



## CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

### § 31.11 General license for use of iodine-125 or iodine-131 for in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) No person shall receive, acquire, possess, use or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form AEC-483, "Registration Certificate—In Vitro Testing with 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 Form AEC-483 with registration number assigned. The registrant shall furnish on Form AEC-483 the following information and such other information as may be required by that form:

- (1) Name and address of the registrant;
- (2) The location of use; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests

with byproduct materials as authorized under the general license in paragraph (a) of this section, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the byproduct materials.

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

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use a total amount of iodine-125 and/or iodine-131 in excess of 200 microcuries.

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee 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,<sup>1</sup> nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of

<sup>1</sup> A State to which the Commission has transferred certain regulatory authority over radioactive material by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

§ 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, which authorizes manufacture and distribution of iodine-125 or iodine-131 for distribution to persons generally licensed by the Agreement State.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Atomic Energy Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

*Mallinckrodt - Nuclear*  
Name of manufacturer

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Division of Materials Licensing, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing with Byproduct Material Under General License", Form AEC-483. The report shall be furnished within 30 days after effective date of such change.

(f) 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 byproduct materials covered by that general license.

### NOTE

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, an "Application for Byproduct Material License," Form AEC-313, should be filed to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Isotopes Branch, Division of Materials Licensing.