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Date June 21, 1973

TO Rosemary Griffith FROM W. D. Douglass

Subject

For ☐ initial ☐ signature ☐ approval ☐ comments ☐ discussion ☒ information

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Message

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PART 35—HUMAN USES OF BYPRODUCT MATERIAL*‡

[¶ 14,560]

Sec.
35.1 Purpose and scope.
35.2 License requirements.
35.3 Definitions.

Specific Licenses

35.11 Specific licenses for human use of byproduct material in institutions.
35.12 Specific licenses to individual physicians for human use of byproduct material.
35.13 Specific licenses for human use of byproduct material in sealed sources.
35.14 Specific licenses for certain diagnostic uses of byproduct material in humans.

General Licenses

35.31 General license for medical use of quantities of byproduct material.
35.100 Schedule A—Groups of diagnostic uses of byproduct material in humans.

† AUTHORITY: The provisions of this Part 35 issued under secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended; 42 U. S. C. 2111, 2201, 2232, 2233. For the purposes of section 223, 68 Stat. 958, as amended; 42 U. S. C. 2273, § 3531(c)(4) and (5) issued under 161b, 68 Stat. 948; 42 U. S. C. 2201(b).

[¶ 14,560a]

Sec. 35.1. Purpose and scope.—This part prescribes regulations governing the licensing of byproduct material for human uses. It includes special requirements for issuance of specific licenses authorizing human use of byproduct material, general licenses for human use of byproduct material of specified types and forms, and certain regulations governing the holders of such specific and general licenses. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part.

[¶ 14,560b]

Sec. 35.2. License requirements.—No person subject to the regulations in this chapter shall receive, possess, use, or transfer byproduct material for any human use except in accordance with a specific or general license issued pursuant to the regulations in this part and Parts 30 and 32 or 33 of this chapter.

[Sec. 35.2 as amended April 7, 1970, effective May 22, 1970 (35 F. R. 6428).]

[¶ 14,560c]

Sec. 35.3. Definitions.—As used in this part:

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

(b) "Physician" means an individual licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

* Part 35 recodified effective August 25, 1965 (30 F. R. 8185).

‡ The Atomic Energy Commission gave notice in the Federal Register of March 9, 1973 (38 F. R. 6399) that it is considering the amendment of the title of Part 35 to read as follows:

"Part 35—Medical uses of radioisotopes (byproduct material."

Interested persons who desire to submit written comments or suggestions in connection with the proposed amendment should send them to the Secretary of the Commission, U. S. Atomic Energy Commission, Washington, D. C. 20545. Attention: Chief, Public Proceedings Staff, not later than April 23, 1973.

† Citation of authority as amended July 13, 1970, effective July 17, 1970 (35 F. R. 11459). —CCH.

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SPECIFIC LICENSES

[¶ 14,561]

Sec. 35.11. Specific licenses for human use of byproduct material in institutions.—An application by an institution for a specific license for human use of byproduct material will be approved if:

(a) The applicant satisfies the general requirements specified in Sec. 30.33 of this chapter;

(b) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnosis, and therapeutic use of radioisotopes within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations;

(c) The applicant possesses adequate facilities for the clinical care of patients;

(d) The physician designated on the application as the individual user has substantial experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients; and

(e) If the application is for a license to use unspecified quantities or multiple types of byproduct material, the applicant has previously received a reasonable number of licenses for a variety of byproduct materials for a variety of human uses.

[¶ 14,561a]

Sec. 35.12. Specific licenses to individual physicians for human use of byproduct material.—An application by an individual physician for a specific license for human use of byproduct material will be approved if:

(a) The applicant satisfies the general requirements specified in Sec. 30.33 of this chapter;

(b) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(c) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician shall furnish suitable evidence of such experience with his application. A statement from the medical isotope committee in the institution where he acquired his experience, indicating its amount and nature may be submitted as evidence of such experience.)

