

Rules and Regulations

Title 10—ATOMIC ENERGY

Chapter I—Atomic Energy Commission

LICENSING OF BYPRODUCT MATERIAL

On December 17, 1964, the Commission issued for public comment (29 F.R. 17915) a proposed recodification of its regulations—"Licensing of Byproduct Material", 10 CFR Part 30 and "Radiation Safety Requirements for Radiographic Operations", 10 CFR Part 31. Public comments indicate that the recodification is a desirable step toward simplifying the format of these regulations. Public comments also included some additional suggestions for further revisions of Parts 30 and 31. These suggested changes are being evaluated by the Commission staff in conjunction with other revisions which may be published at a later date.

In the recodification, common requirements applicable to all byproduct material licensing are retained in Part 30 while the remainder of the sections are relocated in proposed new parts designated Parts 31, 32, 33, 34, 35, and 36, each of which is applicable to certain classes or categories of uses or users of byproduct material. The requirements of Parts 31-36 are in addition to those of Part 30 and other applicable provisions in the Commission's regulations.

The parts as recodified are:

Part 30—Rules of General Applicability to Licensing of Byproduct Material. This part includes licensing and related provisions which apply generally to all byproduct material users, licensees or applicants for licenses, and includes such matters as definitions; exemptions; general requirements for specific licenses; common terms and conditions of licenses; inspections, records and tests; and enforcement procedures.

Part 31—General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items. This part includes general licenses for quantities of and items containing byproduct material. It does not include general licenses for export and certain of the general licenses for import, which are set out in Part 36, or general licenses for medical uses which are set out in Part 35.

Part 32—Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material. This part includes the special requirements applicable to specific licenses to manufacture, distribute, or import byproduct material or

¹ The provisions of present Part 31 are incorporated in a Part 34, and Part 31 is reassigned to General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items.

items containing byproduct material for distribution to persons exempted under Part 30 or generally licensed under Parts 31 or 35.

Part 33—Specific Licenses of Broad Scope for Byproduct Material. This part includes provisions applicable to licenses for multiple quantities and types of byproduct material under which activities involving the use of byproduct material in processing for distribution and research and development are carried on.

Part 34—Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations. This part includes the licensing requirements for use of sealed sources in radiography (presently set out in § 30.24 (g) of Part 30) and the radiation safety requirements for persons holding licenses for radiography now contained in Part 31.

Part 35—Human Uses of Byproduct Material. This part includes the special requirements for (1) licensing of individual physicians for human use of byproduct material, (2) licensing of human use of byproduct material in sealed sources and (3) licensing of human use of byproduct material in institutions, now set out in § 30.24 (a), (b) and (c) of Part 30. It also includes a general license for medical use of certain quantities of byproduct material, now set out in § 30.29.

Part 36—Export and Import of Byproduct Material. This part includes the requirements for specific licenses, the general licenses and other provisions relating to export and import of byproduct material.

A cross-reference table has been placed at the end of each part to permit easy comparison of the old regulations with the new. Parts 30-36 include the substance of applicable rules or amendments adopted and made effective during the period between the date of the notice (Dec. 17, 1964), and the effective date of the rule set forth below. The text of the amendment set forth below is substantially the same as the text of the proposed rule published on December 17, 1964, except for the following:

1. The text of § 30.12 (§ 30.6 of the present regulation) has been revised to reflect the amendment of § 30.6 which was published in the FEDERAL REGISTER on October 20, 1964, and became effective January 18, 1965.

2. The text of § 31.5 (30.21(c) of the present regulation) and § 32.51 (30.24(f) of the present regulation) has been revised to reflect the amendments of §§ 30.21(c) and 30.24(f) which were published in the FEDERAL REGISTER on January 7, 1965, and became effective February 6, 1965.

3. The text of § 30.16 (30.12 of the present regulation) and § 31.7 (30.21(d) of the present regulation) §§ 32.15, 32.16, 32.17, 32.40, 32.53, 32.54, 32.55, 32.56, 32.101 (30.24(j) and 30.24(m) of the present regulation) has been revised to

reflect the amendments of §§ 30.12, 30.21 (d), 30.24(j), and 30.24(m) which were published in the FEDERAL REGISTER on March 13, 1965, and became effective April 12, 1965.

4. The text of § 30.14 (30.9 of the present regulation) has been revised to reflect the amendments of § 30.9 which were published in the FEDERAL REGISTER on April 3, 1965, to be effective May 3, 1965.

5. The text of §§ 36.21 (30.33(b) of the present regulation), has been revised to reference the list of countries in § 36.50, Schedule A, rather than referencing " * * * Cuba or countries or areas now or hereafter listed as Subgroup A countries or destinations in § 371.3 of the comprehensive export schedule of the United States Department of Commerce (15 CFR 371.3)." The term "Subgroup A countries" is no longer used in the export regulations of the Department of Commerce. Other minor editorial changes have been made in Part 36.

6. The text of Part 32 has been revised to include § 32.70 (30.24(k) of the present regulation) and Part 35 has been revised to include § 35.31 (30.29 of the present regulation). §§ 30.24(k) and 30.29 were added to Part 30 by amendments which were published in the FEDERAL REGISTER on May 13, 1965, to be effective June 12, 1965.

The purpose of the recodification of Part 30 is to simplify and clarify the format of the present regulations, so that persons subject to byproduct material licensing regulations can conveniently use and understand them. No substantive changes have been made and the requirements under the present regulations are not changed by the recodification.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the Commission is amending Chapter I of Title 10 of the Code of Federal Regulations by deleting Parts 30 and 31 and substituting therefor new Parts 30, 31, 32, 33, 34, 35, and 36 reading as hereinafter set forth. This amendment is published as a document subject to codification to be effective sixty (60) days after publication in the FEDERAL REGISTER.

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201)

Dated at Washington, D.C., this 27th day of May 1965.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

PART 30—RULES OF GENERAL APPLICABILITY TO LICENSING OF BYPRODUCT MATERIAL

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AUTHORITY: The provisions of this Part 30 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 82, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2112, 2232, 2233. For the purposes of sec. 223, 68 Stat. 958; 42 U.S.C. 2273, § 30.34(c) issued under sec. 161b., 68 Stat. 948; 42 U.S.C. 2201 (b) and §§ 30.51 and 30.52 issued under sec. 161 p., 68 Stat. 950; 42 U.S.C. 2201(p).

GENERAL PROVISIONS

§ 30.1 Purpose and scope.

This part prescribes rules governing licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and exemptions from the licensing requirements permitted by section 81 of the Act, applicable to all persons in the United States.

§ 30.2 Resolution of conflict.

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

§ 30.3 Activities requiring license.

Except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, use, import or export byproduct material except as authorized in a specific or general license issued pursuant to the regulations in this chapter.

§ 30.4 Definitions.

As used in this part and Parts 31-36 of this chapter:

(a) "Act" means the Atomic Energy Act of 1954, including any amendments thereto;

(b) Terms defined in section 11 of the Act shall have the same meaning when used in the regulations in this part and Parts 31-36 to the extent such terms are not specifically defined in this part;

(c) "Agreement State" means any State with which the Commission has entered into an effective agreement under subsection 274b. of the Act. "Non-agreement State" means any other State;

(d) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(e) "Commission" means the Atomic Energy Commission and its duly authorized representatives;

(f) "Curie" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

(g) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

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

(i) "License", except where otherwise specified means a license for byproduct material issued pursuant to the regulations in this chapter;

(j) "Microcurie" means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

(k) "Person" means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission, any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

(l) "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;

(m) "Production facility" means production facility as defined in the regulations contained in Part 50 of this chapter;

(n) "Radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;

(o) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radio-

graphic exposure devices, sealed sources or related handling tools, or survey instruments in radiography;

(p) "Radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of byproduct materials;

(q) "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and Parts 31-36 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

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

(s) "Source material" means source material as defined in the regulations contained in Part 40 of this chapter;

(t) "Special nuclear material" means special nuclear material as defined in the regulations contained in Part 70 of this chapter;

(u) "United States", when used in a geographical sense, includes all territories and possessions of the United States, the Canal Zone and Puerto Rico;

(v) "Utilization facility" means a utilization facility as defined in the regulations contained in Part 50 of this chapter.

§ 30.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and Parts 31-36 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 30.6 Communications.

Except where otherwise specified, all communications and reports concerning the regulations in this part and Parts 31-36 and applications filed under them, should be addressed to the Director of Regulation, U.S. Atomic Energy Commission, Washington, D.C., 20545. Communications, reports and applications may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 4915 St. Elmo Avenue, Bethesda, Md.; or at Germantown, Md.

EXEMPTIONS

§ 30.11 Exemptions from licensing.

The Commission may upon the application of any interested person, or upon its own initiative, exempt certain classes or quantities of byproduct material or kinds of uses or users from the requirements for a license set forth in section 81 of the Act and in the regulations in this part and Parts 31-36 when it makes a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

§ 30.12 Persons using byproduct material under certain Atomic Energy Commission contracts.

Any prime contractor of the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Commission, manufactures, produces, transfers, receives, acquires, owns, possesses, uses, imports, or exports byproduct material for: (a) The performance of work for the Commission at a United States Government-owned or controlled site, including the transportation of byproduct material to or from such site and the performance of contract services during temporary interruptions of such transportation; (b) research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or (c) the use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel. In addition to the foregoing exemptions, any prime contractor or subcontractor of the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, uses, imports or exports byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety. Any person exempt from licensing under this part prior to the effective date of this amendment who would otherwise be required by virtue of this section to obtain a license shall continue to be so exempt on an interim basis. Such interim exemption shall expire 60 days from the effective date of this amendment, unless within said 60-day period either an application for a license covering the activity or an application for an appropriate exemption under this section is filed with the Commission. If either such application is filed within such 60-day period, the interim exemption shall remain in effect until final action in the matter is taken by the Commission.

§ 30.13 Carriers.

Common and contract carriers and the United States Post Office Department are exempt from the regulations in this part and Parts 31-36 and the requirements for a license set forth in section 81 of the Act to the extent that they transport byproduct material in the regular course of their business as carriers.

