

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, 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.

Licensee			
1. Isomedix (Puerto Rico) Inc. State Road 690 Km-1.7 Barrio Sabana Hoyos	3. License number 52-23041-01	3020206	
2. P. O. Box 415 Vega Alta, Puerto Rico 00762	4. Expiration date October 31, 1986		
	5. Docket or Reference No. 29-19769-01		
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. Cobalt 60	A. Sealed sources (AECL Model C-188, Types 1, 2, 3, or 4)	A. Not to exceed 14,250 curies per source and 3,000,000 curies total	
B. Cesium 137	B. Sealed sources	B. Not to exceed 10 microcuries per source	
9. Authorized use			
A. For possession and use in an AECL Model IR-107 wet storage custom irradiator for sterilization of medical products and other items except those of explosive or hazardous nature.			
B. For use as instrument check sources.			

CONDITIONS

10. Licensed material shall be used only at Macco Industrial Park, State Road, 690 Km. 1.7, Vega Alta, Puerto Rico.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material shall be used by, or under the supervision and in the physical presence of, George Dietz, George Baker, John Masefield, William M. Owens, or other individuals designated by George Dietz, Corporate Radiation Protection Officer.

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License number

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(cont'd)

CONDITIONS

13. The Radiation Protection Officer for the activities authorized by this license is George Dietz, John Masefield, William Owens, George Baker or any other licensee employee who meets the training and experience criteria specified in letter dated July 27, 1984, and has been approved by the Isomedix (Corporate) Radiation Safety Committee.
14. Each individual user under this license shall be designated in accordance with the "Operator Designation and Training" procedures described in Sections 9 and 10 of the application for license dated May 22, 1981.
15. A. Each sealed source containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- B. The test shall be capable of detecting the presence of 0.05 microcurie of contamination on the test sample. The test samples shall be taken from appropriate accessible surfaces of the device in which the sealed source is permanently or semi-permanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.
- C. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source 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 five (5) days of the test with U.S. Nuclear Regulatory Commission, Region II, Division of Radiation Safety and Safeguards, Nuclear Material Safety Section, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
16. Written instructions in Section 8 - 1 of application for licensee dated May 22, 1981 shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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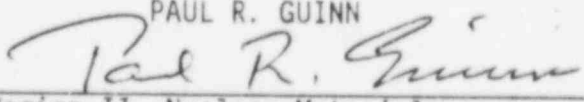
17. This license does not authorize repairs or alterations of the irradiator involving removal of shielding or access to the licensed material except as provided otherwise by specific condition of this license. Removal, replacement and disposal of sealed sources shall be performed only "AECL" or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.
18. After the initial installation of the irradiator and after subsequent installations of Cobalt 60 sources and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report of the results of the surveys shall be sent to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, not later than thirty (30) days following installation of the source. A copy of such report shall also be sent to the U. S. Nuclear Regulatory Commission, Region II, 101 Marietta Street, Atlanta, Georgia 30323.
19. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated May 22, 1981; letter dated September 22, 1981; the AECL Radiation Survey Report attached to letter dated June 13, 1984; and letter dated July 27, 1984. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

PAUL R. GUINN

Date SEP 14 1984

By


Region II, Nuclear Materials
Safety Section
101 Marietta Street, Suite 2900
Atlanta, GA 30323