APPENDIX C—Continued

Material	Microcuries
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)	50
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)	50
Uranium-233	.01
Uranium-234—Uranium-235	.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	.1

NOTE: For purposes of §§ 20.203 and 20.304, where there is involved a combination of isotopes in known amounts the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity"). Example: For purposes of § 20.304, if a particular batch contains 20,000 μc of Au^{198} and 50,000 μc of C^{14}, it may also include not more than 300 μc of I^{131}. This limit was determined as follows:

$$\frac{20{,}000\ \mu c\ Au^{198}}{100{,}000\ \mu c} + \frac{50{,}000\ \mu c\ C^{14}}{100{,}000\ \mu c} + \frac{300\ \mu c\ I^{131}}{1{,}000\ \mu c} = 1$$

The denominator in each of the above ratios was obtained by multiplying the figure in the table by 1,000 as provided in § 20.304.

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

Dated at Germantown, Md., this 7th day of April 1970.

For the Atomic Energy Commission.

W. B. McCOOL,
Secretary.

[F.R. Doc. 70-4556; Filed, Apr. 21, 1970; 8:45 a.m.]

EXEMPTION OF SMALL QUANTITIES OF BYPRODUCT MATERIAL

On August 10, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 11414) proposed amendments to 10 CFR Parts 30, 31, 32, and 35 of its regulations. The proposed amendments to Part 30 would exempt from licensing requirements the receipt, possession, use, transfer, ownership, or acquisition of small quantities of byproduct material. The proposed amendments to Part 31 would revoke the general license for small quantities of byproduct material currently set forth in §§ 31.4 and 31.100, Schedule A. Conforming amendments would also be made to the title and to § 31.2 of 10 CFR Part 31. The proposed amendments to Part 32 would establish (a) criteria for the issuance of specific licenses for the manufacture, processing, production, packaging, repackaging, import or commercial distribution of the exempt quantities of byproduct material, and (b) certain license conditions for these specific licenses. The proposed amendment to Part 35 would clarify that the proposed exempt quantities of byproduct material are not for use in humans.

On the same date, the Commission published (33 F.R. 11413) proposed amendments to 10 CFR Part 20, "Standards for Protection Against Radiation," to conform the byproduct material portions of Appendix C, 10 CFR Part 20, to the quantities to be exempted in Part 30. The proposed amendments would also add americium-241 and change certain other quantities listed in Appendix C, 10 CFR Part 20.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notices of proposed rule making in the FEDERAL REGISTER. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments with certain additions and modifications discussed below.

The quantity of iodine-134 in the proposed schedule of exempt quantities, § 30.71, Schedule B, was incorrectly listed as 100 microcuries and has been reduced to 10 microcuries.

The proposed exempt quantity of carbon-14 in § 30.71, Schedule B, has been reduced from 1,000 microcuries to 100 microcuries. The 1,000-microcurie quantity was derived on the basis of limits on concentrations in air for soluble forms of carbon-14. The reduced quantity reflects consideration in the criteria used to arrive at the scheduled exempt quantities, of a permissible concentration of carbon-14 in air in insoluble form.

The note at the end of proposed § 30.71, Schedule B, was misleading at that location and has been deleted. Clarification that an exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions does not exceed unity, has been incorporated into § 32.19, the section which sets forth conditions of specific licenses to be issued to commercial suppliers of exempt quantities.

The proposed exemption from licensing requirements for small quantities of byproduct material would not have included the distribution of products containing such material. The effect of revoking the general license, § 31.4 of Part 31, would be to limit distribution of products now being distributed under that general license to specific licensees or to persons exempted or generally licensed by other provisions of AEC regulations, such as the general license for certain measuring, gauging, or controlling devices set forth in § 31.5 of Part 31. In order to emphasize the distinction between the exemption for quantities of byproduct material and exemptions for products containing byproduct material, proposed § 32.18 of Part 32 has been modified to indicate more clearly the types of material which commercial suppliers may distribute as exempt quantities. In addition, a new § 30.15(a)(9) has been added to Part 30 to provide exemption from licensing requirements for possession and use of ionizing radiation measuring instruments containing internal calibration or standardization sources of byproduct material in amounts not exceeding the pertinent schedule of exempt quantities. Such sources, when installed inside instruments, constitute a smaller risk than as separate quantities, and specific provision for their use under exemption is warranted.

In order to avoid causing undue hardship to distributors of other products which are presently being transferred as generally licensed quantities, the revocation of the general license in § 31.4 will not become effective until 6 months after publication of this notice of rule making in the FEDERAL REGISTER. If a petition for exemption of such a product from specific licensing requirements is filed prior to revocation of the general license, the Director of Regulation will consider extending the general license until such time as the petition for exemption is finally determined. The 6-month delay in revocation will also permit commercial suppliers now distributing quantities of byproduct material under the general license, to obtain the required specific licenses or license amendments and to implement requirements regarding labels and brochures.

The terms and conditions of § 31.2(b) applicable to the general licenses for certain devices and equipment (§ 31.3) and for small quantities (§ 31.4) are considered to be of such small significance to the remaining generally licensed

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devices and equipment that they will be revoked concurrently with revocation of the general license for small quantities, rather than modified to remove references to quantities as was proposed.