§ 30.14 Exempt concentrations.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31-36 of this chapter to the extent

that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(c) A manufacturer, processor, or producer of a product or material in an agreement State is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31, 32, 33, 34 and 36, to the extent that he transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by an agreement State or the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an agreement State, except in accordance with a license issued pursuant to § 32.11 of this chapter or the general license provided in § 150.20 of Part 150.

§ 30.15 Certain luminous timepieces.

(a) Except for persons who apply tritium to luminous timepieces or hands or dials and persons who import for sale or distribution luminous timepieces or hands or dials containing tritium, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36 of this chapter to the extent that such person receives, possesses, uses, transfers, exports, owns or acquires luminous timepieces or hands or dials containing tritium.

(b) Any person who desires to apply tritium to luminous timepieces or hands or dials for sale or distribution, or desires to import for sale or distribution luminous timepieces or hands or dials containing tritium, should apply for a specific license, pursuant to § 32.14 of this chapter, which license states that the luminous timepieces or hands or dials may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

§ 30.16 Lock illuminators installed in automobile locks.

Any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36 of this chapter to the extent that he receives, possesses, uses, transfers, exports, owns or acquires lock illuminators each containing not more than 15 millicuries of tritium or 2 millicuries of promethium 147 installed in an automobile lock. The manufacture, installation into automobile locks, or importation for sale or dis-

tribution of lock illuminators whether or not installed in automobile locks, is not included in this exemption, but may be authorized by a specific license under the provisions of Part 32 of this chapter.

§ 30.17 Balances of precision.

(a) Except for persons who apply tritium to balances of precision or the parts thereof and persons who import for sale or distribution balances of precision or the parts thereof containing tritium, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36 of this chapter to the extent that he receives, possesses, uses, transfers, exports, owns or acquires such balances or balance parts, provided that each balance part contains not more than 0.5 millicurie of tritium and each balance contains not more than 1.0 millicurie of tritium.

(b) Any person who desires to apply tritium to balances of precision or the parts thereof for sale or distribution or desires to import for sale or distribution balances of precision or the parts thereof containing tritium, should apply for a specific license, pursuant to § 32.18 of this chapter, which license states that the balances of precision or the parts thereof may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

LICENSES

§ 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part and Parts 32-36. General licenses are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

§ 30.32 Applications for specific licenses.

(a) Applications for specific licenses should be filed on Form AEC-313, "Application for Byproduct Material License", with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545. Applications may be filed in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 4915 St. Elmo Avenue, Bethesda, Md.; or at Germantown, Md. Information contained in previous applications, statements or reports filed with the Commission may be incorporated by reference, provided that such references are clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be

¹ Export shipment of precision balances is subject to the licensing authority and regulations of the Department of Commerce. Issuance of an exemption by the Atomic Energy Commission for export of tritium contained in balances of precision or the parts thereof does not relieve any person from complying with the licensing requirements and regulations of the Department of Commerce.

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granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and Parts 32-36 will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property; and

(4) The applicant satisfies any special requirements contained in Parts 32-36.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form AEC 374, "Byproduct Material License").

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and the regulations in Parts 31-36 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b) No license issued or granted pursuant to the regulations in this part and Parts 31-36, nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Commission pursuant to the regulations in this part and Parts 31-36 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and Parts 31-36 shall carry with it the right to receive, acquire, own, possess and import byproduct material and to transfer such material to other licensees within the United States authorized to receive such material.

(d) Each license issued pursuant to the regulations in this part and Parts 31-36 shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and Parts 31-36, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

§ 30.35 References in licenses outstanding on effective date of recodification of this part.

References to sections of Parts 30 and 31 and to Parts 30 and 31 in licenses outstanding on the effective date of this recodification shall be deemed to be references to the sections of Parts 30-36 and to Parts 30-36 superseding those denoted in the outstanding licenses.

§ 30.36 Expiration of licenses.

Except as provided in § 30.37(b), each specific license shall expire at the end of the day, in the month and year stated therein.

§ 30.37 Applications for renewal of licenses.

(a) Applications for renewal of a specific license shall be filed in accordance with § 30.32.

(b) In any case in which a licensee, not less than thirty (30) days prior to the expiration of his existing license, has filed an application in proper form for renewal or for a new license, such existing license shall not expire until the application has been finally determined by the Commission.

§ 30.38 Applications for amendment of licenses.

Applications for amendment of a license shall be filed in accordance with § 30.32 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

§ 30.39 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 30.33 and Parts 32-36 of this chapter.

RECORDS, INSPECTIONS AND TESTS

§ 30.51 Records.

Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and Parts 31-36 shall keep records showing the receipt, transfer, export and disposal of such byproduct material.

§ 30.52 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times op-

portunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

§ 30.53 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and Parts 31-36, including tests of:

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

ENFORCEMENT

§ 30.61 Modification and revocation of licenses.

(a) The terms and conditions of each license issued pursuant to the regulations in this part and Parts 31-36 shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

§ 30.62 Right to withhold or recall byproduct material.

The Commission may withhold, recall or order the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefor or approved by the Commission.

§ 30.63 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regu-

ation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

SCHEDULES

§ 30.70 Schedule A—Exempt concentrations.

Element (atomic number)	Isotope	Column I Gas concentration uc/ml ¹	Column II Liquid and solid concentration uc/ml ²
Antimony (51)	Sb 122		3×10 ⁻⁴
	Sb 124		2×10 ⁻⁴
	Sb 125		1×10 ⁻⁴
Argon (18)	A 37	1×10 ⁻⁷	
	A 41	4×10 ⁻⁷	
Arsenic (33)	As 73		5×10 ⁻³
	As 74		5×10 ⁻⁴
	As 76		2×10 ⁻⁴
	As 77		8×10 ⁻⁴
Barium (56)	Ba 131		2×10 ⁻³
	Ba 140		3×10 ⁻³
Beryllium (4)	Be 7		2×10 ⁻²
Bismuth (83)	Bi 206		4×10 ⁻⁴
Bromine (35)	Br 82	4×10 ⁻⁷	3×10 ⁻³
Cadmium (48)	Cd 109		2×10 ⁻³
	Cd 115m		3×10 ⁻⁴
	Cd 115		3×10 ⁻⁴
Calcium (20)	Ca 45		9×10 ⁻⁴
	Ca 47		5×10 ⁻⁴
Carbon (6)	C 14	1×10 ⁻⁶	8×10 ⁻³
Cesium (55)	Ce 141		9×10 ⁻⁴
	Ce 143		4×10 ⁻⁴
	Co 144		1×10 ⁻⁴
	Cs 131		2×10 ⁻²
	Cs 134m		6×10 ⁻²
	Cs 134		9×10 ⁻³
Chlorine (17)	Cl 38	9×10 ⁻⁷	4×10 ⁻²
Chromium (24)	Cr 51		2×10 ⁻²
Cobalt (27)	Co 57		6×10 ⁻³
	Co 58		1×10 ⁻³
	Co 60		5×10 ⁻³
Copper (29)	Cu 64		3×10 ⁻³
Dysprosium (66)	Dy 165		4×10 ⁻³
	Dy 166		4×10 ⁻⁴
Erbium (68)	Er 169		9×10 ⁻⁴
	Er 171		1×10 ⁻³
Europium (63)	Eu 152		6×10 ⁻⁴
	(T _{1/2} = 9.2 Hrs)		
	Eu 155		2×10 ⁻³
Fluorine (9)	F 18	2×10 ⁻⁶	8×10 ⁻³
Gadolinium (64)	Gd 153		2×10 ⁻³
	Gd 159		8×10 ⁻⁴
Gallium (31)	Ga 72		4×10 ⁻⁴
Germanium (32)	Ge 71		2×10 ⁻²
Gold (79)	Au 196		2×10 ⁻³
	Au 198		5×10 ⁻³
	Au 199		2×10 ⁻³
Hafnium (72)	Hf 181		7×10 ⁻⁴
Hydrogen (1)	H 3	5×10 ⁻⁶	3×10 ⁻²
Indium (49)	In 113m		1×10 ⁻²
	In 114m		2×10 ⁻⁴
Iodine (53)	I 126	3×10 ⁻⁹	2×10 ⁻³
	I 131	3×10 ⁻⁹	2×10 ⁻³
	I 132	8×10 ⁻⁹	6×10 ⁻⁴
	I 133	1×10 ⁻⁹	7×10 ⁻⁴
	I 134	2×10 ⁻⁹	1×10 ⁻³
Iridium (77)	Ir 190		2×10 ⁻³
	Ir 192		4×10 ⁻⁴
	Ir 194		3×10 ⁻⁴
Iron (26)	Fe 55		8×10 ⁻³
	Fe 59		6×10 ⁻⁴
Krypton (36)	Kr 85m	1×10 ⁻⁶	
	Kr 85	3×10 ⁻⁶	
Lanthanum (57)	La 140		2×10 ⁻⁴
Lead (82)	Pb 203		4×10 ⁻³
Lithium (71)	Li 7		1×10 ⁻²
Manganese (25)	Mn 52		3×10 ⁻⁴
	Mn 54		1×10 ⁻³
	Mn 56		1×10 ⁻³
Mercury (80)	Hg 197m		2×10 ⁻³
	Hg 197		3×10 ⁻³
	Hg 203		2×10 ⁻³
Molybdenum (42)	Mo 99		2×10 ⁻³
Neodymium (60)	Nd 147		6×10 ⁻⁴
	Nd 149		3×10 ⁻³
Nickel (28)	Ni 65		1×10 ⁻³
Niobium (Columbium) (41)	Nb 95		1×10 ⁻³
	Nb 97		9×10 ⁻³
Osmium (76)	Os 185		7×10 ⁻⁴
	Os 191m		3×10 ⁻²
	Os 191		2×10 ⁻²
	Os 193		6×10 ⁻⁴
Palladium (46)	Pd 103		3×10 ⁻³
	Pd 109		9×10 ⁻⁴

