

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below, to use such material for the purpose(s) and at the place(s) designated below, to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

DL-060696-08

Licensee	
1. Caribbean Bioresearch, Inc.	3. License Number 52-25099-02
2. P.O. Box 325 San Germán, Puerto Rico 00753	4. Expiration Date June 30, 2001
	5. Docket or Reference No. 030-34032

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen 3	A. Foil Sources contained in Packard Instrument Model 885 detector cells	A. Not to exceed 150 millicuries per foil
B. Nickel 63	B. Any foil or plated source in a compatible detector cell registered pursuant to 10 CFR 32.210	B. No single source to exceed 8 millicuries per source
C. Hydrogen 3	C. Solid and liquid waste.	C. 10 curies

9. Authorized Use:
- A. and B. Foil and/or plated source in a detector cell (registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation) for use in compatible gas chromatograph for sample analysis.
  - C. For storage only incident to disposal.

**CONDITIONS**

- 10. Licensed material shall be used only at the licensee's facilities located at El Retiro Industrial Park, B Street, Corner C, San Germán, Puerto Rico.
- 11. The Radiation Protection Officer for this license is Oliver W. Kilham, Ph.D.
- 12. Licensed material shall be used by, or under the supervision of, Oliver W. Kilham, Ph.D.
- 13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 14. A. The sources specified in Item 7 shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

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**CONDITIONS**

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15. B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (i) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (ii) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II ATTN: Chief, Nuclear Materials Licensing/Inspection Branch, 101 Marietta Street, NW, Suite 2900, Atlanta, GA 30323. The report shall specify the source involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by Varian Instruments Group. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
16. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
- B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperature from exceeding 225 degrees Centigrade.
16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
17. The licensee shall maintain records of information important to safe and effective decommissioning at the location specified in Condition 10 in accordance with the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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CONDITIONS

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- 18. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 19. Maintenance, repair, cleaning, replacement and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
- 20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - A. Application dated November 25, 1995

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

HECTOR BERMUDEZ

DATE \_\_\_\_\_

BY

  
\_\_\_\_\_  
Region II, Division of Nuclear Materials Safety  
101 Marietta Street, N.W., Suite 2900  
Atlanta, Georgia 30323

UNITED STATES NUCLEAR REGULATORY COMMISSION  
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

31.5(c)

**PART  
31**

**GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL**

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er 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)-(c) [Reserved]

(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.

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 in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to § 32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.

§ 31.4 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0018.

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.8, and 31.11.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 31.11, Form NRC-483 is approved under control number 3150-0038.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material; and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or

10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) in accordance with the instructions provided by the labels; or

(ii) by a person holding a specific license pursuant to Parts 30 and 32 of

Authority Secs 81 161 183 of Stat. U.S. 948, 954, as amended (42 U.S.C. 2111, 2201, 2231) secs 201, as amended 21C 88 Stat. 1242 as amended, 1244 (42 U.S.C. 5841, 5842) Section 31.8 also issued under sec. 274, 73 Stat. 686 (42 U.S.C. 2021)

§ 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.

§ 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), 30.41, 30.50 to 30.63 and Parts 19, 20, and 21 of this chapter unless indicated otherwise in the language of the general license.

§ 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:

Attention is directed particularly to the provisions of the regulations in Part 30 of this chapter which relate to the labeling of containers.

§ 31.5 Certain measuring, gauging or controlling devices.<sup>1</sup>

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for

<sup>1</sup> Persons possessing byproduct material in devices under the general license in § 31.5 before Jan. 15, 1978, may continue to possess, use or transfer that material in accordance with the requirements of § 31.5 in effect on Jan. 14, 1978.

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this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon the occurrence of a failure of or damage to, or any indication of a possible 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 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Director of the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, a report containing a brief description of the event and the remedial action taken;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with Part 110 of this chapter.

(8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State, to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device.

(9) Shall transfer the device to another general licensee only

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee, or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee

(10) Shall comply with the provisions of §§ 20.2201 and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts 19, 20, and 21 of this chapter.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material

§ 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 and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter. *Provided, That:*

(a) [Deleted 39 FR 43531.]

(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 the label is prohibited.

(d) [Deleted 39 FR 43531.]

§ 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 10 curies of tritium or 300 millicuries of promethium-147 and that each device has been manufactured, assembled or initially transferred 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 Parts 19, 20, and 21 of this chapter, except that they shall comply with the provisions of §§ 20.2201 and 20.2202 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.