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

OCT 15 1992

MEMORANDUM FOR: Donald Lanham
Document Management Branch
Office of Information Resources Management

FROM: Sam Jones
Regulatory Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

SUBJECT: DOCUMENT TO BE PLACED IN PDR

Please transmit to the PDR the enclosed Strawman rule language regarding Parts 30, 32 and 35. This document should be placed with the PRM-35-9 file.

If you have any questions, please call me at 492-3738.

Sam Jones

Sam Jones
Regulatory Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

Enclosure:
Draft rule language

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

In § 30.34, paragraph (i) is deleted in its entirety.

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

1. § 32.72 is replaced by the following:

§ 32.72 Manufacture, preparation, and transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.

(a) An application for a specific license to manufacture, prepare, and distribute radioactive drugs containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy; or

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

(3) The applicant submits information on the radionuclide; chemical and physical form; maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding that will be provided for the safe handling and storage of radioactive drugs; and

(4)(i) The applicant submits copies of labels to be applied to radioactive drugs, as specified in 10 CFR 35.60 and 35.61, to be transferred for commercial distribution. The labels shall include the radionuclide, quantity of radioactivity, and date and time of assay. In addition, the label, or the leaflet or brochure that accompanies the radioactive drug contains a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the radioactive drugs to persons licensed to use byproduct material listed in 10 CFR 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

(ii) The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by the U.S. Food and Drug Administration.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section may prepare radioactive drugs for medical use provided that the radioactive drug is prepared by either an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.25. For purposes of this section, the terms "authorized nuclear pharmacist" and "medical use" will have the same definitions as stated in 10 CFR 35.2.

(c) A licensee shall possess instrumentation and use it to measur .he radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall (1) as appropriate for the use of the instrument, perform tests on each instrument for accuracy, linearity, and geometry dependence, and make adjustments when necessary, before initial use, annually, and following repair; and (2) check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA and other Federal and State requirements governing radioactive drugs.

2. § 32.73 is deleted in its entirety.

PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

1. In § 35.2, the term "authorized nuclear pharmacist" is added and the term "medical use" is revised to read as follows:

§ 35.2 Definitions.

* * * * *

"Authorized nuclear pharmacist" means a pharmacist who is identified as an authorized nuclear pharmacist on a Commission license that authorizes the possession and use of byproduct material in the practice of nuclear pharmacy.

* * * * *

"Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to: (1) patients as directed by an authorized user for the purpose of diagnosis or therapy, or (2) human subjects under the supervision of an authorized user for the purpose of obtaining scientific information.

2. § 35.6 is added to read as follows:

§ 35.6 Provisions for research involving human subjects.

Research involving human subjects shall be conducted in accordance with the common Federal Policy for the Protection of Human Subjects as implemented by the appropriate Federal agency.

3. § 35.7 is added to read as follows:

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

4. § 35.12(e) is added to read as follows:

An applicant that satisfies the requirements specified in 10 CFR 33.13, may apply for a Type A specific license of broad scope.

5. **§ 35.15 is added to read as follows:**

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following: (a) the provisions of § 35.13(b); and (b) the provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license.

6. **In § 35.25, redesignate existing paragraph (b) as paragraph (c).**

§ 35.25 Supervision.

* * * * *

(b) A licensee that prepares byproduct material for medical use shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to:

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

(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and

(3) Periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

7. § 35.49 is deleted in its entirety.

8. **In § 35.50, paragraph (a) is revised to read as follows:**

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

(a) A licensee shall possess a dose calibrator and use it to measure the activity of dosages of photon-emitting radioactive drugs prior to administration to each patient or human subject.

* * * * *

(e)(2) For paragraph (b)(2) of this section, 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 initials of the individual performing the test.

(e)(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the initials of the individual performing the test.

(e)(4) For paragraph (b)(4) of this section, 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 initials of the individual performing the test.