[¶ 14,561b]

Sec. 35.13. Specific licenses for human use of byproduct material in sealed sources.—An application for a specific license for use of a sealed source for human use will be approved if:

(a) The applicant satisfies the general requirements specified in Sec. 30.33 of this chapter; and

(b) The applicant or, if the application is made by an institution, the individual user (1) has specialized training in the therapeutic use of the radioactive device considered (teletherapy unit, beta applicator, etc.) or has experience equivalent to such training; and (2) is a physician.

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[¶ 14,561c]

Sec. 35.14. Specific licenses for certain diagnostic uses of byproduct material in humans.—(a) An application for a specific license pursuant to Sec. 35.11 or Sec. 35.12 for any diagnostic use of byproduct material specified in Group I or Group II of Sec. 35.100 will be approved for all of the diagnostic uses within the group which includes the use specified in the application if:

(1) The applicant satisfies the requirements of Sec. 35.11 or Sec. 35.12;

(2) The applicant or the physician designated in the application as the individual user has adequate clinical experience in the performance of diagnostic procedure specified in the appropriate group in Sec. 35.100; and

(3) The applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic procedures specified in the appropriate group in Sec. 35.100.

[Sec. 35.14 as added October 6, 1967, effective November 13, 1967 (32 F. R. 14265).]

GENERAL LICENSES

[¶ 14,562]

Sec. 35.31. General license for medical use of certain quantities of byproduct material.—(a) A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, the following byproduct materials in capsules, disposable syringes or other forms of prepackaged individual doses:

(1) Iodine 131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;

(2) Iodine 131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(3) Iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(4) Cobalt 58 for the measurement of intestinal absorption of cyanocobalamin;

(5) Cobalt 60 for the measurement of intestinal absorption of cyanocobalamin;

(6) Chromium 51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

NOTE: Section 32.70 of this chapter requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include the following statement in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Atomic Energy Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

.....
(Name of manufacturer)

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form AEC-482, "Registration Certificate—Medical Use of Byproduct Material Under General License" with the Director of Licensing, U. S. Atomic Energy Commission, Washington, D. C., 20545, and received from the Commission a validated copy of the Form AEC-482 with registration number assigned. The registrant shall furnish on Form AEC-482 the following information and such other information as may be required by that form:

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Section 35.32 proposed.

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medicine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of Sec. 35.31 of this chapter and that he is competent in the use of such instruments.

(c) A physician who receives, possesses, or uses a pharmaceutical containing byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine 131,

(ii) 200 microcuries of iodine 125,

(iii) 5 microcuries of cobalt 58,

(iv) 5 microcuries of cobalt 60, and

(v) 200 microcuries of chromium 51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection;

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section;

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

(5) He shall not transfer the byproduct material to a person who is not authorized to receive it pursuant to a license issued by the Commission or an agreement State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director of Licensing, any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form AEC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Part 20 of this chapter with respect to the byproduct materials covered by the general license.

[Sec. 35.31 as amended effective January 11, 1973 (38 F. R. 1271).]

The following Section 35.32 is proposed.*

[¶ 14,562a]

Sec. 35.32. Conditions of licenses for medical uses of radioisotopes.—(a) The user of radioisotopes in or applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a

* The Atomic Energy Commission gave notice in the Federal Register of March 9, 1973 (38 F. R. 6300) that it is considering the adoption of new Sec. 35.32.

Interested persons who desire to submit written comments or suggestions in connection with the proposed amendment should send them to the Secretary of the Commission, U. S. Atomic Energy Commission, Washington, D. C. 20545. Attention: Chief, Public Proceedings Staff, not later than April 23, 1973.

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general license or a specific license, including a specific license of broad scope, issued by the Commission (authorized physician).

(b) No authorized physician may delegate to persons who are not physicians under the supervision of the authorized physician, the following:

(1) The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.

(2) The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered.