Element (atomic number)	Isotope	Column I	Column II
		Gas concentration uc/ml ¹	Liquid and solid concentration uc/ml ²
Phosphorus (15)	P 32		2×10 ⁻⁴
Platinum (78)	Pt 191		1×10 ⁻³
	Pt 193m		1×10 ⁻³
	Pt 197m		1×10 ⁻³
	Pt 197		1×10 ⁻³
Potassium (19)	K 42		3×10 ⁻³
Praseodymium (59)	Pr 142		3×10 ⁻⁴
	Pr 143		5×10 ⁻⁴
Promethium (61)	Pm 147		2×10 ⁻³
	Pm 149		4×10 ⁻³
Rhenium (75)	Re 183		6×10 ⁻³
	Re 186		9×10 ⁻⁴
	Re 188		6×10 ⁻⁴
Rhodium (45)	Rh 103m		1×10 ⁻³
	Rh 105		1×10 ⁻³
Rubidium (37)	Rb 86		7×10 ⁻⁴
Ruthenium (44)	Ru 97		4×10 ⁻³
	Ru 103		8×10 ⁻⁴
	Ru 105		1×10 ⁻³
	Ru 106		1×10 ⁻⁴
Samarium (62)	Sm 153		8×10 ⁻⁴
Scandium (21)	Sc 46		4×10 ⁻⁴
	Sc 47		9×10 ⁻⁴
	Sc 48		3×10 ⁻⁴
Selenium (34)	Se 75		3×10 ⁻³
Silicon (14)	Si 31		9×10 ⁻³
Silver (47)	Ag 105		1×10 ⁻³
	Ag 110m		3×10 ⁻⁴
	Ag 111		4×10 ⁻⁴
Sodium (11)	Na 24		2×10 ⁻³
Strontium (38)	Sr 89		1×10 ⁻⁴
	Sr 91		7×10 ⁻⁴
	Sr 92		7×10 ⁻⁴
	S 35	9×10 ⁻³	6×10 ⁻⁴
Tantalum (73)	Ta 182		4×10 ⁻⁴
Technetium (43)	Tc 96m		1×10 ⁻¹
	Tc 96		1×10 ⁻³
Tellurium (52)	Te 125m		2×10 ⁻³
	Te 127m		6×10 ⁻⁴
	Te 127		3×10 ⁻³
	Te 129m		3×10 ⁻⁴
	Te 131m		6×10 ⁻⁴
	Te 132		3×10 ⁻⁴
Terbium (65)	Tb 160		4×10 ⁻⁴
Thallium (81)	Tl 200		4×10 ⁻²
	Tl 201		3×10 ⁻³
	Tl 202		1×10 ⁻³
	Tl 204		1×10 ⁻²
Thulium (69)	Tm 170		5×10 ⁻⁴
	Tm 171		5×10 ⁻³
Tin (50)	Sn 113		9×10 ⁻⁴
	Sn 125		2×10 ⁻⁴
Tungsten (Wolf-rum) (74)	W 181		4×10 ⁻³
	W 187		7×10 ⁻⁴
	V 48		3×10 ⁻⁴
Xenon (54)	Xe 131m	4×10 ⁻⁶	
	Xe 133		3×10 ⁻⁶
	Xe 135		1×10 ⁻⁶
Ytterbium (70)	Yb 175		1×10 ⁻³
Yttrium (39)	Y 90		2×10 ⁻⁴
	Y 91m		3×10 ⁻²
	Y 91		3×10 ⁻⁴
	Y 92		6×10 ⁻⁴
	Y 93		3×10 ⁻⁴
Zinc (30)	Zn 65		1×10 ⁻³
	Zn 69m		7×10 ⁻⁴
	Zn 69		2×10 ⁻²
	Zr 95		6×10 ⁻⁴
Zirconium (40)	Zr 97		2×10 ⁻²
	Zr 97	1×10 ⁻¹⁰	1×10 ⁻⁶

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of § 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:
 Concentration of Isotope A in Product +
 Exempt concentration of Isotope A
 Concentration of Isotope B in Product
 Exempt concentration of Isotope B ≤ 1

¹ Values are given only for those materials normally used as gases.
² uc/gm for solids.

CROSS REFERENCE TABLE

New section	Old section
30.1	30.1, 30.2
30.2	New
30.3	30.3
30.4	30.4
30.5	30.5
30.6	New
30.11	30.8
30.12	30.6
30.13	30.7
30.14	30.9, 30.32(f)
30.15	30.10
30.16	30.12
30.17	30.14
30.31	30.20
30.32	30.22
30.33	30.23, 30.31(a)
30.34	30.32(a)-(d), 30.31(b), 30.38
30.35	New
30.36	30.34
30.37	30.35
30.38	30.36
30.39	30.37
30.51	30.41
30.52	30.43
30.53	30.44
30.61	30.51
30.62	30.52
30.63	30.61
30.70	30.73

PART 31—GENERAL LICENSES FOR CERTAIN QUANTITIES OF BY-PRODUCT MATERIAL AND BY-PRODUCT MATERIAL CONTAINED IN CERTAIN ITEMS

- Sec. Purpose and scope.
- 31.1 Terms and conditions.
- 31.2 Certain devices and equipment.
- 31.3 Certain quantities of byproduct material.
- 31.4 Certain measuring, gauging or controlling devices.
- 31.5 General license to install devices generally licensed in § 31.5.
- 31.6 Luminous safety devices for use in aircraft.
- 31.7 Americium 241 in the form of calibration or reference sources.
- 31.8 General license to own byproduct material.

SCHEDULES

- 31.100 Schedule A—Generally licensed quantities.

AUTHORITY: The provisions of this Part 31 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 82, 183, 68 Stat. 935, 954; 42 U.S.C. 2111, 2112, 2233. For the purpose of sec. 223, 68 Stat. 958; 42 U.S.C. 2273, § 31.2(b) issued under sec. 161b., 68 Stat. 948; 42 U.S.C. 2201(b).

§ 31.1 Purpose and scope.

This part establishes general licenses for certain quantities of byproduct material and byproduct material contained in certain items. Part 30 of this chapter also contains provisions applicable to the subject matter of this part.

§ 31.2 Terms and conditions.

(a) The general licenses provided in this part are subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), 30.51 to 30.63 and Parts 20 and 36 of this chapter¹ unless indicated otherwise in the language of the general license.

¹ Attention is directed particularly to the provisions of the regulations in Part 20 of this chapter which relate to the labeling of containers.

(b) Persons who transfer, receive, acquire, own, possess, use or import items and quantities of byproduct material pursuant to the general licenses provided in §§ 31.3 and 31.4:

(1) Shall not effect an increase in the radioactivity of said items or quantities by adding other radioactive material thereto, by combining byproduct material from two or more such items or quantities, or by altering them in any other manner so as to increase thereby the rate of radiation therefrom;

(2) Shall not administer externally or internally, or direct the administration of, said items or quantities or any part thereof to a human being for any purpose, including, but not limited to, diagnostic, therapeutic, and research purposes;

(3) Shall not add, or direct the addition of, said items or quantities or any part thereof to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being;

(4) Shall not include said items or quantities or any part thereof in any device, instrument, apparatus (including component parts and accessories thereto) intended for use in diagnosis, treatment or prevention of disease in human beings or animals or otherwise intended to affect the structure or any function of the body of human beings or animals.

§ 31.3 Certain devices and equipment.

A general license is hereby issued to transfer, receive, acquire, own, possess and use byproduct material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the Commission.

(a) *Static elimination device.* Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device.

(b) *Spark gap and electronic tubes.* Spark gap tubes and electronic tubes which contain byproduct material consisting of not more than 5 microcuries per tube of cesium 137, or nickel 63, or krypton 85 gas, or not more than one microcurie per tube of cobalt 60.

(c) *Light meter.* Devices designed for use in measuring or determining light intensity which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 200 microcuries of strontium 90 per device.

(d) *Ion generating tube.* Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device or of a total of not more than 50 millicuries of hydrogen 3 (tritium) per device.

§ 31.4 Certain quantities of byproduct material.

A general license is hereby issued to transfer, receive, acquire, own, possess, use and import the quantities of byprod-

uct material listed in § 31.100, Schedule A, provided that no person shall at any one time possess or use, pursuant to the general licensing provisions of this section, more than a total of ten such scheduled quantities.

§ 31.5 Certain measuring, gauging or controlling devices.

(a) Subject to the provisions of this section, a general license is hereby issued to own, receive, acquire, possess and use byproduct material when contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license contained in this section applies only to devices which have been:

(1) Manufactured in accordance with the specifications contained in a specific license issued by the Commission to the manufacturer of the device pursuant to § 32.51 of this chapter, or in accordance with the specifications contained in a specific license issued to the manufacturer by an agreement State; and

(2) Installed on the premises of the general licensee by a person authorized to install such devices under a specific license issued to the installer by the Commission pursuant to Parts 30 and 32 or by an agreement State, provided that the specific license referred to in subparagraph (1) of this paragraph contains provisions authorizing the transfer of such devices to, and the installation of such devices in the premises of, general licensees.

(c) The general license contained in this section applies only to devices which (1) are labeled in accordance with the provisions of the specific license which authorizes the distribution of the device to general licensees, and (2) bear a label containing the following or a substantially similar statement which contains the information called for in the following statement:

This device, generally licensed pursuant to § 31.5 of 10 CFR, Part 31, has been manufactured and distributed pursuant to license No. _____ issued by _____ (insert either "Atomic Energy Commission" or name of agreement State, whichever is applicable).

