Title 10 - Atomic Energy

CHAPTER I - ATOMIC ENERGY COMMISSION

PART 31 - GENERAL LICENSES FOR BYPRODUCT MATERIAL

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

General License for Use of Carbon-14 for In Vitro Clinical or Laboratory Testing

On September 26, 1973, the Atomic Energy Commission published in the FEDERAL REGISTER (38 FR 26813) proposed amendments of its regulations 10 CFR Parts 31 and 32 which would authorize any physician, clinical laboratory, or hospital to use carbon-14 in units not exceeding 10 microcuries each, in in vitro clinical or laboratory tests, subject to the conditions set out in § 31.11(b), (c), (d), (e), and (f).

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments by November 12, 1973. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published September 26, 1973.

Under the provisions of the general license, as amended, the general licensee may issue a purchase order on a standing basis for a supply of carbon-14 in prepackaged units to be

delivered at any rate of shipment. Hospitals use vials containing 1.5 microcuries of carbon-14 in large numbers when operating an automated system for detecting bacteria in blood and other fluids.

The general license as amended in no way affects transactions involving exempt quantities subject to § 32.19, nor does it relax any radiological safety controls over the use of carbon-14 in in vitro clinical or laboratory tests.

The general licensee would be required to register with the Commission and receive an acknowledgement of his registration and a registration number before receiving carbon-14 pursuant to the general license. The objectives of the registration requirement are to (1) provide a means of identifying the general licensee, (2) provide assurance that the general licensee is aware of the terms and conditions of the general license prior to receipt of carbon-14 for use under the general license, and (3) facilitate communication with the general licensee.

As amended, § 32.71, which is intended to assure that general licensees receive properly packaged products which are labeled to identify the radioactive contents and to specify that use is restricted to in vitro clinical or laboratory tests, includes requirements for issuance of specific licenses to manufacture or

distribute carbon-14 for use under the general license in § 31.11.

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 of Title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32, are published as a document subject to codification.

1. In 10 CFR Part 31, § 31.11 is amended by amending the title of the section, adding a new paragraph (a)(3), and amending paragraph (d)(1) to read as follows:

§ 31.11 General license for use of byproduct materials for certain 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:

* * * * *

(3) Carbon-14, 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.

* * * * *

(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 § 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, iodine-131, or carbon-14 for distribution to persons generally licensed by the Agreement State.

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2. In 10 CFR Part 32, § 32.71 is amended by adding a new paragraph (b)(3) to read as follows:

§ 32.71 Manufacture and distribution of byproduct materials for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacture or

distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

* * * * *

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

* * * * *

(3) Carbon-14 in units not exceeding 10 microcuries each.

Effective date. - These amendments become effective on 1-10-74

(Secs. 81, 161, Pub. Law 83-703, 68 Stat. 935, 948 (42 U.S.C. 2111, 2201))

Dated at Bethesda, Md. this 23rd day of November 1973.

For the Atomic Energy Commission.

L. Manning Muntzing
Director of Regulation