within 5%
Cobalt 57	One millicurie or more	Within 5%

V&D 35.50a The TF agrees that there should be a clear statement that the licensee must possess a dose calibrator.

V&D 35.50b1 The paragraph does not appear to accomplish any more than proposed 35.50a2

V&D 35.50b2 The suggested paragraph would require that two specific radionuclides be used, and establishes higher actifity levels than are stated in the proposed draft. It is not necessary to use Cs-137 and Co-57 to test the accuracy of a dose calibrator; other radionuclides are available. The TF believes that 50 uCi is a sufficiantly high activity to test for accuracy.

V&D 35.50b3 re i, the TF believes that to test for linearity outside the range of patient dosage measurements is unnecessary and inconsistent with ALARA principles. re ii, the TF believes that testing by serial dilutions is inaccurate and inconsistent with ALARA principles.

V&D 35.50b4 The paragraph does not appear to add to proposed 35.50a4.

V&D 35.50c Cesium-137 and Co-57 are not uniquely qualified for use when testing a dose calibrator. It is not necessary to use a calibrated source when checking for constancy.

V&D 35.50d This duplicates proposed 35.50b.

V&D 35.50e This duplicates proposed 35.50a

check, the activity measured, and the initials of the individual who performed the check.

(2) The record required in paragraph ~~(a)~~(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 ~~(a)~~(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 ~~(a)~~(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~~.

Replace with attached; see pp. 60a & 60b

~~(a) The licensee shall calibrate survey instruments annually and following repair;~~

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

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

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

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

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

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

35.51. Requirement for survey instruments; calibration and check of survey instruments.

(a) The licensee shall have in his possession and available for use the following radiation detection instruments:

(1) A low-level survey meter capable of detecting 0.1 milliroentgen per hour.

(2) A high-level survey meter capable of reading up to 1 Roentgen per hour.

[Ed. Note: Licensees who have only Subpart D materials would need an exemption from (2) above. Licensees who have only Subpart H materials would need an exemption from (1) and (2) above. ELD can provide the wording.]

(b) The licensee shall calibrate survey instruments annually and following repair.

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

(1) Perform the calibration with radionuclide sources at distances sufficient to approximate point sources; and

(2) Calibrate all scale readings up to 1 Roentgen per hour; and

(3) Calibrate two readings on each scale up to 1 Roentgen per hour; and

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

(d) To satisfy the requirements of paragraph (a) of this section, the licensee may:

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

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

(3) Have the survey instrument calibrated by a person or firm outside of the licensee's organization provided that the licensee obtains written assurance that the calibration has been performed as specified in paragraphs (c) and (d) above.

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

(f) The licensee shall keep a record of each calibration required in paragraph (a) above for the duration of use of the instrument. To satisfy the requirements of this paragraph, the record must include:

T.F. reply

(1) A description of the calibration procedure; and

(2) A description of the source radionuclide used and its estimated activity.

V&D 35.51a The TF agrees that there should be a clear statement that the licensee must possess a survey instrument. The TF, and the industry, are divided on the necessary range of measurement capability. The suggested wording could be used to elicit public comment.

V&D 35.51b This duplicates proposed 35.51a.

V&D 35.51c Suggested c1 is universal practice. re c2, see proposed b1. re c3, see proposed b2. re c4, see proposed b3.

V&D 35.51d re d1 and d2, see proposed c1 and c2. Suggested d3 accomplishes nothing. The burden of proof already lies on the licensee.

V&D 35.51e This duplicates proposed 35.51d.

V&D 35.51f This duplicates proposed 35.51f.

(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 function 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 keep a record of each calibration required in paragraph (a) above for the duration of use of the instrument. To satisfy the requirements of this paragraph, the record must include:

(1) A description of the calibration procedure; and

(2) A description of the source radionuclide used and its estimated activity.

See new §§ 35.52a, 35.52b, 35.52c on pp 61a, b & c, attached

§ 35.53 Measurement of radiopharmaceutical dosages. See attached T.S. reply

The licensee shall:

(a) Assay before human use the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a radionuclide that emits electromagnetic radiation in the form of gamma rays or x-rays.

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

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

(1) Generic name of the radiopharmaceutical, its lot number, and expiration date;

(2) Patient's name and identification number;

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

(4) Date and time of the measurement.

See new § 35.57 on p. 61d See attached T.S. reply

§ 35.58 Authorization for calibration and reference sources.

Any person authorized by § 35.2 for human use of byproduct material may receive, possess, and use byproduct material in sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of

35.52a. Procedures for ordering and receiving packages containing radioactive material.

(a) The licensee shall establish and implement written procedures for ordering radioactive materials. As a minimum, these procedures shall be sufficient to ensure that the radionuclide and chemical or physical form ordered are authorized by the license and that, considering the quantities on hand, the quantity ordered will not exceed the possession limits on the license.

(b) The licensee shall establish and implement written procedures for receiving packages containing radioactive material during normal working hours and during off-duty hours. As a minimum, these written procedures shall require:

(1) That packages containing radioactive material be delivered to a specified location in the licensee's facility;

(2) That individual(s) be designated who will accept packages containing radioactive material that are delivered after normal working hours; and

(3) That the individual(s) designated as required in subparagraph (2) be given written instructions. As a minimum, these written instructions shall:

(i) Specify whom to contact if a package appears wet or damaged; and

(ii) Be sufficient to ensure that packages containing radioactive material that are delivered after normal working hours are secured against unauthorized removal and in such a manner that radiation levels in unrestricted areas meet the requirements in §20.205(b) of this chapter.

VaDH35.52a Receipt of material in excess of that permitted by the license would be a violation that, the TF assumes, would drive the licensee to establish the procedure out of self-preservation. The licensee has a vested financial interest in every other item cited because if the package is not received by the proper person, and secured, it may be lost but must still be paid for. Section 20.205b need not be repeated here.

35.52b. Procedures for safely opening packages containing radioactive material.

The licensee shall establish and implement written procedures for safely opening packages containing radioactive material. As a minimum, these written procedures shall require:

(a) That each package containing byproduct material be opened in accordance with the established written procedure.

(b) That each package be monitored to determine that the surface exposure rate is less than 200 milliroentgens per hour.

(c) That if the surface exposure rate exceeds 200 milliroentgens per hour, the individual shall stop the procedure and notify the radiation safety officer immediately.

(d) That the final source container shield be wipe tested and that the wipe be checked with a calibrated low-level survey meter ot other suitable detection instrumentation to detect the presence of unacceptable contamination levels.

T.F.

p61b VED 35.52b Section 20.205d requires that each licensee have package opening procedures. The entire suggested section belongs in Part 20 because nothing in it is peculiar to the human use of byproduct material.

35.52c. General rules for safe use of radioactive materials.

The licensee shall establish and implement written procedures governing the safe use of radioactive material. As a minimum, these written procedures shall require:

(a) The use of laboratory coats or equivalent protective clothing at all times in areas where unsealed radioactive materials are being used or stored; and

(b) The use of waterproof gloves at all times when handling radioactive material; and

(c) That hands and clothing be monitored every time that an individual exits an area where unsealed radioactive materials are used or stored; and

(d) That individuals do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored; and

(e) That individuals do not store food, drink, or personal effects in any area where radioactive material is used or stored; and

(f) That each individual wear his or her assigned film or TLD whole body monitoring badge at all times in areas where radioactive material is used or stored; and

(g) That each individual wear his or her assigned film or TLD finger badge at all times during activities that involve elution, preparation, assay, or administration of millicurie quantities of radioactive material; and

(h) That individuals do not pipette radioactive solutions by mouth.

T.F. Hyde - See comment on preceding page (61)

35.57 Authorization to perform in vitro tests under the general license issued pursuant to § 31.11.

Any person authorized by §35.2 of this part for human use of byproduct material is also authorized to use byproduct material under the general license in §31.11 of this chapter for the specified in vitro uses without filing Form NRC-483 as required by §31.11(b): Provided that:

a. The licensee is subject to the other provisions of §31.11, and

b. The licensee's work done pursuant to this authorization for the general license is physically and administratively separated from the human use activities conducted under the licensee's specific license.

T.F. replies

p61d V&D 35.57 ELD concurs with the TF proposal that this request simply be added to the application form as a line entry. See proposed form NRC-313MH item 4.

this chapter or equivalent Agreement State regulations for check, calibration, and reference use if such sources do not exceed 6 millicuries each.

§ 35.59 Requirements for possession of sealed sources.

(a) A licensee in possession of a sealed source for human use shall use the source in accordance with the instructions supplied by the manufacturer, and shall maintain such instructions in a legible form convenient to users of the source.

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

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

(2) Test the source for leakage at intervals not to exceed six months, ~~unless the manufacturer has indicated that the source has been~~ or at such other intervals as are approved by the Commission or an Agreement State ~~for leak testing at longer intervals.~~ and described on the manufacturer's label or brochure.

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

(1) Take the test sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate;

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

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

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

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

(1) Immediately withdraw the sealed source from use and store, decontaminate, repair, or dispose of the source in accordance with Parts 20 and 30 of this chapter; and

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

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

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

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

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

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

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

(6) Sources containing only hydrogen-3.