(Name of supplier)

(d) Persons who own, receive, acquire, possess or use a device pursuant to the general license contained in this section:

(1) Shall not transfer, abandon or dispose of the device except by transfer to a person authorized by a specific license from the Commission or an agreement State to receive such device and shall furnish to the Director of the appropriate Atomic Energy Commission Regional Compliance Office listed in Appendix "D" of Part 20 of this chapter, "Standards for Protection Against Radiation", within 30 days after any trans-

* Devices acquired not more than 8 months after the effective date of this recodification, may bear labels referring instead to "§ 30.21(c) of 10 CFR, Part 30," until the label is replaced.

fer, a report containing the name of the manufacturer of the device, the type of device, the manufacturer's serial number of the device, and the name and address of the person receiving the device;

(2) Shall assure that all labels affixed to the device at the time of receipt and bearing the statement, "Removal of this label is prohibited by regulations of the Atomic Energy Commission", are maintained thereon and shall comply with all instructions contained in such labels;

(3) Shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at the time of installation of the device or replacement of the byproduct material on the premises of the general licensee and thereafter at no longer than six-month intervals or at such longer intervals not to exceed three years as are specified in the label required by § 31.5(c); provided that devices containing only krypton need not be tested for leakage, and devices containing only tritium need not be tested for any purpose;

(4) Shall have the tests required by subparagraph (3) of this paragraph and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person holding a specific license from the Commission or an agreement State to manufacture, install or service such devices;

(5) Shall, within 30 days after the occurrence of a failure of or damage to the shielding of the radioactive material or the on-off mechanism or indicator or upon the detection of 0.005 microcuries or more of removable radioactive material, furnish to the Director of the appropriate Atomic Energy Commission Regional Compliance Office listed in Appendix "D" of Part 20 of this chapter, "Standards for Protection Against Radiation", a report containing the name of the manufacturer of the device, the type of device, the manufacturer's serial number of the device and a brief description of the event and the remedial action taken; and shall maintain records of all tests performed on the devices as required under this section, including the dates and results of the tests and the names of the persons conducting the tests;

(6) Upon the occurrence of a failure of or damage to, or any indication of possible failure of or damage to, the shielding or containment of the radioactive material or the on-off mechanism or indicator, shall immediately suspend operation of the device until it has been repaired by the supplier or other person holding a specific license from the Commission or an agreement State to manufacture, install or service such devices, or disposed of by transfer to a person authorized to receive the byproduct material contained in the device;

(7) Shall be exempt from the requirements of Part 20 of this chapter, except that such persons shall comply with the provisions of §§ 20.402 and 20.403 of this chapter.

(e) Persons who possess byproduct material pursuant to this general license shall not export such byproduct material

without a specific license from the Commission authorizing such export.

§ 31.6 General license to install devices generally licensed in § 31.5.

Any person who holds a specific license issued by an agreement State authorizing the holder to manufacture, install or service a device described in § 31.5 within such agreement State is hereby granted a general license to install and service such device in any non-agreement State; *Provided, That:*

(a) Such person shall file a report with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, within 30 days after the end of each calendar quarter in which any device is transferred or installed. Each such report shall identify each general licensee under § 31.5 by name and address, the type of device transferred, and the quantity and type of byproduct material contained in the device.

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the agreement State.

(c) Such person assures that any labels required to be affixed to the device under regulations of the agreement State which licensed manufacture of the device bear a statement that "Removal of this label is prohibited by the regulations of the Atomic Energy Commission."

(d) Such person shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in § 31.5.

§ 31.7 Luminous safety devices for use in aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium 147 contained in luminous safety devices for use in aircraft, provided each device contains not more than four curies of tritium or 100 millicuries of promethium 147 and that each device has been manufactured, assembled or imported in accordance with a license issued under the provisions of § 32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the agreement State.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of Part 20 of this chapter, except that they shall comply with the provisions of §§ 20.402 and 20.403 of this chapter.

(c) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium 147.

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium 147 except in accordance with the provisions of Part 36 of this chapter.

(e) This general license does not authorize the ownership, receipt, acquisition,

possession or use of promethium 147 contained in instrument dials.

§ 31.8 Americium 241 in the form of calibration or reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium 241 in the form of calibration or reference sources:

(1) Any person in a non-agreement State who holds a specific license issued by the Commission which authorizes him to receive, possess, use and transfer byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4(g) of this chapter, which holds a specific license issued by the Commission which authorizes it to receive, possess, use and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued by the Commission to the manufacturer or importer of the sources pursuant to § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the agreement State.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), and 30.51 to 30.63 of this chapter, and to the provisions of Part 20 of this chapter. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium 241 in such sources;

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations 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. Do not remove this label.

CAUTION — RADIOACTIVE MATERIAL — THIS SOURCE CONTAINS AMERICIUM 241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or importer)

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Commission or an agreement State to receive the source.

(4) Shall store such source, except when the source is being used, in a closed container adequately designed and con-

structed to contain americium 241 which might otherwise escape during storage.

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium 241.

(e) This general license does not authorize the export of calibration or reference sources containing americium 241.

§ 31.9 General license to own byproduct material.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

SCHEDULES

§ 31.100 Schedule A—Generally licensed quantities.

The following quantities of byproduct material are generally licensed pursuant to § 31.4.

Byproduct material	Column No. I	Column No. II
	Not as a sealed source (microcuries)	As a sealed source (microcuries)
Antimony (Sb 124).....	1	10
Arsenic 76 (As 76).....	10	10
Arsenic 77 (As 77).....	10	10
Barium 140—Lanthanum 140 (Ba-La 140).....	1	10
Beryllium (Be 7).....	50	50
Cadmium 109—Silver 109 (CdAg 109).....	10	10
Calcium 45 (Ca 45).....	10	10
Carbon 14 (C14).....	50	50
Cerium 144 — Praseodymium (CePr 144).....	1	10
Cesium—Barium 137 (CsBa 137).....	1	10
Chlorine 36 (Cl 36).....	1	10
Chromium 51 (Cr 51).....	50	50
Cobalt 60 (Co 60).....	1	10
Copper 64 (Cu 64).....	50	50
Europium 154 (Eu 154).....	1	10
Fluorine 18.....	50	50
Gallium 72 (Ga 72).....	10	10
Germanium 71 (Ge 71).....	50	50
Gold 198 (Au 198).....	10	10
Gold 199 (Au 199).....	10	10
Hydrogen 3 (Tritium)(H 3).....	250	250
Indium 114 (In 114).....	1	10
Iodine 131 (I 131).....	10	10
Iridium 192 (Ir 192).....	10	10
Iron 55 (Fe 55).....	50	50
Iron 59 (Fe 59).....	1	10
Lanthanum 140 (La 140).....	10	10
Manganese 52 (Mn 52).....	1	10
Manganese 56 (Mn 56).....	50	50
Molybdenum 99 (Mo 99).....	10	10
Nickel 59 (Ni 59).....	1	10
Nickel 63 (Ni 63).....	1	10
Niobium 95 (Nb 95).....	10	10
Palladium 109 (Pd 109).....	10	10
Palladium 103—Rhodium 103 (Pd-Rh 103).....	50	50
Phosphorus 32 (P 32).....	10	10
Polonium 210 (Po 210).....	0.1	1
Potassium 42 (K-42).....	10	10
Praseodymium 143 (Pr 143).....	10	10
Promethium 147 (Pm 147).....	10	10
Rhenium 186 (Re 186).....	10	10
Rhodium 105 (Rh 105).....	10	10
Rubidium 86 (Rb 86).....	10	10
Ruthenium 106—Rhodium 106 (RuRh 106).....	1	10
Samarium 153 (Sm 153).....	10	10
Scandium 46 (Sc 46).....	1	10
Silver 105 (Ag 105).....	1	10
Silver 111 (Ag 111).....	10	10
Sodium 22 (Na 22).....	10	10
Sodium 24 (Na 24).....	10	10
Strontium 89 (Sr 89).....	1	10

Byproduct material	Column No. I Not as a sealed source (micro-curies)	Column No. II As a sealed source (micro-curies)
Strontium 90—Yttrium 90 (SrY).....	0.1	1
Sulfur 35 (S 35).....	50	50
Tantalum 182 (Ta 182).....	10	10
Technetium 96 (Tc 96).....	1	10
Technetium 99 (Tc 99).....	1	10
Tellurium 127 (Te 127).....	10	10
Tellurium 129 (Te 129).....	1	10
Thallium 204 (Tl 204).....	50	50
Tin 113 (Sn 113).....	10	10
Tungsten 185 (W 185).....	10	10
Vanadium 48 (V 48).....	1	10
Yttrium 90 (Y 90).....	1	10
Yttrium 91 (Y 91).....	1	10
Zinc 65 (Zn 65).....	10	10
Beta and/or Gamma emitting byproduct material not listed above.	1	10

CROSS REFERENCE TABLE

New section	Old section
31.1.....	New
31.2.....	30.21(b)
31.3.....	30.21(a) (1), 30.71
31.4.....	30.21(a) (2)
31.5.....	30.21(c) (1)-(5)
31.6.....	30.21(c) (6)
31.7.....	30.21(d)
31.8.....	30.21(e)
31.9.....	30.21(f)
31.100.....	30.72

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE, OR IMPORT EXEMPTED AND GENERALLY LICENSED ITEMS CONTAINING BYPRODUCT MATERIAL

Sec.

32.1 Purpose and scope.**Subpart A—Exempt Concentrations and Items**

- 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: requirements for license.
- 32.12 Same: Material transfer reports.
- 32.13 Same: Prohibition of introduction.
- 32.14 Certain luminous timepieces: requirements for license to apply or import tritium.
- 32.15 Certain automobile lock illuminators: requirements for license to install or import.
- 32.16 Same: quality control.
- 32.17 Same: material transfer reports.
- 32.18 Balances of precision: requirements for license to apply or import tritium.
- 32.19 Same: material transfer reports.
- 32.40 Schedule A—Prototype tests for automobile lock illuminators.

Subpart B—Generally Licensed Items

- 32.51 Certain measuring, gauging or controlling devices generally licensed under § 31.5 of this chapter: requirements for license to distribute.
- 32.52 Same: material transfer reports.
- 32.53 Luminous safety devices for use in aircraft: requirements for license to manufacture, assemble, repair or import.
- 32.54 Same: labeling of devices.
- 32.55 Same: quality control; prohibition of transfer.
- 32.56 Same: material transfer reports.
- 32.57 Calibration or reference sources containing Americium 241: requirements for license to manufacture or import.

Sec.