(3) The determination of the route of administration,

(4) The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(c) Subject to the provisions of paragraphs (b), (d), (e), (f), and (g) of this section, an authorized physician may permit technicians and other paramedical personnel to perform the following activities:

(1) Preparation and quality control testing of radiopharmaceuticals and sources of radiation,

(2) Measurement of radiopharmaceutical doses prior to administration,

(3) Use of appropriate instrumentation for the collection of data to be used by the physician,

(4) Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable Federal, State or local laws.

(d) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to paragraph (c) of this section shall:

(1) Prior to such permission, determine that such technicians and other paramedical personnel have been properly trained to perform their duties. This training shall include training in the following subjects, as applicable to the duties assigned:

(i) General characteristics of radiation and radioactive materials.

(ii) Physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used.

(iii) Mathematics and calculations basic to the use and measurement of radioactivity, including units of quantity of radioactivity (curies, millicuries, microcuries) and units of radiation dose and radiation exposure.

(iv) Use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments.

(v) Principles and practices of radiation protection.

(vi) Additional training in the above subjects, as appropriate, when new duties are added.

(2) Assure that such technicians and other paramedical personnel receive appropriate retraining in the subjects listed in paragraph (d)(1) of this section to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology.

(3) Keep records showing the bases for such determinations of proper training, and

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(4) Retain responsibility as licensee or authorized user for the satisfactory performance of such activities.

(e) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists will be deemed to satisfy the training requirements of paragraphs (d)(1) and (2) of this section.

(f) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training (including retraining as required to keep abreast of developments in technology) such personnel or for otherwise determining that such personnel are properly trained to perform their duties. With respect to licenses in effect on (effective date of rule), a licensee who is permitting or who desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section shall file the information required by this paragraph with the Director of Licensing, U. S. Atomic Energy Commission, Washington, D. C. 20545, with his next application for amendment or renewal of the license or within 1 year of (effective date of rule), whichever occurs first.

(g) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician (not necessarily a physician authorized by the Commission to be a user of radioisotopes) shall be immediately accessible.

The following Section 35.33 is proposed.*

[¶ 14,562a-1]

Sec. 35.33. Notifications and reports of misadministrations.—(a) Each licensee shall notify the Director of the appropriate Atomic Energy Commission Regulatory Operations Regional Office listed in Appendix D of 10 CFR Part 20 of the Commission's regulations by telephone and telegraph of any misadministration of radiopharmaceuticals or any misadministration of radiation from teletherapy and brachytherapy sources. This notification shall be made within 24 hours after such misadministration is known. For the purpose of the requirements of this section, misadministration is defined to include the administration of:

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

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

(3) A dose of a radiopharmaceutical, or exposure from a radiation source, outside of the intended dose range prescribed by the physician or by a route of administration other than that intended by the physician.

(b)(1) Whenever a misadministration of a radiopharmaceutical or radiation from a teletherapy or brachytherapy source could cause a demonstrably adverse effect on the patient to whom it was administered, the licensee or the

** The Atomic Energy Commission gave notice in the Federal Register of March 9, 1973 (38 F. R. 6390) that it is considering the adoption of new Sec. 35.33.

Interested persons who desire to submit written comments or suggestions in connection with the proposed amendment should send them to the Secretary of the Commission, U. S. Atomic Energy Commission, Washington, D. C. 20545. Attention: Chief, Public Proceedings Staff, not later than April 23, 1973.

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authorized physician shall promptly notify the patient or a responsible relative of the patient of the misadministration unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient.

(2) If death occurs after a judgment is made by the physician that notification to the patient or a responsible relative of the patient of the misadministration would be contrary to the best interests of the patient and the misadministration may have been a contributory cause of the death, the licensee or the authorized physician shall notify a responsible relative of the patient of the misadministration unless the physician makes an additional determination that such notification would be contrary to the best interests of a surviving relative of the patient.