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

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

(g) Any licensee in possession of a sealed source shall conduct a quarterly physical inventory of all sealed sources in the licensee's possession. The licensee shall keep inventory records for two years. The inventory records must contain the model and serial number of each source, the identity of each source radionuclide and its estimated activity, the location of each source, and the signature of the Radiation Safety Officer.

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

(i) The licensee shall keep a record of the surveys required in paragraph (h) of this section for two years. The record must include

p63 35.59? This seems a good time to get industry comment on whether iridium and tantalum wires should be available.

the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields.

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

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

§ 35.61 Vial shields.

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

§ 35.62 Syringe labels.

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

§ 35.63 Vial labels.

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

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

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

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

p64 35.62 The TF believes the suggested change would be unduly prescriptive. The NF would like public comment on this.

See insert on p.64a the T.F. agrees.

35.70. Surveys for contamination and ambient exposure rate.

(c) The surveys required in paragraphs (a) and (b) above shall be sufficiently sensitive to detect 0.1 milliroentgens per hour.

(d) The licensee shall establish decontamination action levels and shall ensure that the radiation safety officer is notified whenever those levels are exceeded.

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

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

See new text, p. 65a

~~§ 35.75~~ Release of patients containing radiopharmaceuticals or permanent implants.

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

§ 35.80 Mobile service technical requirements.

A licensee providing mobile service shall:

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

Insert new (b) & (c) - see p. 65b

~~(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~~;

(d) ~~(c)~~ Secure or keep under constant surveillance and immediate control all byproduct material;

(e) ~~(d)~~ Check equipment transported to the location of use as described in ~~§~~ 35.50 and 35.51, prior to human use;

Insert new (f) and (g) - see p. 65b

~~(e) Carry a calibrated survey meter in each vehicle that is being used to transport byproduct material, and survey for ambient radiation exposure rate with a low range survey meter prior to departure from the location of byproduct material use; and~~

(h) ~~(f)~~ Keep a record of the surveys required in subsection ~~(g)~~ for one year. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in

35.75. Release of patients containing radiopharmaceuticals or permanent implants

The licensee shall not authorize release from confinement for medical care any patient:

(a) Administered iodine 131 or colloidal gold 198 until the residual activity is 30 millicuries or less; or

(b) Administered a permanent brachytherapy implant until the exposure rate from the patient is less than or equal to 6 milliroentgens per hour at one meter from the patient.

35.80. Mobile service technical requirements.

(b) Ensure that at least one physician designated on the license as an on-site physician is present at the location of use whenever byproduct material is used at that location.

(c) Bring into each location of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste. (The facility utilizing the mobile service cannot receive, possess, or store byproduct material other than the amount of material remaining in the patient.)

(f) Recalibrate, in accordance with the manufacturer's instructions, all diagnostic equipment transported to the location of use. This recalibration shall be prior to human use.

(g) Before leaving each location of use, perform a survey to ensure that all sources of radioactive material have been removed and that the location is free of radioactive contamination.

T.F. 2=35.70a

p65b V&D 35.80b The TF believes that an on-site physician is not needed for the types of studies that a mobile service can perform. The hazard of the studies is roughly comparable to that of giving a blood sample or having a stomach x-ray.

V&D 35.80c This duplicates proposed 35.80b.

V&D 35.80f The TF does not believe uncalibrated equipment poses a risk but is amenable to including the suggestion to elicit public comment.

V&D 35.80g This appears to duplicate proposed 35.80b and f.

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.

See new text, p.66a

~~§ 35.90 Storage of volatiles and gases.~~

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

See T.F. typing box

§ 35.92 Decay-in-storage.

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

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

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

(3) Removes or obliterates all radiation labels; and

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

(b) For paragraphs (a)(1), ~~and~~ (a)(2) and (a)(4) of this section, the licensee shall keep a record of each disposal for two years. The record must include the date of the disposal, the date on which the byproduct material was stored, the model number of the survey instrument used, the background radiation level, and the name of the individual who performed the disposal. [the results of the monitoring required in paragraph (a),

T.F. agrees

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

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

(a) The licensee shall use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake,

35.90. Special requirements for use of volatiles and gases.

The licensee shall:

(a) Store volatile radiopharmaceuticals and radioactive gases in a fume hood with adequate airflow or in a container with two airtight barriers against release.

(b) Conduct procedures that involve opening and preparing therapeutic liquid iodine 131 solutions in a fume hood with adequate airflow.

(c) At least every six months, measure the airflow rates in each area where radioactive gases are used or stored to ensure continued complaince with §§20.103 and 20.106 of this chapter.

(d) Test radioactive gas trapping devices at least monthly to ensure that they are performing according to the manufacturer's specifications and to ensure continued compliance with §§20.103 and 20.106 of this chapter.

T.F.

p66a V&D 35.90a This is similar to proposed 35.90.

V&D 35.90b, c, and d These measures are appropriate for high volume users of I-131. The TF is amenable to incorporating them in Subpart F. For diagnostic quantities, the TF believes the suggested requirements are overly prescriptive.

dilution, or excretion in accordance with the product labeling or package insert instructions for use supplied by the radiopharmaceutical manufacturer, except as provided in paragraph (b) of this section:

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

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

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

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

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate;

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

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

Subpart E--Group II/III (imaging)

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

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

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

(2) Technetium-99m as pertechnetate;

p67 35.100b A professional nuclear pharmacist has said that, if the chemical form has been changes, the licensee would not be using one of the listed radiopharmaceuticals.

However, T.F. would incorporate the words if necessary to achieve agreement.

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

(i) Sulfur colloid;

(ii) Pentetate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphate;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin; and

(xiii) Succimer.

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

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

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

~~(7) Chromium-51 as human serum albumin;~~

(8) Gold-198 in colloidal form;

(9) Mercury-197 as chlormerodrin;

(10) Selenium-75 as selenomethionine;

(11) Strontium-85 as nitrate;

(12) Ytterbium-169 as pentetate sodium;

(13) Indium-113m as chloride;

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

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

(b) The licensee using the radiopharmaceuticals listed in paragraph (a) of this section for clinical procedures other than those

specified in the product labeling or package insert shall comply with the product labeling or package insert regarding:

(1) Physical form and chemical form;

(2) Route of administration; and

(3) Dosage range.

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

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

§ 35.204 Permissible molybdenum-99 concentration.

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

(b) The licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test each generator eluate or extract for molybdenum-99 concentration.

(c) The licensee shall maintain a record of molybdenum concentration test results for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium, expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the date of the test, and the initials of the individual who performed the test.

§ 35.205 Control of aerosols and gases.

The licensee who administers radioactive aerosols or gases shall do so with a system that will prevent the unintended dispersal of the byproduct material. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

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

§ 35.300 Use of radiopharmaceuticals for therapy.

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

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

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

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

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

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

§ 35.304 Safety instruction.

see new text, p. 70a

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

(1) Patient control;

(2) Visitor control;

(3) Contamination control; and

(4) Waste control.

(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.

35.304. Personnel instruction concerning radiopharmaceutical therapy.

The licensee shall provide oral and written instruction concerning patient control, visitor control, contamination control, and waste control to all personnel caring for each patient undergoing radiopharmaceutical therapy. These instructions shall be sufficient to ensure that:

(a) Patients treated with iodine 131 or gold 198 are confined to a private room with a private toilet for the duration of treatment, except for special medical purposes approved by the radiation safety officer; and

(b) The room of any patient treated with iodine 131 or gold 198 will be maintained as a restricted area as defined in §20.3(a)(14) of this chapter for the duration of the treatment and until surveyed for contamination and released for unrestricted use following the treatment; and

(c) Contaminated items are not released for unrestricted use or disposal; and

(d) The radiation safety officer will be notified if the therapy patient dies or requires surgery during the treatment.

T.F. wp

p70a V&D 35.304 The introductory paragraph is similar to proposed 35.304(a). re a, the TF does not believe a private toilet is a critical safety need for radiopharmaceutical therapy patients. re b, section 20.105 already identifies those instances in which a licensee must declare an area restricted. There is no need to reiterate them. re c, release of contaminated items would be contrary to 20.301. There is no need to reiterate this. The TF is amenable to including suggested paragraph d.

There appears to be a distinction "good practice" and "working rules" that have site specific significance apply to all licenses.

Subpart G--Group VI (sources for brachytherapy)

§ 35.400 Use of sources for brachytherapy.

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

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

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

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

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

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

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

~~(g) Tantalum-182 as wire~~.

§ 35.404 Release of patients treated with temporary implants.

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

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

§ 35.405 Safety instruction.

(a) ~~The licensee shall provide written radiation safety instructions to all individuals caring for the patient undergoing brachytherapy.~~

p71 35.400 d and g This seems a good time to get industry comment on whether iridium and tantalum wires should be available.