- 32.58 Same: labeling of devices.
- 32.59 Same: leak testing of each source.
- 32.60 Same: material transfer reports.
- 32.70 Manufacture and distribution of byproduct materials for medical use under general license.
- 32.101 Schedule B—Prototype tests for luminous safety devices for use in aircraft.
- 32.102—Schedule C—Prototype tests for calibration or reference sources containing Americium 241.

Subpart C—Quality Control Sampling Procedures

- 32.110 Quality control sampling procedures under certain specific licenses.

AUTHORITY: The provisions of this Part 32 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2232, 2233.

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture, distribute or import items containing byproduct material for distribution to (1) persons exempted from the licensing requirements of Part 30 of this chapter, or (2) persons generally licensed under Parts 31 or 35 of this chapter. This part also prescribes certain regulations governing holders of such licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses.

(b) 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.

Subpart A—Exempt Concentrations and Items**§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: requirements for license.**

An application for a specific license authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

- (a) Satisfies the general requirements specified in § 30.33 of this chapter;
- (b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and

transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

§ 32.12 Same: Material transfer reports.

Each person licensed under § 32.11 shall file a report in duplicate with the Director, Division of Materials Licensing, United States Atomic Energy Commission, Washington, D.C., 20545, describing the type and quantity of each product or material into which byproduct material has been introduced during the reporting period, name and address of the person who owns or possesses the product or material into which byproduct material has been introduced, the type and quantity of byproduct material introduced into each such product or material, and the initial concentrations of byproduct material in the product or material at time of transfer of the byproduct material by the licensee. The report shall be submitted within 30 days after the end of each calendar year in which the licensee introduces byproduct material into a product or material pursuant to a license granted under § 32.11.

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an agreement State, except in accordance with a license issued pursuant to § 32.11 or the general license provided in § 150.20 of Part 150.

§ 32.14 Certain luminous timepieces: requirements for license to apply or import tritium.

An application for a specific license to apply tritium contained in luminous compounds to timepieces or hands or dials, or to import timepieces or hands or dials containing tritium for use pursuant to § 30.15 of this chapter will be approved if:

- (a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;
- (b) The applicant submits sufficient information relating to the chemical and physical composition and characteristics of the luminous compound(s), the method of application of each compound, quality control procedures and prototype testing of luminous dials; and
- (c) The tritium is bound in the luminous compound in a non-water-soluble and non-labile form and the compound is bound to the dials or hands. The

tritium will be considered to be properly bound to the dials and hands if there is no visible flaking or chipping and the total loss of tritium does not exceed 5 percent of the total tritium when prototype dials and hands are subjected to the following tests in the order specified below:

(1) Attachment of dials to a vibrating fixture and vibration at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2 G for a period of not less than one hour; and

(2) Attachment of the hub ends of the hands to a clamp and bending of hands over a one-inch diameter cylinder; and

(3) Total immersion of the dials and hands used in the tests described in subparagraphs (1) and (2) of this paragraph in 100 milliliters of water at room temperature for a period of 24 consecutive hours and analysis of the test water for its radioactive material content by liquid scintillation counting or other equally sensitive method.

(d) Not more than a total of 25 millicuries of tritium will be applied per timepiece; and

(e) Not more than a total of 5 millicuries of tritium will be applied per hand and not more than 15 millicuries will be applied per dial (bezels when used shall be considered as part of the dial).

§ 32.15 Certain automobile lock illuminators: requirements for license to install or import.

An application for a specific license to install lock illuminators into automobile locks, or to import for sale or distribution lock illuminators in automobile locks for use pursuant to § 30.16 of this chapter will be approved if:

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

(b) The applicant submits sufficient information regarding the lock illuminators pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium 147 in each lock illuminator;

(2) Details of construction and design of the lock illuminator;

(3) Details of the method of binding or containing the tritium or promethium 147;

(4) Details of the method of installing the lock illuminators into the automobile lock so that the lock illuminator is not readily removable from the automobile lock;

(5) Procedures for and results of prototype testing to demonstrate that the lock illuminator will not become detached from the lock and the tritium or promethium 147 will not be released to the environment under the most severe conditions likely to be encountered in normal use of the lock illuminator;

(6) Quality control procedures to demonstrate that production lots of the lock illuminators will meet the specifications established by the Commission for such lock illuminators;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate

determination of the safety of the lock illuminator.

(c) Each lock illuminator will contain no more than 15 millicuries of tritium or 2 millicuries of promethium 147. The levels of radiation from each lock illuminator containing promethium 147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

(1) The tritium or promethium 147 is bound in the luminous compound in a nonwater soluble and nonlabile form, and the compound is incorporated and bound in the lock illuminator in such a manner that the tritium or promethium 147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling;

(2) The tritium or promethium 147 is incorporated in the lock illuminator so as to preclude direct physical contact by any person with the tritium or promethium 147.

(3) The method of installing the lock illuminator into the automobile lock is such that the lock illuminator will not become detached from the lock under the most severe conditions which are likely to be encountered in normal use and handling;

(4) The device consisting of the automobile lock with the installed lock illuminator has been subjected to the prototype tests and meets the requirements prescribed by § 32.40, Schedule A.

§ 32.16 Same: quality control.

Each person licensed under § 32.15 shall:

(a) Maintain quality control in the manufacture of lock illuminators, or the installation of lock illuminators into automobile locks;

(b) Subject production lots to such quality control tests as may be required as a condition of the license issued under § 32.15 sampled in accordance with § 32.110; and

(c) Visually inspect each device in production lots and reject any device which has an observable physical defect that could affect containment of the tritium or promethium 147.

§ 32.17 Same: material transfer reports.

Each person licensed under § 32.15 shall file an annual report with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, which shall state the total quantity of tritium or promethium 147 transferred to other persons under § 30.16 of this chapter, during the reporting period, in the form of lock illuminators contained in automobile locks. Such report shall identify by name and address all persons to whom a total of more than 5 curies of tritium or promethium 147 were distributed under § 30.16 of this chapter during the reporting period. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter.

§ 32.18 Balances of precision: requirements for license to apply or import tritium.

An application for a specific license to apply tritium to balances of precision or

the parts thereof, or to import balances of precision or the parts thereof containing tritium, for use pursuant to § 30.17 of this chapter will be approved if:

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

(b) The applicant submits sufficient information regarding the balance parts pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium in each balance part;

(2) Details of construction and design of the balance part;

(3) Details of the method of incorporation and binding of the tritium in the balance part;

(4) Procedures for and results of prototype testing of balance parts to demonstrate that the tritium contained in each part will not be released or be removed from the part under normal conditions of use of the balance;

(5) Details of quality control procedures to be followed in the fabrication of balance parts containing tritium; and

(6) Any additional information, including experimental studies and tests, required by the Commission to facilitate determination of the safety of the balance part.

(c) Each balance part will contain no more than 0.5 millicurie of tritium and each balance will contain no more than 1.0 millicurie of tritium.

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium in the balance part is such that the tritium will not be released or be removed from the part under normal conditions of use and handling; and

(2) The tritium is incorporated or enclosed in the balance part so as to preclude direct physical contact with the tritium by any person under ordinary circumstances of use.

§ 32.19 Same: material transfer reports.

Each person licensed under § 32.18 shall file an annual report with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, which shall state the total quantity of tritium transferred to other persons under § 30.17 of this chapter, during the reporting period, in the form of balances of precision or the parts thereof. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter.

§ 32.40 Schedule A—Prototype tests for automobile lock illuminators.

An applicant for a license pursuant to § 32.15 shall conduct the following prototype tests on each of five prototype devices, consisting of the automobile lock with the installed illuminator, in the following order:

(a) The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine which simulates the most severe conditions of normal use;

(b) The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to an equivalent treatment in a test device

simulating such a fall. The drop test shall be repeated 100 times from random orientations;

(c) The device shall be attached to a vibratory fixture and vibrated at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2 G for a period of not less than 1 hour;

(d) On completion of the foregoing tests, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry into the lock illuminator. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the lock illuminator, or water entering the lock illuminator, shall be considered leakage;

(e) After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium 147. Any evidence of damage to or failure of any device which could affect the containment of the tritium or promethium 147 in such devices shall be cause for rejection of the design on which such prototype devices were constructed or manufactured if the damage or failure is attributable to design defect. Loss of tritium or promethium 147 from each tested device shall be measured both by sampling the immersion test water used in paragraph (d) of this section and by wiping with filter paper the entire accessible area of the lock illuminator. Measurements of tritium or promethium 147 shall be made in an apparatus calibrated to measure tritium or promethium 147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium 147 in the device is found in the immersion test water of the test in paragraph (d) of this section, or if more than 2,200 disintegrations per minute of tritium or promethium 147 on the filter paper is measured after any of the tests in paragraphs (a) to (d) of this section the device shall be rejected.

Subpart B—Generally Licensed Items

§ 32.51. Certain measuring, gauging or controlling devices generally licensed under § 31.5 of this chapter: requirements for license to distribute.

An application for a specific license to distribute devices, containing byproduct material, designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere, to persons generally licensed under § 31.5 of this chapter will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

(1) The byproduct material contained in the device will not be lost;

(2) No person would receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device can be safely operated by persons not having training in radiological protection; and

(4) The byproduct material within the device would not be accessible to unauthorized persons.

(c) In describing the label or labels and contents thereof to be affixed to the device, the applicant should separately indicate those instructions and precautions which are necessary to assure safe operation of the device. Such instructions and precautions shall be contained on labels bearing the statement, "Removal of this label prohibited by regulations of the Atomic Energy Commission."

(d) In the event the applicant desires that the device be tested for proper operation of the on-off mechanism and indicator, if any, and for leakage of radioactive material, subsequent to the initial tests required by § 31.5(d)(3) of this chapter, at intervals longer than six months but not exceeding three years, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device. In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information on particulars which include, but are not necessarily limited to:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

§ 32.52 Same: material transfer reports.

Each licensee authorized under § 32.51 to distribute the devices described therein to generally licensed persons shall:

(a) Report to the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, all transfers of such devices to persons generally licensed under § 31.5 of this chapter. Such report shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of byproduct material contained in the device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to generally licensed persons; and

(b) Furnish to each general licensee to whom he transfers such device a copy of the general license contained in § 31.5 of this chapter.