Proposed § 32.19(b) has been revised to permit the presentation of some of the information required in a label on immediate containers of exempt quantities to be presented instead on an accompanying brochure. In many cases, it is impractical to put all of the wording on the immediate container because of size or use limitations. Under the revised § 32.19(c), the immediate container of each quantity, or separately packaged fractional quantity, is required, as a minimum, to bear a durable, legible label identifying the isotope and the quantity of radioactivity, as well as the words "Radioactive Material."

Proposed § 32.20 has been revised to clarify the requirement for an annual summary report of the total quantity of each isotope transferred under a specific license issued pursuant to § 32.18. Records must be maintained of individual transactions, indicating the name and address of the recipient and the kinds and quantities of byproduct material transferred, but such detailed information is not required to be included in the annual report. The revised reporting requirement would require the licensee to furnish the specified information or state that no transfers were made during the reporting period.

The rules set forth below would (a) exempt from licensing small quantities of byproduct material, (b) revoke the existing general license for similar quantities of byproduct material, (c) exempt from licensing specified quantities of byproduct material contained in calibration sources installed in ionizing radiation measuring instruments, (d) establish requirements for issuance of specific licenses for distribution of exempt quantities of byproduct material, and (e) clarify wording in Part 35 regarding use of exempt quantities of byproduct material in humans. Persons holding an AEC or an Agreement State byproduct material license authorizing manufacture, processing, or production of byproduct material are authorized under the exemption to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license, on an exempt basis. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, bioassay samples, tagged compounds, counting standards, etc., which involve negligible risks. A producer, packager, repackager, or importer who intends to distribute, on a commercial basis, quantities of byproduct material for use under the exemptions, even if licensed to manufacture, process, or produce such quantities by an Agreement State, would be required to obtain a specific license from the Commission authorizing the import or commercial distribution of such quantities. To obtain a license, the applicant must meet the criteria of § 32.18, 10 CFR Part 32.

The Commission has found that the exemption from licensing of small quantities of byproduct material and of ionizing radiation measuring instruments containing certain internal calibration or standardization sources under the conditions set forth in the following amendments will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30, 31, 32, and 35 are published as a document subject to codification. The amendments to 10 CFR Parts 30, 32, and 35 shall become effective thirty (30) days after publication in the FEDERAL REGISTER, and the amendments to 10 CFR Part 31 shall become effective 6 months after publication in the FEDERAL REGISTER.

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

1. In § 30.15(a) of 10 CFR Part 30, a new subparagraph (9) is added to read as follows:

§30.15 Certain items containing byproduct material.

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who import for sale or distribution the following products containing byproduct material, 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 the following products:

* * * * *

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of byproduct material not exceeding the applicable quantity set forth in § 30.71, Schedule B.

* * * * *

2. A new § 30.18 is added to 10 CFR Part 30 to read as follows:

§ 30.18 Exempt quantities.

(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 Parts 30–34 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person who possesses byproduct material received or acquired prior to October 22, 1970 under the general license then provided in § 31.4 of this chapter is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30–34 of this chapter to the extent that such person possesses, uses, transfers or owns such byproduct material.

(c) This section does not authorize the production, packaging, repackaging, or import of byproduct material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, import or transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

3. A new § 30.71 *Schedule B* is added to 10 CFR Part 30 to read as follows:

§ 30.71 Schedule B.

Byproduct material	*Microcuries*
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 72 (Ga 72)	10
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100

Byproduct material	Microcuries
Hydrogen 3 (H 3)	1,000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct material	0.1

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

4. The title of 10 CFR Part 31 is revised to read as set forth above.

5. Section 31.1 of 10 CFR Part 31 is amended to read as follows:

§ 31.1 Purpose and scope.

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

6. Sections 31.2(b), 31.4, and 31.100 of 10 CFR Part 31 are revoked.

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

7. New §§ 32.18, 32.19, and 32.20 are added to 10 CFR Part 32 to read as follows:

§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: requirements for license.

An application for a specific license to manufacture, process, produce, package, repackage, import, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

§ 32.19 Same: conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from AEC or Agreement State licensing requirements; (2) bear the words "Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

§ 32.20 Same: records and material transfer reports.

Each person licensed under § 32.18 shall maintain records identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State, and stating the kinds and quantities of byproduct material transferred. An annual summary report stating the total quantity of each isotope transferred under the specific license shall be filed with the Director, Division of Materials Licensing, U.S. Atomic Energy Commission, Washington, D.C. 20545. Each report shall cover the year ending June 30, and shall be filed within thirty (30) days thereafter. If no transfers of byproduct material have been made pursuant to § 32.18 during the reporting period, the report shall so indicate.

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

8. Section 35.2 of 10 CFR Part 35 is amended to read as follows:

§ 35.2 License requirements.

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

(Sec. 81, 68 Stat. 935; 42 U.S.C. 2111; sec. 161, 68 Stat. 948; 42 U.S.C. 2201)

Dated at Germantown, Md., this 7th day of April 1970.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

[F.R. Doc. 70-4557; Filed, Apr. 21, 1970; 8:45 a.m.]