See new text, p. 71a

See T.F. 4 p. 71a

35.405. Personnel instruction concerning brachytherapy.

The licensee shall provide oral and written instruction concerning (1) patient control and visitor control and (2) the size and appearance of the brachytherapy sources, to all personnel caring for each patient undergoing brachytherapy. These instructions must be sufficient to assure that:

(a) For the duration of treatment, patients treated with brachytherapy sources be confined to a private room with a private toilet except for special medical purposes approved by the radiation safety officer; and

(b) The room of any patient treated with brachytherapy sources will be maintained as a restricted area as defined in §20.3(a)(14) of this chapter for the duration of the treatment and until surveyed for the presence of displaced sources and released for unrestricted use following the treatment; and

[Ed. Note: Some sources such as iodine 125 seeds may deserve an exemption from paragraph (b). ELD can supply the wording.]

(c) Patient clothing, linen, bandages and dressings are not released for unrestricted use or disposal until surveyed for the presence of displaced sources; and

(d) The radiation safety officer be notified if (1) sources become loose or separated from the patient, or (2) the patient dies or requires surgery during the course of treatment; and

(e) Brachytherapy sources be handled at all times with remote handling tools and never by hand.

p71a VAD 35.405 The TF is amenable to including source description in the required training. The TF does not believe a private toilet is a critical safety need for brachytherapy patients. re b, section 20.105 identifies those instances in which a licensee must declare an area restricted. Proposed 35.404 would accomplish the same purpose as the suggested requirement for surveying a room for displaced sources. re c, the loss of a seed would be contrary to 20.301. The TF is amenable to including suggested paragraph d. Section 20.101 establishes dose limits for the hands.

This indicates a general misunderstanding of the problems. These patient are rarely ambulatory and use portable urinals. These may be flushed down drain, but there are many site specific

To satisfy this requirement, the instructions must describe procedures for:

(1) Patient control; and

(2) Visitor control.

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

§35.406 New section, see p. 72a

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

§ 35.500 Use of sealed sources for diagnosis.

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

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

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

Subpart I--Group VIII (teletherapy)

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

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

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

(b) Cesium-137 as a sealed source.

§ 35.604 Information to be submitted with application.

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

35.406. Accountability of brachytherapy sources

The licensee shall establish and implement written procedures for accountability of brachytherapy sources. To satisfy this requirement, these procedures shall:

(a) Designate the individual on the licensee's staff responsible for the accountability program.

(b) Require the maintainence of a brachytherapy source accountability ledger that shows the location of each brachytherapy source within the licensee's facility at all times.

(c) Require that the appropriate notations be made to the ledger each time that a source is checked out or returned to storage.

p72a V&D 35.406 The TF believes that the intent of the suggested section is accomplished by proposed 35.404b, but is amenable to including the suggested language.

~~§ 35.605 Maintenance and repair restrictions.~~

New text, see p. 73a

~~Only a person specifically licensed by the NRC or an Agreement State to perform teletherapy unit maintenance and repair shall maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.~~

T.E. suggests new p. 73a

§ 35.606 Amendments.

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

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

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

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

(d) Relocating the teletherapy unit;

(e) Removing the teletherapy unit;

(f) Changing the source; or

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

§ 35.610 Emergency instructions.

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

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

T.E. suggests

(b) The procedure to be followed (i) should the operator be unable to turn the primary beam of radiation off with controls outside the treatment room [and] or (ii) if any other abnormality occurs;

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

35.605. Restrictions on work done on teletherapy units.

The following shall be performed only by persons specifically licensed by NRC or an Agreement State to perform such services:

(a) Installation, relocation, or removal of teletherapy units containing sources; and

(b) Source exchange; and

(c) Any maintenance, repair, or adjustment operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

p73a VAB 35.605 The control requirements in suggested 35.605a and b are already met by requiring a license amendment before moving a teletherapy unit (see proposed 35.606). Suggested c is identical to proposed 35.605.

§ 35.620 Doors, interlocks, and warning systems.

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

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

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

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

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

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

§ 35.621 Radiation monitoring device.

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

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

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

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

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

(f) If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor

for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.

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

§ 35.622 Viewing system.

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

T.F. agrees

§ 35.623 New section; see page 75a

§ 35.630 Dosimetry equipment.

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

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

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

T.F. agrees

35.623 Requirement for electrical and/or mechanical stops to limit use of the primary beam of radiation.

Prior to inititation of a treatment program, each teletherapy unit shall be equipped with electrical and/or mechanical stops limiting use of the primary beam of radiation so as to ensure compliance with §20.105(b) of this chapter as evidenced by a special teletherapy survey as required by §§35.640 and 35.641 of this part. Necessary use restrictions shall be fully described in the special teletherapy survey reports submitted in accordance with §35.644 of this part.

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.

See p.80a for text of new section § 35.640 and new opening to paragraph (a) of 35.641.

~~§ 35.641 Radiation measurements following installation of a source.~~

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

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

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

(i) That 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) That 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.

See p.80b for text of new paragraph (c)

(c) The licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the model number and serial number of the instrument used to measure radiation levels, each radiation level measured around the teletherapy source while in the off position and the average of all measurements, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour, the calculated

35.640. Circumstances requiring a special teletherapy survey.

A special teletherapy survey as further described in §§35.641 and 35.642 must be performed:

(a) Before a treatment program is begun and after each installation of a teletherapy source; and

(b) After any changes are made in:

(i) The treatment room shielding; and

(ii) The location of the teletherapy unit within the treatment room; and

(iii) The use of the teletherapy unit that could result in increase radiation levels outside the treatment room; and

(c) After relocation of the teletherapy unit to a new facility.

35.641. Radiation measurements required for a special teletherapy survey.

(a) Under the circumstances described in §35.640, the licensee shall make measurements to verify that:

35.641. Radiation measurements required for a special teletherapy survey.

(c) The licensee shall maintain a record of the radiation measurement made in accordance with the requirements of subparagraphs (a) and (b) of this section for the duration of the license. The record must include the date of the measurement, the manufacturer's name, model number and serial number of both the teletherapy unit and source, the circumstance in §35.640 that required the measurements, the manufacturer's name, model number and serial number of the instrument used to measure radiation levels, each radiation level measured around the teletherapy source while in the off position and the average of all measurements, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

35.642. Facility checks required for a special teletherapy survey.

(a) Under the circumstances described in §35.640, the licensee shall promptly test all systems listed in §35.633(g) for proper function.

~~maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.~~

See p. 80b for new title for § 35.642 and new text for (a)

~~§ 35.642 Facility checks following installation of a source.~~

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

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.633(g), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or test the malfunctioning system.

(c) The licensee shall maintain a record of the facility checks following installation of a source for the duration of the license. 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.

§ 35.644 Reports of special teletherapy surveys ~~following installation of a source~~.

The licensee shall mail copies of the results of the surveys and tests required at §§ 35.641, 35.642, and the output from the teletherapy source expressed as roentgens per hour at a distance of one meter from the source and determined during the full calibration required in § 35.632, to the following two addresses within thirty days following ~~each installation of a teletherapy source~~ completion of the changes described in § 35.640 that necessitated a special teletherapy survey:

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

(b) The appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter.

§ 35.645 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.

See new (b) on p. 82a

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

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

Subpart J--Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

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

(a) Be certified by:

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

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

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

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

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

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

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

(4) 20 hours of radiation biology;

(5) 30 hours of radiopharmaceutical chemistry; and

(6) One year of full time experience in medical radiation safety at an institution under the supervision of the individual listed as the

35.645. Five year inspection.

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

Radiation Safety Officer on a Commission or Agreement State license that authorizes the human use of byproduct material.

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

§ 35.901 Radiation safety officer training exception.

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

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

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

(a) Be certified in:

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

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

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

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

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

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

(4) 20 hours of radiation biology; and

(5) 30 hours of radiopharmaceutical chemistry; or

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

§ 35.920 Training for imaging and localization studies.

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

(a) Be 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 (within the previous five years)

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

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

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

(i) 100 hours of radiation physics and instrumentation;

(ii) 30 hours of radiation protection;

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

(iv) 20 hours of radiopharmaceutical biology; and

(v) 30 hours of radiation chemistry.

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

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

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

(iii) Calculating and safely preparing patient doses;

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

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

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

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

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

(ii) Selecting the proper radiopharmaceutical and dosage;

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

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

(v) Patient followup; or

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

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

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

(a) Be certified in

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

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

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

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

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

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

(iv) 20 hours of radiation biology;

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

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

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

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

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

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

§ 35.940 Training for therapeutic use of brachytherapy sources.

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

(a) Be 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, ~~by the~~ as a "Fellow of the British Faculty of Radiology" or ~~the British~~ "Fellow of the Royal College of Radiology"; or

T.F. signed

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

(b) Have completed 200 hours of instruction and 500 hours of supervised work experience in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and ~~a period~~ 3 years of supervised clinical experience.

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

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

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

(iv) 25 hours of radiation biology.

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

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

(ii) Checking survey meters for proper operation;

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

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

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

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

§ 35.941 Training for ophthalmic use of strontium-90.