§ 32.53 Luminous safety devices for use in aircraft: requirements for license to manufacture, assemble, repair or import.

An application for a specific license to manufacture, assemble, repair or import luminous safety devices containing tritium or promethium 147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

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

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium 147 in each device;

(2) Details of construction and design;

(3) Details of the method of binding or containing the tritium or promethium 147;

(4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium 147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(5) Any quality control procedures proposed as alternatives to those prescribed by § 32.55;

(6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) Each device will contain no more than four curies of tritium or 100 millicuries of promethium 147. The levels of radiation from each device containing promethium 147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium or promethium 147 in the device is such that the tritium or promethium 147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The tritium or promethium 147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(3) The device is so designed that it cannot easily be disassembled; and

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.101, Schedule B.

§ 32.54 Same: labeling of devices.

A person licensed under § 32.53 to manufacture, assemble or import devices containing tritium or promethium 147 for distribution to persons generally licensed under § 31.7 of this chapter shall affix to each device a label which shall include the manufacturer's or importer's license number, the radiation symbol prescribed by § 20.203(a) of this chapter,

a statement that the device contains tritium or promethium 147, as appropriate, and is generally licensed by the USAEC pursuant to § 31.7 of this chapter, and such other information as may be required by the Commission, including disposal instructions when appropriate. If the Commission determines that labeling on the device is not feasible and that an unreasonable risk to the health and safety of the public will not be created, it may dispense with the labeling of the device on condition that a leaflet bearing the prescribed information is enclosed in the container in which the device is shipped.

§ 32.55 Same: quality control; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium 147.

(b) Each person licensed under § 32.53 shall subject a number of devices from each production lot, sampled in accordance with § 32.110, to the following quality control procedures:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be rejected.

(2) The immersion test water from the preceding test in subparagraph (1) of this paragraph shall be measured for tritium or promethium 147 content by an apparatus that has been calibrated to measure tritium or promethium 147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium 147 in any device is found to have leaked into the immersion test water, the leaking device shall be rejected.

(3) The levels of radiation from each device containing promethium 147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be rejected.

(c) An application for a license or for amendment of a license may include a description of quality control procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that they will assure the rejection of any device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium 147 in any 24-hour period.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter any luminous safety device which has been

tested and rejected under the criteria and procedures specified in this section.

§ 32.56 Same: material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director, Division of Materials Licensing, United States Atomic Energy Commission, Washington, D.C., 20545, which shall state the total quantity of tritium or promethium 147 transferred to persons generally licensed under § 31.7 of this chapter. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium 147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.

§ 32.57 Calibration or reference sources containing americium 241: requirements for license to manufacture or import.

An application for a specific license to manufacture or import calibration or reference sources containing americium 241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium 241 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium 241 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium 241, to demonstrate that the americium 241 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium 241.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium 241, that:

(1) The method of incorporation and binding of the americium 241 in the source is such that the americium 241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C.

§ 32.58 Same: labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations 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. Do not remove this label.

CAUTION — RADIOACTIVE MATERIAL — THIS SOURCE CONTAINS AMERICIUM 241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or importer)

§ 32.59 Same: leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium 241 prior to transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium 241. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing americium 241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

§ 32.60 Same: material transfer reports.

Each person licensed under § 32.57 shall file an annual report with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545, which shall state the total quantity of americium 241 transferred to persons generally licensed under § 31.8 of this chapter. The report shall identify each general licensee by name and address, state the kinds and numbers of sources transferred, and specify the quantity (in microcuries) of americium 241 in each kind of source. Each report shall cover the calendar year and shall be filed within thirty (30) days after the end of each calendar year.

§ 32.70 Manufacture and distribution of byproduct materials for medical use under general license.

An application for a specific license to distribute byproduct material for use by physicians under the general license of § 35.31 of this chapter will be approved if:

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

(b) The applicant submits evidence that the byproduct material is to be manufactured, labeled, and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration,

has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare;

(c) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

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)

§ 32.101 Schedule B—Prototype tests for luminous safety devices for use in aircraft.

An applicant for a license pursuant to § 32.53 shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in the following steps:

Step 1. The internal temperature of the test chamber shall be reduced to -62° C. (-80° F.) and the device shall be maintained for at least 1 hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber shall be raised to -54° C. (-65° F.) and maintained until the temperature of the device has stabilized at -54° C. at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54° C.

Step 4. The internal temperature of the chamber shall be raised to -10° C. ($+14^{\circ}$ F.) and maintained until the temperature of the device has stabilized at -10° C., and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.

Step 5. The internal temperature of the chamber shall be raised to $+85^{\circ}$ C. (185° F.) at atmospheric pressure. The temperature of the device shall be stabilized at $+85^{\circ}$ C. and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature shall be reduced to $+71^{\circ}$ C. (160° F.) at atmospheric pressure. The temperature of the device shall be stabilized at $+71^{\circ}$ C. for a period of 30 minutes.

Step 7. The chamber temperature shall be reduced to $+55^{\circ}$ C. (130° F.) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber shall be reduced to $+30^{\circ}$ C. (86° F.) and the pressure to 138 millimeters of mer-

cury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

Step 9. The temperature of the test chamber shall be raised to $+35^{\circ}$ C. (95° F.) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to $+20^{\circ}$ C. (68° F.) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

(b) *Vibration tests.* This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted directly on gas-turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under

both resonant and cycling conditions according to the following Vibration Test Schedule (Table I):

VIBRATION TEST SCHEDULE

TABLE I

[Times shown refer to one axis of vibration]

Type	Vibration at room temperature	Vibration at 160° F. (71° C.)	Vibration at -65° F. (-54° C.)
Resonance.....	Minutes 60	Minutes 15	Minutes 15
Cycling.....	60	15	15

(1) *Determination of resonance frequency.* Individual resonance frequency surveys shall be conducted by applying vibration to each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

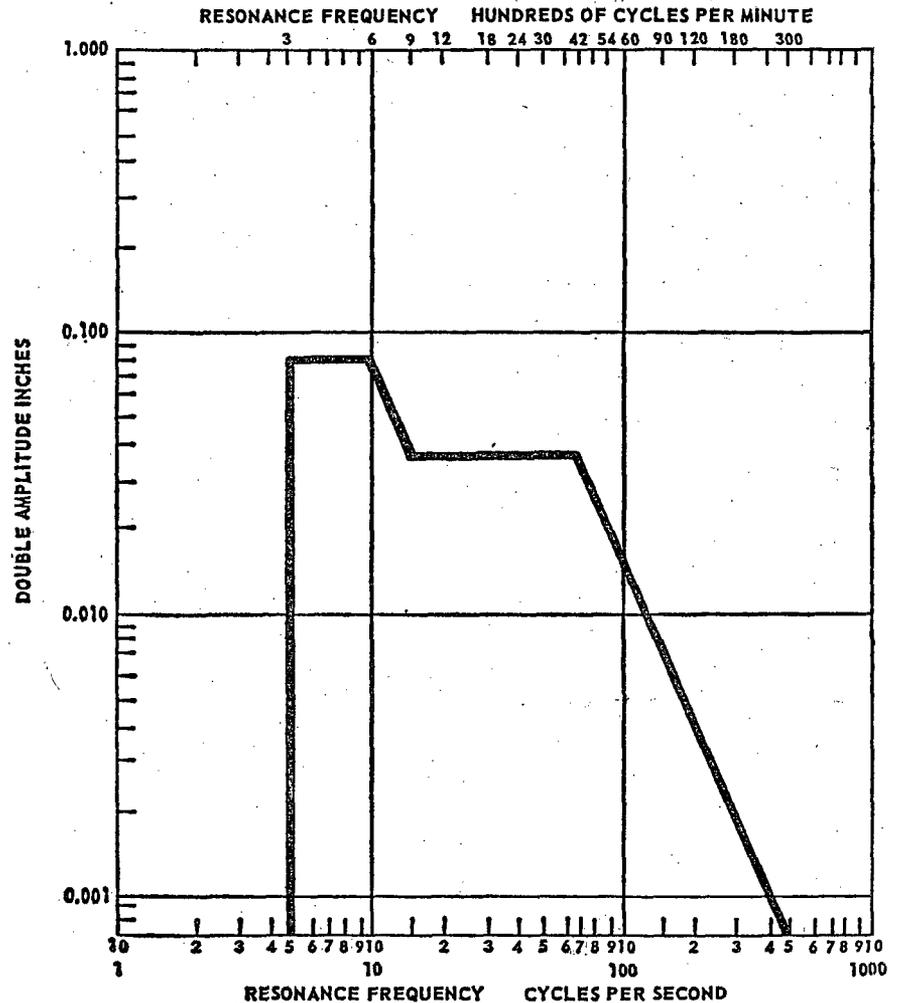


FIGURE 1—Amplitude of vibration at resonance frequency.

(2) *Resonance tests.* The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

(3) *Cycling.* Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in Table I.

(c) *Accelerated weathering tests.* The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Corex D glass shall surround the arc to cut off the ultraviolet radiation below a wavelength of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50° C. plus or minus 3° C. Temperature measurements shall be made with a black panel thermometer.

(d) *Shock test.* The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

(f) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium 147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium 147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium 147 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium 147 in the water used in the hermetic seal and waterproof test prescribed by test paragraph (e) of this section shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium 147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium 147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium 147 in any device shall be cause for rejection of the tested device.

§ 32.102 Schedule C—Prototype tests for calibration or reference sources containing americium 241.

An applicant for a license pursuant to § 32.57 shall, for any type of source which is designed to contain more than 0.005 microcurie of americium 241, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcurie of americium 241, as follows:

(a) *Initial measurement.* The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) *Dry wipe test.* The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test.* The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test.* The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has

dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) *Dry wipe test.* On completion of the preceding tests in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

(f) *Observations.* Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

Subpart C—Quality Control Sampling Procedures

§ 32.110 Quality control sampling procedures under certain specific licenses.