9. **§ 35.52 is added to read as follows:**

§ 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radioactive drugs.

(a) This section does not apply to unit dosages of alpha- or beta-emitting radioactive drugs that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72.

(b) For other than unit dosages, a licensee shall possess instrumentation and use it to measure the radioactivity of alpha- or beta-emitting radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radioactive drugs prior to administration to each patient or human subject. In addition, the licensee shall (1) as appropriate for the use of the instrument, perform tests on each instrument for accuracy, linearity, and geometry dependence, and make adjustments when necessary, before initial use, annually, and following repair; and (2) check each instrument for constancy and proper operation at the beginning of each day of use.

10. In § 35.53, paragraphs (a), (b), and (c)(3) are revised as follows:

§ 35.53 Measurement of dosages of byproduct material for medical use.

* * * * *

(a) Measure the activity of each dosage of a photon-emitting radioactive drug prior to administration to each patient or human subject.

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radioactive drug prior to administration to each patient or human subject.

except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72;

* * * * *

(c)(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 30 microcuries;

* * * * *

11. § 35.100 is replaced by the following:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either: (1) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, or (2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the training requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

12. § 35.200 is replaced by the following:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies.

A licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that is either: (1) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, or (2) prepared

by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the training requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

13. § 35.300 is replaced by the following:

§ 35.300 Use of unsealed byproduct material for therapeutic administration.

A licensee may use for therapeutic administration any unsealed byproduct material prepared for medical use that is either: (1) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, or (2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the training requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

14. § 35.400 is replaced by the following:

§ 35.400 Use of sources for brachytherapy.

A licensee may use any brachytherapy source provided that either (1) the NRC or an Agreement State has issued a certificate of registration for that purpose pursuant to the provisions of 10 CFR 32.210(e) or applicable Agreement State requirements, or (2) the NRC has approved an application submitted by the licensee pursuant to the provisions of 10 CFR 30.32(g).

15. § 35.500 is replaced by the following:

§ 35.500 Use of sealed sources for diagnosis.

A licensee may use any sealed source for diagnosis provided that either (1) the NRC or an Agreement State has issued a certificate of registration for

that purpose pursuant to the provisions of 10 CFR 32.210(e) or applicable Agreement State requirements, or (2) the NRC has approved an application submitted by the licensee pursuant to the provisions of 10 CFR 30.32(g).

16. § 35.600 is replaced by the following:

§ 35.600 Use of sealed sources in a teletherapy unit.

A licensee may use any sealed source in a teletherapy unit provided that either (1) the NRC or an Agreement State has issued a certificate of registration for that purpose pursuant to the provisions of 10 CFR 32.210(e) or applicable Agreement State requirements, or (2) the NRC has approved an application submitted by the licensee pursuant to the provisions of 10 CFR 30.32(g).

17. In § 35.910, paragraph (a)(4) is added to read as follows:

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

* * * * *

(a)(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

* * * * *

18. In § 35.920, paragraph (a)(4) is added to read as follows:

§ 35.920 Training for imaging and localization studies.

* * * * *

(a)(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

* * * * *

19. In § 35.961, redesignate existing paragraph (b) as (c) and add a new paragraph (b) to read as follows:

§ 35.961 Training for teletherapy physicist.

* * * * *

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

* * * * *

20. § 35.980 is added to read as follows:

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be an individual who, in addition to the requirement of possessing valid state pharmacy licensure or registration:

(a) Has current board certification as a nuclear pharmacist (BCNP) by the Board of Pharmaceutical Specialties, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) chemistry of byproduct material for medical use; and

(E) radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following:

(A) shipping, receiving, and performing related radiation surveys;

(B) use of and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure alpha- or beta-emitting radioactive drugs;

(C) calculating and safely preparing patient dosages;

(D) using administrative controls to avoid mistakes in the administration of byproduct material;

(E) using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Dated at Rockville, Maryland, this _____ day of _____, 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.