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

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

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

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

(i) 6 hours of radiation physics and instrumentation;

(ii) 6 hours of radiation protection;

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

(iv) 8 hours of radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must include the use of strontium-90 under the supervision of an authorized user (at an institution) for the ophthalmic treatment of five individuals and must include the examination of each individual to be treated, calculation of the dose to be administered, post-administration followup, and review of each individual's case history.

§ 35.960 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:

See new text for (a) on p. 89a → (a) ~~Be certified in radiology or therapeutic radiology by the American Board of Radiology; or~~

→ (b) Have completed ~~170~~ 200 hours of instruction, 500 hours of supervised work experience, and ~~500 hours~~ 3 years of supervised clinical experience, in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit.

T.F. 2

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

(i) 100 hours of radiation physics and instrumentation;

(ii) ~~30~~ 40 hours of radiation protection;

(iii) ~~20~~ 25 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) ~~20~~ 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:

See new text for (b)(2) on page 89b

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~~(i)~~ Checking the operation of survey meters;

(ii) Calculating radiation doses to be administered;

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

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

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

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

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

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the ~~interpretation of teletherapy results;~~ and

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

review of patients' progress and possible need to modify originally prescribed dose as warranted by patients' reaction to radiation;

35.960. Training for teletherapy.

(a) Be certified in:

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

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

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

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

35.960 Training for teletherapy.

(b)(2)(i) Review the initial source calibration and periodic spot-check measurements of teletherapy units; and

(ii) Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes; and

(iii) Calibration of ion chambers and survey meters; and

(iv) Preparation of treatment plans and treatment times for teletherapy and brachytherapy; and

(v) Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.

(iv) Radiological physics; or

[7590-01]

§ 35.961 Training for qualified teletherapy calibration expert.

(a) 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:

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

(i) ~~(1)~~ Therapeutic radiological physics; or

(ii) ~~(2)~~ Roentgen ray and gamma ray physics; or

(iii) ~~(3)~~ X-ray and radium physics; or

(2) ~~(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 work experience under the supervision of a qualified teletherapy calibration expert at an institution where teletherapy is performed. To satisfy this requirement, the neophyte qualified teletherapy calibration expert must have performed the tasks listed in §§ 35.59, 35.632, 35.633, and 35.641 of this part under the supervision of a qualified teletherapy calibration expert during the year of work experience.

(b) See new text, p. 90a

§ 35.970 Experienced physician training exception.

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

§ 35.971 New physician training exception.

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

Subpart K--Enforcement

§ 35.990 Violations.

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

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

full time training in therapeutic radiological physics and one year of

T.F. agrees on this page 90 & 90a

35.961. Training for qualified teletherapy calibration expert.

(b) Licensees that have their teletherapy units calibrated by persons who do not meet the criteria in §35.961(a) may request a license amendment excepting them from the requirements of §35.961(a). This request, accompanied by the appropriate amendment fee (§170.31 of 10 CFR 170) must include the name of the proposed qualified expert, a description of his training and experience including information similar to that specified in §35.961(a)(2), reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the past 10 years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in §35.961(a)(1). The individual's qualifications will be evaluated by NRC's consultants in medical physics. The amendment request should be sent to the appropriate address shown in §35.16.

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

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

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

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

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

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

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

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

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

The following amendments are also made to existing parts of the regulations in this chapter. The authority for these conforming amendments is: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 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:

§ 30.4 Definitions.

* * * * *

(h) "Human use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings;

* * * * *

(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;

* * * * *

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

§ 30.34 Terms and conditions of licenses.

* * * * *

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

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

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

* * * * *

4. Section 31.11(b) is amended by deleting "§35.14(c)" and inserting ~~"Part 35."~~ "§35.57"

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

5. Section 32.70 is removed.

6. Section 32.72 paragraph (a)(4)(i) is 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:

* * * * *

92 31.11b The NRC proposes a separate line item on the application form rather than an undocumented license.

(4)(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label affixed to each package, or the leaflet or brochure that accompanies each package, contains a statement that the unit dosage radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to Part 35, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

7. Section 32.73 paragraphs (a)and (a)(5)(ii) are 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 ~~for use by~~ 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. Section 32.74 paragraphs (a) and (a)(3) are revised to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500 of this chapter will be approved if:

* * * * *

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission

for distribution to persons licensed to use byproduct material identified in §§ 35.58, 35.400, and 35.500 of 10 CFR Part 35 or under an equivalent license of an Agreement State.

* * * * *

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

9. Section 40.4 is amended by revising paragraph (g) to read as follows:

§ 40.4 Definitions.

* * * * *

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

* * * * *

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

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE TELEPHONE NO.: AREA CODE( ) _____ _____	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
2. PERSON TO CONTACT REGARDING THIS APPLICATION TELEPHONE NO.: AREA CODE( ) _____ _____	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. _____ c. ☐ RENEWAL OF LICENSE NO. _____
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*	5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

NRC FORM 313M (9-81)

ENCLOSURE 2

disagree with this proposed form supported proposed rule.

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE

- ☐ Names and Specialties Attached; and
- ☐ Duties as in Appendix B; or _____ *(Check One)*
- ☐ Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- ☐ Supplements A & B Attached for Each Individual User; and
- ☐ Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- ☐ Appendix C Form Attached; or
- ☐ List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

- ☐ Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached; and
- ☐ Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT

- ☐ Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM

- ☐ Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- ☐ Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- ☐ Appendix F Procedures Followed; or
- ☐ Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- ☐ Appendix G Rules Followed; or
- ☐ Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

- ☐ Appendix H Procedures Followed; or
- ☐ Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- ☐ Appendix I Procedures Followed; or
- ☐ Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- ☐ Appendix J Form Attached; or
- ☐ Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- ☐ Appendix K Procedures Followed; or
- ☐ Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- ☐ Detailed Information Attached; and
- ☐ Appendix L Procedures Followed; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- ☐ Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- ☐ Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- ☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*

(2) TITLE

c. DATE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-913

APPENDIX M

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xe-133)

The following information should be submitted in support of requests to use Xe-133:

1. Quantities to be used

   a. Patient information

      (1) Number of studies expected per week

      (2) Average activity per patient

   b. State the desired possession limit. This should be sufficient to provide for shipments whose calibration dates are several days after receipt.

2. Use and Storage Areas

   a. Describe the area(s) in which you plan to use and store Xe-133. A diagram such as that in Figure M-1 is acceptable. Include in the diagram the availability of shielding materials and the proximity to unrestricted areas.

   b. Describe the ventilation in all areas where Xe-133 is used and stored. (Ventilation features should also be indicated on a diagram such as that in Figure M-1.) The location of supply and exhaust vents, the *measured* airflow rates for each vent, and the fraction of air that is recirculated by the system should be indicated. Describe any changes in flow rates that may exist between heating and cooling seasons.

   c. All areas where xenon is used should be under negative pressure. State the type and frequency (at least semiannually) of periodic measurements that you will make to determine that airflow rates are maintained as described in Item 2b.

3. Procedures for Routine Use

   a. Describe the procedures to be followed for routine use of Xe-133, giving particular attention to radiological safety factors.

   b. If you plan to use a special apparatus for administration and collection of Xe-133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)

4. Emergency Procedures

   Describe the emergency procedures to be followed in case of an accidental release of Xe-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

5. Air Concentrations of Xe-133 in Restricted Areas

   No licensee shall permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity that would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material of 1×10^{-5} μCi/ml.

   You may evaluate your situation by making actual measurements of Xe-133 concentrations or by means of calculations. If you choose the latter approach, you may make simplifying assumptions, PROVIDING they are reasonable, conservative, and stated explicitly in your request.

   In actual use and storage, some Xe-133 will be released into the room from the storage and administration devices, rebreathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of Xe-133 that is lost.

   The following procedures may be used to calculate the air concentration of Xe-133 in restricted areas:

   a. Estimate the maximum amount of activity to be used per week (A).

   b. Estimate the fraction of Xe-133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.

   c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the Xe-133 (V).