(a) Each production lot of devices licensed under §§ 32.14, 32.15, or 32.53 shall be sampled in accordance with Sampling Table A in this section. If the permissible number of rejects specified in Sampling Table A for a lot of that size is exceeded, all devices in that lot shall be sampled or the entire lot rejected. If ten (10) or more successive lots have been tested and none of them includes a larger number of rejects than specified in Sampling Table A, the succeeding lots may be sampled in accordance with Sampling Table B in this section.

(b) If any lot sampled in accordance with Sampling Table B includes a larger number of rejects than specified in Sampling Table B for a lot of that size, all devices in that lot shall be sampled or the entire lot rejected. Succeeding lots shall be sampled in accordance with the provisions of paragraph (a) of this section.

(c) Sampling Table A:

Lot size	Sample size	Permissible number of rejects
Less than 15.....	All	0
15-110.....	15	0
111-180.....	25	0
181-300.....	35	0
301-500.....	50	1
501-800.....	75	2
801-1,300.....	110	3
1,301-3,200.....	150	4
3,201-8,000.....	225	5
8,001-22,000.....	300	7

(d) Sampling Table B:

Lot size	Sample size	Permissible number of rejects
Less than 5.....	All	0
5-110.....	3	0
111-180.....	5	0
181-300.....	7	1
301-500.....	10	1
501-800.....	15	1
801-1,300.....	22	2
1,301-3,200.....	30	2
3,201-8,000.....	45	3
8,001-22,000.....	60	4

CROSS REFERENCE TABLE

<i>New section</i>	<i>Old section</i>
32.1.....	New
32.11.....	30.24(h) (1)
32.12.....	30.24(h) (2)
32.13.....	30.32(f)
32.14.....	30.24(i)
32.15.....	30.24(m) (1) (i)-(iv)
32.16.....	30.24(m) (2)
32.17.....	30.24(m) (3)
32.18.....	30.24(o) (1)
32.19.....	30.24(o) (2)
32.40.....	30.24(m) (1) (v) (a)-(e)
32.51.....	30.24(f)
32.52.....	30.32(e)
32.53.....	30.24(j) (1) (i)-(iv)
32.54.....	30.24(j) (1) (vi)
32.55.....	30.24(j) (2)
32.56.....	30.24(j) (3)
32.57.....	30.24(n) (1) (i)-(iv)
32.58.....	30.24(n) (2)
32.59.....	30.24(n) (3)
32.60.....	30.24(n) (4)
32.70.....	30.24(k)
32.101.....	30.24(j) (1) (v) (a)-(f)
32.102.....	30.24(n) (1) (v)
32.110.....	30.25

PART 33—SPECIFIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

<i>Sec.</i>	
33.1	Purpose and scope.
REQUIREMENTS FOR SPECIFIC LICENSES	
33.11	Licenses for multiple quantities or types of byproduct material for use in research and development.
33.12	Licenses for multiple quantities or types of byproduct material for use in processing.

AUTHORITY: The provisions of this Part 33 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2232, 2233.

§ 33.1 Purpose and scope.

This part prescribes requirements for the issuances of specific licenses of broad scope for byproduct material and certain regulations governing holders of such 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.

REQUIREMENTS FOR SPECIFIC LICENSES

§ 33.11 Licenses for multiple quantities or types of byproduct material for use in research and development.

An application for a specific license for multiple quantities or types of byproduct material for use in research and development will be approved if:

- The applicant satisfies the general requirements specified in § 30.33 of this chapter; and
- The applicant has received a reasonable number of licenses for a variety of radioisotopes for a variety of research and development uses; and
- The applicant has established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and ap-

prove, in advance of purchase of radioisotopes, proposals for such uses; and

(d) The applicant has appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

§ 33.12 Licenses for multiple quantities or types of byproduct material for use in processing.

An application for a specific license for multiple quantities and types of byproduct material for use in processing for distribution to other authorized persons will be approved if:

- The applicant satisfies the general requirements specified in § 30.33 of this chapter; and
- The applicant has received a reasonable number of licenses for processing and distribution of a variety of radioisotopes; and
- The applicant has appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

CROSS REFERENCE TABLE

<i>New section</i>	<i>Old section</i>
33.1.....	New
33.11.....	30.24(d)
33.12.....	30.24(e)

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

<i>Sec.</i>	
34.1	Purpose and scope.
34.2	Definitions.
34.3	Applications for specific licenses.
Subpart A—Specific Licensing Requirements	
34.11	Issuance of specific licenses for use of sealed sources in radiography.
Subpart B—Radiation Safety Requirements	
EQUIPMENT CONTROL	
34.21	Limit on levels of radiation for radiographic exposure devices and storage containers.
34.22	Locking of radiographic exposure devices and storage containers.
34.23	Storage precautions.
34.24	Radiation survey instruments.
34.25	Leak testing, repair, tagging, opening, modification and replacement of sealed sources.
34.26	Quarterly inventory.
34.27	Utilization logs.

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANT

34.31	Limitations.
34.32	Operating and emergency procedures.
34.33	Personnel monitoring control.

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

34.41	Security.
34.42	Posting.
34.43	Radiation surveys and survey records.

EXEMPTIONS

34.51	Applications for exemptions.
Appendix A.	

AUTHORITY: The provisions of this Part 34 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2232, 2233.

§ 34.1 Purpose and scope.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety requirements for persons using such sealed sources in radiography. 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. Nothing in this part shall apply to uses of byproduct material for medical diagnosis or therapy.

§ 34.2 Definitions.

As used in this part:

- "Radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of byproduct materials;
- "Radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;
- "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;
- "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure;
- "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;
- "Storage container" means a device in which sealed sources are transported or stored.

(c) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;

(d) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure;

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

(f) "Storage container" means a device in which sealed sources are transported or stored.

§ 34.3 Applications for specific licenses.

Applications for specific licenses for use of sealed sources in radiography shall be filed on Form AEC 313R, "Application for Byproduct Material License—Use of Sealed Sources in Radiography."

Subpart A—Specific Licensing Requirements

§ 34.11 Issuance of specific licenses for use of sealed sources in radiography.

An application for a specific license for use of sealed sources in radiography will be approved if:

- The applicant satisfies the general requirements specified in § 30.33 of this chapter;
- The applicant will have an adequate program for training radiographers and radiographers' assistants and submits to the Commission a schedule or description of such program which specifies the:
 - Initial training;
 - Periodic training;

(3) On-the-job training;

(4) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Commission regulations and licensing requirements, and the operating and emergency procedures of the applicant; and

(5) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(c) The applicant has established and submits to the Commission satisfactory written operating and emergency procedures as described in § 34.32;

(d) The applicant will have an adequate internal inspection system, or other management control, to assure that Commission license provisions, Commission regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographers' assistants;

(e) The applicant submits a description of its over-all organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(f) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources, for possible leakage and contamination and submits to the Commission a description of such procedures including:

- (1) Instrumentation to be used,
- (2) Method of performing test, e.g., points on equipment to be smeared and method of taking smear, and
- (3) Pertinent experience of the person who will perform the test.

Subpart B—Radiation Safety Requirements

EQUIPMENT CONTROL

§ 34.21 Limits on levels of radiation for radiographic exposure devices and storage containers.

Radiographic exposure devices measuring less than four (4) inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at six (6) inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and ten (10) milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

§ 34.22 Locking of radiographic exposure devices and storage containers.

Each radiographic exposure device shall be provided with a lock or outer locked container designed to prevent un-

authorized or accidental removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to § 34.41. Each storage container likewise shall be provided with a lock and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

§ 34.23 Storage precautions.

Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

§ 34.24 Radiation survey instruments.

The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and Part 20 of this chapter. Each radiation survey instrument shall be calibrated at intervals not to exceed three (3) months and after each instrument servicing and a record maintained of the latest date of calibration. Instrumentation required by this section shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured.

§ 34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Commission to do so.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to § 34.11 (f). Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with Commission regulations. A report shall be filed, within 5 days of the test, with the Director, Division of Materials Licensing, U.S. Atomic Energy

Commission, Washington, D.C., 20545, describing the equipment involved, the test results, and the corrective action taken. A copy of such report shall be sent to the Director of the appropriate Atomic Energy Commission Regional Compliance Office listed in Appendix D of Part 20 of this chapter "Standards for Protection Against Radiation."

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

§ 34.26 Quarterly inventory.

Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received and possessed under his license. The records of the inventories shall be maintained for inspection by the Commission, and shall include the quantities and kinds of by-product material, location of sealed sources, and the date of the inventory.

§ 34.27 Utilization logs.

Each licensee shall maintain current logs, which shall be kept available for inspection by the Commission at the address specified in the license, showing for each sealed source the following information:

- (a) A description (or make and model number) of the radiographic exposure device or storage container in which the sealed source is located;
- (b) The identity of the radiographer to whom assigned; and
- (c) The plant or site where used and dates of use.

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANTS

§ 34.31 Limitations.

(a) The licensee shall not permit any person to act as a radiographer until such person:

(1) Has been instructed in the subjects outlined in Appendix A of this part and shall have demonstrated understanding thereof;

(2) Has received copies of and instruction in the regulations contained in this part and the applicable sections of Part 20 of this chapter, AEC license(s), and the licensee's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the radiographic exposure devices, sealed sources, related handling tools and survey instruments which will be employed in his assignment.

(b) The licensee shall not permit any person to act as a radiographer's assistant until such person:

(1) Has received copies of and instructions in the licensee's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(2) Has demonstrated competence to use under the personal supervision of the radiographer the radiographic exposure devices, sealed sources, related handling tools and radiation survey instruments which will be employed in his assignment.

§ 34.32 Operating and emergency procedures.

The licensee's operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of licensed sealed sources and radiographic exposure devices to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in Part 20 of this chapter "Standards for Protection Against Radiation";

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing radiographic exposure devices, storage containers and sealed sources;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, posting of vehicles and control of the sealed sources during transportation;

(g) Minimizing exposure of persons in the event of an accident;

(h) The procedure for notifying proper persons in the event of an accident; and

(i) Maintenance of records.