(c) In addition to the notification required by paragraph (a) of this section, each licensee shall make a report in writing within 30 days to the Director of Regulatory Operations, U. S. Atomic Energy Commission, Washington, D. C. 20545, with a copy to the Director of the appropriate Regulatory Operations Regional Office specified in Appendix D of 10 CFR Part 20, of each misadministration. The report required under this paragraph need not include the name of the patient but shall describe the nature, extent, and cause of the misadministration and the corrective steps taken or planned to assure against a recurrence. If the misadministration could cause a demonstrably adverse effect on the patient or if death occurs and the misadministration may have been a contributory cause of the death, the report shall either confirm that the patient or a responsible relative of the patient has been notified of the misadministration as required by paragraph (c)(1) and (2) of this section or shall state that notification was not given because in the physician's judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. If the patient or relative is not notified, the physician shall confirm that this decision was reviewed by a local Ethics Committee or an equivalent group of peers and shall state whether or not the committee or group concurred with the decision.

(d) Any notification or report filed with the Commission pursuant to paragraphs (a) and (c) of this section shall be prepared so that any details which would identify the patient will be stated in a separate part of the notification or report.

[¶ 14,562b]

Sec. 35.100. Schedule A—Groups of diagnostic uses of byproduct material in humans.—(a) *Group I.* Uptake, dilution, and excretion studies (does not include scans or tumor localizations).

(1) Iodine 131 or iodine 125 as sodium iodide for thyroid function studies.

(2) Iodine 131 or iodine 125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(3) Iodine 131 or iodine 125 as labeled rose bengal for liver function studies.

(4) Iodine 131 or iodine 125 as labeled fats or fatty acids for fat absorption studies.

(5) Iodine 131 or iodine 125 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies.

(6) Chromium 51 as labeled human serum albumin for gastrointestinal protein loss studies.

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(7) Chromium 51 as sodium chromate for determination of red blood cell volumes and studies of red blood cell survival time.

(8) Iron 59 as chloride, citrate, or sulfate for iron turnover studies.

(9) Cobalt 58 or cobalt 60 as labeled cyanocobalamin (vitamin B-12) for intestinal absorption studies.

(10) Potassium 42 as chloride for potassium space determinations.

(b) *Group II.* Scans and tumor localizations.

(1) Iodine 131 as sodium iodide for thyroid scans.

(2) Iodine 131 as iodinated human serum albumin (IHSA) for brain tumor localizations and cardiac scans.

(3) Iodine 131 as macroaggregated iodinated human serum albumin for lung scans.

(4) Iodine 131 as colloidal (microaggregated) iodinated human serum albumin for liver scans.

(5) Iodine 131 as labeled rose bengal for liver scans.

(6) Iodine 131 as iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, or sodium acetrizoate for kidney scans.

(7) Iodine 131 as sodium iodipamide for cardiac scans.

(8) Chromium 51 as sodium chromate for spleen scans.

(9) Gold 198 in colloidal form for liver scans.

(10) Mercury 197 as chlormerodrin for kidney and brain scans.

(11) Mercury 203 as chlormerodrin for brain scans.

(12) Strontium 85 as nitrate or chloride for bone scans in patients with diagnosed cancer.

(13) Technetium 99m as pertechnetate for brain scans.

(14) Technetium 99m as pertechnetate for thyroid scans.

(15) Technetium 99m as pertechnetate for salivary gland and blood pool scans other than placenta localizations.

[Sec. 35.100 as added October 6, 1967, effective November 13, 1967 (32 F. R. 14265), and amended March 31, 1970, effective April 9, 1970 (35 F. R. 5802); February 10, 1971, effective March 5, 1971 (36 F. R. 4368).]

CROSS REFERENCE TABLE

New section	*Old section*
35.1	New
35.2	New
35.3	30.4(e) and (i)
35.11	30.24(a)
35.12	30.24(b)
35.13	30.24(c)
35.14	New
35.31	30.29
35.100	New

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[AEC Regulation, Part 36, begins on page 20,399.]

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