   d. For restricted areas, § 20.103 of 10 CFR Part 20 requires that

$$\frac{A}{V} \times f \leq 1 \times 10^{-5} \mu Ci/ml.$$

ENCLOSURE 3

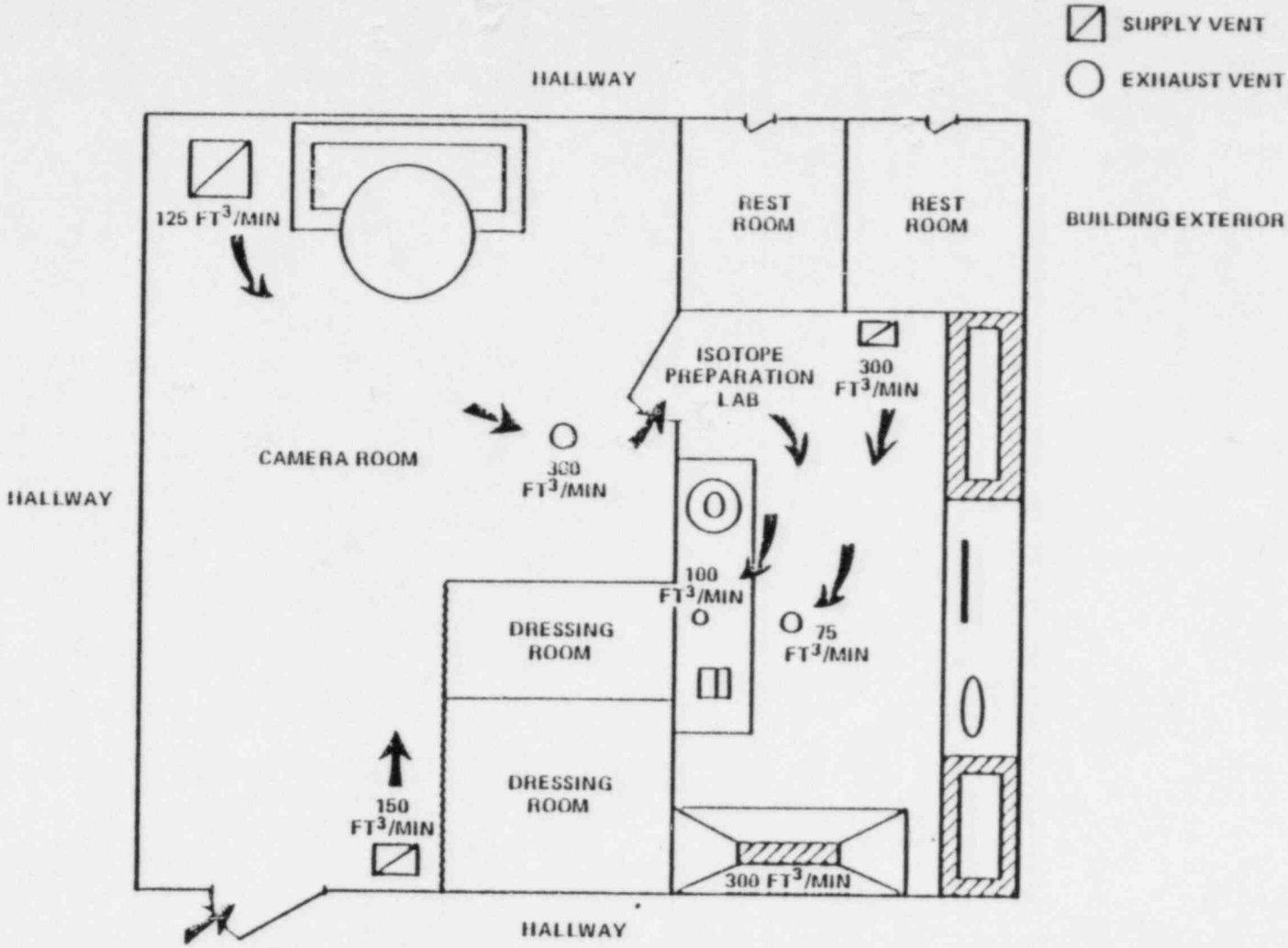

FIGURE M-1

EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

e. Sample Problem

A nuclear medicine laboratory plans to use 10 mCi Xe-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance with § 20.103 of 10 CFR Part 20?

Maximum activity used per week

$$A = \frac{10\ mCi}{patient} \times \frac{10\ patients}{week}$$

$$\times\ 1 \times 10^{3}\ \frac{\mu Ci}{mCi}$$

$$= 1 \times 10^{5}\ \frac{\mu Ci}{week}$$

Assume a loss rate of 20 percent (f)

$$V = \frac{A \times f}{1 \times 10^{-5}\ \mu Ci/ml}$$

$$= \frac{1 \times 10^{5}\ \mu Ci/week \times 0.20}{1 \times 10^{-5} \mu Ci/ml}$$

$$= 2.0 \times 10^{9}\ ml/week.$$

The required ventilation rate is

$$\frac{2.0 \times 10^{9}\ ml/week}{40\ hr/week}$$

$$\div \frac{1.7 \times 10^{6}\ ml/hr}{ft^{3}/min} = 30\ ft^{3}/min$$

The answer shows that, in order to meet the requirements of § 20.103 of 10 CFR Part 20, the imaging room (RESTRICTED AREA) must have a ventilation rate of at least 30 ft^3/min with no recirculation of air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of Xe-133 as low as reasonably achievable in accordance with paragraph 20.1(c) of 10 CFR Part 20.

If the ventilation rate is inadequate to meet the requirements of § 20.103 of 10 CFR Part 20, consider methods of increasing ventilation or reducing the patient load.

The following table gives the amount of Xe-133 that can be released per week without exceeding the permissible levels for Xe-133 in restricted areas.

Ventilation Rate (ft^3/min)	*Maximum Xe-133 Released per 40-Hour Week (mCi)*
100	67.9
500	339.7
1,000	679.4

6. Air Concentrations of Xe-133 in Unrestricted Areas

a. Disposal of Xe-133 by Dilution through Exhaust Systems (less desirable).

One method for disposal of Xe-133 is by release to the atmosphere through an air exhaust system. Licensees are required to perform surveys (measurements or calculations) to ensure that they are in compliance with paragraph 20.1(c) and § 20.106 of 10 CFR Part 20. Paragraph 20.1(c) requires that the concentrations of Xe-133 in effluents to unrestricted areas be as low as is reasonably achievable by the current state of technology, and § 20.106 requires that the concentrations, averaged over a period of 1 year, shall not exceed 3×10^{-7} µCi/ml.

Many facilities do not have sufficient airflow to achieve the necessary dilution. The following procedure may be used to estimate the concentrations of Xe-133 in effluents to unrestricted areas.

(1) Estimate the maximum amount of Xe-133 to be released per year (A). This should include all anticipated losses during administration, storage, and disposal.

(2) Determine the flow rate of the exhaust system, and describe the methods and equipment used for measuring the airflow rates.

(3) Calculate the airflow per year (V).

(4) Calculate the average concentrations for unrestricted areas. Section 20.106 of 10 CFR Part 20 requires that

$$C = \frac{A}{V} \leq 3 \times 10^{-7}\ \mu Ci/ml.$$

(5) Sample Problem

A nuclear medicine laboratory plans to use 10 mCi per patient and will perform a maximum of 10 studies per week. A fume hood is available for disposal of Xe-133 and has a measured airflow of 168 ft/min with an opening of 3 ft^2. What is the average concentration of Xe-133 at the point of release

from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filters, must be considered.)

$$A = \frac{10 \text{ patients}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10^3 \ \mu\text{Ci}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{yr}}$$

$$A = 5.2 \times 10^6 \ \mu\text{Ci/yr}$$

$$V = 168 \frac{\text{ft}}{\text{min}} \times 8 \text{ ft}^2 \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 1344 \frac{\text{ft}^3}{\text{min}} \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 2.01 \times 10^{13} \text{ ml/yr}$$

$$C = \frac{5.2 \times 10^6 \ \mu\text{Ci/yr}}{2.01 \times 10^{13} \text{ ml/yr}}$$

$$C = 2.6 \times 10^{-7} \ \mu\text{Ci/ml}$$

The following table gives the amount of Xe-133 that can be released per week without exceeding an average concentration of 3×10^{-7} μCi/ml.

Exhaust Rate (ft^3/min)	*Average Release of Xe-133 per Week (mCi)*
100	8.6
500	42.8
1,000	85.6
1,500	128.4

If the exhaust is released to a restricted area, e.g., a roof to which access is controlled, you should also describe the physical controls you use to restrict access to the restricted area; the number, wording, size, and location of warning signs placed in the vicinity of the restricted area; your program for ensuring that personnel entering the restricted area receive proper instruction in accordance with §19.12 of 10 CFR Part 19; your program for ensuring that personnel entering the restricted area are monitored in accordance with §20.202 of 10 CFR Part 20; and the surveys you will perform in accordance with §20.201 of 10 CFR Part 20.

b. Adsorption of Xe-133 onto Charcoal Traps

This is the disposal method of choice. The advantage of this disposal method is that Xe-133 is trapped onto charcoal or other adsorbing medium. Filters containing Xe-133 are then stored for decay.

One difficulty with this approach is that charcoal is not 100 percent efficient for trapping Xe-133. If this is your method of disposal, you should consider the following points:

(1) Describe how you will handle the problem of leakage from such trapping devices. Exhaust from trapping devices and from areas of use and storage may be vented to the outdoors or other unrestricted areas. Submit calculations to show that air concentrations of Xe-133, averaged over 1 year, do not exceed 3×10^{-7} μCi/ml. (See example in Item 6a.)

(2) Describe how you will ensure that collection and trapping devices are performing according to specifications, both initially and on a continuing basis. Include in your description how you will monitor traps to determine when saturation occurs and filter must be replaced. Where adequate, manufacturer's instructions relevant to trap testing may be incorporated in the application.

(3) Describe your procedures for handling saturated filters. Your discussion should include a description of the area (a diagram would be useful), available shielding, proximity to restricted areas, ventilation, and an evaluation of average concentrations of Xe-133 in air. (See example in Item 5e.)