§ 34.33 Personnel monitoring control.

(a) The licensee shall not permit any person to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such person shall wear a film badge and either a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers shall be capable of measuring doses from zero to at least 200 milliroentgens. A film badge shall be assigned to and worn by only one person.

(b) Pocket dosimeters and pocket chambers shall be read and doses recorded daily. A film badge shall be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range. The film badge reports received from the film badge processor and records of pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Commission.

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

§ 34.41 Security.

During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part 20 of this chapter, except (a) where the high radi-

ation area is equipped with a control device or an alarm system as described in § 20.203(c) (2) of this chapter, or (b) where the high radiation area is locked to protect against unauthorized or accidental entry.

§ 34.42 Posting.

Notwithstanding any provisions in § 20.204(c) of this chapter, areas in which radiography is being performed shall be conspicuously posted as required by § 20.203 (b) and (c) (1) of this chapter.

§ 34.43 Radiation surveys and survey records.

(a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in § 34.24 is available and used at each site where radiographic exposures are made.

(b) A physical radiation survey shall be made after each radiographic exposure during a radiographic operation to determine that the sealed source has been returned to its shielded condition.

(c) A physical radiation survey shall be made to determine that each sealed source is in its shielded condition prior to securing the radiographic exposure device and storage container as specified in § 34.22.

(d) Records shall be kept of the surveys required by paragraph (c) of this section and maintained for inspection by the Commission.

EXEMPTIONS

§ 34.51 Applications for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

APPENDIX A

- I. Fundamentals of radiation safety.
 - A. Characteristics of gamma radiation.
 - B. Units of radiation dose (mrem) and quantity of radioactivity (curie).
 - C. Hazards of excessive exposure of radiation.
 - D. Levels of radiation from licensed material.
 - E. Methods of controlling radiation dose.
 1. Working time.
 2. Working distances.
 3. Shielding.
- II. Radiation detection instrumentation to be used.
 - A. Use of radiation survey instruments.
 1. Operation.
 2. Calibration.
 3. Limitations.
 - B. Survey techniques.
 - C. Use of personnel monitoring equipment.
 1. Film badges.
 2. Pocket dosimeters.
 3. Pocket chambers.
- III. Radiographic equipment to be used.
 - A. Remote handling equipment.
 - B. Radiographic exposure devices.
 - C. Storage containers.
- IV. The requirements of pertinent Federal Regulations.
- V. The licensee's written operating and emergency procedures.

CROSS REFERENCE TABLE

New section	Old section
34.1	New
34.2	31.3 (a)-(f)
34.3	New
34.11	30.24(g)
34.21	31.101
34.22	31.102
34.23	31.103
34.24	31.104
34.25	31.105
34.26	31.106
34.27	31.107
34.31	31.201
34.32	31.202
34.33	31.203
34.41	31.301
34.42	31.302
34.43	31.303
34.51	31.401
Appendix A	Appendix A, Part 31

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Sec.	
35.1	Purpose and scope.
35.2	License requirements.
35.3	Definitions.
SPECIFIC LICENSES	
35.11	Specific licenses for human use of by-product material in institutions.
35.12	Specific licenses to individual physicians for human use of byproduct material.
35.13	Specific licenses for human use of by-product material in sealed sources.
GENERAL LICENSES	
35.31	General license for medical use of certain quantities of byproduct material.

AUTHORITY: The provisions of this Part 35 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2232, 2233.

§ 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.

§ 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 Part 30 of this chapter or with an exemption under Part 30 of this chapter.

§ 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.

SPECIFIC LICENSES

§ 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 § 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.

§ 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 § 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.)

§ 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 § 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.

§ 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 (NaI¹³¹) 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, Division of Materials 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:

(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 medi-

cine, 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 § 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, Division of Materials 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.

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)
35.31	30.29

PART 36—EXPORT AND IMPORT OF BYPRODUCT MATERIAL

Sec.	Purpose and scope.
36.1	Purpose and scope.
36.2	Communications.
36.3	License requirements for export of byproduct material.

SPECIFIC LICENSES

- Sec.
36.11 Applications for specific licenses.
36.12 Issuance of specific licenses for export of byproduct material.

GENERAL LICENSES

- 36.21 Export of certain byproduct material to countries other than Schedule A countries.
36.22 Export of certain quantities of tritium and polonium 210.
36.23 Export of americium 241.

SCHEDULES

- 36.50 Schedule A.

AUTHORITY: The provisions of this Part 36 issued under sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Interpret or apply secs. 81, 82, 182, 183, 68 Stat. 935, 953, 954; 42 U.S.C. 2111, 2112, 2232, 2233.

§ 36.1 Purpose and scope.

This part prescribes regulations governing specific licenses for the export of byproduct material and establishes certain general licenses for the export from and import into the United States of byproduct material. 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.

§ 36.2 Communications.

(a) All communications and reports concerning the regulations in this part with regard to export should be addressed to the Director, Division of State and Licensee Relations, U.S. Atomic Energy Commission, Washington, D.C., 20545.

(b) All communications and reports concerning the regulations in this part with regard to import should be addressed to the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C., 20545.

(c) Communications and reports may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 4915 St. Elmo Avenue, Bethesda, Md.; or at Germantown, Md.

§ 36.3 License requirements for export of byproduct material.

(a) No person shall export byproduct material from the United States except as authorized pursuant to the regulations in this part and Part 30.

(b) No person shall export byproduct material from the United States knowing or having reason to believe that it is to be reexported directly or indirectly, in whole or in part, from the country of ultimate destination shown on the export license, shipper's export declaration, bill of lading, or commercial invoice, unless either:

(1) The reexport has been authorized by the Commission; or

(2) At the time of export, the material may be exported directly from the United States to the new country of ultimate destination under the terms of one of the general licenses established in this part.

SPECIFIC LICENSES

§ 36.11 Applications for specific licenses.

Applications for specific licenses for export of byproduct material from the United States shall be filed in triplicate on Form AEC-7 with the Director, Division of State and Licensee Relations, U.S. Atomic Energy Commission, Washington, D.C., 20545. Applications may also be filed in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 4915 St. Elmo Avenue, Bethesda, Md.; or at Germantown, Md.

§ 36.12 Issuance of specific licenses for export of byproduct material.

The Commission may, upon application by an interested person, issue a license authorizing the export of byproduct material to a country or destination listed in § 36.50, Schedule A, for the export of byproduct material in quantities or forms not authorized for export under general license if, in the opinion of the Commission, the proposed export would not be inimical to the common defense and security.

GENERAL LICENSES

§ 36.21 Export of certain byproduct material to countries other than Schedule A countries.

Any licensee may export byproduct material covered by his license to any country or destination not listed in § 36.50, Schedule A: *Provided*, That the authority conferred by this section shall apply only to byproduct material having an atomic number from 3 to 83, inclusive, and to tritium when contained in luminous safety devices installed in aircraft and distributed as generally licensed items pursuant to § 31.7 of this chapter.

§ 36.22 Export of certain quantities of tritium and polonium 210.

(a) A general license is hereby issued authorizing any person to export from the United States to any foreign country except Poland or Rumania or countries or destinations listed in § 36.50, Schedule A, 5,000 curies of tritium and 5,000 curies of polonium 210 in a calendar quarter. Not more than 1,000 curies of tritium may be exported by any person to any one country or destination in a calendar quarter and not more than 100 curies of tritium may be exported by any person in a single shipment under this general license. Exports under this general license may be in one or more of the following forms or products only:

- (1) Tritium activated luminous paint;
- (2) Tritium labeled organic compounds;
- (3) Tritiated accelerator targets;
- (4) Polonium 210 static eliminators;
- (5) Polonium 210 neutron sources;
- (6) Tritium or polonium 210 calibration standards;
- (7) Luminescent light sources;
- (8) Tritium sources for chromatography instruments;
- (9) Electron tubes; or
- (10) Tritium as a contaminant of helium 3 in a concentration not to exceed

2.5 millicuries of tritium per liter of helium 3.¹

(b) A person exporting byproduct material pursuant to the general license established by paragraph (a) of this section, shall file with the Collector of Customs, or the Postmaster, one copy, in addition to those otherwise required, of the Shipper's Export Declaration, covering each export, marked for transmittal to the Director, Division of State and Licensee Relations, U.S. Atomic Energy Commission, Washington, D.C., 20545. In addition to such other information as may be required, the following information shall be included in the Shipper's Export Declaration: Identification of the byproduct material; the quantity in curies; and the ratio of tritium to the total quantity of hydrogen if the material is tritium-activated luminous paint.

§ 36.23 Export of americium 241.

A general license designated AEC-GRO-BMG is hereby issued authorizing any person to export americium 241 from the United States to any foreign country except Poland or Rumania or countries or destinations listed in § 36.50, Schedule A.

SCHEDULES

§ 36.50 Schedule A.

- (a) Albania.
- (b) Bulgaria.
- (c) China, including Manchuria (and excluding Taiwan (Formosa)) (includes Inner Mongolia; the provinces of Tsinghai and Sikkang; Sinkiang; Tibet; the former Kwantung Leased Territory, the present Port Arthur Naval Base Area and Liaoning Province).
- (d) Communist-controlled area of Viet Nam.
- (e) Cuba.
- (f) Czechoslovakia.
- (g) East Germany (Soviet Zone of Germany and the Soviet Sector of Berlin).
- (h) Estonia.
- (i) Hungary.
- (j) Latvia.
- (k) Lithuania.
- (l) North Korea.
- (m) Outer Mongolia.
- (n) Union of Soviet Socialist Republics.

CROSS REFERENCE TABLE

New section	Old section
36.1	New
36.2	New
36.3	30.33 (a) and (h)
36.11	New
36.12	30.33 (e)
36.21	30.33 (b)
36.22	30.33 (d) and (f)
36.23	30.33 (g)
36.50	30.75

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¹ Export shipments of helium gas are subject to the licensing authority and regulations of the Department of State. Issuance of a specific or general license by the Commission for tritium contained in helium 3 does not relieve any person from complying with the licensing requirements and regulations of the Department of State applicable to the export of helium 3.