USEFUL CONVERSIONS

1 mCi = 10^3 μCi

1 ft^3 = 2.832×10^{-2} m^3 = 2.832×10^4 ml

1 ft^3/min = 1.699×10^6 ml/hr

= 6.797×10^7 ml/40-hr week

= 1.484×10^{10} ml/yr

1 week = 168 hr

RECOMMENDATIONS FOR OTHER CHANGES TO THE REGULATION

Section 35.15:

- Assign letter to each of the words defined in this section. – contractor to DRR guidance
- Make changes necessary (e.g., define "podiatrist", "dentist"; revise "human use") to resolve issues raised by Lixi, Inc. – T.F. will do
- Amend the definition of "authorized user" to include the special responsibilities of a physician as opposed to those of an authorized user on an industrial license. – ELD advises against putting prescriptive requirements
- Define "on-site physician" in terms of the physician who has at least 30 hours of training in basic radioisotope handling techniques and who may be present at the locations serviced by the mobile service licensee. – disagree

Section 35.16:

- Paragraphs (a) - (c) are not very clear and should be revised. – disagree but will consider minimal wording
- The establishment of licensing functions in Regions II, IV and V should be recognized and appropriate changes made. – agree – wasn't clear was changed.

Section 35.30:

- More work is needed on this section to make all conforming changes to require that all licensees (not just institutional licensees) must have an ALARA program. – wouldn't be restrictive to require program where a single physician private office.

Section 35.32:

- More work is needed on this section to make all conforming changes to require that all licensees (not just institutional licensees) must have a Radiation Safety Officer. – agree with simple fix

Section 35.34:

- Suggest that this provision be changed to require that the visitor be SPECIFICALLY named as a user on a CURRENT NRC license (i.e, his name actually appear in the license condition that reads: Licensed material shall be used by _____) – unduly restrictive

ENCLOSURE 4

Section 35.58:

- Suggest that the regulation continue the authorization for higher activities of certain short-lived radionuclides for calibration and reference standards. These standards need not be sealed sources. The current authorization is in §35.14(d).

Section 35.75:

- Recommend that further study be made of the levels at which iodine-131, colloidal gold-198 and permanent implant patients may be released from a hospital. The originally suggested measurement of 6 mR/hr at 1 meter assumes that the radioactive material is acting as a point source. This is not a valid assumption for many cancer patients treated with iodine-131 for metastases. Also neither the existing license condition on this matter, nor SECY 83-62, nor our mark-up copy considers the radiopharmaceutical therapy patient as a potential cause of contamination (e.g., his home, family, etc.), but only as a potential source of radiation exposure. More consideration needs to be given to these matters.

Sections 35.100, 35.200 and 35.300:

- It is not clear what is intended in the paragraph of each of these sections that includes a provision similar to the following: "Any byproduct material in a radiopharmaceutical and for a diagnostic use . . . . authorized by the Food and Drug Administration or by the licensee's Radioactive Drug Research Committee . . . . "

  1. If "authorized by the Food and Drug Administration" means that the radiopharmaceutical is the subject of a "Notice of Claimed Investigation Exemption for a New Drug" (IND) accepted by the FDA, then the regulation should so state. Otherwise, the wording should be clarified.

  2. FDA's regulations in 21 CFR 361.1(a) (copy attached) are quite specific as to the types of studies that come under the purview of an RDRC. It is not clear why SECY 83-62 mentions RDRC-approved studies in the referenced sections of the regulation when FDA does not permit them to approve studies that have an immediate diagnostic or therapeutic benefit to the participating patient.

  3. Not all licensees have or need a Radioactive Drug Research Committee (RDRC). RDRCs are established under FDA regulations and approved by FDA. FDA intends that an RDRC at a major medical center (e.g., NIH) could provide

assistance to smaller hospitals in the community. Accordingly, the words "the licensee's" could be replaced by "a".

Sections 35.100, 35.200, 35.300, 35.400 and 35.500:

- It is not clear why each of the referenced sections begins by requiring the licensee to use the radiopharmaceutical, sealed source, generator and/or reagent kit in accordance with the instructions in the manufacturer's package insert. This is more restrictive than the current regulations. The current regulations require that licensees ELUTE GENERATORS OR PROCESS RADIOACTIVE MATERIAL WITH A REAGENT KIT in accordance with instructions in the manufacturer's brochure (see §35.14(b)(4)(i)). In the case of sealed sources the current regulations require that the licensee follow the RADIATION SAFETY AND HANDLING INSTRUCTIONS in the manufacturer's brochure (see §35.14(b)(5)(iv)). The statements used in SECY 83-62 should be revised to incorporate the current requirements only.

Section 35.606:

- Suggest that some additional consideration be given to requiring a license amendment in each of the cases specified in SECY 83-62; license amendments are not now required in each of these cases. For example, if a teletherapy license already authorizes the exact sealed source that the licensee wants to install in his unit (i.e., by manufacturer's name and model number; activity of new source is within possession limits specified on the license), there is no need for an amendment.

Section 35.610:

- Paragraph (a) is not related to emergency instructions. Either the title of this section should be changed or the requirements in paragraph (a) should be moved to another section.

Section 35.620:

- The title of this section is misleading. After reading the text of this section, one realizes that the interlocks and warning systems pertain to entrances/doors, not to every interlock and warning system required for teletherapy licensees.

Section 35.630:

- This section of the regulation should be revised to require that, regardless of the length of time between calibrations, the licensee must perform constancy tests of his dosimetry system. This recommendation is consistent with those of NRC's consultants in a telephone conference call pertaining to the resolution of the AAPM Petition for Rule Making and with those in NCRP Report 69 (see paragraph 5.3).

Section 35.622:

- Suggest changing title of this section and adding a requirement for an aural communication system; see NCRP Report 34, paragraph 6.1.6.

Section 35.910:

- Suggest that this section be reexamined.

  1. No clinical experience is required for the non-Board certified physician.

  2. Also it is not clear why 200 hours of didactic training is required for the physician wanting to use only Gen/Group I materials. Originally NRC increased the didactic training in basic radioisotope handling techniques to 200 hours because of the increased radiation safety problems associated with the use of generators and reagent kits, materials and procedures that are not included in Gen/Group I.

Section 35.930:

- Suggest that this section be reexamined.

  1. The Advisory Committee on the Medical Uses of Isotopes approved certification in Radiation Oncology by the American Osteopathic Board of Radiology as being evidence of adequate training and experience for Group V procedures (i.e., use of iodine-131 to treat thyroid cancer and use of colloidal gold-198). The Committee did not make a similar recommendation with regard to Group IV procedures. In view of the fact that use of iodine-131 to treat thyroid cancer presupposes experience with diagnosis of thyroid function and treatment of hyperthyroidism, then the problem is with the physician's apparent lack of clinical experience with both soluble and colloidal forms of phosphorus-32.

2. It is not clear how a non-Board certified physician will ever qualify for Groups IV/V because clinical experience with colloidal gold-198 is required, but this material is not commercially available in the United States. Also it is not clear if the present practice of authorizing a physician for some of the clinical procedures in a given Group will be continued. For example, will a physician with soluble phosphorus-32 experience be authorized to use just that material? If the present practice is to be continued, then this section needs to be revised and to show clearly that, in order to be authorized to use iodine-131 for treatment of cancer, the physician must have fulfilled the clinical experience requirements to use iodine-131 to treat hyperthyroidism.

Section 35.950:

- Recommend adding a new section to establish training and experience requirements for physicians who wish to use diagnostic sealed sources. The Task Force has developed a text for this new section.

Conforming amendment to Section 32.72:

- Suggest deleting the phrase "unit dosage" because this makes §32.72 more restrictive than it is now. Currently, there is no prohibition against the manufacture and distribution of multidose containers.

- Suggest that the required licensing statement specify for which Groups (or pursuant to which section of the regulation) the recipient must be licensed in order to receive the specified material. For example, under the current regulations iodine-131 might be authorized for distribution to persons licensed for Groups I and II, if the iodine-131 were intended for diagnostic uses only.

Conforming amendment to Section 32.74:

- Suggest that the required licensing statement make it clear exactly which licensees may receive a particular sealed source or device. For example, brachytherapy sources should be authorized for distribution to Group VI licensees only.

RT 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

UTHORITY: Secs. 201, 502, 505, 701, 52 at. 104[illegible]2 as amended, 1050-53 as ended, [illegible]5-56 as amended by 70 Stat. and 72 Stat. 948 (21 U.S.C. 321, 352, 355,) (5 U.S.C. 553, 554, 702, 703, 704); 21 R 2.120, unless otherwise noted.

OURCE: 39 FR 19877, June 4, 1974, unless herwise noted.

Subpart A—General Provisions

32.1 Scope.

An over-the-counter antiflatulent oduct in a form suitable for oral administration is generally recognized as fe and effective and is not misbrandd if it meets each of the following nditions and each of the general nditions established in § 330.1 of is chapter.

Subpart B—Active Ingredients

32.10 Antiflatulent active ingredients.

Simethicone: maximum daily dose 0 mg. There is no dosage limitation this time for professional labeling.

32.15 Combination with non-antiflatulent active ingredients.

An antiflatulent may contain any nerally recognized as safe and effece antacid ingredient(s) if it is indied fo[illegible]e solely for the concurrent mptom[illegible] of gas associated with artburn, sour stomach or acid indistion.

Subpart C—[Reserved]

Subpart D—Labeling

§ 332.30 Labeling of antiflatulent products.

(a) *Indications.* The labeling of the product shall identify the product as an "antiflatulent" and/or "to alleviate or relieve the symptoms of gas."

(b) *Directions for use.* The labeling of the product contains the recommended dosage per time interval (e.g., every 4 hours) or time period (e.g., 4 times a day) broken down by age groups if appropriate, followed by "except under the advice and supervision of a physician." The words "or as needed" may be used after the recommended dosage per time interval or time period.

[39 FR 19877, June 4, 1974, as amended at 40 FR 11719, Mar. 13, 1975]

§ 332.31 Professional labeling.

(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.

(b) Professional labeling for an antiflatulent-antacid combination may contain information allowed for health professionals for antacids and antiflatulents.

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

§ 361.1 Radioactive drugs for certain research uses.

(a) Radioactive drugs (as defined in § 310.3(n) of this chapter) are generally recognized as safe and effective when administered, under the conditions set forth in paragraph (b) of this section, to human research subjects during the course of a research project intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial). Certain basic research studies, e.g., studies to determine whether a drug localizes in a particular organ or fluid space and to describe the kinetics of that localization, may have eventual therapeutic or diagnostic implications, but the initial studies are considered to be basic research within the meaning of this section.

(b) The conditions under which use of radioactive drugs for research are considered safe and effective are:

(1) *Approval by Radioactive Drug Research Committee.* A Radioactive Drug Research Committee, composed and approved by the Food and Drug Administration in accordance with paragraph (c) of this section, has determined, in accordance with the standards set forth in paragraph (d) of this section, that:

(i) The pharmacological dose is within the limits set forth in paragraph (b)(2) of this section;

(ii) The radiation dose is within the limits set forth in paragraph (b)(3) of this section;

(iii) The radiation exposure is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain;

(iv) The study meets the other requirements set forth in paragraph (d) of this section regarding qualifications of the investigator, proper licensure for handling radioactive materials, selection and consent of research subjects, quality of radioactive drugs used, research protocol design, reporting of adverse reactions, and approval by an appropriate Institutional Review Committee; and

(v) The use of the radioactive drug in human subjects has the approval of the Radioactive Drug Research Committee.

(2) *Limit on pharmacological dose.* The amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings. If the same active ingredients (exclusive

dosimetry systems to be used for calibrating cesium-137 teletherapy units.

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

(c) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instrument that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factors that were deduced, and the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that an intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

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

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

(2) Before treating humans under the following conditions:

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

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

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

(3) At intervals not exceeding one year.

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

(or for the axis distance)

(1) The output within ±3 percent for the range of field sizes and for the range of distances used in radiation therapy;

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

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

(4) Timer accuracy;

(5) On-off error; and

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

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

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

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

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

(g) The licensee shall keep a record of each calibration for the duration of the license. The record must include the date of the calibration, the model number and serial number of both the teletherapy unit, the manufacturer's name, and the source

model number and serial number of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the qualified teletherapy calibration expert.

§ 35.633 Periodic spot-checks.

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

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

(1) Timer accuracy;

(2) On-off error;

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

(4) The accuracy of all distance measuring and localization devices used for treating humans;

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

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

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

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

(e) The licensee shall have a qualified teletherapy calibration expert perform the spot-check measurements or review the results of the

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

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

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

(1) Electrical interlocks at each teletherapy room entrance;

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

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

(4) The viewing system;

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

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

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

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

(j) The licensee shall keep a record of each spot-check required by paragraphs (a) and (f) of this section for two years. The record must include the date of the spot-check, the manufacturer's name, model number and serial number of both teletherapy unit and source, the model number and serial number of the instrument used to measure the output of the teletherapy unit, ~~the measured time accuracy, the calculated on-off error,~~ a radiograph of a single field with the location of the light field indicated on the radiograph, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated

Draft response to Enclosure 4 of Chilk/Vacca&DelMedico memo 4-26-83 plm

Part 35 Task Force response to items raised in Enclosure 4 of
Vacca and DelMedico memorandum to Chilk dated April 26, 1983

35.15

1. This recommendation is contrary to DRR guidance.
2. The TF is still working on these definitions.
3. ELD advises against putting prescriptive requirements in a definition.
4. The TF believes the hazard of diagnostic radiopharmaceuticals is such that "supervision" meets the need.

35.16

1. The TF disagrees, but is willing to consider alternate language.
2. This was not the case when the TF circulated the draft for concurrence. It will be included.

35.30

1. The TF does not believe a licensee with one physician and a few technicians needs a formal written ALARA program. The physician would be the only individual qualified to sit on the oversight committee.

35.32

The TF agrees that all applicants should identify an RSO.

35.34

The TF believes this would be unduly restrictive. It would not allow qualified physicians identified on an Agreement State license or working under an NRC Broad License to assist an NRC licensee.

35.58

The TF does not believe these materials are frequently used, but is amenable to the suggestion.

/

35.75

The TF agrees that I-131 in a cadaver patient is not a point source. However, for safety purposes the TF believes that this rate results in about the same degree of safety as the currently imposed (by license condition) 30mCi release limit. It is technically difficult and inconsistent with ALARA principles to verify compliance with the currently imposed license condition. The proposed rulemaking describes a measurement that any licensee can make. The TF believes that there is insufficient information from NCRP and other experts on which to draft a regulation that properly balances the patient's welfare with the safety of the family and public. The TF believes that voluntary guidance from the physician to the patient is the best resolution of this problem at this time.

35.100, .200, .300

1. The intent of the wording was to include both IND's and NDA's. Both are mechanisms used by the FDA to regulate the distribution of pharmaceuticals.
2. Under the current regulation scheme it is not clear to the licensee whether, despite the fact that his RDRC has approved a human use radiopharmaceutical study, the proposed study could be carried out legally under the NRC license used to procure the radiopharmaceutical. This is true because the proposed use may be contrary to the instructions on the radiopharmaceutical label that licensees would be required to follow. (see the opening paragraph of the cited sections, and the discussion of sections 35.100 through .500 below)
3. The TF is aware that not every licensee has a RDRC. The TF is amenable to the suggestion.

35.100, .200, .300, .400, .500

The interpretation that the licensee is not limited to uses described on the radiopharmaceutical label is not recognized in the industry. See the confusing wording of current section 35.14(b)(1), for example. No expert outside the agency who has seen the proposed wording has told the TF that the proposed restriction would inhibit the practice of medicine. This also applies to generators and sealed sources.

35.606

The TF believes that the changes identified in this proposed section are of sufficient moment to require notification to the agency. agree

35.610

The TF is amenable to retitling of the section.

35.620

The TF does not understand why the title is misleading. The section requires a door at each entrance, electrical interlocks that will turn the unit off if someone enters the room when it is turned on, and indicator lights that would warn an individual that the unit is turned on and should therefore not enter the room. Whence the title, "Doors, interlocks, and warning systems."

35.630

Some experts in the industry have indicated that commercially available constancy check devices are not sufficiently precise to require their use by licensees. Were the use of a constancy check device required, the agency would have to specify an action level at which measurement instrumentation would have to be recalibrated. agree The appropriate action level (on the order of a 2% discrepancy) is similar to the imprecision of constancy check devices used by some experts.

35.622

The TF does not believe an aural communication system is needed for safety during regular operation or emergencies.

35.910

The TF will consider suggestions for required clinical experience and alternate suggestions for formal training.

35.930

1. The TF believes the level of hazard and safety techniques for I-131 and P-32 are sufficiently similar to allow a board-certified physician to use either safely.
2. Concerning colloidal gold-198, this requirement was taken from the revised training and experience criteria recently published in the Federal Register (January 21, 1982). The TF is amenable to withdrawing the requirement. If a physician has all the training required, he may use all the material identified. If he does not have all the training required, he may apply for an exemption under proposed section 35.29.

35.950

The TF has developed training and experience criteria for human use with diagnostic sealed sources. The TF proposes to add this section before publishing the proposed rulemaking in the FR.

32.72

1. The TF agrees with the recommendation.
2. The TF believes that the supplier has made a good faith effort to limit distribution to licensed individuals by requiring that distribution be limited to persons licensed for human use. The supplier should not be required to have safety measures that would interdict purchases by prevaricating practitioners.

32.74

See discussion 32.72 No. 2 above.

faxed to Bill 5 09 83

May 9, 1983 nlm

DRAFT Task Force Response to Vacca and DelMedico Enclosures 1, 2, and 3 (Markup of Part 35 and suggestions) attached to Chilk/Vacca&DelMedico memo dated April 26, 1983.

NOTES: 1. "Proposed refers to the document submitted by the Task Force (TF).
2. "V&D" and "suggested" refer to the markup and other enclosures submitted by Vacca and DelMedico.

ENCLOSURE 1

p49 35.16 The form number should be changed so that applicants don't use an old form.

p51 35.18 See 35.16 comment.

35.28 See 35.16 comment.

35.28a This proposed change would place the staff in the role of providing, and requiring the use of, free consultation whether needed or not. Furthermore, it would not provide the regulatory restraing that the TF infers is desired by Vacca and DelMedico because a disingenuous applicant could submit conservative procedures for review and then, on receipt of his license, revise them.

35.30 The TF does not believe a small licensee with one physician and a few technicians needs a formal ALARA program. The physician would be the only individual qualified to sit on the oversight committee.

p54 35.32 The TF agrees that each licensee should identify an RSO.

p55 35.33b4 The TF believes the licensee is best qualified to determine the necessary training frequency. For procedures that are done only once every several months, training should precede each procedure. For procedures that are done each day and audited by the authorized user or RSO, there is no need for periodic training. V&D b4ii and b4iii simply restate current 19.12 and are superfluous.

35.33b5iii The TF agrees.

p56 35.35 V&D 35.35a appears to be identical to proposed 35.80a. The TF believes that to restrict a mobile service to unlicensed clients would unnecessarily interfere with the delivery of medical care. For example, this would prohibit a mobile service from providing technical assistance to a small licensee whose sole technician is on vacation. V&D 35.35c is identical to proposed 35.35b.

p57 35.37d The TF agrees.

p59 V&D 35.50a The TF agrees that there should be a clear statement that the licensee must possess a dose calibrator.

V&D 35.50b1 The paragraph does not appear to accomplish any more than proposed 35.50a2

V&D 35.50b2 The suggested paragraph would require that two specific radionuclides be used, and establishes higher actifity levels than are stated in the proposed draft. It is not necessary to use Cs-137 and Co-57 to test the accuracy of a dose calibrator; other radionuclides are available. The TF believes that 50 uCi is a sufficiently high activity to test for accuracy.

V&D 35.50b3 re i, the TF believes that to test for linearity outside the range of patient dosage measurements is unnecessary and inconsistent with ALARA principles. re ii, the TF believes that testing by serial dilutions is inaccurate and inconsistent with ALARA principles.

V&D 35.50b4 The paragraph does not appear to add to proposed 35.50a4.

V&D 35.50c Cesium-137 and Co-57 are not uniquely qualified for use when testing a dose calibrator. It is not necessary to use a calibrated source when checking for constancy.

V&D 35.50d This duplicates proposed 35.50b.

V&D 35.50e This duplicates proposed 35.50c.

p60 V&D 35.51a The TF agrees that there should be a clear statement that the licensee must possess a survey instrument. The TF, and the industry, are divided on the necessary range of measurement capability. The suggested wording could be used to elicit public comment.

V&D 35.51b This duplicates proposed 35.51a.

V&D 35.51c Suggested c1 is universal practice. re c2, see proposed b1. re c3, see proposed b2. re c4, see proposed b3.

V&D 35.51d re d1 and d2, see proposed c1 and c2. Suggested d3 accomplishes nothing. The burden of proof already lies on the licensee.

V&D 35.51e This duplicates proposed 35.51d.

V&D 35.51f This duplicates proposed 35.51f.

p61a V&D 35.52a Receipt of material in excess of that permitted by the license would be a violation that, the TF assumes, would drive the licensee to establish the procedure out of self-preservation. The licensee has a vested financial interest in every other item cited

because if the package is not received by the proper person, and secured, it may be lost but must still be paid for. Section 20.205b need not be repeated here.

p61b V&D 35.52b Section 20.205d requires that each licensee have package opening procedures. The entire suggested section belongs in Part 20 because nothing in it is peculiar to the human use of byproduct material.

p61c V&D 35.52c See p61b comment.

p61d V&D 35.57 ELD concurs with the TF proposal that this request simply be added to the application form as a line entry. See proposed form NRC-313MH item 4.

p62 35.59 The TF agrees with the suggested wording.

p63 35.59f This seems a good time to get industry comment on whether iridium and tantalum wires should be available.

p64 35.62 The TF believes the suggested change would be unduly prescriptive. The TF would like public commen on this.

p64a 35.70 The TF agrees with the suggested wording.

p65a V&D 35.75a It is technically difficutl and inconsistent with ALARA principles to verify compliance with the suggested wording.

p65b V&D 35.80b The TF believes that an on-site physician is not needed for the types of studies that a mobile service can perform. The hazard of the studies is roughly comparable to that of giving a blood sample or having a stomach x-ray.

V&D 35.80c This duplicates proposed 35.80b.

V&D 35.80f The TF does not believe uncalibrated equipment poses a risk but is amenable to including the suggestion to elicit public comment.

V&D 35.80g This appears to duplicate proposed 35.80b and f.

p66a V&D 35.90a This is similar to proposed 35.90.

V&D 35.90b, c, and d These measures are appropriate for high volume users of I-131. The TF is amenable to incorporating them in Subpart F. For diagnostic quantities, the TF believes the suggested requirements are overly prescriptive.

p67 35.100b A professional nuclear pharmacist has said that, if the chemical form has been changes, the licensee would not be using one of the listed radiopharmaceuticals.

p68 35.200a14 The TF does not believe there is any need to delete this diagnostic gas administered by inhalation from the group of diagnostic liquids administered by injection. Xenon is a noble gas whose MPC is based on submersion in a cloud. If there is excessive spillage it will be detected by the technicians' film badges.

p69 35.200b1 Seep67 comment.

p70a V&D 35.304 The introductory paragraph is similar to proposed 35.304a. re a, the TF does not believe a private toilet is a critical safety need for radiopharmaceutical therapy patients. re b, section 20.105 already identifies those instances in which a licensee must declare an area restricted. There is no need to reiterate them. re c, release of contaminated items would be contrary to 20.301. There is no need to reiterate this. The TF is amenable to including suggested paragraph d.

p71 35.400 d and g This seems a good time to get industry comment on whether iridium and tantalum wires should be available.

p71a V&D 35.405 The TF is amenable to including source description in the required training. The TF does not believe a private toilet is a critical safety need for brachytherapy patients. re b, section 20.105 identifies those instances in which a licensee nust declare an area restricted. Proposed 35.404 would accomplish the same purpose as the suggested requirement for surveying a room for displaced sources. re c, the loss of a seed would be contrary to 20.301. The TF is amenable to including suggested paragraph d. Section 20.101 establishes dose limits for the hands.

p72a V&D 35.406 The TF believes that the intent of the suggested section is accomplished by proposed 35.404b, but is amenable to including the suggested language.

p73a V&D 35.605 The control requirements in suggested 35.605a and b are already met by requiring a license amendment before moving a teletherapy unit (see proposed 35.606). suggested c is identical to proposed 35.605.

p74 35.621b The TF agrees.

35.621f The TF believes that if it is not properly operating, it is not a survey instrument.

p75a 35.623 It is not necessary to use mechanical or electrical stops to ensure compliance with 20.105b. They are one of several alternatives available to the licensee to comply with the requirements of that section.

p76 35.630c The TF agrees.

p77 35.632b1 Several physicists reviewed the language used by the TF and found it sufficiently descriptive without the parenthetical insertion.

35.632b3 The TF agrees.

35.632g The TF agrees.

p79 35.633j The TF agrees that the additional identifiers should be added. The TF believes that timer accuracy and on-off error are both critical elements of a spot check program and should be recorded.

p80a V&D 35.640 The TF is amenable to the suggested wording.

p80b V&D 35.641c The suggested wording is virtually identical to the proposed wording. The TF agrees.

V&D 35.642 The TF agrees.

p81 35.644 The TF agrees.

p82a V&D 35.645b The TF agrees.

p82 35.645c The TF agrees.

p83 35.910a3 The TF agrees.

p84 35.920a3 The TF agrees.

p86 35.930a2 This certification was approved for high activity radiopharmaceutical therapy authorization in a FR notice published January 21, 1982.

p87 35.940b See the TF wording in subsection 3

p88 35.941b2 The proposed wording matches that published in a FR notice on January 21, 1982.

p89a V&D 35.960 The TF agrees.

p89 35.960b The TF agrees. ***BILL--CHECK THIS***

p89b V&D 35.960 The TF agrees except for ii, which is out of place here.

p90 35.961b re for mal training and work experience, the TF agrees.

p90a V&D 35.961b This information should be submitted under proposed 35.29, exemptions.

p92 31.11b The TF proposes a separate line item on the application form rather than an undocumented license.

p93 32.73a5ii The proposed wording simply changes the section citation for Part 35. The TF does not understand the need for the suggested wording.

ENCLOSURE 2

Enclosure 2 is the form that is currently used for Part 35 applications. The TF believes the proposed form elicits sufficient information to establish eligibility for licensure and to provide a legal basis for appropriate enforcement actions.

ENCLOSURE 3

Enclosure 3 would require that special calculations be done before using Xe-133 gas. The calculations would be required to ensure that the Xe-133 concentration in the imaging clinic air does not exceed MPC. The TF notes that xenon is a noble gas. The MPC is based on external exposure due to submersion in a cloud, not internal dose. Therefore, the exposure would be adequately measured by whole body dosimeters.